Dr. Charlie Fazio

Disease Management

Addressing Care Needs

Discussion

- What is Disease Management?
- Why offer Disease Management from the Health Plan?
- The Value of Disease Management
- Future Delivery of Disease Management.....A Pilot for Physician-Directed Care
- Questions

The Role of Disease Management

- Proactively identifies individuals with given disease states or those at highest risk for health care costs or disease complications
- Empowers participants to be informed and engaged in self-management
- Patient-centered education and support is guided by nurses and other health care professionals, and provided in a variety of media (mail, web, audio)
- Identifies care gaps early and aids in care coordination between providers and participants
- Focuses on preventing complications and improving health outcomes with evidence-based care. This lowers costs.

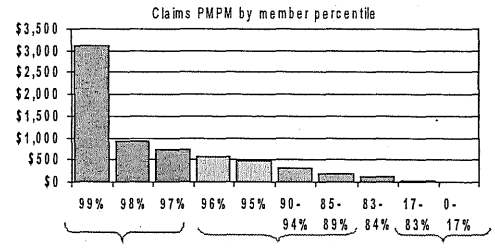
Why Health Plans Offer Disease Management?

1. To improve gaps in care against evidence-based guidelines
   - In 2005, only 15.5% of diabetics in Minnesota met all five cardiovascular-related treatment goals[1]
2. Clinic health systems are designed more for acute care medicine/ clinics do not have the systems or personnel to support disease management principles
3. To meet market demand
4. A strategy to reduce health care costs

[1] Minnesota Community Measurement Project, 2005

The Purpose:

Right Care, Right Time, Quality Provider



Small Changes Make a Difference....Changes in HbA_{1c} levels and associated average health care costs over three years[1]

Patient classification	10 to 9%*	9 to 8%†	8 to 7%†	7 to 6%
Diabetes with heart disease and hypertension	$4116 ± 1178	$3090 ± 960	$2237 ± 1083	$1504 ± 1378
Diabetes with heart disease	$2796 ± 777	$2088 ± 632	$1503 ± 712	$1002 ± 906
Diabetes with hypertension	$1703 ± 458	$1260 ± 374	$897 ± 417	$588 ± 525
Diabetes only	$1205 ± 394	$869 ± 309	$601 ± 303	$378 ± 348

Data are means ± SE. * p<0.01; † p<0.05. Gilmer, et al.

MEDICA

Medica's Diabetes Comprehensive Program Resources

Low Risk	Moderate Risk	High Risk

- Welcome Packet
- www.Medica.com
- Value Connections
- 24/7 Nurseline
- Newsletters
- Clinical Education Mailings
- Annual Quality of Life survey (random sampling)
- Risk Assessment
- Depression Screening
- Education
- Individualized Interventions – Member
- Individualized Interventions – Physician
- Scale & BP monitor, Glucometer
- Home Health Visits

MEDICA

Value of Diabetes Disease Management

After implementing Medica's Diabetes Program

- The number of diabetic members with A1c <=7 (target) improved from 53.9% to 61.1%[1]
- The number of diabetic members with LDL (bad cholesterol) <=100 improved from 54.8% to 65.9%[1]
- Members with diabetes went to the hospital and emergency room less often[2]
  - Hospital admits ↓ 15.4%
  - Emergency room visits ↓ 2.6%

1 -CorSolutions Clinical Evaluation, Year 2; High acuity > 6 months
2 –Reden & Anders Financial Evaluation, Year 1; Medica diabetes population

MEDICA

Value of Diabetes Disease Management

Clinical
- Health Care Costs
  - Outpatient Care
  - Inpatient Stays
- Clinical Outcomes

Economic
- More Time at Work
- Greater Productivity
- Reduced Disability (ST/LT)

Quality of Life
- Events Averted (e.g. heart attack, retinopathy, etc.)
- Deaths Averted
- New Cases of Diabetes Averted
- Patient/Physician Satisfaction
- General Perceived Health

MEDICA

The Link Between Behavioral Health Conditions and Physical Health

Co-morbid conditions - the connection between depression and physical health

Prevalence of Depression in Chronic and Severe Medical Conditions

Condition	% with Depression
General Population	17.5%
Arthritis	25.3%
Cancer	30.3%
Diabetes → with complications	25.0% 70.0%
Coronary Heart Disease	34.5%
Chronic Lung Disease	30.9%
Hypertension	22.4%
Neurological Disorder	37.5%
Parkinson's	40.0%

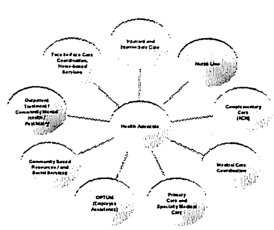
- Overall, it's estimated major depression exists in 36% of patients with coexisting medical conditions [1]

MEDICA

Delivering Coordinated Consumer Driven Behavioral Health

Health Advantage by Medica℠
"a personalized depression management program"

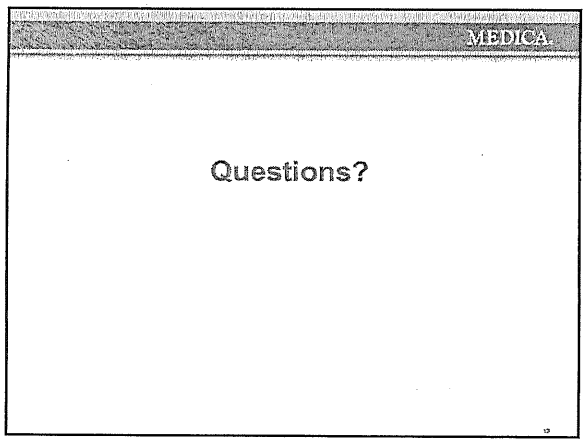
- Comprehensive member identification and outreach
- Regularly scheduled telephone calls from trained clinicians
- Care coordination for physical and behavioral health issues across the spectrum of care
- A total of 778 members have opted-in for program services
- Member program satisfaction is 85%



MEDICA

Future Delivery of Disease Management: A Pilot for Health System-Directed Care

- Background: Disease management supports practitioner/patient interactions. It is an activity that could be delivered from within a health system for many patients
- In development for 2006
- Piloting with 2-3 clinic systems
- Clinics and health plan will partner more directly to identify, track and manage patients
- Proposed value: Coordinate and manage chronic care at primary provider setting, transfer funding to our provider network and improve provider and member satisfaction


MEDICA
Questions?

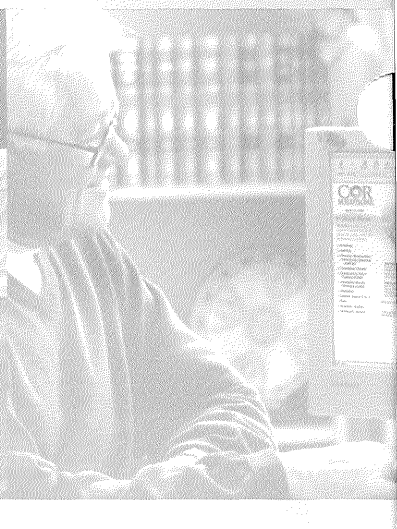
CorChoices℠

Welcome to Medica's Program for Healthier Living.

MEDICA®

In partnership with COR SOLUTIONS®

Together,
we can make a
difference in how you **feel**.



Your health plan has contracted with CorSolutions, Inc. to provide you with a health management program. Your health plan will pay CorSolutions for all costs associated with your participation in the programs available to you.

If you would rather not participate in this program or receive additional information from CorSolutions, you can withdraw by calling us toll-free at

1-800-775-3422

Otherwise, we will assume that you wish to participate in our programs and to receive additional information from CorSolutions.

If you have any questions about CorSolutions and the health management programs available to you, please contact us. We would be happy to answer any of your questions and provide you with more details about how you can take advantage of these programs.

MEDICAOOI-1104

CorChoices℠

A Disease Management program for members of Medica®

Now the program that's helped thousands of people can help you live a healthier life, too.

Dear Member:

Medica® is proud to bring you "CorChoices℠," a program that offers valuable information and support to help you manage your condition and live a healthier life. This program is offered to you at no additional cost by CorSolutions®, Medica's partner in helping improve your health.

CorChoices helps support the care provided by your doctor and offers you access to a full range of resources to keep you feeling your best. You can:

- Visit www.medica.com/member resources/disease management for online access to current information about specific chronic conditions;
- Call Voice Connections℠ at 1-877-COR-5266 for unlimited toll-free access to our health library;
- Or call NurseConnections ℠ toll-free at 1-800-775-3422 to speak directly with a registered nurse any time, day or night, about your health concerns or any program questions you may have.

The materials in this welcome packet will give you support and information to help you better manage your health condition. We are also enclosing a magnet that will keep your doctor's phone number and our 24-hour nurse support line close at hand.

In the future, we will send you *CorNews*, a quarterly newsletter that covers the latest news about your condition. In addition, a CorSolution's nurse may contact you to offer more support and education.

Please take some time to read through the enclosed materials and start putting them to work. This program has helped improve the quality of life for many people. And, we hope that it can do the same for you. If at any time, should you no longer wish to participate in the program, please contact us at 1-800-775-3422.

Sincerely,

Richard P. Vance, M.D.
President and CEO,
CorSolutions

Merritt O'Brien, M.A.
Clinical Program Manager,
Medica

P.S. Remember, there is no additional charge for this program, so keep your magnet handy and call us whenever you wish! We can accommodate any special communications needs you may have in order to speak with a nurse. If you have special needs, please call 1-866-676-0470, or access our web site at www.medica.com/member resources/disease management and a CorSolutions professional will assist you in reaching a nurse.

CorChoices℠

Helping you make changes for the better.

Diabetes

COR SOLUTIONS®

Table of Contents

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the American Diabetes Association

What is *diabetes?*

Diabetes means there's too much glucose in your blood. Glucose is a sugar that the cells of your body use for energy. Diabetes occurs when your pancreas (an organ near your stomach) does not make any insulin or when it does not make enough to keep up with your body's demand. You may also be insulin resistant, which means your body cannot use insulin correctly.

What is insulin?

Insulin is a hormone that is released when your body is digesting food. It works like a key, unlocking your body's cells so sugar can move from your blood into the cells. When your body is unable to make insulin, or use it effectively, sugar builds up in your bloodstream.

Who's at risk for diabetes?

The exact causes of diabetes are unknown. There are several factors, however, that are associated with the risk for type 2 diabetes:

- Family history of diabetes
- Obesity
- Certain racial and ethnic groups (African-Americans, Native Americans, Hispanic Americans, Asian-Americans and Pacific Islanders)
- Over 45 years of age
- High blood pressure
- Occurrence of gestational diabetes or birth of a baby over 9 pounds

Is all diabetes the same?

No. There are four different types of diabetes.

Type 1 diabetes

(Formerly insulin-dependent or juvenile onset diabetes)

About 10% of people with diabetes have type 1 diabetes.

- Pancreas does not make any insulin
- Usually occurs before age 20
- Insulin is required daily to live

Type 2 diabetes

(Formerly non-insulin-dependent or adult onset diabetes)

About 90% of people with diabetes have type 2 diabetes.

- Pancreas produces *some* insulin, at least initially, but the cells are unable to use it correctly
- Usually occurs in overweight people over 45
- May be managed by diet and exercise alone
- Oral medication or insulin may be needed if blood sugar level remains high

Gestational diabetes

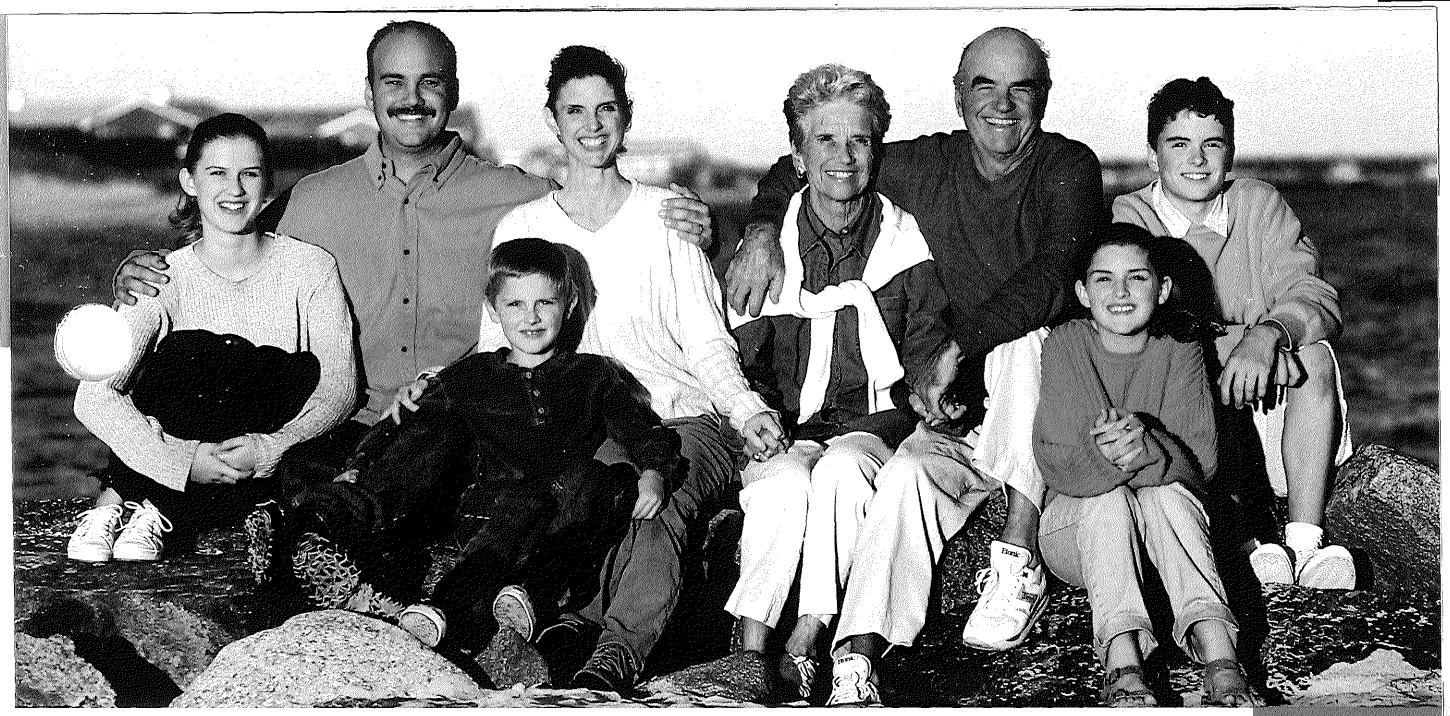
(Diabetes during pregnancy)

- Hormones of pregnancy cause insulin resistance
- Usually goes away when the baby is born
- Increases risks for developing diabetes later

Other specific types

Diabetes may also result from removal of the pancreas, drugs, malnutrition, infections or other illnesses.

What type of diabetes do you have? _____



Why is diabetes self-management so important?

A blood sugar level that is too high can lead to serious complications. If left untreated over many years, high blood sugar levels can damage nerves and blood vessels and cause changes in vital organs. These complications can affect your heart, eyes, teeth/gums, kidneys, skin and feet, as well as things like sexual function and digestion. Blood sugar levels that get too low can also cause symptoms. The program will help you learn the best ways to *avoid* problems and stay healthy.

PROOF that you can stay healthy

A study of people with type 1 diabetes* showed that maintaining near-normal blood sugar levels:

- reduced eye disease risk by 76%
- reduced kidney disease risk by 50%
- reduced nerve disease risk by 60%

More recent studies have also shown decreased complications for type 2 diabetes.

What's the best way to manage diabetes?

The most important thing you can do is keep your blood sugar level close to the target range your doctor recommends. The American Diabetes Association (ADA) recommendations are listed in the Blood Sugar Target Levels chart on page 4. How do you reach your target goals? By *balancing* those things that cause blood sugar to rise with tools that help you lower it.

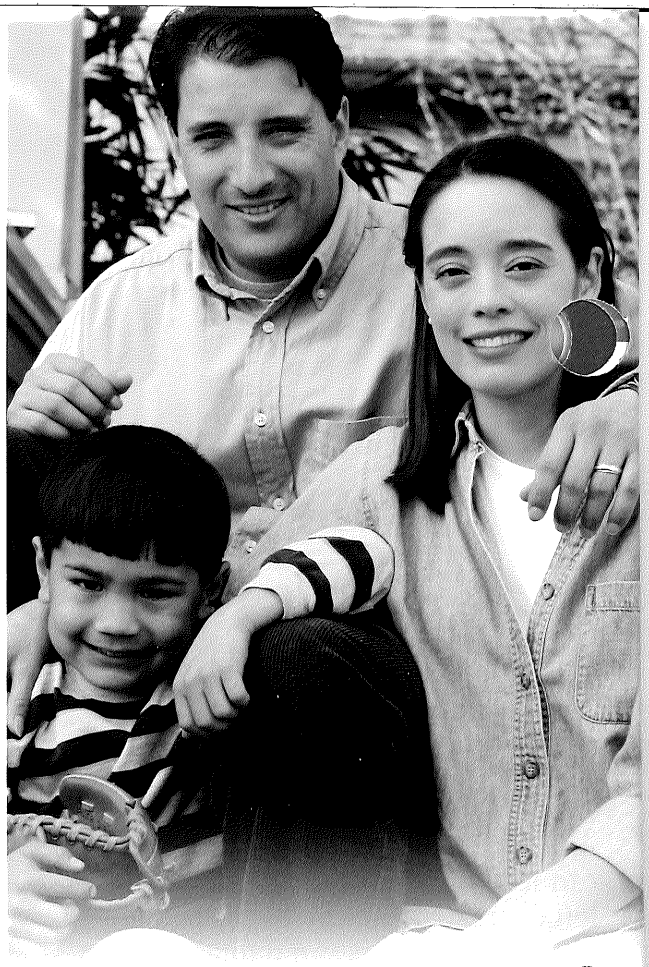
Five tools for blood sugar control

1. **Regular monitoring**
2. **Smart meal planning**
3. **Physical activity**
4. **Medication management**
5. **Stress control**

*Source: 1993 Diabetes Control and Complications Trial (DCCT), National Institute of Diabetes and Digestive and Kidney Disorders.

It's a matter of setting *goals.*

This guide offers 10 healthy goals, based on ADA guidelines. If you try to follow them and make them a part of your life, you're more likely to feel good and stay well.



GOAL #1

Monitor Blood Sugar Regularly

Know your A1C number! It tells how well you're managing your diabetes over time.

Blood Sugar Target Levels

Test	Frequency	Test Times	Goal	Take Action
Self-test using a blood sugar meter	As often as your doctor recommends. If taking insulin, 4-6 times a day is ideal.	Before meals and at bedtime.	80-120 mg/dL*	Below 80 or above 140
		Before bedtime if you are taking sulfonylureas, Prandin® or insulin.	100-140 mg/dL	Below 100 or above 160
Hemoglobin A1C (A1C) measures average blood sugar level over 2- to 3-month period.	Twice yearly if within target goal. Quarterly if not within target goal, or if therapy (diet, exercise or Rx) changes.	Time of day does not affect test results.	7% or less	8% or above

*Blood sugar levels are expressed as mg/dL or milligrams per deciliter of blood.

On the following pages, you'll learn how to take action when your blood sugar level is too high or too low.

How do I test my blood sugar?

You'll need a blood sugar meter if you don't have one. Drug stores have many to choose from and instructions are included. You'll also need test strips, a special needle called a lancet and a lancing device to hold the needle. The test is fast, easy and painless with today's newer devices. The meter "reads" your blood sugar level, which shows up as a number on a screen. If you have any questions, call our nurse.

How often should I test?

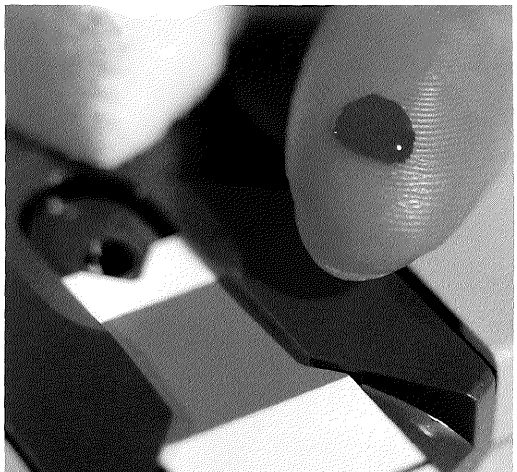
Blood sugar levels change throughout the day. The ADA recommends testing at least four times a day if you're on insulin. If you're taking oral medication, you might test two to four times a day. Be sure to ask your doctor how frequently you should test each day and what your target range should be each time. You'll feel your best when you stay close to your goals.

Remember!

Keeping blood sugar levels close to normal can reduce complications by 50% to 80%!

What causes blood sugar changes?

- What you eat and drink
- Physical activity
- Stress or sickness
- Insulin shots and diabetes pills
- Other medications
- Hormone changes for some women



When is a good time for testing?

Your doctor can tell you the best times to test. They may include:

- Before meals
- One or two hours after meals
- Before bed and/or
- During the night

You may also want to test:

- When you're sick or feeling shaky
- Before and after exercise
- After making changes in insulin, medication, diet or exercise
- When you're gaining or losing weight
- If you have warning signs of high or low blood sugar levels
- Before driving a car or operating dangerous equipment if you're on insulin or have had low blood sugar reactions

If you only test a few times a day, alter the times you test every few days. That helps you see how your blood sugar levels change throughout the day.

Track your results!

Use your Daily Health Manager to keep a record of your blood sugar levels. When they're out of your target range, note the time of day and any changes in your routine that may have affected them. If you're consistently out of the target range for two or three days, talk to our nurse or your doctor. As you get to know your blood sugar patterns, you'll know when to make appropriate adjustments.

Are there other ways to monitor diabetes?

Yes. The Hemoglobin A1C (A1C test) is an equally important part of blood sugar monitoring. This test shows your average blood sugar level for the past two to three months. The ideal goal is less than 7%. Anytime your number is 8% or over, ask your doctor about adjusting your diabetes care plan. Then repeat the test in three months. People with high A1C levels have a much higher risk for developing long-term complications. So be sure to test and record A1C results on your Personal Health Manager.

GOAL #2

Eat Your Way to Good Health

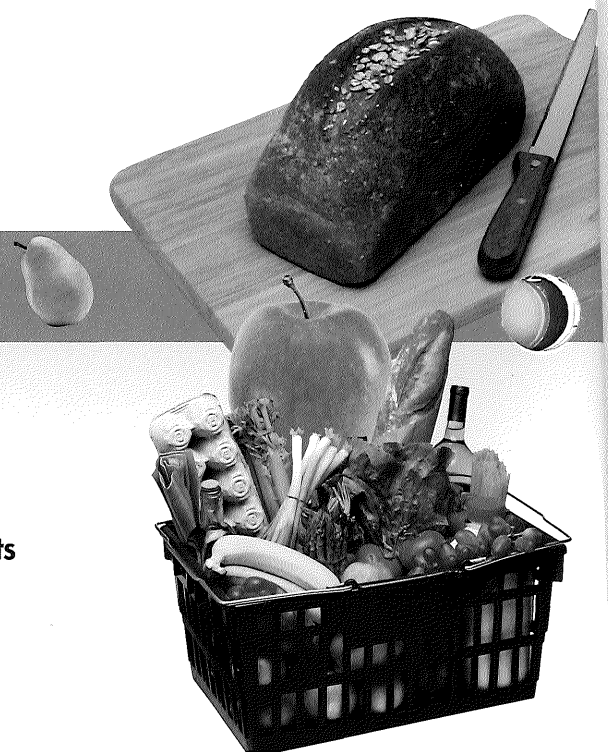
- Eat a variety of foods daily.
- Eat high-fiber foods.
- Have less fat, sugar and salt.
- Eat meals and snacks at regular times each day.
- Eat about the same amount every day.
- Try not to skip meals.
- Balance food intake with activity and medication.

Why is diet so important?

There are three nutrients in foods that supply calories or energy to your body — carbohydrates (starches and sugars), proteins and fats. As food is digested, carbohydrates are broken down into sugar and released into your blood stream. That causes your blood sugar to rise. To stay within your blood sugar target range, you need to balance carbohydrate intake with activity and/or medication. It's also important to understand how various foods affect your body.

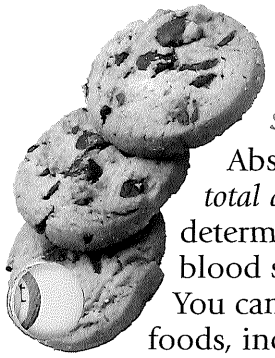
What should I know about carbohydrates?

Carbohydrates come from bread, rice, potatoes and other starches. They also come from sweets. All carbohydrates are changed into blood sugar 90 to 120 minutes after eating. You should know which foods contain them and be aware of how many carbohydrates you eat.



Common "Carb" Sources

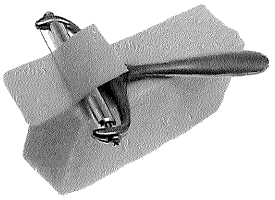
- bread
- cereal
- fruits
- milk
- noodles
- pastries
- rice
- vegetables
- candy and other sweets



Can I eat foods with sugar?

Absolutely, because *it's the total amount of carbohydrates* that determines the effect on your blood sugar — not the food itself. You can eat most of your favorite foods, including those that contain sugar. Just count them as part of your total carbohydrate intake. Remember, though, that sweets are often high in fat and calories, and low in vitamins, minerals and fiber.

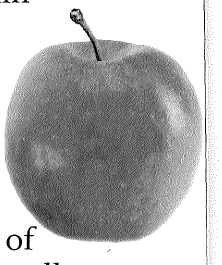
Do proteins and fats affect blood sugar?



Some of the protein you eat can turn into sugar, but it doesn't seem to affect your blood sugar level very much. Fats are not converted to sugar at all. A high amount of fat or protein may slow digestion, however. That can affect your blood sugar level in the hours after you eat.

So why is a low-fat diet necessary?

Fat is high in calories and it can cause you to gain weight. Being overweight can lead to insulin resistance. The number of calories you should eat in a day depends on whether you want to gain, maintain or lose weight. Our nurse can help determine the right weight and caloric intake for you. When you maintain your target weight, it's easier to reach your desired blood sugar, blood fat and blood pressure levels.



What are saturated fats?

Saturated fats are found in foods of animal origin, such as meats, egg yolks and dairy foods. They're also in coconut, palm and palm kernel oil, used in many processed and prepared foods. When you eat foods with saturated fat, you can increase your cholesterol. That's a waxy, fatty substance made in the liver, which can build up on the walls of your blood vessels. High cholesterol can block arteries and lead to heart disease. A diet that's *low* in saturated fats can help *prevent* heart problems. On page 21, you'll learn how to control cholesterol and protect your heart.

How does fiber affect me?

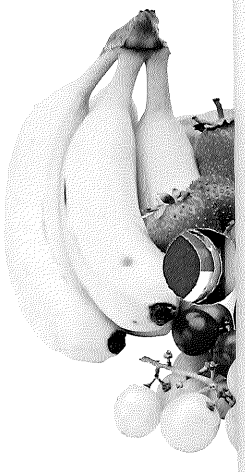
High-fiber foods, like fruits, vegetables, grains and beans help fill you up so it's easier to eat less. They also lower cholesterol without raising blood sugar.

What about alcohol?

Alcohol can lower blood sugar and interact with medication. It may also hide signs of low blood sugar, especially when you haven't eaten. Some drinks contain large amounts of carbohydrates (beer, drink mixes). Plus, alcohol is very high in calories and can cause you to gain weight. Depending upon your medication, if your diabetes is well controlled, it may be okay to have an occasional drink *with a meal.* Check with our nurse or your doctor.

Let Labels Be Your Guide

Be sure to look at food labels. They tell you exactly what's in the food, so you can control what you eat. Remember that if you eat more or less than what's listed as a serving, you get more or less of each nutrient.



Nutrition Facts

Serving size 1/2 cup (114 g) ← Serving size
Servings per Package 4

Amount Per Serving	
Calories 90 Calories from Fat 30 ← Number of calories per serving	
	% Daily Value*
Total Fat 3 g ← Amount of total fat per serving	**5%**
Saturated Fat 0 g ← Amount of saturated fat per serving	**0%**
Cholesterol 0 g ← Amount of cholesterol per serving	**0%**
Sodium 300 mg	**13%**
Total Carbohydrate 13 g ← Note total carbohydrate (not just sugar) and grams (g) rather than percent (%)	**4%**
Dietary Fiber 3 g ← Amount of dietary fiber per serving	**12%**
Sugars 3 g	
Protein 3 g	
Vitamin A 80% • Vitamin C	**60%**
Calcium 4% • Iron	**4%**

***Percent Daily Values are based on a 2,000 calorie diet. Your Daily Values may be higher or lower depending on your calorie needs:**

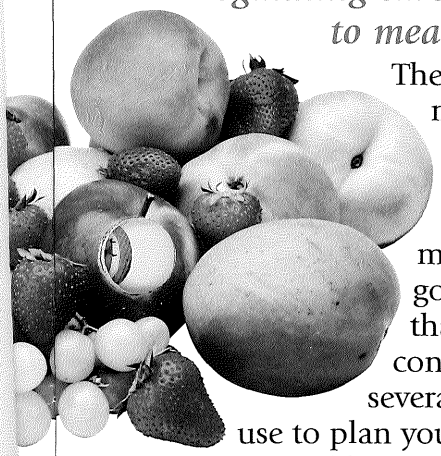
		2,000 calories	2,500 calories
Total Fat	Less than	65 g	80 g
Sat. Fat	Less than	20 g	25 g
Cholesterol	Less than	300 mg	300 mg
Sodium	Less than	2400 mg	2400 mg
Total Carbohydrate		300 g	375 g
Dietary Fiber		25 g	30 g

Calories per gram:
Fat 9 • Carbohydrate 4 • Protein 4

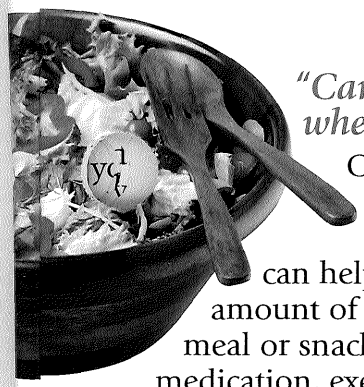
We have additional materials to help with your diet and meal planning. To receive free copies, call our toll-free support line.

Let the Food Pyramid help!
The Food Pyramid shows each food group with the number of servings you should have daily for good nutrition. Most of your foods should come from the grain/starch, vegetable and fruit groups. Your smallest intake should be from fats, sweets and alcohol.

Regulating carbohydrates is key to meal planning.



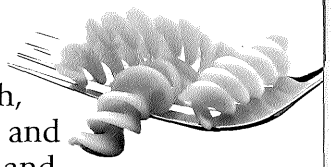
The goal of any diabetes meal plan is to balance carbohydrate intake with activity and medication to meet your blood sugar goals. The best way to do that is by maintaining a consistent diet. There are several methods you can use to plan your meals. The Food Pyramid helps you monitor the type and amount of food you're eating. An Exchange System adds variety with foods of equal content. Many people count servings or grams of carbohydrates. What's most important is following a routine that focuses on eating the same amount of carbs every day.



"Carb counting" helps when you take insulin.

Counting carbs gives you a more accurate idea of how much you eat. A dietitian can help you learn the total amount of carbohydrates to eat at a meal or snack, based on your medication, exercise patterns and weight goals. Then you can eat a combination of foods that provide a consistent amount. You should check food labels for the number of carb grams in each serving.

How does an Exchange Plan work?



It classifies food into three groups: "carbohydrates"(starch, fruit, milk, vegetables and other carbs), "meats" and "fats." One serving of a food within each group has about the same amount of carbohydrate, protein, fat and calories. Once you're familiar with them, you can exchange one choice for another within the same group, according to your preferences, without changing your carb intake.

Tips for Carbohydrate Consistency

- Eat the same number of meals and snacks each day.
- Always eat around the same time each day.
- Read labels and measure foods so you know how much you're eating.
- Eat the same amount of "carbs" at each meal or snack.

Follow these suggestions...

- Maintain a consistent carb intake.
- Test blood sugar often and adjust food intake as needed.
- Cut portions if you need to lose weight.
- Carry healthy snacks in case a meal is delayed.
- Limit your fat and salt intake if needed.

Fats, sweets and alcohol
A serving can be:
1/8 avocado, 1T cream cheese, 1t butter, oil/margarine, 10 peanuts
1/2 cup ice cream, 2 small cookies

Milk
(2-3 servings daily; about 12 g carbohydrates/serving)
A serving can be:
1 cup milk, 1 cup yogurt

Meat and others
(2-3 servings daily; 0 g carbohydrates/serving)
A serving can be: 2-3 oz. cooked lean meat, poultry or fish, 1/2-3/4 cup tuna, 1 egg

Vegetables
(3-5 servings daily; about 5 g carbohydrates/serving)
A serving can be: 1 cup raw vegetables, 1/2 cup cooked vegetables, 1/2 cup tomato juice

Fruits
(2-4 servings daily; 15 g carbohydrates/serving) A serving can be:
1 small fresh fruit, 1/2 cup fruit juice
1/2 cup canned fruit, 1/4 cup dried fruit

Grains, beans and starchy vegetables
(6 or more servings daily; about 15 g carbohydrates/serving) A serving can be:
1/2 small bagel or English muffin, 1/2 cup cooked beans, lentils, peas or corn, 1 small potato

GOAL #3

Stay Active

How does exercise affect blood sugar?

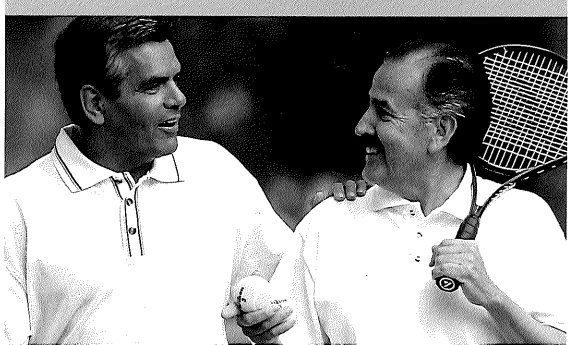
Exercise, diet and medication all work together to keep your blood sugar in your target range. It's important to know how exercise affects your blood sugar level, so you can adjust your diet and medication as necessary.

Why is exercise important?

Physical activity is one of the best things you can do for diabetes. It helps control blood sugar by using the sugar in your body as fuel for the exercising muscle. Exercise helps control weight, lowers blood pressure and "bad" (LDL) cholesterol. It also increases "good" (HDL) cholesterol and reduces stress. Be sure to check with your doctor and make sure your blood sugar is in good control before starting any exercise program.

Did you know?

Activity can lower blood sugar for up to 24 hours, but the greatest effect is during the first four to six hours.



Exercise Do's and Don'ts

1. Test blood sugar levels.

If you take insulin or pills for diabetes:

- **DO NOT** exercise if sugar le is greater than 250 mg/dL.
- **DO** eat a snack if sugar level is less than 100 mg/dL.

2. Avoid injuries to your feet.

- **DO** wear good, comfortable shoes and socks.
- **DO** check feet for irritations after exercise.
- **DO** keep weight off your feet if your diabetes has caused a loss of sensation in your feet. *Choose swimming or cycling instead.*

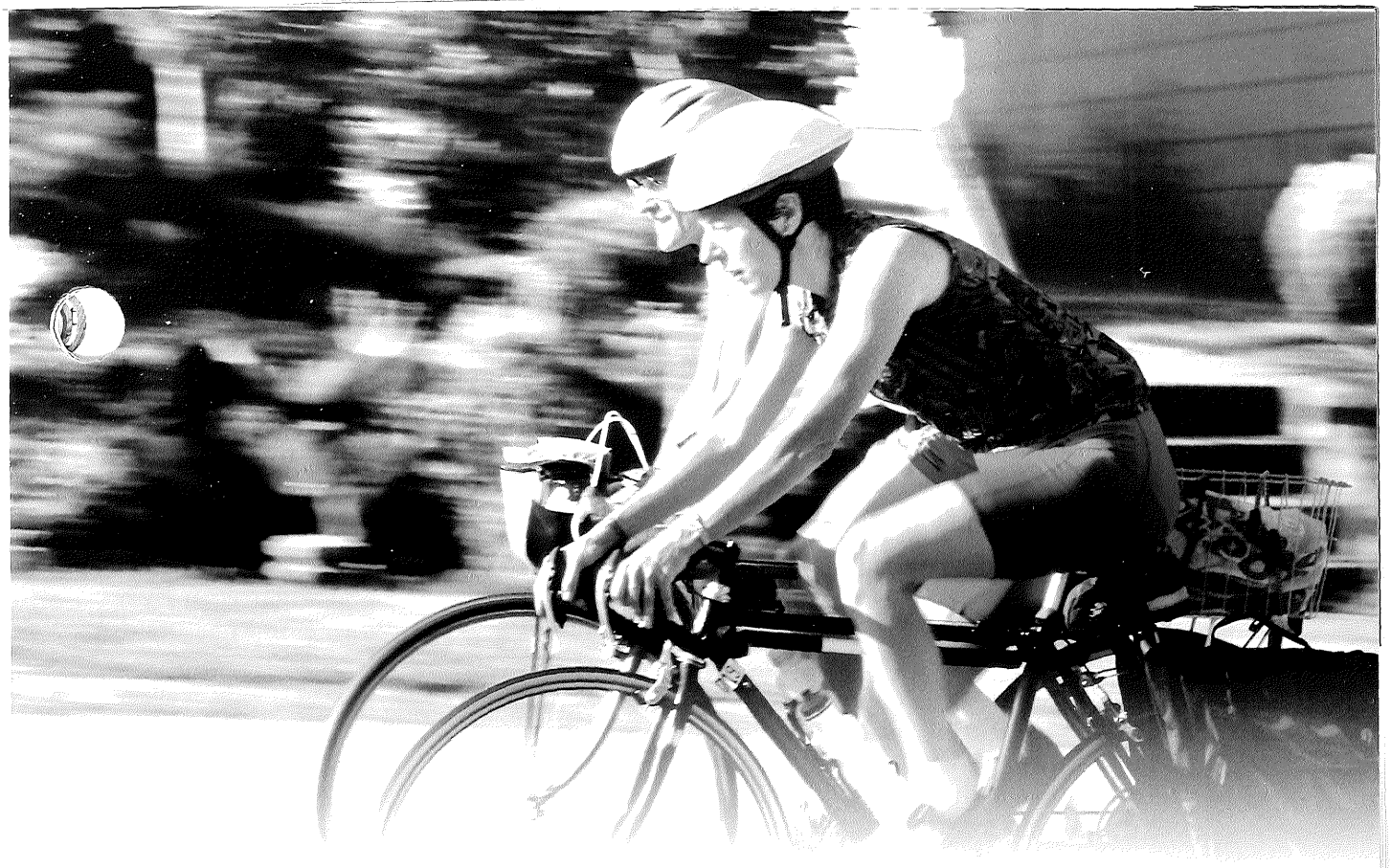
3. If you have complications like eye or kidney disease or uncontrolled high blood pressure:

- **DO NOT** lift weights.
- **DO NOT** do heavy exercising.

Dial your doctor FOR

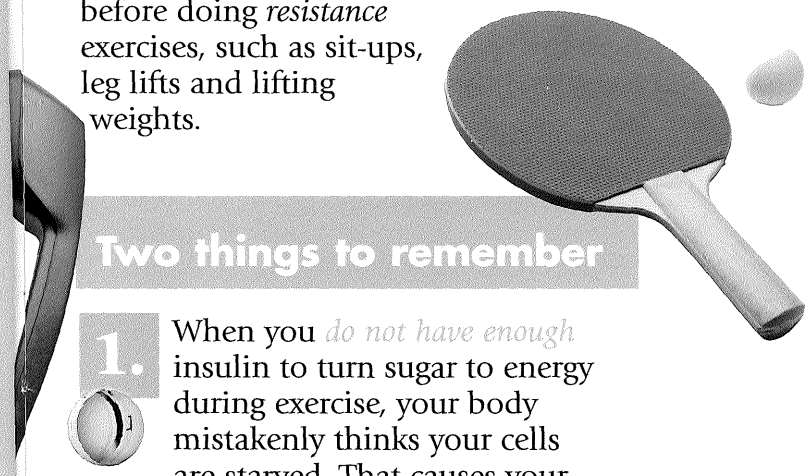
- Pain or tightness in chest, jaw, arms, neck or back
- Unusual fatigue or shortness of breath
- Lightheadedness, dizziness or confusion
- Irregular heartbeat
- Unusual pain in muscles or joints

Be sure to check your blood sugar level after working out to see how exercise affects it.



What type of exercise is best?

Choose an aerobic activity you enjoy. Take a walk, play tennis, swim or ride a bike. Begin with five- or ten-minute sessions and gradually work up to more. It doesn't have to be strenuous, but it should feel like you're making an effort. If losing weight is a goal, exercise *longer*, not harder. Check with your doctor before doing *resistance* exercises, such as sit-ups, leg lifts and lifting weights.



Two things to remember

1. When you *do not have enough* insulin to turn sugar to energy during exercise, your body mistakenly thinks your cells are starved. That causes your body to make *more* glucose and your blood sugar level goes up.

2. When there's *too much* insulin in your blood during exercise, your muscles quickly remove sugar from your blood, causing your blood sugar level to fall.

Rx for healthy exercise

1. Start slowly to warm up muscles. Stretch after you've warmed up for five or ten minutes.

2. Use your ability to talk to judge how hard you're working:
   - If you're too winded to talk, slow down.
   - If talking is easy, speed up a bit.

3. You can also check your pulse to see how hard you're working. (Ask our nurse or your doctor what your target heart rate should be.)

4. Increase exercise gradually, week by week.

5. Always cool down before you stop. Then stretch.

6. Be sure to drink enough water before, during and after exercise so you don't get dehydrated.

GOAL #4

Take Medication Correctly

Please talk to your doctor to learn more about any changes or new medications that may be available.

Who needs medication and insulin?

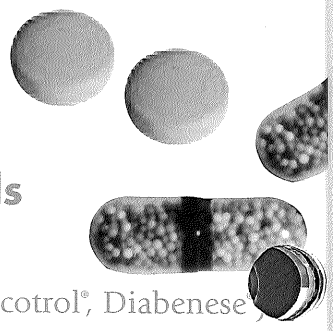
People with type 1 diabetes require insulin to live. If you have type 2 diabetes, you may need pills, insulin shots or both if your blood sugar level remains high, despite diet and exercise.

What do diabetes pills do?

Pills *won't* cure your diabetes. They *can* help you maintain good blood sugar levels when used with proper diet and exercise. It's important to know which pills you take, and how and when to take them. It's equally important to take them regularly. If you forget to take your pills, post notes around the house. Never take more than one day's dose at a time. If you have questions, ask our nurse or your doctor.

What if I have problems with my medication?

Call your doctor if your sugar levels are suddenly higher, or if you notice any side effects. You may need to switch your pills, change your dose or add insulin.



Types of Diabetes Pills

Sulfonylureas
(e.g., Amaryl®, Glucotrol®, Diabenese®)

help the pancreas make more insulin and help your body use insulin better. That, in turn, lowers your blood sugar.

Biguanides
(e.g., Glucophage®)

lower the amount of sugar your liver makes and help your body use insulin better.

Alpha-glucosidase inhibitors
(e.g., Precose® and Glyset®)

slow digestion of carbs, causing a slower and lower rise of blood sugar after meals.

Thiazolidinediones
(e.g., Avandia® and Actos®)

help your muscles make better use of your insulin, decrease insulin resistance and lower the amount of sugar made by the liver.

Meglitinides
(e.g., Prandin®)

help the pancreas make more insulin, lowering blood sugar.

Combination medications
(e.g., Glucovance®, made up of Metformin® and Glyburide®)

help your body make more insulin, and lower insulin resistance so you can use it better.

D-phenylalanines
(e.g., Starlix)

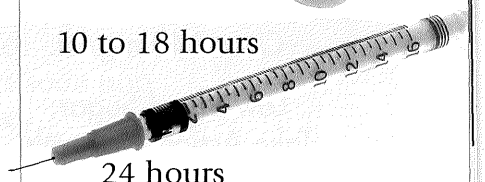
help the pancreas secrete more insulin after meals

Warning!

Some diabetes pills (sulfonylureas, D-phenylalanines and meglitinides) increase the body's natural insulin supply and can cause low blood sugar. Make sure you know the possible side effects for your pills.

Types of Insulin

Name of Insulin	Speed	Starts Working	Duration
Lispro (Humalog®)	Rapid	5 to 15 minutes	3 to 4 hours
Regular	Fast	1/2 to 1 hour	4 to 6 hours
NPH or Lente	Intermediate	2 to 4 hours	10 to 18 hours
Ultralente	Long-acting	3 to 5 hours	18 to 24 hours
NPH and Regular Combination (70/30 or 50/50)	Fast and intermediate	30 minutes	10 to 18 hours
Humalog and NPH Combination (75/25)	Rapid and intermediate	5 to 15 minutes	10 to 18 hours
Glargine (Lantus)	Long-acting	2 to 4 hours	24 hours



What should I know about insulin?

There are currently four types. All work at different speeds and are effective for different lengths of time. Your doctor can help you decide which type or combination of insulin you need, how much you need and when to take it for the best control.

How do I take insulin?

It cannot be given in a pill form because it would be digested in your stomach and unable to get into your bloodstream. So a small, short needle is used to deliver it directly into the fatty tissue under the skin. Usually it's injected in the stomach, thighs or buttocks. You can rotate your injection sites. Just make sure each injection is at least one and a half inches apart.

How much insulin do I need?

It depends on your blood sugar levels, weight, activity level, how much you eat, and your other medication(s). You may need less insulin when you are more active, or more insulin if you'll be eating more than usual.

When is the best time to take it?

Your insulin program will depend on your blood sugar levels and the timing and content of your meals, as well as your activity levels and type of insulin. The amount of insulin injected can also be changed depending on your pre-meal blood sugar level.

If you're on an intensive insulin therapy program, you'll want to learn how to adjust the amount of your insulin to meet your target blood sugar levels. That will give you greater flexibility over the timing and quantity of your meals. Ask our nurse or your doctor how to make appropriate insulin adjustments.

Did you know?

Insulin injected into the stomach is absorbed the fastest.

GOAL #5

Know How to Treat High and Low Blood Sugar

High Blood Sugar:
Take Action for Fasting Levels
Over 140 mg/dL

Low Blood Sugar:
Take Action for Levels
Below 80 mg/dL

What should I know about highs and lows?

What's important is frequent testing, since many people do not notice symptoms of high blood sugar. Some people cannot feel symptoms of low blood sugar either. Testing helps you take steps to control blood sugar without letting your level get too high or low.

Type 1 diabetes alert

When blood sugar levels stay high and your body can't use sugar for energy, your body burns fat for fuel. That can cause damaging acids, called ketoacids, to build up in your blood and spill into your urine. This is called ketoacidosis and it's a medical emergency. If untreated, it can lead to serious illness and coma. Signs include nausea or vomiting, diarrhea, and rapid, shallow breathing.

Signals for Action	Causes	Signs & Symptoms
High Blood Sugar (Hyperglycemia)		
If blood sugar level stays above 140 mg/dL, you may have **hyperglycemia.** This can lead to serious illness and requires adjustments in your daily care plan.	**1.** TOO MUCH of the things that RAISE blood sugar, like: • Overeating • Stress **2.** TOO FEW of the things that LOWER it, like: • Not enough insulin or pills • Missed doses of insulin or pills • Using insulin that's expired • Too little exercise **3.** ILLNESS, infection or drug interactions	• Going to the bathroom m than usual • Headache/moodiness • Thirst or hunger • Weight loss without trying • Dry skin • Blurry vision
Low Blood Sugar (Hypoglycemia)		
If blood sugar levels drop below 80 mg/dL, you may have **hypoglycemia.** It can cause symptoms in people who take insulin or certain diabetes pills.	**1.** TOO MUCH of the things that lower blood sugar levels, like: • Skipped or delayed meals • Too much insulin • Too many diabetes pills • More exercise than usual • Alcohol **2.** TOO LITTLE food **3.** INTERACTIONS with other medications	• Headache • Sweating or shakiness • Feeling nervous or irritated • Hunger or weakness • Dizziness or confusion • Fast heartbeat

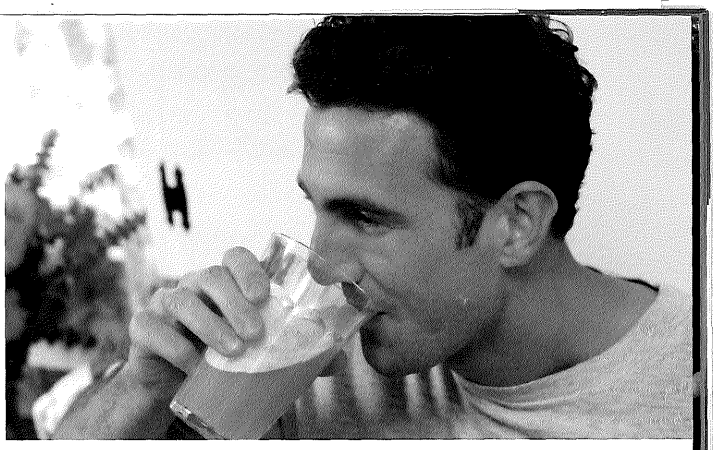
For more information on high and low blood

How will I know if I have ketoacids?

It's easy to test your urine for ketoacids. If you have type 1 diabetes, you should get test strips at the drug store and keep them handy. (People with type 2 diabetes rarely produce ketoacids, but some doctors recommend testing for those who are seriously ill.) Having small traces of ketoacids can be normal. If your level is moderate or high, call your doctor immediately.

Low Blood Sugar Safety Tips

- Always carry glucose tablets or fast-acting sugar.
- Wear some form of diabetes ID.
- Never drive if your blood sugar is below 90 mg/dL.



Fast-Acting 15-Gram Carbs For Hypoglycemia

1/2 cup fruit juice
1/2 cup non-diet soda pop
1T syrup or honey
2T raisins
3-6 hard candies
3 sugar packets
2-3 glucose tablets

Action Plan	Call Doctor IF
1. Take your usual medicine. 2. Check blood sugar level regularly. 3. Think about what may have contributed to your high blood sugar level. 4. Make adjustments in your diabetes care plan accordingly.	• Your fasting blood sugar level is always higher than 140 mg/dL OR two blood sugar tests in a row are greater than 300 mg/dL. • You are sick, your blood sugar stays over 240-300 mg/dL, or you have symptoms of ketoacidosis.

1. Eat or drink something with 15 grams of fast-acting sugar. Check the Fast-Acting 15-Gram Carbs list, and keep some of those things on hand. 2. Wait 15 minutes, then check your blood sugar level again. If it's still less than 80, or if you don't feel better, treat again with 15 grams of fast-acting carbs. 3. When your blood sugar level starts to go up, eat your regular meal or a small snack, such as an 8-oz. glass of milk and half of a peanut butter sandwich.	• You have low blood sugar reactions often and are taking insulin or certain diabetes pills. ***NOTE:*** *You could pass out from a very low blood sugar level. It's important to have glucagon available. It's a hormone that raises blood sugar levels. Ask your doctor if you need a prescription. It comes in a kit and should be injected quickly for severe low blood sugar reactions when you pass out or become too confused to help yourself. Be sure to tell family members, friends and co-workers where you keep it and how to use it.*

ugar, call our support line.

GOAL #6

Take Special Care When You're Sick

Illness or infection can cause your blood sugar level to rise. Without proper care, the problem could become serious. It's important to talk with your doctor and set up a sick day plan, so you and/or a caregiver will know what to do.

What's the best plan for you?

Here's what you should ask your doctor:

- How often should I check blood sugar levels and test my urine for ketoacids?
- What should I eat if I can't tolerate solid food?
- How much fluid should I have?
- Will I need additional medication or insulin and when should it be taken?
- When should I contact you?

Sick day action guide

The ADA recommends the following general guidelines:

1. Check blood sugar level every four hours until you're better.
2. Take your medication unless your doctor tells you not to; ask if additional insulin is needed.
3. Test your urine for ketoacids every 4 to 6 hours if blood sugar is over 240-300 mg/dL.
4. Try to have your usual amount of "carbs" and 1/2 cup of fluid every 30 to 60 minutes.
5. Record blood sugar levels, signs and symptoms. Use your Daily Health Manager!

What if I'm too sick to eat or take my medication?

No matter how you feel, you must continue to take your medication. If you're too sick to eat *regular* meals, ask our nurse or your doctor what you should eat and drink. If you can't keep your medication down, be sure to call your doctor.

Call the doctor IF

- You've been sick or had a fever for a couple of days and aren't getting better.
- Vomiting or diarrhea continues for more than six hours.
- You have moderate to high ketoacids in your urine.
- Your glucose level is higher than 240 mg/dL even with the extra insulin your sick day plan may require.
- You take diabetes pills and your blood sugar climbs above 240 mg/dL before meals and stays there for more than 24 hours.
- You have symptoms of ketoacidosis, dehydration or any other serious condition.

GOAL #7

If You Smoke, Take Steps to Quit!

Smoking has proven to be unhealthy, but it's even more dangerous when you have diabetes. That's because it can aggravate many of the problems you already face.

How does smoking impact diabetes?

You can suffer the effects in several ways. Smoking can:

- restrict the flow of oxygen, damaging and constricting your blood vessels
- increase the likelihood of nerve damage and kidney disease
- raise your blood glucose level, making it harder to manage your diabetes
- worsen existing foot ulcers, leading to leg and foot infections

Did you know?

Among people with diabetes who need foot amputations, 95% are smokers.

Can't I just cut down?

It's never easy to change long-time habits. It is important, however, that you stop smoking completely.

There's always help if you need it.

A free smoking cessation kit is available as part of this program. Feel free to call and request a copy.

No butts about it!

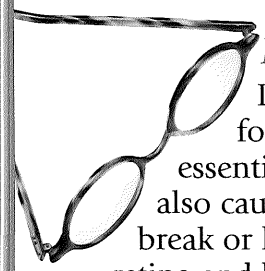
Circle the tips you plan to try:

1. Use a nicotine patch or gum.
2. Keep sugarless mints on hand.
3. Make a sincere promise to your family.
4. Reward yourself every day you don't smoke.
5. Ask for suggestions from ex-smokers.

GOAL #8

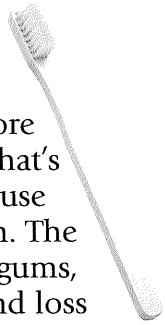
Prevent Complications with Good Diabetes Care

High levels of blood sugar can cause serious problems over time. Medical advancements have made great strides in helping to detect, prevent and even correct many of the side effects of diabetes. Protecting your health, however, is still vital. Let's take a closer look at what you can do to avoid the complications of diabetes.



Eye disease

Diabetes causes vision changes for many people, so eye care is essential. High blood sugar levels can also cause small vessels in the eye to break or leak. They can also damage the retina and block vision. Diabetic retinopathy is the leading cause of blindness in adults under age 65. Common problems, like cataracts and glaucoma, are twice as likely to occur and often, at an earlier age.



Dental disease

Gum problems (or periodontal disease) occurs more often and more severely in people with diabetes. That's because high levels of sugar can cause bacteria to build up in your mouth. The results are red, tender or bleeding gums, which can lead to bone damage and loss of teeth. Good dental care can help.

Kidney disease

Both high blood sugar and high blood pressure can damage your kidneys, making it harder to filter out wastes. This is called diabetic nephropathy. Kidney damage can't be reversed, and there are no symptoms until it's severe. Eventually, the kidneys can stop functioning completely. Diabetes is the leading cause of dialysis in our country. It's also responsible for more than one-third of all cases of end-stage kidney disease.

Protect yourself with regular tests and exams

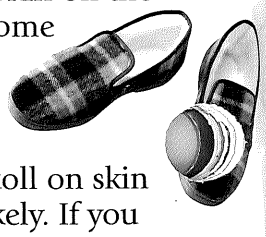
Exam	Frequency
Dilated eye exam	Annually
Dental exam/cleaning	Every 6 months
Kidney/urine protein screen	Annually
Foot checks and exams	Daily and at each doctor visit; a thorough exam yearly
Lipid profile	Annually (or every other year if levels are healthy)
Blood pressure check	Every doctor's visit

Nerve damage

When high blood sugar levels damage nerves, they're no longer able to carry messages properly. About 60%-70% of people with diabetes develop some form of nerve damage, or diabetic neuropathy. It can affect the feet, hands, digestion or sexual performance. Symptoms include a tingling, burning or jabbing feeling; weak muscles; fainting; vomiting; impotence; bladder infections or diarrhea.

Skin problems

Damaged nerves and narrowed blood vessels can both lead to dry, itchy skin. You may have spots of various colors, blisters, fatty bumps (lipodystrophy) and rashes. Skin on the hands and feet may also become waxy and tight.



Foot problems

When nerve damage takes a toll on skin and feet, injuries are more likely. If you have a loss of sensation (a condition called peripheral neuropathy), you may not notice an injury. Poor circulation also keeps sores from healing and makes infections more likely. Foot injuries can become severe and even lead to amputation. That's why it's so important to examine and care for your feet regularly.

How can you improve circulation to your feet?

Use them, even if it's just for walking!

- Avoid sitting for long periods of time.
- Try to prop feet up when sitting.
- When feet are propped, rotate ankles and wiggle toes.
- Keep your cholesterol levels in the target range.
- Stop using nicotine.

Heart and blood vessel damage

Along with high blood sugar levels, things like high blood pressure and high cholesterol can contribute to many problems in your body. You can help avoid complications by taking good care of your heart. We'll review that next.

Action Plan for Better Health

Eye Care

- Have annual eye exams and mention your diabetes to your eye doctor.
- Be sure the doctor dilates your pupils to detect blood vessel changes.
- Call your eye doctor if you notice any changes between exams.
- Laser surgery is an option to keep damage from getting worse, but early detection is key!

Dental Care

- Brush your teeth twice a day.
- Floss your teeth daily and rinse with water.
- Gently brush your tongue, which can trap germs.
- Tell your dentist you have diabetes and schedule visits and cleanings twice a year.
- Call the dentist about bleeding, sore or swollen gums, sore or loose teeth or trouble chewing.

Kidney Care

- Have your doctor check your kidneys every year with blood and urine tests.
- The urine test, called the microalbumin test, checks for high levels of protein in the urine. That's a condition called microalbuminuria. It gives you an early warning if a kidney is not working well.
- Medications, called ACE inhibitors, may prevent or delay further damage.

Nerve Control

- Pain can be treated with antidepressant drugs, exercises or special skin cream medications.
- Surgery can sometimes help.
- Treatments are available when stomach, gut or bladder nerves are affected.
- If applicable, talk to your doctor about sexual problems.

Skin Care

- Maintain a good diabetes care plan.
- Check for cuts and keep them clean.
- Moisturize often, except where skin touches skin.

Foot Care

- Wash and dry feet carefully.
- Moisturize, but not between toes.
- Protect from extreme temperatures.
- Wear cotton or wool socks that fit properly.
- Wear shoes that fit well.
- Check shoes for anything rough before wearing.
- Avoid going barefoot.
- Check daily for injuries. Call your doctor if you notice an area that's red, swollen or tender.
- Wash cuts carefully.
- Do not use harsh chemicals, such as corn or callous removers. Have corns and calluses removed by a healthcare professional.

Record all test results on your Personal Health Manager and discuss them when you see your doctor!

GOAL #9

Adopt a Heart-healthy Lifestyle

Action Plan	Goal
Blood Pressure	Less than 130/80
Cholesterol	Less than 200
Full Lipid Profile	HDL: Above 45 for men and 55 for women LDL: Below 100 Triglycerides: Less than 150

Heart-healthy Tips

1. Maintain target blood sugar levels.
2. Maintain blood pressure below 130/80.
3. Maintain fat and cholesterol goals.
4. Lose weight if necessary.
5. Become or stay active.
6. Stop smoking.
7. Reduce stress.
8. Take aspirin if your doctor says it's OK.

How does diabetes affect my heart?

People with diabetes have a much higher risk of heart attacks and stroke than others. In fact, those with type 2 diabetes have a two to four times greater chance of developing heart disease. You can help protect your heart by following the goals above.

Why is heart disease common with diabetes?

It's partly due to changes in the circulation system caused by the impact of high blood sugar on blood vessels. They become clogged and blood flow is restricted throughout the body. People with diabetes have a higher risk for heart disease if they have:

- Higher than average blood pressure (or hypertension)
- Higher than average levels of cholesterol
- Higher than average triglycerides
- High levels of insulin
- Higher weight

What does high blood pressure do?

It makes it harder for your heart to pump blood throughout your body. The increased pressure against artery walls can cause:

- a faster rate of damage to the blood vessels that serve your heart
- a faster rate of damage to your kidneys
- a faster rate of damage to your eyes

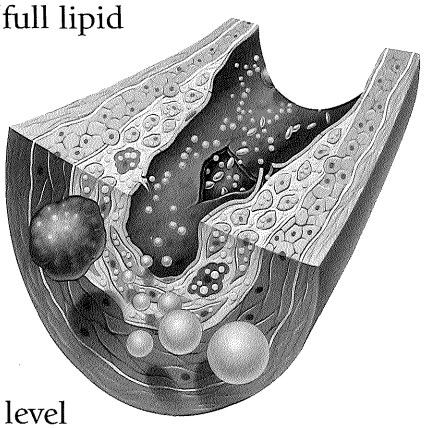
How can I tell if my blood pressure is high?

Generally, there are no symptoms. That's why you should have your blood pressure checked every time you see the doctor. If it's over your target goal, you should try to bring it down.

Aspirin helps prevent blood clots that can block arteries.

How do you measure cholesterol?

In addition to annual blood tests, you should have a fasting "full lipid panel" every year. (If your LDL level is under 100, every other year is fine.) A ' panel measures evel of triglycerides or fats found in your blood. It also tells you about the different types of cholesterol. Your HDL level is a measure of "good cholesterol." It helps clear away cholesterol that may be blocking your blood vessels. The "bad" kind, or LDL cholesterol, clogs your blood vessels, narrowing them and making it harder for blood to flow through. Staying within recommended goals can help you avoid heart and blood vessel problems.



Lower blood pressure 3 ways!

lication can help, and so can suggestions:

1. Eat less salt.
2. Get more exercise.
3. Lose weight.

Signs and symptoms of heart and blood vessel problems

- Chest pressure
- Shortness of breath and fatigue
- Swollen ankles
- Irregular heartbeat
- Dizziness
- Numbness in one arm or leg
- Slurred speech
- Cramping in buttocks, thighs or calves during exercise
- Sometimes, there are no symptoms

Do You Know What Lowers Cholesterol?

- Eating less fatty meats
- Limiting egg yolks to 2-3 per week
- Switching to nonfat or low-fat dairy foods
- Using olive or canola oils, and soft margarine
- Avoiding high-fat fast food and convenience foods

Record test results on your Personal Health Manager and call your doctor if you have symptoms of heart and blood pressure problems.

GOAL #10

Reduce Stress and Anxiety

What is stress?

Stress is anything that produces a strain on you. It can result from upsetting things like illness or job pressures. Or it can come from *good* things, like a new puppy or holiday parties. Some stress is necessary, but too much is not good for your health. It can affect your blood sugar, increase your risk of heart problems, and may hinder good diabetes self-care.

How does stress affect you physically?

It causes your body to release hormones that raise your heart rate and blood pressure. You start to breathe faster, and your blood sugar increases to give your muscles extra energy to react to the stressful situation.

How do you manage stress?

Make a list of all the things that tend to upset you. Then think about what you can do to make them better. Can you change the situation? Try controlling your body's response by relaxing more. Or cope with stress by talking with friends, enjoying a hobby or finding other ways to take your mind off your problem.

Don't let your emotions control you!

Having diabetes can be very stressful and it can bring out all kinds of emotions. Denial, depression and anger are feelings many people with diabetes have experienced. When you're first diagnosed, it's normal to believe there must be some mistake. It's also normal to be sad or angry over the lifestyle adjustments it requires. The inability to get beyond these emotions, however, can put your health in danger.

How can you deal with denial?

Circle the solutions you plan to try.

- Learn about diabetes and the best ways to stay healthy.
- Tell yourself that diabetes does not go away.
- Convince yourself of the benefits of good self-care.
- Write down your goals and the reasons behind them.
- If meal planning is hard for you, talk to a dietitian.
- Ask friends and family members for their support.

Feeling depressed?

Occasional sadness is understandable. Managing diabetes isn't easy, and it's normal to wonder, "Why me?" You may feel tired. Or you may lose your appetite or interest in things you once enjoyed. If you've been feeling this way for two weeks or more, however, it's time to get some help.

- Talk about problems with friends or family. It can often make a world of difference.
- Discuss your symptoms with your doctor. There may be a physical cause for your depression. Poor diabetes control can make you tired and anxious. It can also affect your appetite. You may also be experiencing side effects from medication.
- If your doctor rules out physical causes, consider seeing a specialist who can help you.

How do you handle anger?

Do you find that you get angry easily because of your diabetes? Anger can only make things worse. Here's what you can do:

1. Keep a diary and record the instances when you become angry.
2. When you feel tension coming on, try to calm yourself. Use some of the techniques for managing stress.
3. Put your anger to work for you by learning to change your reactions.

Prepare for changes in your routine.

Travel can be especially stressful for people with diabetes. Planning meals, managing blood sugar levels and remembering to take medication are all harder away from home. Follow our Tips for Travel to avoid blood sugar highs and lows.

Know that help is always at hand.

Sharing what bothers you with family and friends can make it easier to find solutions. There may also be places in your community with support groups. Our nurse or your doctor may be able to refer you to appropriate resources.

Tips for Travel

1. Discuss adjustments with your doctor for the timing of medicine, food and activity.
2. Test blood sugar level more often when traveling.
3. Carry extra blood sugar testing supplies, insulin or pills in case of delays or problems.
4. Keep medicine and supplies with you in carry-on luggage.
5. Always carry some form of ID that says you have diabetes.
6. Keep snacks with you to guard against low blood sugar reactions.

For more information on stress management, call our 24-hour support line.

Tap into these helpful resources for more information.

Want to know more?
For more details on any of the topics covered in this guide, a list of recommended resources follows. A glossary is also provided for explanations of the medical terms used.

Questions? Ask a nurse.
Remember, when you participate in our program, you have the support of a registered nurse for answers and information, day or night. Feel free to call anytime. For more information on pertinent, health-oriented topics, you can also access our website.

www.ecorsolutions.com

Or call the CorSolutions Voice Connections℠ Line toll-free at 877-267-5266.

Resource Guide

ASSOCIATIONS

American Diabetes Association
1701 North Beauregard Street
Alexandria, VA 22311
(800) 232-3472
www.diabetes.org
(Information on local support groups, classes and advocacy services provide some social support information.)

Juvenile Diabetes Research Foundation International
120 Wall Street, 19th Floor
New York, NY 10005
(800) 223-1138
(212) 785-9500
www.jdf.org

National Diabetes Information Clearinghouse
Box NDIC
One Information Way
Bethesda, MD 20892
(301) 654-3327
(800) 860-8747
www.niddk.nih.gov/health/diabetes/ndic.htm

American Dietetic Association
216 W. Jackson Boulevard, Suite 800
Chicago, IL 60606-6995
(312) 899-0040
www.eatright.org

ASSOCIATIONS (Cont.)

American Council of the Blind
1155 15th Street NW, Suite 1004
Washington, D.C. 20005
(800) 424-8666
www.acb.org

Check your telephone directory or Internet for a local diabetes chapter.

BOOKS

Diabetes Burnout: What to Do When You Can't Take it Anymore
William H. Polonsky, PhD, CDE
American Diabetes Association, November 1999
ISBN# 1580400337
Paperback, $18.95

The Diabetes Problem Solver: Quick Answers to Your Questions about Treatment and Self-Care
Nancy Touchette, PhD
American Diabetes Association, June 1999
ISBN# 1580400094
Paperback, $19.95

INTERNET SITES

American Diabetes Association
www.diabetes.org

CDC Diabetes Home Page
www.cdc.gov/diabetes

For an online diabetes resource guide:
www.mendosa.com/diabetes.htm

National Institute of Diabetes and Digestive and Kidney Diseases
www.niddk.nih.gov

National Eye Institute
www.nei.nih.gov

Glossary

ACE inhibitors (abbreviation for Angiotensin-Converting Enzyme Inhibitor) - category of drugs that block certain chemicals in the body from contracting the arteries, causing salt retention and injury to the lining of blood vessels

aerobic activity - any form of physical exercise, like walking, biking or swimming, that requires additional effort by the heart and lungs to meet the increased demand for oxygen. If the exercise exceeds the oxygen carrying capacity, lactic acid and potential bodily harm may result. This is called anaerobic activity.

blood pressure - a measure of the force applied against artery walls as blood is pumped through the body. The top reading, systolic blood pressure, measures the force of the heart's contraction and the ability of the blood vessels to absorb this shock. The bottom reading, the diastolic blood pressure, measures the ability of the small blood vessels to drain off this pressure.

cataract - clouding of the lens of the eye or its surrounding membrane that obstructs the passage of light

cholesterol - a fat that helps make up our body cell walls and is a building block for necessary hormones. In excess, cholesterol is stored in our arteries, usually in the form of LDL cholesterol, and starts the process of artery damage.

circulatory system - the system of blood, blood vessels and heart concerned with the movement of blood throughout the body

dehydration - a reduced amount of water in our circulation. In diabetes, it can result from the excess loss of water in the urine caused by high sugar levels in the blood and then, in the urine.

end stage kidney disease - the point at which the kidney is so badly damaged or scarred that dialysis or transplantation is required for survival

full lipid panel - test that measures the concentration of triglycerides, cholesterol and other fats in the blood

gestational diabetes - type of diabetes that only occurs when a woman is pregnant and has sugar in the blood at a higher than normal level. The two dangers of this condition are the harm to the baby if the sugar level is not controlled during the pregnancy and the mother's increased risk for developing permanent diabetes in the future.

glaucoma - a disease associated with increased pressure within the eye; can damage the optic nerve and cause impaired vision and blindness

glucose - a simple sugar found in the blood which, along with fatty acids, serves as the body's main source of energy; also known as dextrose

glucagon - one of the hormones made by the pancreas that raises blood sugar and is released when levels fall below normal; also given by injection during emergencies when a person cannot eat or drink

HDL cholesterol - high-density lipoprotein, or "good" cholesterol, which helps to remove LDL or "bad" cholesterol from artery walls and sees that it is disposed of elsewhere

heart attack - also known as myocardial infarction; a sudden event that occurs when blood flow is nearly or completely blocked and part of the heart muscle dies; usually accompanied by severe pain under the breastbone, but in diabetes especially, may not be associated with any symptoms

hemoglobin A1C - a simple blood test used in the treatment of diabetes, showing the average amount of sugar in the blood over the last 2 to 3 months; not influenced by what you ate the night before

hyperglycemia - condition commonly associated with diabetes, in which the blood sugar level is higher than normal. A person is diagnosed as having diabetes if fasting blood sugar level is greater than 126 mg/dL on two consecutive occasions.

hypertension - blood pressure that is above the normal range (greater than 130 systolic and greater than 80 diastolic)

hypoglycemia - condition commonly associated with diabetes, in which the blood sugar level is too low (less than 80 mg/dL); can cause dizziness, sometimes fainting or, in severe cases, convulsions, coma or death; or may not be recognized by the patient

insulin - the major hormone responsible for easing the entrance of sugar, amino acids (protein) and fatty acids into cells to be used for energy and building cell parts; released by the pancreas into the bloodstream when blood sugar levels rise above normal; may also be injected when the body cannot make enough on its own

insulin resistance - a common condition in which the body, especially the liver and muscles, respond to take up blood sugar, when the insulin levels are higher than usual. About 20% of patients with this condition will develop type 2 diabetes due to the pancreas' inability to keep up with the body's increasing demand for insulin.

ketoacids - chemicals made by the body when too little insulin or too much sugar in the blood causes the body to burn fat instead of sugar for energy. The waste product from fat metabolism is ketoacids which, if built up over a long time, can lead to serious illness and coma.

ketoacidosis - severe, out-of-control high sugar levels, lack of insulin and the release of insulin-fighting hormones; a condition that requires emergency treatment, including intake of fluids and insulin; occurs when the body starts using stored fat for energy and ketoacids build up in the blood

lancet - a fine, sharp-pointed blade or needle used to prick the skin for a drop of blood to test blood sugar

lancing device - holds the lancet used to test blood sugar

LDL - low-density lipoprotein, or "bad" cholesterol, which contributes to plaque buildup and narrowing of the coronary arteries

mg/dL - milligrams per deciliter of blood; used to express the level of triglycerides, cholesterol and sugar in the bloodstream

microalbumin test - urine test that checks for the existence of special protein in the urine

microalbuminuria - condition in which small amounts of albumin are present in the urine but are greater than normal (more than 30 mg in 24 hours); an early warning that a kidney is not working well and requires treatment

nephropathy - disease of the kidneys caused by damage to the small blood vessels or to the units in the kidneys that clean the blood; occurs more often in people who have had diabetes for a long time

pancreas - an organ behind the lower part of the stomach that makes the hormones insulin and glucagon, in addition to enzymes for digestion

periodontal disease - damage to the gums that affects more people with diabetes than those without it

retinopathy - a disease of the small blood vessels in the retina of the eye that can cause temporary or permanent changes in vision

saturated fat - fats derived from meat, dairy products and hydrogenated shortenings which contribute to high cholesterol levels and increased risk of coronary artery disease

stroke - disease caused by blockage of a blood vessel to the brain which could affect the ability to speak or move part of the body, such as an arm or leg

triglyceride - type of fat in the blood which, in excess, may lead to plaque buildup in the artery walls

type 1 diabetes (formerly known as juvenile onset diabetes and insulin-dependent diabetes) - occurs when the pancreas does not make any insulin and the person must take insulin every day to live

type 2 diabetes (formerly called non-insulin-dependent diabetes and adult onset diabetes) - occurs when the pancreas produces some insulin but the cells are more resistant to its action than usual. In some cases, especially soon after diagnosis, it may be managed by diet and exercise alone but oral medication or insulin may be needed if blood sugar levels remain high.

CorSolutions is the nation's leading provider of lifestyle change and treatment support programs. Firmly committed to staying at the forefront of medicine, we're setting new standards in healthcare as we work to improve the quality of people's lives. Our exclusive MULTIFIT℠ approach, developed at Stanford University, and our leading-edge technology link the physician, nurse and patient as never before. Together, we're successfully reducing symptoms, lowering risk and improving the health and well-being of those in our programs.

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www.ecorsolutions.com

DIACG 0403

Medications	Dose	Freq.

Family Doctor

Address

Phone

Health Insurance

Policy No.

Social Security No.

Date of Birth

In case of emergency, contact:

Name

Address

Phone

COR SOLUTIONS

0403

CorChoices℠

Personal Health Manager

Name

Address

Phone

COR SOLUTIONS.

2-Year Diabetes Review

			Year _____				Year _____			
	Goal	Initial	3 Month	6 Month	9 Month	Annual	3 Month	6 Month	9 Month	Annual
DATE										
Weight										
A1C	<7%									
Blood Pressure	<130/80									
Foot Exam	Every Visit									
Dental cleaning	Bi-Annual									
Kidney/Urine protein	Annual									
Dilated Eye Exam	Annual									
FULL LIPID PANEL: Cholesterol	<200									
FULL LIPID PANEL: HDL	Women: >55 Men: >45									
FULL LIPID PANEL: LDL	<100									
FULL LIPID PANEL: Triglycerides	<150									

For easy reference, please list your medications on the reverse side.

CorChoices℠

Daily Health Manager

CORE SOLUTIONS

Name

Address

City

State Zip

Telephone ( )

Be sure to update your Daily Health Manager every day to help keep track of your progress!

Questions? Call our 24-hour support line.

Week starting Monday: October 2 (Date)

	BREAKFAST		LUNCH			DINNER	BEDTIME	
DAY	Blood Glucose/ Medication	Food/Activity	Blood Glucose/ Medication	Food/Activity	Blood Glucose/ Medication	Food/Activity	Blood Glucose/ Medication	Food
Mon	183 16N/6R	1/2 bagel 6 oz o.j. rice krispies 4 oz milk, coffee walked-2 miles	201	tuna sandwich apple, salad iced tea	150 12N/6R	pasta 2 slices bread salad apple pie	250 2R	no snack
Tue	201 16N/6R	1/2 Eng. muffin 6 oz o.j. rice krispies, milk	228	tuna salad orange NO BREAD golfed-9 holes	120 12N/6R	chicken, potato green beans 2 slices bread fruit	140	pretzels
Wed	190 16N/6R	1/2 bagel 1/2 grapefruit swam-1/4 mile	135	turkey sandwich apple, 2 cookies iced tea	133 12N/6R	fish, corn on cob salad, peas 1 slice bread fruit salad	115	cereal, 1/2 cup milk

Week starting Monday: _____ (Date)

	BREAKFAST		LUNCH		DINNER		BEDTIME	
DAY	Blood Glucose/ Medication	Food/Activity	Blood Glucose/ Medication	Food/Activity	Blood Glucose/ Medication	Food/Activity	Blood Glucose/ Medication	Food/Activity
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Week starting Monday:_____ (Date)

	BREAKFAST		LUNCH		DINNER		BEDTIME	
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Week starting Monday:_____ (Date)

	BREAKFAST		LUNCH		DINNER		BEDTIME	
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Week starting Monday:_____ (Date)

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DAY	Blood Glucose/ Medication	Food/Activity	Blood Glucose/ Medication	Food/Activity	Blood Glucose/ Medication	Food/Activity	Blood Glucose/ Medication	Food/Activity
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Week starting Monday:_____ (Date)

	BREAKFAST		LUNCH		DINNER		BEDTIME	
DAY	Blood Glucose/ Medication	Food/Activity	Blood Glucose/ Medication	Food/Activity	Blood Glucose/ Medication	Food/Activity	Blood Glucose/ Medication	Food/Activity
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Week starting Monday:_____ (Date)

	BREAKFAST		LUNCH		DINNER		BEDTIME	
DAY	Blood Glucose/ Medication	Food/Activity	Blood Glucose/ Medication	Food/Activity	Blood Glucose/ Medication	Food/Activity	Blood Glucose/ Medication	Food/Activity
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Week starting Monday:_____ (Date)

	BREAKFAST		LUNCH		DINNER		BEDTIME	
DAY	Blood Glucose/ Medication	Food/Activity	Blood Glucose/ Medication	Food/Activity	Blood Glucose/ Medication	Food/Activity	Blood Glucose/ Medication	Food/Activity
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Week starting Monday:_____ (Date)

	BREAKFAST		LUNCH		DINNER		BEDTIME	
DAY	Blood Glucose/ Medication	Food/Activity	Blood Glucose/ Medication	Food/Activity	Blood Glucose/ Medication	Food/Activity	Blood Glucose/ Medication	Food/Activity
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Week starting Monday:_____ (Date)

	BREAKFAST		LUNCH		DINNER		BEDTIME	
DAY	Blood Glucose/ Medication	Food/Activity	Blood Glucose/ Medication	Food/Activity	Blood Glucose/ Medication	Food/Activity	Blood Glucose/ Medication	Food/Activity
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Week starting Monday:_____ (Date)

	BREAKFAST		LUNCH		DINNER		BEDTIME	
DAY	Blood Glucose/ Medication	Food/Activity	Blood Glucose/ Medication	Food/Activity	Blood Glucose/ Medication	Food/Activity	Blood Glucose/ Medication	Food/Activity
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Week starting Monday:_____ (Date)

	BREAKFAST		LUNCH		DINNER		BEDTIME	
DAY	Blood Glucose/ Medication	Food/Activity	Blood Glucose/ Medication	Food/Activity	Blood Glucose/ Medication	Food/Activity	Blood Glucose/ Medication	Food/Activity
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Week starting Monday:_____ (Date)

DAY	BREAKFAST		LUNCH		DINNER		BEDTIME	
	Blood Glucose/ Medication	Food/Activity	Blood Glucose/ Medication	Food/Activity	Blood Glucose/ Medication	Food/Activity	Blood Glucose/ Medication	Food/Activity
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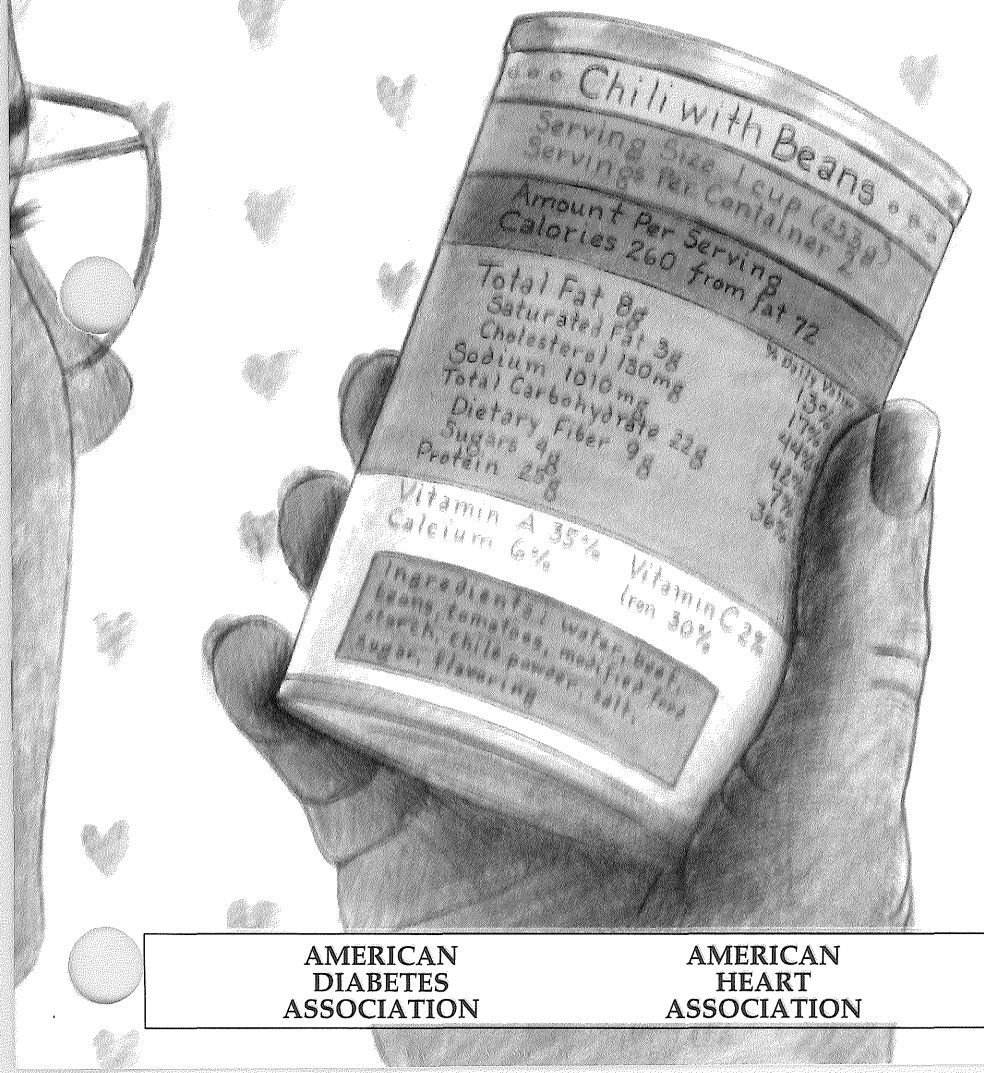
Reading Food Labels

A Handbook For People With Diabetes



AMERICAN DIABETES ASSOCIATION

AMERICAN HEART ASSOCIATION

The American Diabetes Association gratefully acknowledges the contributions of the following health care professionals:

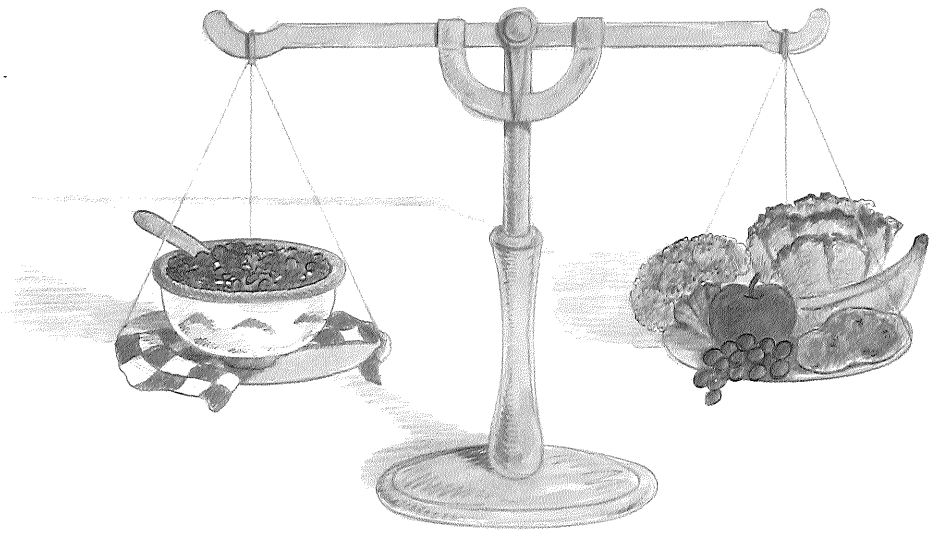
Susan Thom Barlow, RD, LD, CDE; Phyllis Barrier, MS, RD, CDE; Carolyn Leontos, MS, RD, CDE; Clara Schneider, MS, RD, RN, LD, CDE; and Madelyn Wheeler, MS, RD, CDE. Illustrations by Rebecca Schoenfliess.

3 4 5 6 7 8 07 06 05 04 03

Nutrition Facts on Food Labels

Use the **Nutrition Facts** panel on food labels to help you choose healthy foods. When you eat healthy foods, you can better control your diabetes. This booklet will help you use **Nutrition Facts.**

Nutrition Facts list **% Daily Values.** The % Daily Values are based on a 2,000-calorie diet. Most likely, the Daily Values you need are different than those given on the label. Your dietitian will give you your individual Daily Values. People with diabetes need to know their Daily Values for carbohydrate, fat, sodium, and calories. Carbohydrate has the most impact on blood glucose.



See your dietitian. Decide how many calories you need each day and your own **Daily Values** for fat, saturated fat, sodium, carbohydrate, dietary fiber, and protein. Put the numbers on your **Diabetes Nutrition Facts Card** below. Cut out or copy this card to take with you when you shop.

My Diabetes Nutrition Facts Card

My calorie needs are _____ each day.

This breaks down to:

	DAILY VALUES
fat	_____ grams or less
saturated fat	_____ grams or less
sodium	_____ milligrams or less
carbohydrate	_____ grams or more
dietary fiber	_____ grams or more
protein	_____ grams or less

The food label gives a lot of information. Use the canned chili label on the next page to find out:

How many servings are in the can? ____ (Clue: see A.)
How large is each serving? _____ (Clue: see A.)
If you eat the whole can, you'll eat ____ calories. (Clue: see B.)

Answer: 2 servings; 1 cup; 520 calories.

Chili With Beans

Nutrition Facts

(A) **Serving Size 1 cup (253 g)**
Servings Per Container 2

(B) **Amount Per Serving**
Calories 260 **Calories from Fat 72**

	% Daily Value
(C) Total Fat 8g	13%
Saturated Fat 3g	17%
Cholesterol 130 mg	44%
Sodium 1010mg	42%
Total Carbohydrate 22g	7%
Dietary Fiber 9g	36%
(D) Sugars 4g	
Protein 25g	

Vitamin A 35%	**Vitamin C 2%**
Calcium 6%	**Iron 30%**

*Percent Daily Values are based on a 2,000-calorie diet. Your Daily Values may be higher or lower depending on your calorie needs.

Ingredients: water, beef, beans, tomatoes, modified food starch, chili powder, salt, sugar, flavoring

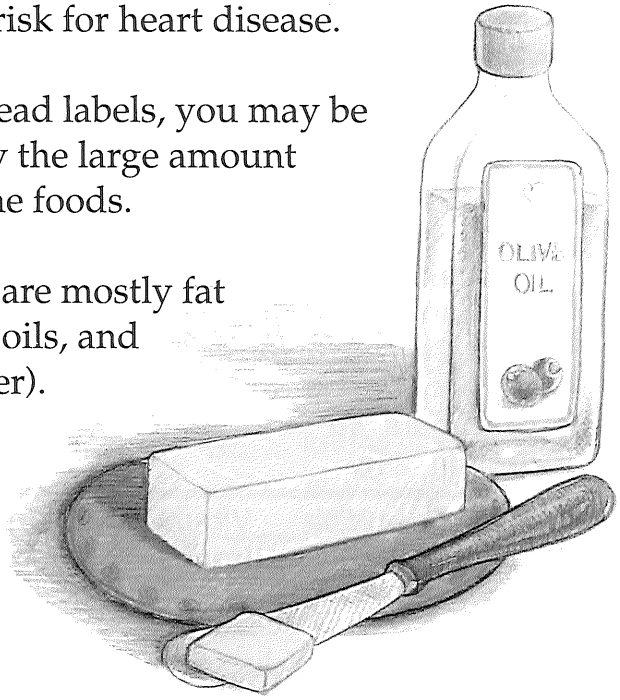
(E)
1 Starch Exchange,
3 Lean Meat Exchanges,
1 Vegetable Exchange

Why Fat Matters

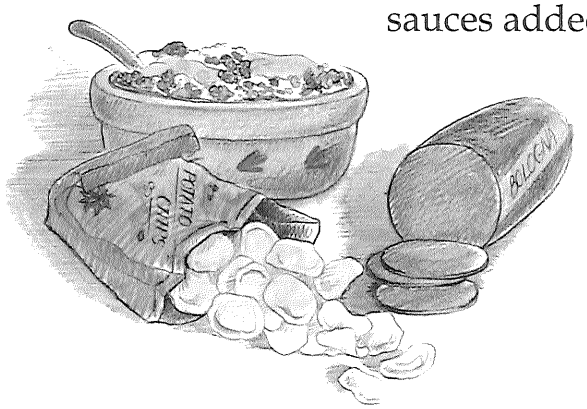
People with diabetes are 2 to 4 times more likely to have heart problems than other people. Eating foods lower in fat, especially **saturated** fat, may lower your risk for heart disease.

When you read labels, you may be surprised by the large amount of fat in some foods.

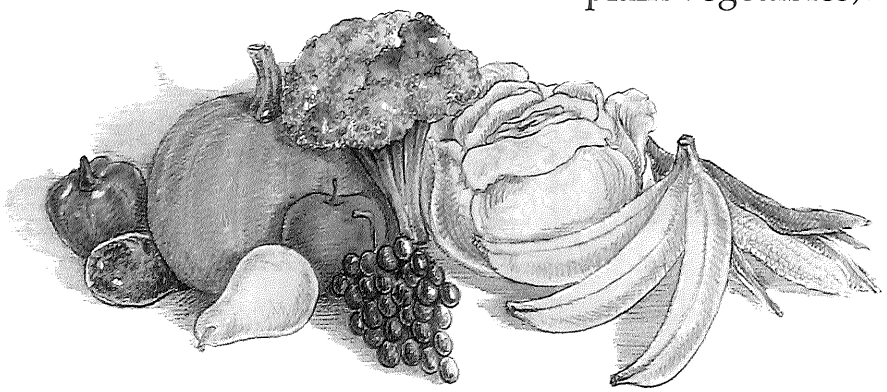
Some foods are mostly fat (margarine, oils, and peanut butter).



Some foods have more fat than you think (casseroles, meat, chips and other snack foods, sauces added to foods).



Some foods have very little fat (fruits, fruit juices, plain vegetables).



Labels Can Tell You If Food Is Low in Fat and Saturated Fat

Fat **Free** has the least amount of fat.

Very low fat and **Low** fat have a little more.

Reduced fat or **Less** fat always means that the food has 25% less fat than the regular version of the food.

Fat from animal foods (meat fat, dairy fat) is more saturated than fat from vegetables (olive or corn oil). Saturated fat raises blood cholesterol which is a risk for heart disease.

Learn to use food labels to help you eat less fat, especially saturated fat, in your daily meal plan.

Here's how!
Look back at the canned chili label on page 3.

When you eat one cup of chili, you eat _____ grams of fat per cup (Clue: see C). (Answer: 8g.)
Use your **Diabetes Nutrition Facts Card** to find out how much fat is left for you to eat during the rest of the day. ____ g (Clue: subtract the grams of fat in the chili from the grams of fat on your card.)

When you eat one cup of this chili, you eat _____ grams of **saturated** fat. (Answer: 3g.)
How much saturated fat is left for you to eat during the rest of the day? ____ g

True or False?

___1. You have a choice of two foods of the same kind and serving size. The one with less fat and less saturated fat is the better choice.

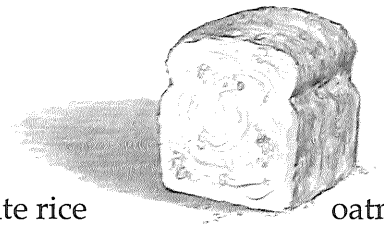
___2. You can eat some high-fat foods if the foods you eat for the rest of the day are low in fat.

(Both 1. and 2. are True.)

Why Carbohydrate Matters

People with diabetes must pay attention to carbohydrate. All carbohydrate turns into blood glucose sooner or later. Carbohydrate comes from many foods. Here are some different foods high in carbohydrate.

CARBOHYDRATES



white rice
brown rice ❦
flours and grains
whole-grain breads ❦
whole-grain cereals ❦
oatmeal ❦
beans/lentils ❦
pasta
fruits ❦
vegetables ❦

Added sugars

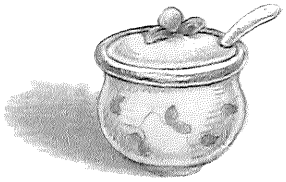
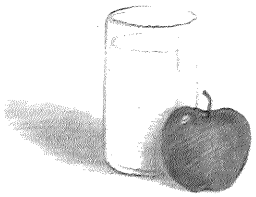


table sugar (sucrose)
corn syrup
dextrose

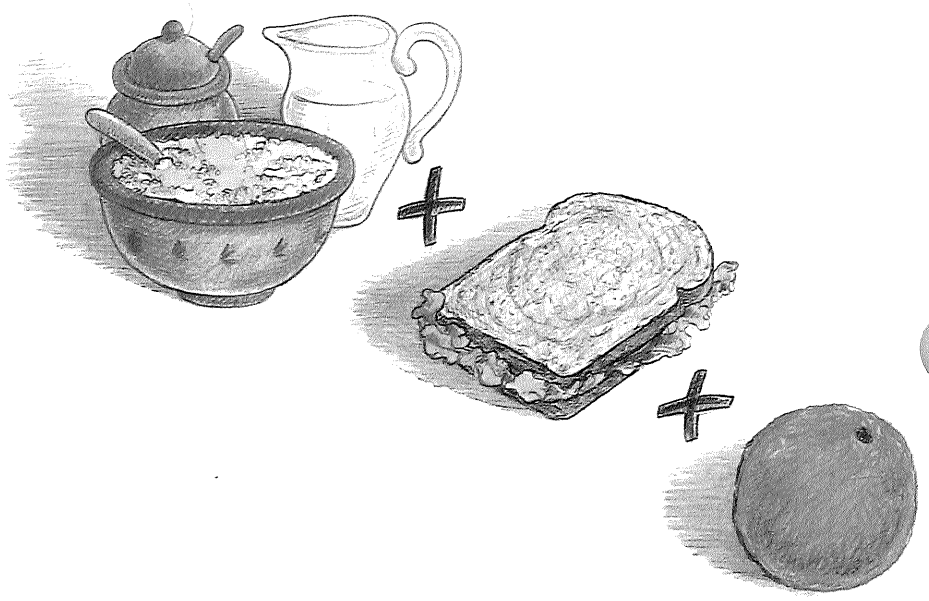
Naturally present sugars



milk sugar (lactose)
fruit sugar (fructose)
fruits and some vegetables ❦

(High-fiber foods have the symbol ❦ .)

Sugars are part of total carbohydrate. These include foods with added sugars and naturally present sugars. **Nutrition Facts** group all sugars together. Food labels such as those on milk or fruit juice show the naturally present sugars. Chili has both naturally present and added sugars. (Clue: see D on page 3.)



Keep in mind that all carbohydrate turns into blood glucose sooner or later! The kinds of carbohydrate are less important than **the total amount of carbohydrate.**

Use the canned chili food label on page 3 to find out about carbohydrate. (You may tear out the page to use it more easily.)

STEP 1:

Find the **ingredients** that are carbohydrate. (Clue: see E.)

beans	modified food starch
tomatoes	sugar

STEP 2:

Look at the **Total Carbohydrate.** One serving has 22 grams. (Clue: see D.)

Use your **Diabetes Nutrition Facts Card** to find out how many more grams of carbohydrate you should eat today. ____ g (Clue: subtract the grams of carbohydrate in the chili from the grams of carbohydrate on your **Diabetes Nutrition Facts Card** on page 2.)

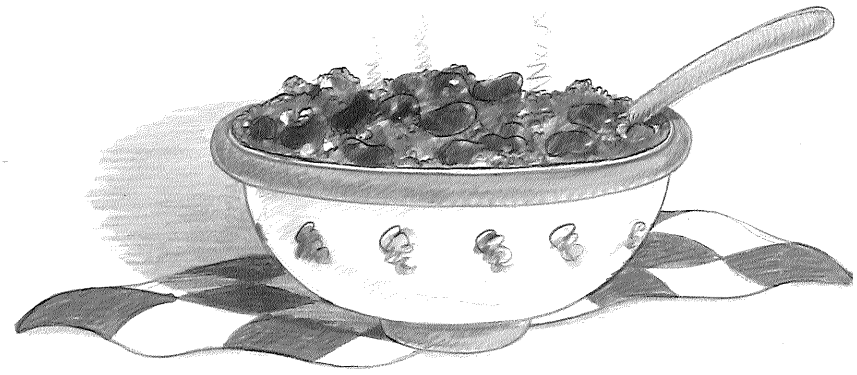
STEP 3:

Look at **Dietary Fiber**. One serving has **9 grams** (Clue: see **D** on page 3.) This is part of the total carbohydrate of **22 grams**. The dietary fiber comes from the **beans** and **tomatoes**.

When you eat one cup of chili, how much more dietary fiber do you need to eat today? ____ g (Clue: subtract the grams of **dietary fiber** in the chili from the total grams of dietary fiber on your **Diabetes Nutrition Facts Card**.)

STEP 4:

Look at **Sugars**. One serving has **4 grams**. (Clue: see **D**.) This is part of the **total carbohydrate** of **22 grams**. This comes from added sugar plus the sugar naturally present in the tomatoes.



The Bottom Line: Balancing the Day

If you eat this chili, you now know how much fat, saturated fat, carbohydrate, and dietary fiber you have left to eat at other meals. You and your dietitian will discuss how to divide the carbohydrate you need over the course of the day. Use the total carbohydrate given on the label to help you count grams of carbohydrates.

Remember:

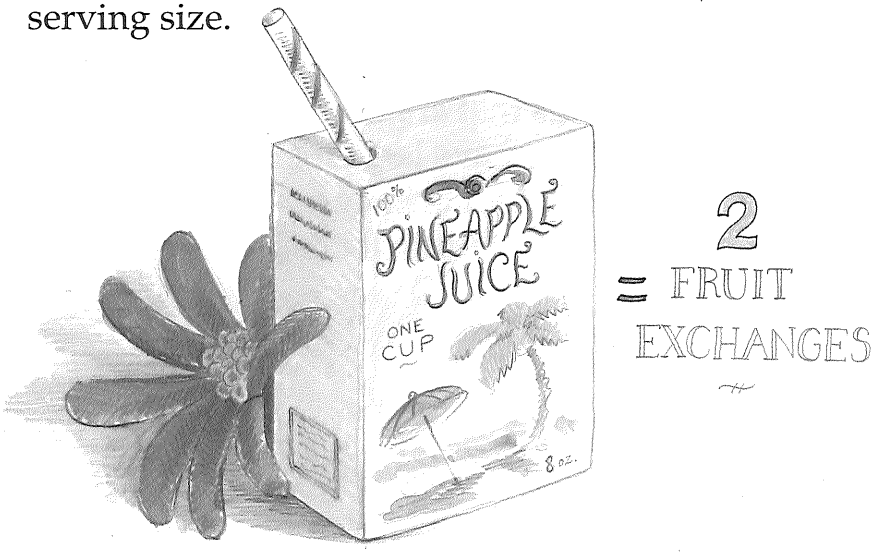
- Choose lean meats and low-fat dairy products. They are low in saturated fat.
- Choose fresh fruits and vegetables. They have vitamins and minerals and no fat.
- Choose foods that are low in added sugars. They may have less fat and calories than foods with more sugar.
- Choose lower-sodium foods.

Nutrition Facts give you useful information no matter how you plan your meals.

- If you follow the *Exchange Lists for Meal Planning*,* remember that the serving size on the label may not be the same as the serving size of an exchange.

For example, the label says the serving size of fruit juice is 1 cup. The exchange list says the serving size of fruit juice is 1/2 cup. If you drink 1 cup of fruit juice, you are drinking 2 Fruit Exchanges, not one. Another example is oatmeal. The label says the serving size is 1 cup. The exchange list says a serving is 1/2 cup. If you eat 1 cup, you eat 2 Starch/Bread Exchanges.

Always check your Exchange Lists for the right serving size.



*To order, visit the American Diabetes Association's online bookstore at http://store.diabetes.org or call 1-800-232-6733.

- If you plan your meals using a carbohydrate counting system, the label will tell you exactly how many grams of carbohydrate are in a serving of food.

- If you count fat grams, the label will tell you how many grams of fat are in a serving of food.

- If you count calories, the label will tell you how many calories are in a serving of food.

- If you count sodium, the label will tell you how many milligrams of sodium are in a serving of food.

To improve your health, eat foods lower in sodium and fat. To round out your healthy lifestyle, exercise daily, keep a healthy body weight, and don't smoke.

My Diabetes Nutrition Facts Card

My calorie needs are _____ each day.

This breaks down to:

	DAILY VALUES
fat	_____ grams or less
saturated fat	_____ grams or less
sodium	_____ milligrams or less
carbohydrate	_____ grams or more
dietary fiber	_____ grams or more
protein	_____ grams or less

Cure • Care • Commitment ®

1701 North Beauregard Street
Alexandria, VA 22311

For more information about nutrition, diabetes, and living well with diabetes, call 1-800-DIABETES (1-800-342-2383)

Fighting Heart Disease and Stroke

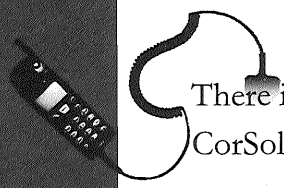
National Center
7272 Greenville Avenue, Dallas, TX 75231-4596

For more information on nutrition, health, heart disease, and stroke, contact your local American Heart Association or call (800) AHA-USA1 (800-242-8721)

Voice Connections℠ from CorSolutions

available to you at any time

TOLL FREE (877) 267-5266



There is another convenient way for you to learn more about your health from CorSolutions.

The *toll free* Voice Connections℠ line is available to you by telephone 24 hours a day with helpful information on a variety of health conditions and ideas for improving your health.

What's more, this service offers you *unlimited access* through exciting technology that's easy to use. When you call, you will be interacting with a computer that understands and responds to your voice. You will simply select the condition you are interested in: diabetes, heart disease, or a respiratory condition. Then you can choose between hearing more about signs and symptoms, medication compliance, stress management, healthy eating, or physical activity. You can also complete a quality of life survey that will help your CorSolutions nurse review your progress and plan for additional care.

Voice Connections℠ is available anytime, day or night–call as many times as you like.

Voice Connections℠

TOLL FREE
(877) COR-5266

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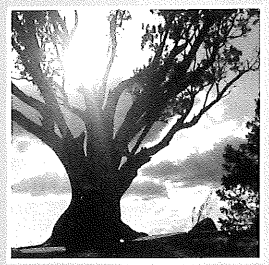
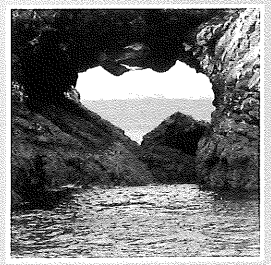
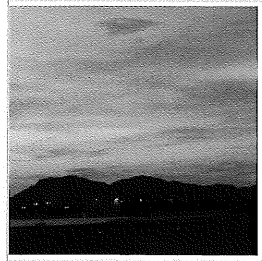


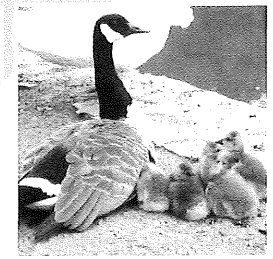
Includes your Personal Health Tracker

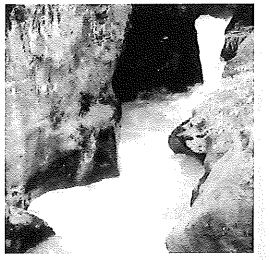
A new year for healthier living

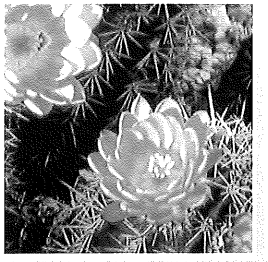


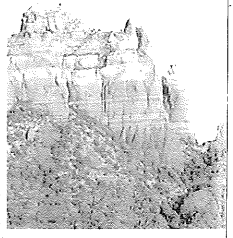
2006











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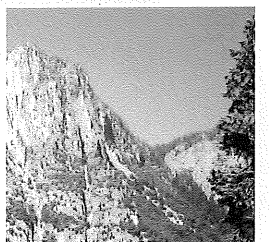
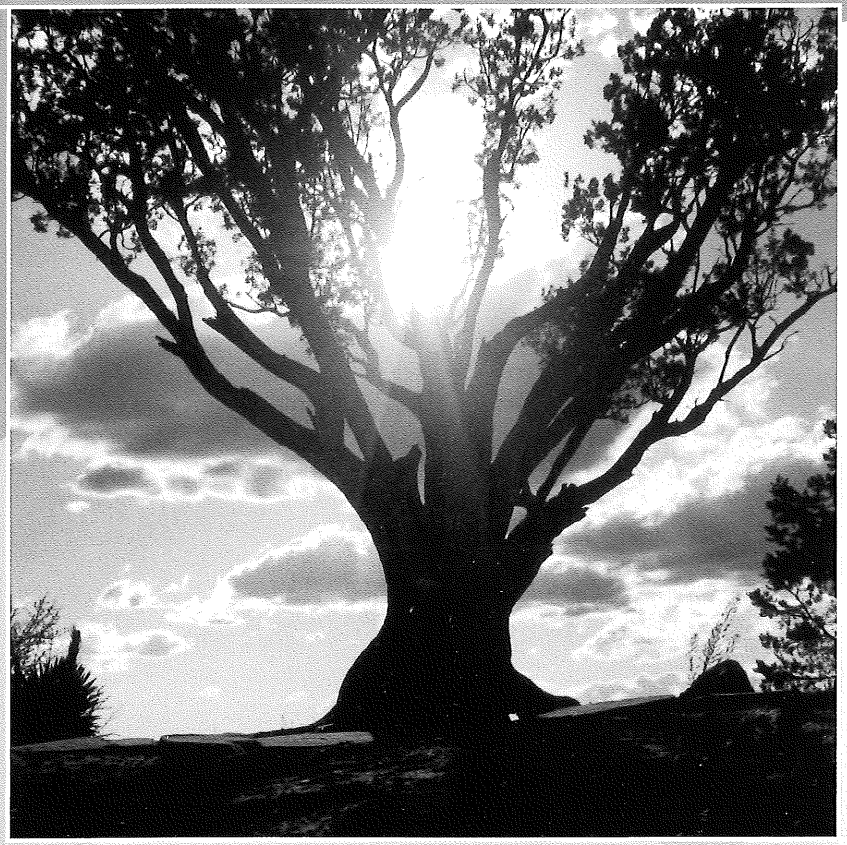


Your healthy future begins with each new day.

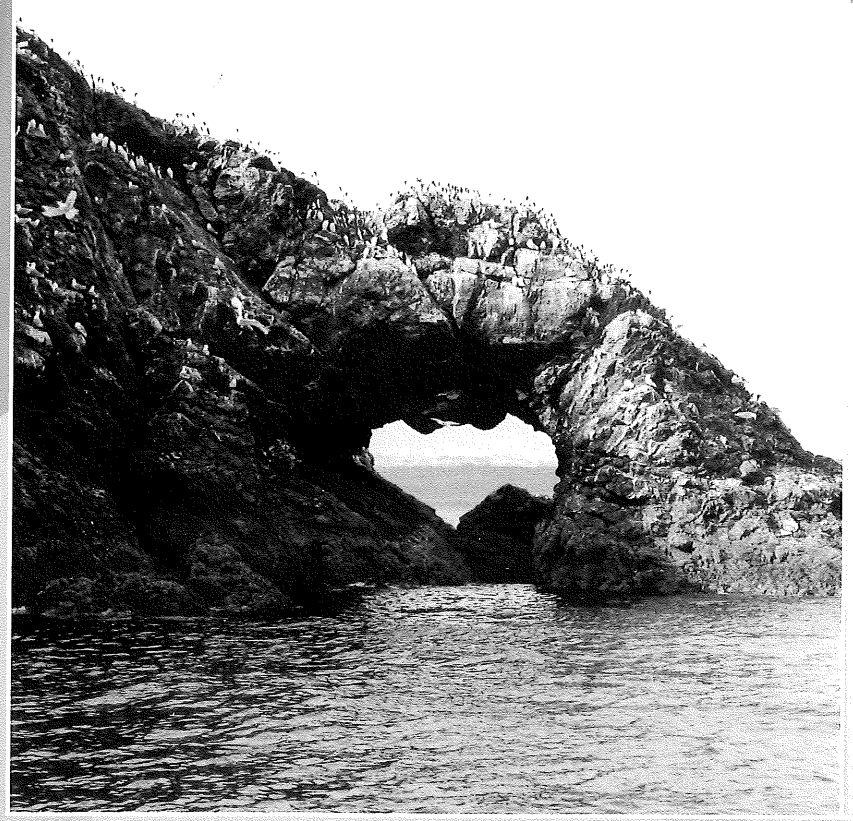


"A New Beginning"
Photo by Shirley Sherrill, R.N.,
CorSolutions Nurse

SUNDAY	MONDAY	TUESDAY	WEDNESDAY	THURSDAY	FRIDAY	SATURDAY
1 **New Year's Day**	2	3	4 National Volunteer Blood Donor Month	5	6	7 Take out the Personal Health Tracker from the center of this calendar and use it as a 2006 health resource.
8	9	10	11	12	13 Have you donated blood lately?	14
15	16 **Dr. Martin Luther King, Jr. Day**	17	18	19	20	21
22	23	24	25	26 As of this month, all food labels must list their trans fat content.	27	28
29	30	31	Learn more about your health from the CorSolutions Voice Connections℠ Line at 877-COR-5266 (877-267-5266)		**DECEMBER 2005** S M T W T F S 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31	**FEBRUARY** S M T W T F S 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28

January 2006

Be good to your heart.



"Kachemak Bay"
Photo by Julie Anne Zeller, R.N.,
CorSolutions Nurse

SUNDAY	MONDAY	TUESDAY	WEDNESDAY	THURSDAY	FRIDAY	SATURDAY
American Heart Month	African-American History Month		1	2 Groundhog Day	3 National Wear Red Day	4
5	6	7	8 Have you had your blood pressure checked recently?	9	10	11
12	13	14 **Valentine's Day**	15	16	17 National Women's Heart Day	18
19	20 **Presidents' Day**	21	22 Take a mall walk with a friend.	23	24	25
26	27	28		To access information on over 5,000 health topics, visit www.ecorsolutions.com		

JANUARY

S	M	T	W	T	F	S
1	2	3	4	5	6	7
8	9	10	11	12	13	14
15	16	17	18	19	20	21
22	23	24	25	26	27	28
29	30	31				

MARCH

S	M	T	W	T	F	S
			1	2	3	4
5	6	7	8	9	10	11
12	13	14	15	16	17	18
19	20	21	22	23	24	25
26	27	28	29	30	31	

February 2006

Everyday, make healthy lifestyle choices.

"Light From Above"
Photo by Kathy Elleray, R.N.,
CorSolutions Nurse

SUNDAY	MONDAY	TUESDAY	WEDNESDAY	THURSDAY	FRIDAY	SATURDAY
FEBRUARY S M T W T F S 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28	**APRIL** S M T W T F S 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30	American Red Cross Month National Nutrition Month	1 **Ash Wednesday**	2	3	4
5	6 Keep your first-aid kit up-to-date.	7	8	9	10	11
12	13	14	15 Are you eating a healthy breakfast each morning?	16	17 **St. Patrick's Day**	18
19	20 Spring Begins	21	22	23	24	25
26	27	28	29	30	31	Learn more about your health from the CorSolutions Voice Connections℠ Line at 877-COR-5266 (877-267-5266)

March 2006

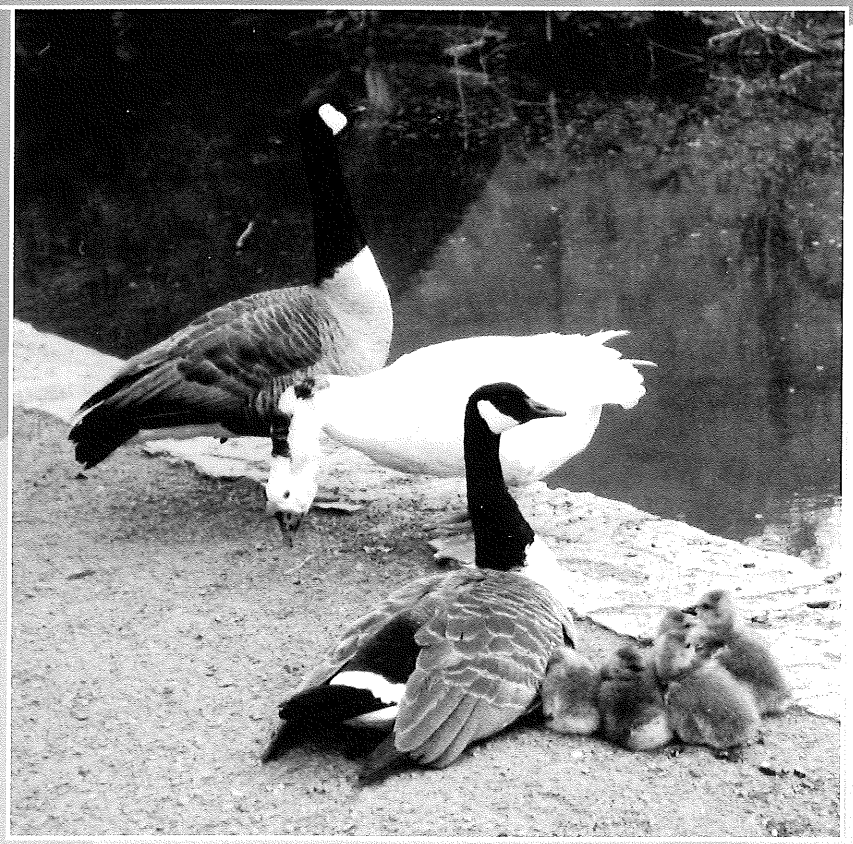
Spring forward with new goals.

"Bouquet"
Photo by Nancy Yetsko, R.N.,
CorSolutions Nurse

SUNDAY	MONDAY	TUESDAY	WEDNESDAY	THURSDAY	FRIDAY	SATURDAY
MARCH S M T W T F S 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31	**MAY** S M T W T F S 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31	Cancer Control Month	To access information on over 5,000 health topics, visit www.ecorsolutions.com		Fasten your seat belt every time you're in the car.	1
2 Daylight-Saving Time Begins	3	4	5	6 National Alcohol Screening Day	7 Alcohol Free Weekend (April 7-9)	8
9 **Palm Sunday**	10	11	12 **Passover** Begins at Sundown	13	14 **Good Friday**	15
16 **Easter**	17 Income Taxes Due	18	19	20	21	22
23 30	24	25	26	27 Watch for changing moles on your skin.	28	29

April 2006

Make time for family and friends—it's healthy.



"Summer's First Swim"
Photo by Kathy Vaders, R.N.,
CorSolutions Nurse

SUNDAY	MONDAY	TUESDAY	WEDNESDAY	THURSDAY	FRIDAY	SATURDAY
Learn more about your health from the CorSolutions Voice Connections℠ Line at 877-COR-5266 (877-267-5266)	1 Older Americans Month National High Blood Pressure Education Month	2	3	4	5	6 National Nurses Week (May 6-12)
7	8	9	10	11	12	13
14 **Mother's Day**	15 Last day to sign up for a Medicare drug plan to avoid higher premiums. Call 1-800-MEDICARE	16	17 National Employee Health & Fitness Day	18	19	20 Armed Forces Day
21	22	23	24	25	26	27
28	29 **Memorial Day**	30	31 National Senior Health & Fitness Day	Asian Pacific American Heritage Month		

APRIL

S	M	T	W	T	F	S
						1
2	3	4	5	6	7	8
9	10	11	12	13	14	15
16	17	18	19	20	21	22
23	24	25	26	27	28	29
30						

JUNE

S	M	T	W	T	F	S
				1	2	3
4	5	6	7	8	9	10
11	12	13	14	15	16	17
18	19	20	21	22	23	24
25	26	27	28	29	30	

May 2006

Balance the demands of life with relaxation.

"Ocean Blue"
Photo by Carolyn Osterberger, R.N.,
CorSolutions Nurse

SUNDAY	MONDAY	TUESDAY	WEDNESDAY	THURSDAY	FRIDAY	SATURDAY
MAY S M T W T F S 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31	**JULY** S M T W T F S 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31	National Safety Month	To access information on over 5,000 health topics, visit www.ecorsolutions.com	1	2	3
4	5	6	7	8	9	10
11 Regular walking can help reduce bone loss.	12	13	14 **Flag Day**	15	16	17
18 **Father's Day**	19	20	21 Summer Begins	22	23	24
25	26	27	28	29	30	Some medicines and sunshine don't mix. Ask your doctor or pharmacist if any drugs you are taking can make your skin more sensitive to the sun.

June 2006

Life is motion—keep active every day.

"Swallowtail"
Photo by Daniel Carter III, R.N.,
CorSolutions Nurse

My Health Tracker

Living healthy means eating right, exercising regularly and scheduling appropriate health screenings for your age, gender and health condition. Use this handy chart to keep track of your health information and the recommended tests and screenings you need. Use the calendar to list reminders of the due dates for your individual vaccinations and screenings.

Please remove this page along the perforation and save it for reference.

General Health Screenings

The health tests and screenings listed in the chart below are recommended for everyone, regardless of chronic health conditions. If you have a chronic condition, find out which tests and screenings you may need to schedule earlier or more frequently. Make copies of this form and give them to all of your doctors.

		Goals				Appointment Dates and Results		
Type of Test	**Recommended Goal**	**My Goal**	**Date Due 2006**	**Date Done 2006**	**Results**	**Date/Results**	**Date/Results**	**Date/Results**
Weight						/	/	/
***BMI**	18.5 - 24.9					/	/	/
Waist Measurement	Men < 40" Women < 35"					/	/	/
Blood Pressure	< 140/90 Heart Failure < 130/85 Diabetes < 130/80					/	/	/
Total Cholesterol	< 200					/	/	/
HDL	≥ 40					/	/	/
LDL	< 100					/	/	/
Triglycerides	< 150					/	/	/
Flu Vaccine	Yearly					/	/	/
Physical Exam	Every 1-3 years					/	/	/
Skin Exam	Every 1-3 years					/	/	/
Dental Exam	Every 6 months					/	/	/
Fecal Occult Blood Test	Yearly after age 50					/	/	/
Colonoscopy	Every 10 years after age 50					/	/	/
Men:								
PSA Test/Prostate Exam	Yearly after age 50					/	/	/
Women:								
Mammogram	Yearly after age 40					/	/	/
Pap Test	Every 1-3 years					/	/	/
Clinical Breast Exam	Every 1-3 years					/	/	/
Bone Density Test	At age 65					/	/	/

* BMI (body mass index) is a measure of weight for height.
BMI can be calculated using pounds and inches with this equation:

$$BMI = \left(\frac{\text{Weight in Pounds}}{(\text{Height in inches}) \times (\text{Height in inches})} \right) \times 703$$

Chronic Conditions

If you have a chronic health condition, it is vital that you schedule the routine tests, screenings and vaccinations you need to prevent complications and monitor your condition. Find out from your doctor if you need to schedule any of these tests or exams. Then use this form to keep track of your health goals, appointments and results.

		Goals				Appointment Dates and Results		
Type of Test	**Recommended Goal**	**My Goal**	**Date Due 2006**	**Date Done 2006**	**Results**	**Date/Results**	**Date/Results**	**Date/Results**
Pneumonia Vaccine	Once or twice in a lifetime					/	/	/
Diabetes								
Self-Monitored Blood Glucose	As recommended by your doctor and 3 or more times daily if taking insulin					/	/	/
A1C < 7%	Every 3 months until normal, then every 6 months					/	/	/
Urine Microalbumin Test	Yearly					/	/	/
Dilated Eye Exam	Yearly					/	/	/
Foot Exam	At every office visit – at least yearly					/	/	/
Diabetes Office Visit	At least every 6 months					/	/	/
Asthma								
Peak Flow Meter	Use daily and when having symptoms					/	/	/
Asthma Action Plan	Work with your doctor to develop your action plan					/	/	/

Medications

Prescription and over-the-counter medications, including herbal supplements and vitamins, can interact. It's important to keep an updated list of your medications in your wallet and on your refrigerator in case of an emergency. If you are ever treated by emergency workers, one of their first questions is what medications you are taking. Use this chart to record your medications. Give copies to your doctors, your pharmacist and a member of your family.

Name of Medication	How Much Do I Take?	When Do I Take It?	What Do I Use It For?
(Example) Aspirin	*81 mg.*	*Every morning*	*Prevent blood clots*

Taking Medication Correctly
–recommendations for preventing errors

Medication is an important part of caring for a chronic condition. It's even more important to know what prescriptions you take, how to take them correctly and what they are designed to do. You shouldn't hesitate to talk to your doctor or nurse if you have any questions or concerns. Also remember that pharmacists play an important role in developing and implementing processes and procedures to help prevent medication errors. To help make sure medications are used safely and effectively, the American Society of Health System Pharmacists (ASHP) recommends that you follow these tips:

- Keep a personal list of all the drugs you take, including prescribed drugs, nonprescription drugs, home remedies, and medical foods and share it with your doctor and nurse.
- Keep a list of medications that you cannot take (for reasons like allergic reactions). Give the reasons why, and share it with your doctor and nurse.
- Tell your doctor exactly how you're taking your prescriptions, especially if you take your medication differently from the original prescription.
- Ask your pharmacist if you have any questions about the treatments or medications you receive.
- Learn the names of the drug products that are prescribed and administered to you, as well as their dosage and strength and schedules.
- Ask your doctor or nurse if you should avoid certain foods, beverages, other medicines or activities while you are taking the drug.
- Request any written information available on the drug product.
- Question anything you don't understand or that doesn't seem right. Be especially alert to unexpected changes, such as receiving a prescription refill that seems to have a different strength or appearance from the original prescription.
- Repeat the information about proper use and effects of your medication to your doctor or nurse to make sure you understand correctly.
- If you're too ill to follow these suggestions, ask a friend or relative to help.

From the American Society of Health System Pharmacists

Please remove this page along the perf... ...ve it for reference

SUNDAY	MONDAY	TUESDAY	WEDNESDAY	THURSDAY	FRIDAY	SATURDAY
JUNE S M T W T F S 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30	**AUGUST** S M T W T F S 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31		Learn more about your health from the CorSolutions Voice Connections℠ Line at 877-COR-5266 (877-267-5266)			1
2	3	4 **Independence Day**	5	6	7 Walking is a good way to lose weight and stay fit.	8
9	10	11	12	13	14	15
16	17 Strawberries and citrus fruits can add fiber to your diet.	18	19	20	21	22
23 30	24 31	25	26	27	28	29

July 2006

Keep the channels of communication flowing.

"Avalanche Creek"
Photo by Janel Hemmerle, R.N.,
CorSolutions Nurse

SUNDAY	MONDAY	TUESDAY	WEDNESDAY	THURSDAY	FRIDAY	SATURDAY
	To access information on over 5,000 health topics, visit www.ecorsolutions.com	1	2	3	4	5
6	7	8	9	10	11	12
13	14	15 Clean out your medicine cabinet this month.	16	17	18	19
20	21	22	23	24	25 Is it time to replace your toothbrush?	26
27	28	29	30	31	**JULY** S M T W T F S 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31	**SEPTEMBER** S M T W T F S 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30

August 2006

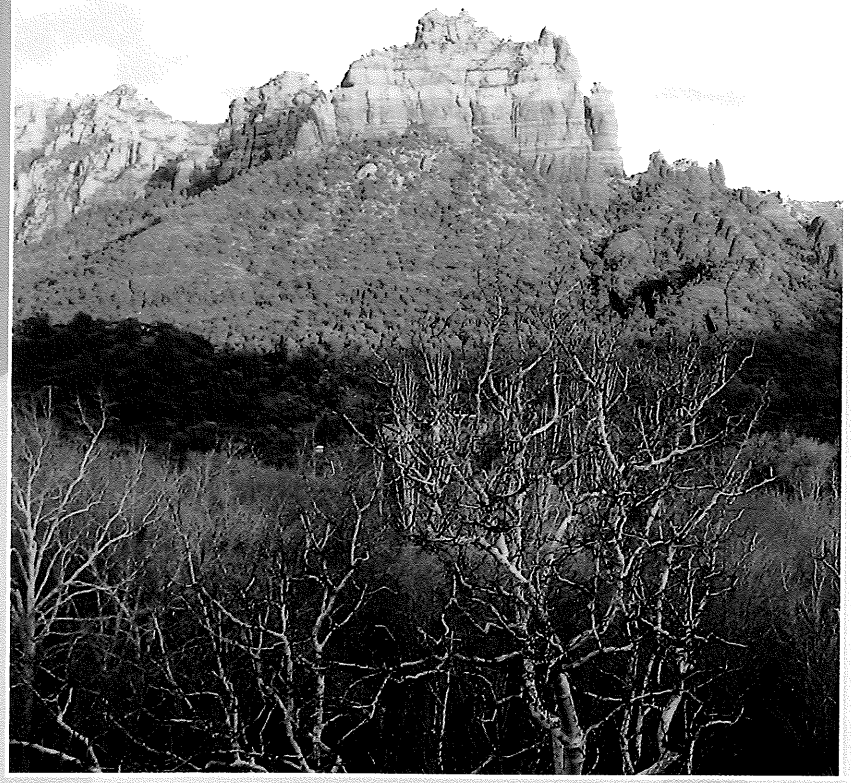
Take time for simple pleasures.

"Blossoms"
Photo by Debra Hedge, R.N.,
CorSolutions Nurse

SUNDAY	MONDAY	TUESDAY	WEDNESDAY	THURSDAY	FRIDAY	SATURDAY
AUGUST S M T W T F S 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31	**OCTOBER** S M T W T F S 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31	Learn more about your health from the CorSolutions Voice Connections℠ Line at 877-COR-5266 (877-267-5266)	National Cholesterol Education Month	Prostate Health Month	1	2
3	4 **Labor Day**	5	6	7	8	9
10 National Grandparents Day	11 **Patriot Day**	12	13 Do you need a flu shot this fall?	14	15 National Hispanic Heritage Month (9/15-10/15)	16
17	18	19	20	21	22 **Rosh Hashanah** Begins at Sundown	23 Autumn Begins **1st Day of Ramadan**
24	25 For information on Medicare benefits, call 1-800-633-4227.	26	27 National Women's Health & Fitness Day	28	29	30

September 2006

Pursue your health goals one step at a time.



"Sedona Sunset"
Photo by Patricia Dobson, R.N.,
CorSolutions Nurse

SUNDAY	MONDAY	TUESDAY	WEDNESDAY	THURSDAY	FRIDAY	SATURDAY
1 **Yom Kippur** Begins at Sundown	2	3	4	5 National Depression Screening Day	6	7 To access information on over 5,000 health topics, visit www.ecorsolutions.com
8 National Fire Prevention Week	9 **Columbus Day**	10	11 Do you have a home fire extinguisher?	12	13	14
15	16	17	18	19	20	21
22	23	24	25	26	27	28
29 Standard Time Begins	30 Check smoke detector batteries.	31 **Halloween**	National Breast Cancer Awareness Month	Talk About Prescriptions Month		

SEPTEMBER

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NOVEMBER

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October 2006

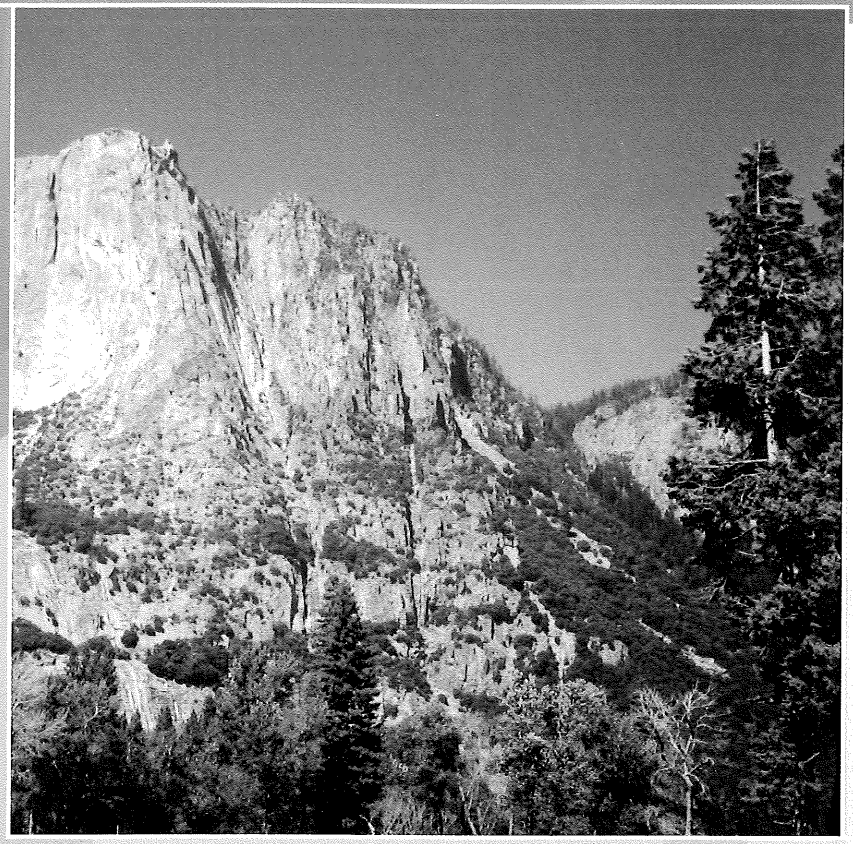
Reduce stress with peaceful places and moments.

"Zen Garden"
Photo by Kristy Olave, R.N.,
CorSolutions Nurse

SUNDAY	MONDAY	TUESDAY	WEDNESDAY	THURSDAY	FRIDAY	SATURDAY
OCTOBER S M T W T F S 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31	**DECEMBER** S M T W T F S 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31	American Diabetes Month COPD Awareness Month	1	2 Have you had your blood sugar levels checked recently?	3	4
5	6	7 **Election Day**	8	9	10	11 **Veterans Day**
12	13	14	15 It's never too late to quit smoking.	16 Great American Smokeout	17	18
19	20	21	22	23 **Thanksgiving Day**	24	25
26	27	28	29	30	Learn more about your health from the CorSolutions Voice Connections℠ Line at 877-COR-5266 (877-267-5266)	National Alzheimer's Disease Awareness Month National American Indian Heritage Month

November 2006

Face life's challenges with the help of others.



"Majesty"
Photo by Tim Burke, R.N.,
CorSolutions Nurse

December 2006

SUNDAY	MONDAY	TUESDAY	WEDNESDAY	THURSDAY	FRIDAY	SATURDAY
NOVEMBER S M T W T F S 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30	**JANUARY 2007** S M T W T F S 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31		To access information on over 5,000 health topics, visit www.ecorsolutions.com		1 World AIDS Day	2
3	4	5	6	7	8	9
10	11	12	13	14	15	16 **1st Day of Hanukkah**
17	18	19 Drinking? Don't drive.	20	21 Winter Begins	22	23
24 31 **New Year's Eve**	25 **Christmas Day**	26 Kwanzaa Begins	27	28	29 At least once a year, review all of your medicines with your doctor.	30

CorSolutions Privacy Policy

CorSolutions respects your personal privacy and is committed to adhering to federal and state privacy laws and industry guidelines in order to protect you and your identity. CorSolutions is provided medical and pharmacy claims data information from the insurance provider or health plan to assist in the early identification of members who may benefit from the various types of services we can provide, including disease management. Pursuant to the Health Insurance Portability and Accountability Act of 1996 (HIPAA), CorSolutions serves in a Business Associate capacity to insurance providers/health plans to provide health management programs. As such, CorSolutions is permitted to use protected health information to assist in providing health management services. Moreover, employers whose health plans have selected our services are not informed which of their employees are in or have been referred to our programs.

Rights:

- The right to have information about CorSolutions, to include programs and services provided on behalf of the sponsoring organization, its staff and its staff qualifications and any contractual relationship.
- The right to decline participation or disenroll from programs and services offered by the organization.
- The right to know which staff members are responsible for managing their services and from whom to request a change.
- The right to be supported by the organization to make decisions interactively with their practitioners regarding health care.
- The right to be informed of all disease/demand/case management or lifestyle modification-related treatment options included or mentioned in clinical guidelines, whether covered or not by the sponsoring organization, and to discuss these with the treating practitioners.
- The right to request restrictions on certain uses and disclosures of personal identified data. In some cases, these requests may be denied.
- The right to request reasonable alternative means of communicating personal identifiable information, including but not limited to requesting that CorSolutions send communications in a closed envelope rather than a post card; send communications to the participant's place of employment; send communications by mail to a designated address; or to speak with the participant by phone at a designated phone number.
- The right to access/copy their health information and to request amendments to it. CorSolutions may charge the participant a reasonable fee for copying and postage.
- The right to revoke consents and authorizations to the extent that they have not been relied upon. However, if a participant revokes consent, please note that CorSolutions may stop providing disease/demand management services to the participant.

- The right to be treated with courtesy, dignity and respect for their personal integrity, without regard to race, religion, national origin, sex, age, disability, marital status, or source of payment.
- The right to have personal identifiable information and medical information kept confidential, to know what entities have access to their information, and to know the procedures used by CorSolutions to ensure privacy and confidentiality.
- The right to request an accounting of all identifiable personal information disclosures not related to treatment, payment, or health care operations.
- The right to request the above or any additional information regarding CorSolutions privacy practices by contacting CorSolutions at 1-800-343-6311 extension 2227.

Responsibilities:

- The responsibility to treat CorSolutions staff, and/or its agents, with courtesy, respect and dignity.
- The responsibility to inform CorSolutions staff, and/or its agents, of any religious belief and/or ethnic custom that would in any way affect and/or conflict with services provided, and the manner in which they may be offered.
- The responsibility to provide CorSolutions staff, and/or its agents, with current and past medical history and functional limitations, if any, including past illnesses, hospitalizations, medications, allergies and other pertinent information necessary to carry out its services.
- The responsibility to follow the Plan of Care as directed by the physician in collaboration with CorSolutions staff, and/or its agents, and the participant.
- The responsibility to inform CorSolutions staff, and/or its agents, if the physician has changed any current medications, treatments, procedures, and/or nutritional guidelines.
- The responsibility to notify CorSolutions and the treating practitioner if the participant decides to disenroll from the program.

Voicing a Complaint:

Any participant wishing to voice a concern or comment about CorSolutions and/or its staff may contact CorSolutions at 1-800-343-6311 extension 2227.

If you believe CorSolutions has violated your privacy rights, you may file a complaint in writing to:

Privacy Officer
CorSolutions, Inc.
9500 West Bryn Mawr
Suite 500
Rosemont, IL 60018

2006

JANUARY

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2007

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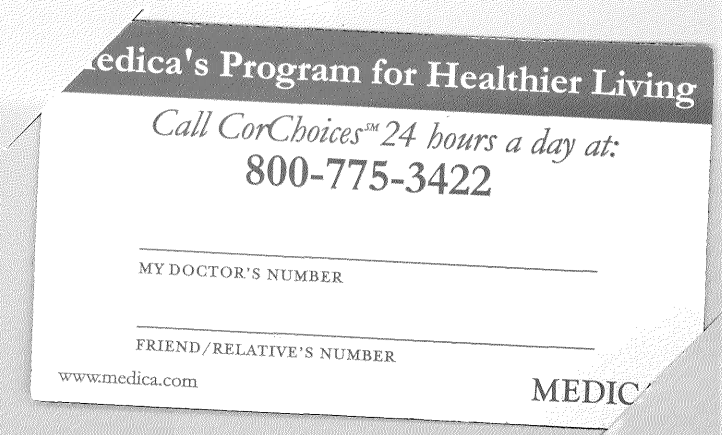
COR SOLUTIONS www.ecorsolutions.com

Remember, we're here to help!

Use this magnet to keep our number handy.



MEDICA®

In partnership with COR SOLUTIONS

These CorSolutions Inc. program materials are not intended as advertising or marketing. They are sent for educational and disease management purposes. Moreover, any references to other organizations (e.g., American Diabetes Association) is not due to a sponsorship relationship between CorSolutions, Inc. and such third party entities. These third party references and materials are included solely for educational and disease management purposes.

Dr Fazio

Health Advantage by Medica℠

A personalized depression management program

MEDICA®

UNITED BEHAVIORAL HEALTH

992-9903

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IN THE
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POSTAGE WILL BE PAID BY ADDRESSEE

MN010-S155
HEALTH ADVANTAGE BY MEDICA
PO BOX 59329
MINNEAPOLIS MN 55459-9784

MEDICA. Health Advantage by Medica℠

Clinician's Name_____

Clinician's # _____

Health Advocate's Name _____

Health Advocate's # _____

UNITED BEHAVIORAL HEALTH 1-866-658-4662

PATIENT HEALTH QUESTIONNAIRE (PHQ-9)

NAME: _____ **DATE:** _____

Over the *last 2 weeks,* how often have you been
bered by any of the following problems?
(use *"✓" to indicate your answer)*

	Not at all	Several days	More than half the days	Nearly every day
1. Little interest or pleasure in doing things	0	1	2	3
2. Feeling down, depressed, or hopeless	0	1	2	3
3. Trouble falling or staying asleep, or sleeping too much	0	1	2	3
4. Feeling tired or having little energy	0	1	2	3
5. Poor appetite or overeating	0	1	2	3
6. Feeling bad about yourself—or that you are a failure or have let yourself or your family down	0	1	2	3
7. Trouble concentrating on things, such as reading the newspaper or watching television	0	1	2	3
8. Moving or speaking so slowly that other people could have noticed. Or the opposite—being so fidgety or restless that you have been moving around a lot more than usual	0	1	2	3
9. Thoughts that you would be better off dead, or of hurting yourself in some way	0	1	2	3
add columns:		+	+	
(Healthcare professional: For interpretation of TOTAL, please refer to accompanying scoring card.) TOTAL:				

10. If you checked off *any* problems, how *difficult* have these problems made it for you to do your work, take care of things at home, or get along with other people?

- **Not difficult at all** _____
- **Somewhat difficult** _____
- **Very difficult** _____
- **Extremely difficult** _____

PHQ-9 SCORING CARD FOR SEVERITY DETERMINATION

for healthcare professional use only

Scoring—add up all checked boxes on PHQ-9

For every ✓: Not at all = 0; Several days = 1;
More than half the days = 2; Nearly every day = 3

Interpretation of Total Score

Total Score	Depression Severity
1-4	Minimal depression
5-9	Mild depression
10-14	Moderate depression
15-19	Moderately severe depression
20-27	Severe depression

Wellness Survey (TOP)

Please complete the following Wellness Survey and return it to your Health Advocate in the self-addressed, stamped envelope enclosed.

The information that you share in this survey will be strictly confidential. The information will be used to help evaluate program effectiveness and enhance care delivery. Your individual answers will not be shared outside of the Health Advantage Program by Medica.

Thank you for your prompt completion of this survey.

UNITED BEHAVIORAL HEALTH

United Behavioral Health
P.O. Box 1459 MN010-S155
6300 Olson Memorial Highway
Minneapolis, MN 55440-1459

UNITED BEHAVIORAL HEALTH

HEALTH ADVANTAGE BY MEDICA WELLNESS SURVEY

Name_____ D.O.B_____ Date_____

Please return the completed survey in the enclosed postage-paid envelope.

	Not At All	A Little Bit	Somewhat	Quite A Bit	Extremely
1. Please tell us how much you agree with the following three statements:					
a. I feel good about myself.	☐	☐	☐	☐	☐
b. I can deal with my problems.	☐	☐	☐	☐	☐
c. I am able to maintain control over my life.	☐	☐	☐	☐	☐

	Not Bothered	Little Bothered	Moderately Bothered	Quite Bothered	Extremely Bothered
2. To what extent have the concerns which led you to seek help interfered with your:					
a. Family Life	☐	☐	☐	☐	☐
b. Social Life	☐	☐	☐	☐	☐
c. Work, Schoolwork, or Housework	☐	☐	☐	☐	☐

	Not Bothered	Little Bothered	Moderately Bothered	Quite Bothered	Extremely Bothered
3 Following are problems or complaints that people sometimes have. For each problem please indicate how much that problem has bothered or distressed you during the past 7 days, including today.					
a. Nervousness or shakiness	☐	☐	☐	☐	☐
b. Feeling lonely	☐	☐	☐	☐	☐
c. Feeling sad or blue	☐	☐	☐	☐	☐
d. Your heart pounding or racing	☐	☐	☐	☐	☐
e. Feeling hopeless about the future	☐	☐	☐	☐	☐
f. Feeling everything is an effort	☐	☐	☐	☐	☐
g. Spells of terror or panic	☐	☐	☐	☐	☐
h. Feeling so restless you couldn't sit still	☐	☐	☐	☐	☐
i. Feelings of worthlessness	☐	☐	☐	☐	☐
j. Feeling suddenly scared for no reason	☐	☐	☐	☐	☐
k. Feeling no interest in things	☐	☐	☐	☐	☐

		Yes		No	
4. Are you currently employed?		☐		☐	

(If yes, please proceed to question 5 below. If no, please skip to question 10 on the next page.)

5. During the past 30 days, how many days were you unable to work because of your physical or mental health? ☐ Days

6. During the past 30 days how many days were you able to work, but had to cutback on how much you got done because of your physical or mental health? ☐ Days

		Yes		No	
7. Are you currently on, have filed, or are considering filing for disability benefits or workers compensation? (Remember that your responses are completely confidential)		☐		☐	
8. Are you experiencing any recent problems at work?		☐		☐	
9. Are you providing care to someone in your family who is ill or disabled?		☐		☐	

Please continue survey on next page

	Excellent	Very Good	Good	Fair	Poor
10. In general, would you say your health is?	☐	☐	☐	☐	☐

	Not Bothered	Little Bothered	Moderately Bothered	Quite Bothered	Extremely Bothered
11. In the past 30 days, how much have you been bothered by physical pain?	☐	☐	☐	☐	☐

		Yes		No	
12. Do you currently have a serious and/or chronic medical condition such as diabetes, cancer, heart disease, asthma, or rheumatoid arthritis?		☐		☐	

	0	1	2-3	4-5	More Than 5
13. In the past 6 months, how many times have you seen a doctor or used other medical services ?	☐	☐	☐	☐	☐

		Yes		No	
14. Have you had a drink or used drugs in the past 30 days? (If yes, please proceed to question 15. If no, please skip to question 21.)		☐		☐	
15. In the past 30 days have you ever felt you ought to cut down on your drinking or drug use?		☐		☐	
16. In the past 30 days have people annoyed you by criticizing your drinking or drug use?		☐		☐	
In the past 30 days have you ever felt bad or guilty about your drinking or drug use?		☐		☐	
18. In the past 30 days have you ever had a drink or used drugs first thing in the morning to steady your nerves or get rid of a hangover?		☐		☐	

19. How many days in the past week did you have a beer, glass of wine, mixed drink, or shot of liquor? ☐ Days

20. On a typical day when you have had a drink, how many glasses, bottles, cans, or shots do you drink? ☐ (Enter # of glasses, bottles, cans, or shots)

21. Please tell us how much you agree with the following statements regarding the therapist you saw/will see based on your current care:	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
a. I was satisfied with my experience of finding an available therapist.	☐	☐	☐	☐	☐
b. My first appointment with a therapist took place (or will take place) within an acceptable timeframe.	☐	☐	☐	☐	☐

At United Behavioral Health we are interested in examining how well we serve different ethnic groups within our member community. Please indicate with what ethnic group you identify most:

- ☐ White, non-hispanic
- ☐ African American or Black
- ☐ Latino or Hispanic
- ☐ American Indian or Alaska native
- ☐ Asian or Pacific Islander
- ☐ Multiple ethnic groups
- ☐ Other ethnic groups
- ☐ Do not wish to disclose

Please remember that you can reach a UBH Intake Counselor 24 hours a day, seven days a week at 1-866-658-4662. If you have specific questions or comments regarding this survey, please call the same number during business hours, 8am to 5 pm, Monday through Friday.

UNITED
BEHAVIORAL HEALTH

Authorization for Release of Information

We are looking forward to working with you so that you receive the care you need. In order for us to better coordinate your care and the services you will receive, we ask that you sign a Release of Information so that Medica and UBH are able to communicate with your providers. Please review and sign the Release of Information below. If you have any questions or concerns, we are here to help. Please call your Health Advocate. The name and number of your Health Advocate is located at the bottom of your "Welcome" Letter.

Member's Name	Birth Date	Member's ID#, SSN, or Chart # (circle one)

Street Address	City	State	Zip Code

I understand that this authorization is voluntary. I understand that my health information may be protected by the Federal Rules for Privacy of Individually Identifiable Health Information (Title 45 of the Code of Federal Regulations, Parts 160 and 164), the Federal Rules for Confidentiality of Alcohol and Drug Abuse Patient Records (Title 42 of the Code of Federal Regulations, Chapter I, Part 2), and/or state laws. I understand that my health information may be subject to re-disclosure by the recipient and that if the organization or person authorized to receive the information is not a health plan or health care provider, the released information may no longer be protected by the Federal privacy regulations.

I understand that my records may contain information regarding my mental health, substance use or dependency, or sexuality, and also may contain confidential HIV/AIDS – related information. I further understand that by signing below, I am authorizing the release or exchange of these records to the parties named below.

I also understand that my health plan may not condition treatment, payment, enrollment, or eligibility for benefits on whether I sign this form, except for certain eligibility or enrollment determinations prior to my enrollment in its health plan, and for health care that is solely for the purpose of creating protected health information for disclosure to a third party.

I understand that I may revoke this authorization at any time by notifying UBH in writing, but if I do, it will not have any effect on any actions UBH took before it received the revocation.

I hereby authorize United Behavioral Health to (check all that apply):

☐ Exchange with ☐ Release to ☐ Obtain from **the parties I have indicated below**

I hereby authorize United Behavioral Health to exchange / release / obtain information:

☐ Verbally only ☐ in written form only ☐ both verbally and in writing

Person/organization receiving/communicating the information:

Name: _____ Phone #_____

Address: _____

Description of individually identifiable health information (check appropriate type(s) of information) to be released/exchanged/obtained:

☐ All
☐ Claims
☐ Eligibility/Benefits
☐ Treatment Plan(s)
☐ Outpatient Progress Reports
☐ Attendance Only
☐ Clinical records used to make benefit determinations (may include HIV/AIDS and/or Substance Abuse information)
☐ All records relating to a Disability claim
☐ All pertinent documentation UBH deems appropriate for the purpose(s) checked below
☐ Other (describe): Coordination of care for "Health Advantage by Medica℠"

The purpose of this release is (check all that apply):

☐ To allow the clinically appropriate management and coordination of the Member's mental health and/or substance abuse treatment and/or coverage under the Member's health benefit plan (Care Management and Coordination).
☐ Benefit Management
☐ Claims Administration/Payment
☐ Employer Mandated Treatment Referral
☐ Administration of a Worker's Compensation claim
☐ Administration of a Disability claim
☐ Subpoena or other legal process
☐ To release physical records described above
☐ Other (describe): Coordination of care for "Health Advantage by Medica℠"

The dates of records to be disclosed: ***(This section must be completed by Virginia residents)***
From ____ / ____ / ____ (MM/DD/YY) To ____ / ____ / ____ (MM/DD/YY)

THE MEMBER OR THE MEMBER'S REPRESENTATIVE MUST READ AND SIGN OR INITIAL THE FOLLOWING STATEMENTS:

I understand that this authorization will expire:

☐ On ____/____/____ (MM/DD/YY) or one year from the date of the signature below (or as set forth by other applicable federal or state law – see below).

or

☐ Once the following event occurs (***does not apply to Illinois residents***):

_____

(Form must be completed before signing)

_____	_____	_____
Signature of Member/Legal Guardian or Member's Representative	Signature of Minor Member	Date
_____	_____	_____
Print Name of Member's Representative	Relationship to the Member	Description of Representative's Authority

YOU MAY REFUSE TO SIGN THIS AUTHORIZATION

- Work with your clinician to decide on a treatment plan that will be most helpful to you.
- Go to each of your appointments.
- Take the medications that are prescribed for you.
- Follow the directions of your doctor.
- At the first sign of not feeling well, call your clinician or Health Advocate.
- If you have medical issues or concerns, please sign a Release of Information form. This form allows your behavioral health clinician to talk to your medical doctor. This helps them to give you the best possible care.
- Please see your clinician at least three times within the first 12 weeks after diagnosis of depression.
- Please stay in touch with your Health Advocate. Your Health Advocate will also follow up with you over the next six months to help ensure that you get all the appropriate care.

If you have any questions, call us at **1-866-658-4662**.
We are available 24 hours a day, seven days a week.
All calls are kept strictly confidential.

UBB06E:150

Depression Self-Appraisal

The following self-appraisal asks questions about some of the symptoms of major depression. If you answer "yes" to two or more of these questions, it might be helpful for you to talk to a professional about your mood and possible depression.

This self-appraisal is not a substitute for a professional evaluation and is not intended to be a self-diagnosis. Only a professional can make a diagnosis. If you have concerns about your mood after answering these questions, please talk to your doctor or contact United Behavioral Health at 1-866-658-4662. We can arrange for a professional consultation.

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UNITED BEHAVIORAL HEALTH

Over the last two weeks, have you noticed that your mood has changed or that you have:	Yes	No
Felt sad or depressed most of the day or nearly every day?		
Lost interest in your regular activities or the things that you usually enjoy?		
Lost or gained weight without trying to or noticed a change in your appetite?		
Had trouble sleeping or overslept?		
Been either agitated and restless or listless?		
Felt a loss of energy or been fatigued?		
Felt worthless or hopeless or felt overly guilty about things?		
Been forgetful or had trouble concentrating or making decisions?		

If you have any questions, call us at **1-866-658-4662**.

We are available 24 hours a day, seven days a week. All calls are kept strictly confidential.

Feel Better Faster

When people get the right resources and treatment for depression, they usually feel better faster and often see an improvement in their overall health. Take advantage of this program by calling our toll-free number today. We are here for you every step of the way.

1-866-658-4662 toll-free

1-800-543-7162 TDD

This program is available through a partnership by Medica and United Behavioral Health. All calls and use of services are kept confidential. Information is restricted to your treating doctors.

Take advantage of this program by calling our toll-free number today.

1-866-658-4662 toll-free

1-800-543-7162 TDD

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UBB05E:150

Health Advantage by Medica℠

— A personalized depression management program >

MEDICA®

Health Advantage by Medica℠

— A personalized depression management program –·–·–·–·–·–·–·–·–·–·–> Your free resource for managing depression

Depression is almost as common as the winter flu — nearly 19 million adults in the U.S. suffer from depression every year. It can occur on its own or result from a medical illness.*

* National Institute of Mental Health

Now there's a free resource for coping with depression and its impact on your life — Health Advantage by Medica,℠ a personalized depression management program.

Designed by Medica and United Behavioral Health, Health Advantage by Medica gives you information, resources and referrals so you get the support that will be most helpful to you.

The Right Treatment for You

This program gets you the help you need in a few simple steps.

Giving you more choices — If you are feeling persistently sad or have symptoms of depression, your primary care physician or other health care provider can recommend you for the program.

We give you a call and invite you to participate. If you choose to participate in the program, we mail you a Member Packet, which includes educational materials, resources and forms for you to fill out and return to us. The program is completely voluntary.

Understanding your needs — Once you decide to participate in the program, we work with you, your physician and other care providers to understand your needs. If you do not already see a therapist, we can arrange for you to visit a mental health clinician whose expertise matches your needs and preferences.

Coordinating your care — Your doctors work to provide you with the best care. We help them work together as a team. We help them communicate to each other.

Working with you — A Health Advocate regularly checks in with you by phone to answer any of your questions and provide ongoing support and assistance. We provide you with educational materials to help you get the care you need. We can refer you to resources that are helpful to you.

MEDICA®

Health Advantage by Medica℠

— A personalized depression management program

Dear (Member Name),

Welcome! We applaud your decision to participate in the depression program provided by Medica and UBH. You are taking an important step toward managing your depression and reducing its impact on your physical health.

As you get started in the program, your Health Advocate will work with you. We will also work with your primary care physician and your mental health clinician. By working together, we can better coordinate your care. Your Health Advocate will contact you regularly to talk about your depression and provide resources, recommendations or referrals. Our goal is to help enhance your quality of life by reducing the impact of depression.

This document is a resource that can help you work more effectively with your doctor and make wise health care choices. However, you should not rely on it to replace necessary medical consultations to meet your individual health care needs. Not all treatments mentioned in this document are covered by all health plans. You and I can discuss coverage and the services that best serve your needs. Details about the program, educational materials about depression and release forms are enclosed. Please fill out the forms and return them to us in the enclosed envelope.

Your UBH Health Advocate will contact you within the next two weeks. Keep in mind that all services and calls are confidential. Information will be shared only among doctors from whom you are receiving treatment. In the meantime, if you have any questions, please do not hesitate to call me.

Sincerely,

Health Advocate Name

Ken Joslyn, M.D.

Health Advocate

Medica Medical Director

UNITED BEHAVIORAL HEALTH

United Behavioral Health
P.O. Box 1459 MN010-S155
6300 Olson Memorial Highway
Minneapolis, MN 55440-1459

MEDICA®

Health Advantage by Medica℠

— *A personalized depression management program*

Medica and United Behavioral Health (UBH) are offering a unique program for Depression. The program is called Health Advantage by Medica℠, a personalized depression management program. It is designed to support and help those with Depression, as well as individuals with a co-occurring medical illness. It is voluntary and at no cost to you.

Medica and UBH understand the impact that Depression can have on an individual's quality of life. Health Advantage by Medica℠ focuses on improving your overall health and overcoming Depression.

The program gives you information, resources and referrals. This allows you to receive the support that will be most helpful to you.

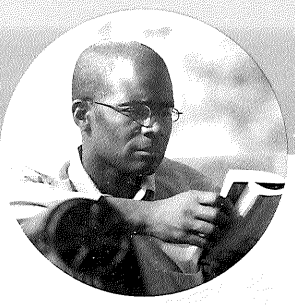
Your Health Advocate is here to assist you every step of the way. We do this by helping you understand your disease more fully and coordinating care and having ongoing communication between both the behavioral and medical professionals involved in your care.

Please review the enclosed member materials.

We are excited to work with you!

UNITED BEHAVIORAL HEALTH

United Behavioral Health
P.O. Box 1459 MN010-S155
6300 Olson Memorial Highway
Minneapolis, MN 55440-1459



Understanding Depression

Nearly 19 million American adults suffer from depression in any given year. The cost in human suffering cannot be measured. Depression can interfere with normal functioning not only for those with the disorder but also those who care about them. Serious depression can affect the family life and the work life of the individual. Depression is a treatable disease. While many people with depression do not seek treatment, most individuals can be helped with medications and/or "talk" therapies. Years of research have made treatments safe and easily accessible.

What is Depression?

Depression is an illness that involves the body, mood and thoughts. It affects the way a person eats and sleeps, the way one feels about oneself, and the way one thinks about life. Depression is not the same as a passing blue mood. It is not a sign of personal weakness. It is not a condition that can be "willed away." People with depression cannot easily "pull themselves together." Without treatment, symptoms can last for weeks, months, or even years. It can even worsen diseases that could lead to death and could lead to suicide. It can have a negative impact on other medical conditions and make people more likely to have or develop other diseases. However, with appropriate treatment most people get better.

Depression comes in different forms, just as with other illnesses, such as heart disease and diabetes. The forms of depression vary by severity, number of symptoms and persistence. Below are a few of the more common forms of depression.

Major depression is a combination of symptoms that interferes with the ability to work, study, sleep, eat, and enjoy pleasurable activities. The symptoms are disabling and may occur only once but are also likely to occur several times during life. In some instances, depression may become severe enough to mimic dementia or cause a disconnection from reality (psychosis).

Dysthymia is a less severe form of depression that is long-term. The symptoms are not disabling, but they may keep someone from optimal functioning and well-being. Many people with dysthymia may also experience a major depression at some time in their lives.

Situational depression or adjustment disorders occur due to a specific stressor. These disorders may last only a short time or they may develop into major depression. The symptoms vary in severity from mild to severe depending on the stressor or the support and defenses available to respond to the stressor.

Symptoms of Depression

Not everyone who is depressed experiences each symptom. Some people experience a few symptoms, some many. The severity of symptoms varies with each individual and also over time.

These symptoms include:

- Persistent sad, anxious or "empty" moods
- Feelings of hopelessness or pessimism
- Feelings of guilt or worthlessness
- Loss of interest or pleasure in hobbies and activities that were once enjoyed, including sex
- Decreased energy or fatigue
- Difficulty concentrating, remembering or making decisions
- Insomnia, early-morning awakening or oversleeping

- Appetite change and/or weight loss/gain
- Thoughts of death or suicide, suicide attempts
- Restlessness or irritability
- Persistent physical symptoms that do not respond to treatment, such as headaches, digestive disorders and chronic pain

Causes of Depression

There is evidence that some types of depression run in families. This suggests that a biological vulnerability can be inherited. Having a family history of depression does not mean that you will become depressed. It means that you may be more likely to become depressed. Not everyone with a genetic makeup for depression becomes depressed. Situational stresses and medical problems may "unlock" the genetic makeup leading to depression.

In some families, major depression occurs in generation after generation. However, it can also occur in people with no family history of depression. Whether inherited or not, depression is associated with changes in brain structures or brain function.

People with low self-esteem who consistently view themselves and the world with pessimism or who are easily overwhelmed by stress are prone to depression. It is not clear whether this indicates a predisposition to depression.

There is increasing evidence showing that physical changes in the body can be accompanied by mental changes as well. Medical conditions and diseases, such as stroke, a heart attack, diabetes, cancer, or Parkinson's disease, can lead to depression. The sick person may become apathetic and unwilling to care for his or her physical needs, making recovery less likely. Untreated depression can also affect a person's response to treatment for his or her medical condition. Certain medications can contribute to depression. Serious loss, difficult relationships, financial difficulty, or any stressful situation can trigger depression. Often, a combination of genetic, psychological and situational factors are involved in the onset of depression.

Diagnosis and Treatment

The first step in getting treatment for depression is to have a physical examination. Certain medications and medical conditions can cause the same symptoms as depression. These should be ruled out through physical examination, interview and possibly laboratory tests. If physical causes are ruled out, a psychological evaluation should be done, either by your physician or by a mental health professional.

A good diagnostic evaluation will include the following:

- Complete history of symptoms
  - When did they start?
  - How long have they lasted?
  - How severe are they?
  - Have you had them before?
  - Have they been treated before?
  - Was the treatment successful?
- History of alcohol or drug use
- Questions about thoughts of suicide or harm to others
- Family history
  - Are there family members with depression?
  - What treatments worked for them?
- Mental status examination

The choice of treatment will depend on the outcome of the evaluation. There are many different types of medications and psychotherapies that can be used to treat depression. Some people with milder forms of depression may do well with psychotherapy (talk therapy) alone. People with moderate to severe depression most often benefit from medication. Most people do best with a combination of medication and therapy.

Medications

There are several different families of medications to treat depression. These medications affect certain chemicals in your brain thought to be responsible for the mental and physical changes associated with depression. These chemicals are called neurotransmitters. Sometimes your doctor will need to try several medications before finding one that is best for you. Knowledge of family members' experiences with medications may be helpful in selecting the medication that is right for you. A complete list of other medications you take (including over-the-counter medications, such as aspirin) is important for limiting the risk of harmful medication interaction. Sometimes the dosage will need to be increased for the medication to be effective. Although some improvements may be seen in the first several days or weeks, doctors recommend that medications for depression be taken daily for at least one month in order to get the full benefit.

Patients often stop medications too soon. They feel better and think they no longer need the medicine. They may think that the medication is not working. They may also have side effects that may temporarily be bothersome. In most cases, the side effects improve or disappear with time or they can be managed by adjusting the dose of medication. In order for the medications to be effective at treating and preventing return of your symptoms, it is important to continue them for at least 6-9 months. Stopping them too quickly could lead to a recurrence of the depression. Some medications must be stopped gradually to give the body time to adjust. Never stop medication without consulting with the doctor. There are some people that will need to take medication indefinitely.

Questions about medications, or problems that may be related to medication, should be discussed with your doctor.

Types of Medication for Depression include:

Tricyclic Antidepressants

- amitriptyline (Elavil)
- doxepine (Sinequan)
- nortriptyline (Pamelor)
- imipramine (Tofranil)
- amitriptyline/perphenazine (Triavil)
- amoxapine (Asendin)
- maprotiline (Ludiomil)
- clomipramine (Anafranil)
- desipramine (Norpramin)
- Vivactil
- Surmontil

Selective Serotonin Reuptake Inhibitors

- Fluoxetine (Prozac)
- Lexapro
- Zoloft
- Celexa
- Paxil CR
- Paxil
- Fluvoxamine (Luvox)

Mixed Reuptake Inhibitors

- Mirtazapint (Remeron)
- Bupropion (Wellbutrin)
- Effexor
- Serzone
- Wellbutrin SR
- Wellbutrin XL
- Effexor XR

Other Antidepressants

- Trazadone (Desyrel)
- Nardil
- Parnate

Side Effects of Antidepressant Medications

All medications, including aspirin, have the potential to cause side effects. Antidepressants may cause mild and, usually, temporary side effects (sometimes referred to as adverse effects) in some people. Typically, these are annoying, but not serious. However, any unusual reactions or side effects or those that interfere with functioning should be reported to the doctor immediately.

The most common side effects of tricyclic antidepressants, and ways to deal with them, are:

- Dry mouth — It is helpful to drink water, chew sugarless gum and clean teeth daily.
- Constipation — Bran cereals, prunes, fruit, and vegetables should be in the diet.
- Bladder problems — Emptying the bladder may be troublesome, and the urine stream may not be as strong as usual. The doctor should be notified if there is marked difficulty or pain.
- Sexual problems — Sexual functioning may change; if worrisome, it should be discussed with the doctor.
- Blurred vision — This will soon pass and usually will not necessitate getting new glasses.
- Dizziness — Rising slowly from the bed or chair is helpful.
- Drowsiness as a daytime problem — This usually quickly passes. A person feeling drowsy or sedated should not drive or operate heavy equipment. More sedating antidepressants are generally taken at bedtime to help sleep and minimize daytime drowsiness.

The newer antidepressants have different types of side effects:

- Headache — This will usually go away.
- Nausea — This is also temporary. But when it occurs, it is transient after each dose.
- Nervousness and insomnia (trouble falling asleep or waking often during the night) — This may occur during the first few weeks; dosage reductions or the passing of time will usually resolve them.
- Agitation (feeling jittery) — If this happens for the first time after the drug is taken and is more than transient, the doctor should be notified.

Note: The FDA has recently issued a warning about increased suicide risk in children taking antidepressants. If you have questions, please talk to your doctor.

Herbal Therapy

Lately, there has been much interest in the use of herbs to treat depression and anxiety. Examples include St. John's Wort, ginseng, echinacea, and gingko. There have been few controlled studies to evaluate the effectiveness and safety of these herbs. There is evidence indicating that some of these herbs may impact the effectiveness of medications for heart disease, AIDS, and other medical problems. Therefore, it is important to discuss the use of any herb with your doctor.

Psychotherapy

Many forms of psychotherapy can help depressed people. Some of these treatments can be brief. They can help patients gain insight and learn how to change the behavioral patterns that may have contributed to their depression. Therapy can also help people learn ways to get more satisfaction out of life. Longer-term therapies may be more useful once the initial disabling symptoms of depression have cleared. Mental health professionals will help determine which type of therapy is best for you.

How to Help Yourself if You are Depressed

Depression can make you feel exhausted, worthless, helpless, and hopeless. Negative thoughts can make you want to give up. It is important to know that some of the negative ideas occurring do not accurately reflect what is going on in your life. These negative feelings may clear when your depression is treated and your symptoms have faded. It is important to try and maintain hope while your treatment is given time to work. In the meantime, here are some suggestions:

- Get regular exercise
- Eat healthy foods and avoid snacking
- Keep a list of tasks to help you complete them
- Keep your appointments with your physician and/or therapist
- Continue to take medications as prescribed
- Take time out for pleasurable activities
- Avoid non-prescribed drugs and alcohol
- Make time to be with friends and family

How Family and Friends Can Help

The most important thing anyone can do to help someone that is depressed is to get him or her the correct diagnosis and treatment. The person may require encouragement to give treatment time to work. Sometimes they may need to get other opinions if treatment is not working. You may need to go to the doctor with them to make sure that the doctor gets accurate information or to help the person understand the treatment suggested. The depressed individual should be encouraged to take medications as suggested by his or her doctor. The individual should avoid non-prescribed drugs and alcohol.

As a friend or family member, you also may need support and information about depression. It is important that you care for yourself in order to effectively support someone that you care about. There are many groups that can provide this support and can be located by calling United Behavioral Health at 1-866-658-4662 or contacting one of the national organizations listed below.

For additional information, contact the following organizations:

National Institute of Mental Health

Federal government agency that provides booklets and fact sheets featuring the latest research-based information on mental illnesses.

Information Resources and Inquiries Branch
6001 Executive Boulevard
Room 8184, MSC 9663
Bethesda, MD 20892-9663

Phone:	1-301-443-4513
Fax:	1-301-443-4279
TDD:	1-301-443-8431
Web site:	http://www.nimh.nih.gov
Email:	nimhinfo@nih.gov

National Alliance for the Mentally Ill (NAMI)

A support and advocacy organization of consumers, families, and friends of people with severe mental illness - over 1,200 state and local affiliates. Local affiliates often give guidance to finding treatment.

Colonial Place Three
2107 Wilson Blvd., Suite 300
Arlington, VA 22201

Phone:	1-800-950-NAMI (6264) or 1-703-524-7600
Web site:	http://www.nami.org

More organizations on following page

Depression & Bipolar Support Alliance (DBSA)

An organization whose purpose is to educate patients, families, and the public concerning the nature of depressive illnesses. Maintains an extensive catalog of helpful books.

730 N. Franklin St., Suite #501
Chicago, IL 60610-7204

Phone: 1-312-988-1150
Fax: 1-312-642-7243
Web site: http://www.dbsalliance.org

National Foundation for Depressive Illness, Inc.

A foundation that informs the public about depressive illness.

P.O. Box 2257
New York, NY 10116

Phone: 1-212-268-4260
Fax: 1-800-239-1265
Web site: http://www.depression.org

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Support Groups in Minnesota

Abbott Northwestern Hospital,
Allina Hospitals and Clinics
Outpatient Clinic — Abbott Northwestern
Hospital Behavioral Health Services
Minneapolis, MN 55404
612-863-5327

Associated Clinic of Psychology — ACP
Counseling and Therapy Services
Minneapolis, MN 55416
612-925-6033

Gina Schuchman, MSW, LICSW
Edina, MN
612-859-0516

Eagan Counseling Clinic
Eagan, MN 55123
651-454-0114

Center For Psychological Services, St Cloud
ɔunseling Services
ɛ Cloud, MN 56301-4820
320-255-0343

Chrysalis
Mental Health Clinic — Outpatient Services
Minneapolis, MN 55407
612-871-0118

Core Psychological Services — St Cloud
Counseling and Therapy Services
St Cloud, MN 56301
320-202-1400

Alison Maule-Kronmiller PhD, LP
St Paul, MN
651-647-5722

Cynthia Wittwer Counseling — Redwood Falls
Equine - Assisted Counseling
Redwood Falls, MN 56283
'07-644-3838

Eagan Counseling Clinic
Eagan, MN 55123
651-454-0114

Fairview Counseling Center
Minneapolis, MN
612-672-6999

Hennepin County Mental Health Center
Acute Care Program
Minneapolis, MN 55415
612-347-5770

Mercy Hospital
Outpatient Clinic
Coon Rapids, MN 55433
763-783-1414

New Ulm Medical Center
Support and Therapy Groups
New Ulm, MN 56073
507-233-1000

Nystrom and Associates, Ltd
Christian-based Counseling Services
New Brighton, MN 55112
651-628-9566

Pilot City Mental Health Center
Therapy Groups
Minneapolis, MN 55411
612-348-4622

Pyramid Counseling Center
Therapy Groups
Golden Valley, MN 55427
763-746-2400

Rape and Sexual Abuse Center
Individual Therapy
Minneapolis, MN 55405
612-825-4357

Rice Education Center — Willmar
Willmar, MN 56201
320-231-8920

United Hospital Outpatient Clinic
St. Paul, MN 55102
651-221-0360

Scott County Mental Health Center
Counseling Services
Shakopee, MN 55379
952-445-7751

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UNITED BEHAVIORAL HEALTH

HealthPartners®

Corporate Office:
8100 34th Avenue South
Bloomington, MN 55425
www.healthpartners.com

Mailing Address:
Mail Stop: 21110T
P.O. Box 1309
Minneapolis, MN 55440-1309

January 31, 2006

Senate Health and Family Security Committee
Senate State Government Budget Division
House Health Care Cost Containment Division

Dear Senators and Representatives,

As one of the pioneers in developing disease management programs in the country, HealthPartners is excited to see chronic disease management as an agenda item and topic for discussion for today's Health Care Solutions Series hearing.

Disease management encompasses a number of different strategies designed to improve patient health and patient outcomes. At HealthPartners this includes tracking and measuring the delivery of quality comprehensive care, providing financial incentives for providing optimal care, and equipping members with the tools needed to improve their health. We constantly measure our results to assure our members are receiving the greatest value for these efforts.

The results of our programs have been very positive. Our first Diabetes Management Program began in 1994. Since that program began, the number of amputations among patients in the Diabetes Management Program has decreased by 45 percent and new cases of retinopathy have declined by 20 percent. In 2005, there were 80 fewer heart attacks within HealthPartners diabetic population because of disease management and improved care delivery. Diabetes care is just one example of where disease management can be utilized to improve patient health.

In accordance with today's Health Care Solutions Series hearing and discussion on chronic disease management, I wanted to provide you with some information about HealthPartners efforts to improve the health of our members and patients through improved health behaviors. Often missed in the discussion of disease management are the steps and tools that can be used to improve a person's health before they are diagnosed with a chronic illness. The attached materials are designed for employers and offer a number of programs available to help employees improve their health.

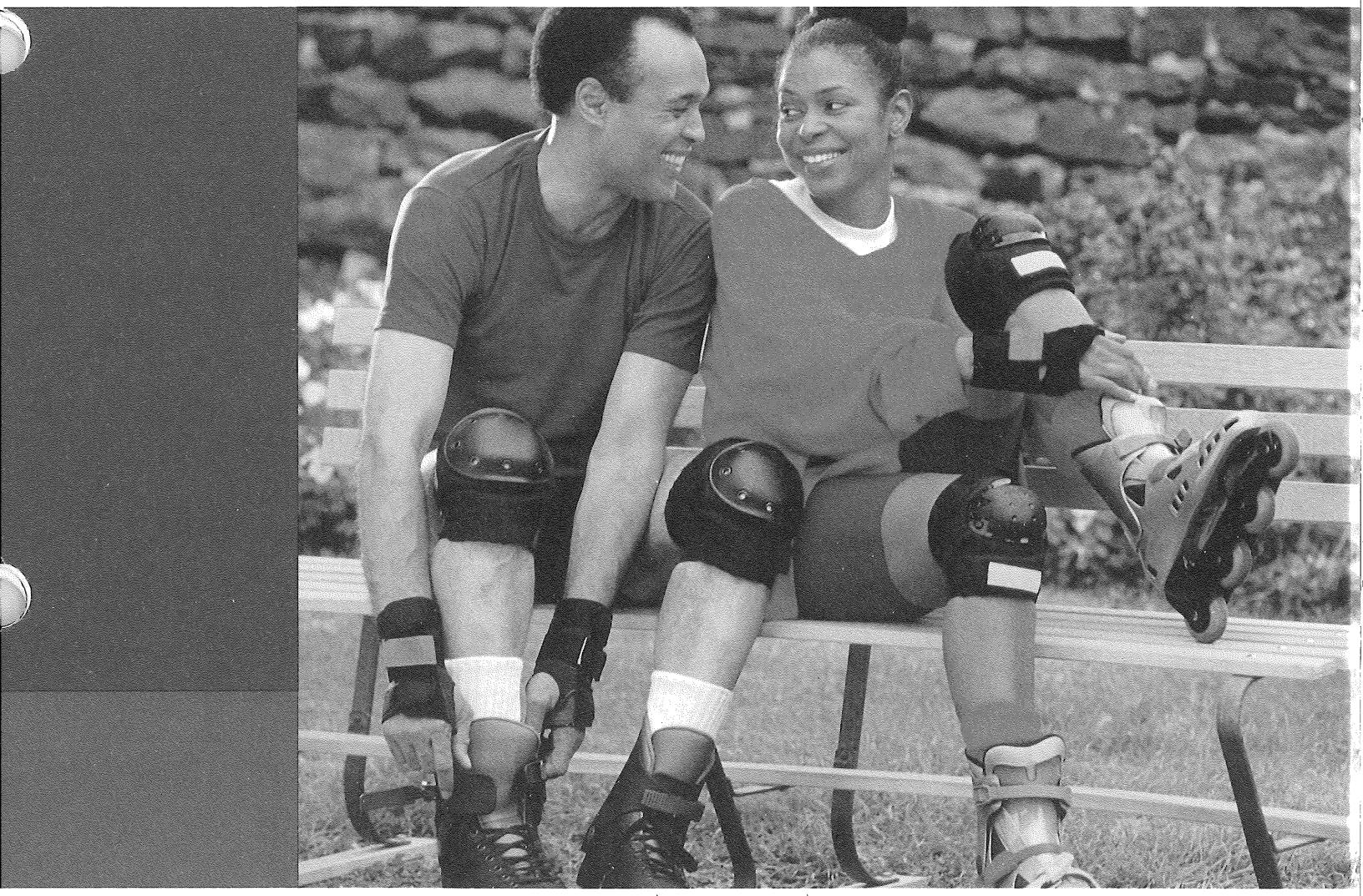
Thank you for the opportunity to provide this information for committee members. If you have any questions about these materials or HealthPartners disease management programs please feel free to contact me.

Sincerely,

Geoff Bartsh
Director of Legislative Affairs

HealthPartners®
Achieve℠

Achieve℠ Programs



HealthPartners®
Achieve℠

Achieve℠ Health Improvement Programs

Promoting healthy lifestyles

Addressing the health needs of all employees

Looking out for the health of all your employees — from those who have active disease to those who are healthy — makes good financial sense. And when it comes to helping your employees pursue healthier lifestyles, HealthPartners Achieve programs deliver the resources you need to empower employees — and contain costs.

Achieve is your health improvement solution

By offering Achieve programs, you can give your employees the resources and support they need to live healthier lives. Achieve programs can help you address important concerns such as employee satisfaction, retention, absenteeism and presenteeism. And Achieve helps you offer health improvement across the board to all employees — including those enrolled in HealthPartners CareSpan℠ disease management programs. It's a win-win solution that works for employers and employees alike.

Advantages for employers

- Reduces overall health care trends, absenteeism and the affects of presenteeism
- Offers a way for employers to support and encourage employee health and wellness
- Provides a support system that is effective and easy for employers and employees to engage in
- Delivers most programs at no/low cost to employers

Advantages for employees

- Offers an outlet and encouragement for employees to be as healthy as they can be
- Delivers personalized solutions that meet individual needs
- Provides something extra for their health care premium dollars
- Promotes increased satisfaction with their employer and their health plan

Personalized programs that support healthy living

Achieve programs come in several formats and cover a variety of topics. Achieve programs are delivered in two ways: direct to member or through the employer. This allows members to take control of their own health and helps employers support — or jump-start — those efforts. Many Achieve programs are also available to non-HealthPartners members.

For employees

These health improvement offerings can be accessed directly by your employees, with topics and programs such as:

- Frequent Fitness
- 10,000 Steps℠ Program
- Healthy Discounts
- *A Call to Change*...Phone Courses
- Self-Care Programs
- Health Assessment (coming soon)
- And much more!

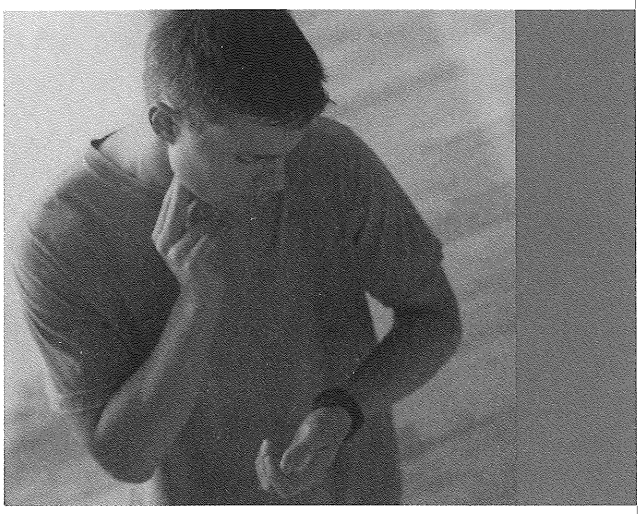
Achieve worksite programs

You can work with HealthPartners to offer these health improvement programs on-site to your employees. You can customize each one and implement programs according to your needs and resources. Achieve worksite programs include:

- Employee Assistance Program (EAP)
- Health Investment Program — Featuring HealthPartners' proprietary health assessment
- Worksite Health-e-Kit℠ programs
- Corporate Influenza Prevention program
- Disability Intervention and Prevention

Achieve — good for employees and employers

When it comes to health and wellness, Achieve delivers the effective tools and programs employees need to lead healthier lifestyles. Employers get

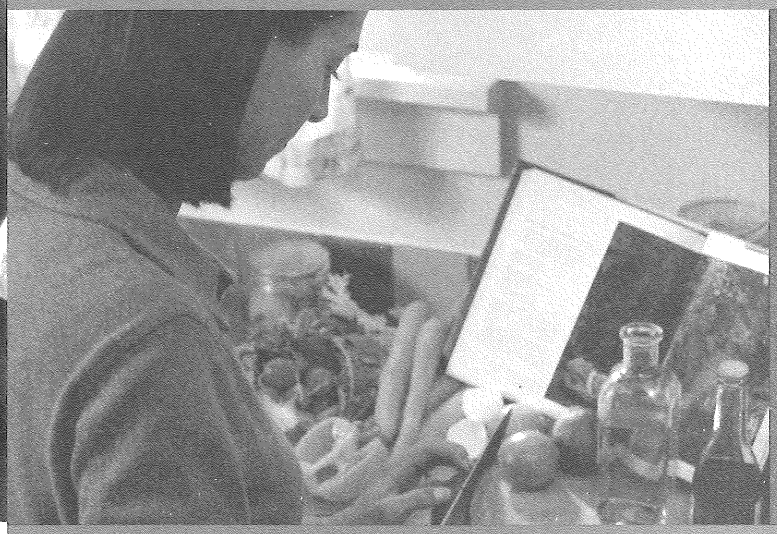


happier, healthier employees who are more productive and less likely to contribute to rising health care costs. Achieve offers real results and real savings – and the opportunity to make wellness a priority in your organization.

Ready to learn more about Achieve?

Contact your consultant, broker or HealthPartners sales representative today!

In their *Trends and Indicators in the Changing Health Care Marketplace, 2004 Update,* the Kaiser Family Foundation reported that 5 percent of the U.S. population accounts for 52.4 percent of total health care spending. About 50 percent of the population had few or no health care expenses — they were responsible for only 3.1 percent of total spending.



HealthPartners®

P.O. Box 1309
Minneapolis, MN 55440-1309
952-883-5200
healthpartners.com

HP450080 9/05

HealthPartners® Achieve℠

A Call to Change... Phone Courses

Our convenient, award-winning phone courses provide your employees with the tools and support they need to make permanent lifestyle changes. Healthier employees translate into less absenteeism, more productivity and better cost trends. These courses offer an easy way to promote healthy behaviors to your employees.

Why phone-based counseling?

- Each course is tailored to meet each participant's needs and offers one-on-one interaction with our professional phone line staff.
- Employees can schedule sessions at their convenience — after work, during lunch, whatever works for them.
- It's a proven way to deliver effective tools that support real and lasting change for happier, healthier, more productive employees.

How Our Phone Courses Work

- After an initial enrollment call, participants receive a course workbook with educational lessons and tools. Participants then schedule additional phone calls when it's convenient for them.
- Participants review lesson materials and complete any personal discovery activities before each phone call.
- Calls are scheduled at one- to two-week intervals. Depending on the course, the phone sessions last up to 30 minutes. Each phone session is tailored to meet the individual's needs.
- When the call is completed, outcomes are documented to track the participant's progress.

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Measurable results and satisfied customers

- Participants in the weight management course lost an average of 13 pounds (2 BMI units) from the start of the phone course and the six-month follow-up.
- Quit rate for participants in the smoking cessation course is 21 percent by course-end. The national average quit rate is 13 percent for phone programs.
- In all, 60% of stress management course participants feel their stress is either "no problem" or "only a slight problem" after completing the course.

Participant satisfaction is high across the board:

- Ninety-eight percent of respondents indicated they were satisfied with the services they received.
- Ninety-eight percent of respondents indicated they would use a phone line course again.

Course Overviews for *A Call to Change...*

Course Name	Course Structure	Course Topics	Course Tools
Solutions for High Blood Pressure℠	Up to three phone calls with either a registered dietitian or pharmacist	Medication management, healthy eating, and physical activity	Course workbook, a personal action plan, food and activity log, and a clinic visit checklist to prepare and guide participants through doctor visits
Healthy Lifestyles, Healthy Weight®	Up to 10 phone calls with either an exercise specialist or registered dietitian	Healthy eating, physical activity and exercise, stress management, weight maintenance, relapse prevention and more	Course workbook, pedometer, food and activity log, action planner, and more
Healthy Choices, Healthy Baby℠	Up to four phone calls with either a health educator or registered dietitian	Healthy weight gain, benefits of breast-feeding, nutrition, physical activity, and stress management	Course workbook and an action planner
Partners in Quitting℠	Up to nine phone calls with a tobacco cessation specialist	Preparing for a quit date, setting a quit date, and practicing skills to manage high-risk situations after quitting	Course workbook and step-by-step quit-smoking "calendar"
Solutions for High Cholesterol℠	Up to three phone calls with either a registered dietitian or pharmacist	Cholesterol-lowering medications, eating healthy and physical activity	Course workbook, a personal action plan, food and activity log, and a clinic visit checklist to prepare and guide participants through doctor visits
Back to Health®	Up to five phone calls with an exercise specialist	Importance of good posture, assessing one's body mechanics, aerobic exercise to increase movement, and tips for coping with pain	Course workbook and exercise plan
Balancing Stress for Healthy Living®	Up to eight phone calls with a health educator	The "how to" steps of time management, positive thinking, relaxation and meditation	Course workbook and an action planner

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Achieve℠

Disability Intervention & Prevention

Comprehensive, coordinated, integrated disability management from the name you know and trust for quality health insurance plans. HealthPartners offers five services to meet your needs.

Certified Workers' Compensation Managed Care Plan

Our plan integrates an array of resources to help employees who have work-related injuries get better — and get back on the job faster. Our comprehensive plan is proven to:

- Reduce lost work time
- Manage costs to ensure best care and best results
- Avoid prolonged disabilities
- Get employees back to work as quickly as possible

Using our 24-hour nurse line, focused provider networks, experienced medical case managers and dedicated customer service representatives, our plan ensures that you and your employees have minimal disruption and continuing support. **Certified by the State of Minnesota Department of Labor*

Return-to-Work Case Management

From the initial assessment to close care oversight that promotes a quick, safe return to work, we make sure the health and confidentiality of your employees — and your bottom line — come first. Our program delivers:

- Proven medical care coordination and return-to-work planning
- Strategies that prevent disabilities from becoming long-term issues
- Cost savings through appropriate medical care and reduced lost work days
- Results-oriented, multi-disciplinary case management

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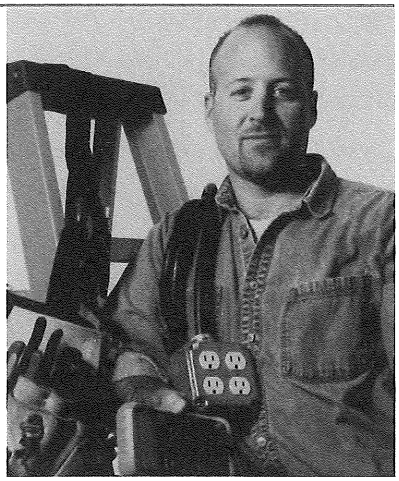

Expert advice can make a big difference in the health and safety of your employees — and the productivity of your company.

Achieve℠

Workers' Compensation Bill Review & Provider Payment

Don't waste valuable staff time sorting through complicated workers' compensation bill review and provider payment issues — put the experts at HealthPartners to work for you. We'll save you time and money — with an expected return on your investment of 40 percent. Choose from 5 levels of expert service:

Level 1 — Bill review engine

Level 2 — Clinical expertise and bill review engine

Level 3 — Level 2, with Certified Workers' Compensation Managed Care Program

Level 4 — Level 2, coupled with HealthPartners' proven Return-to Work Case Management and Certified Workers' Compensation Managed Care Programs

Level 5 — Level 4, paired with an affordable, flexible HealthPartners' health insurance plan

Occupational Medicine Services

Keeping your employees and your workplace safe and healthy through:

Consulting Services. Our occupational medicine staff helps identify and manage a range of worksite hazards.

Clinical Services. We can perform pre-placement, fitness for duty, disability and regulatory exams to assure OSHA, DOT and ADA compliance. Drug and alcohol testing services are available with Medical Review Officer (MRO) follow-up as necessary.

Diagnosis and Treatment. Our providers help speed the recovery process with expert treatment and careful but aggressive return-to-work plans.

Consulting Services

Disability Management Consulting. We'll provide expert medical opinion on cases involving Workers' Compensation, Family Medical Leave Act (FMLA), Americans with Disabilities Act (ADA), short-term disability and long-term disability.

Risk Management & Policy Consulting. Our skilled medical directors work with you on policy development, assessment and regulatory compliance and deliver on-site learning sessions.

Occupational Medicine Consulting. Specialists in ergonomics, worksite safety and occupational medicine perform health hazard evaluations and provide training programs.

Ready to save time and money?

HealthPartners is your link to savings, quality care and superior customer service. To learn more about our Disability Intervention & Prevention programs, call 952-883-7364 today.

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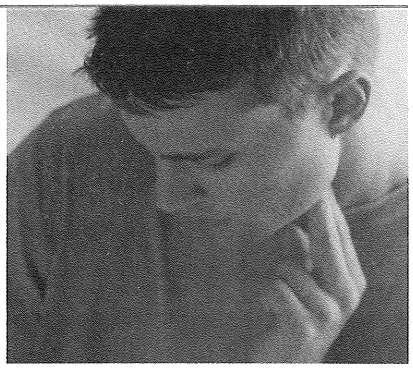
HealthPartners® *Achieve*℠

10,000 Steps® program — Your employees can *count on feeling great®!*



Step up health improvement in your company today

The HealthPartners 10,000 Steps® program motivates your employees to be more active — and can help reduce employer-paid health care costs.

This program can help supercharge your workplace by:

- Reducing absenteeism
- Increasing productivity
- Improving job satisfaction

10,000 steps to feeling great or losing weight

The HealthPartners 10,000 Steps® program helps participants increase the number of steps they take each day and uses a pedometer as a motivational tool. Support is available online or by mail. Most adults average 3,500 to 5,000 steps per day. Simply walking 10,000 steps — realistic, yet challenging — burns an extra 150 calories or more each day. With these 10,000 steps, most people can reach the recommended 30- minute activity level.

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Recent studies prove that being active can reduce the risk of heart disease, diabetes, high blood pressure, some cancers and osteoporosis. The national recommendation is to get 30 minutes of moderate intensity physical activity on most days of the week. Yet more than 60 percent of adults do not get the recommended amount of physical activity — 25 percent are not physically active at all.

Achieve℠

More than 40,000 people to date have participated in this innovative physical activity program:

- More than 80 percent of participants reported the program helped them increase their physical activity
- Several evaluations of participant step tracker logs found a significant increase in steps from week one to week eight
- Most participants reported feeling better overall and having more energy
- Eighty-one percent of participants felt the program assisted them in increasing their physical activity
- One recent evaluation showed those who tracked their steps for eight weeks saw a five-pound weight loss!

How the program works

The *Feel Great* edition gives participants the motivation and tools they need to increase physical activity and maintain it for life. The *Lose Weight* edition gives participants a winning combination of tools and simple, convenient meal ideas to feel great and eat well. Both are available online or in a mail-based format.

Online

The 10,000 Steps® online program includes:

- A state-of-the-art pedometer valued at $29.95
- An interactive, online step-tracking system
- An opportunity to get daily motivational emails
- Tips and reading materials to increase and maintain your active lifestyle
- And more

Mail-based

The 10,000 Steps® mail-based program includes:

- A state-of-the-art pedometer valued at $29.95
- A personal action planner to get started and stay motivated
- A step tracker log
- Biweekly motivational cards for eight weeks and bimonthly cards for the following six months
- And more

Ready to learn more?

Contact your broker, consultant or HealthPartners sales representative today.

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HealthPartners® *Achieve*℠

Help is on the way with HealthPartners Employee Assistance Program (EAP)*

Statistics show that up to 20 percent of employees have severe personal problems — stress, money problems, aging parents, a new baby, addictions, interpersonal conflicts at work and other issues. Personal problems often spill over into the workplace, leaving employers to deal with the impacts and costs associated with absenteeism, turnover rates, tardiness and even accidents. Your greatest asset — employees — could become your greatest liability.

You need an EAP

The health of your employees is crucial to your company's success. By participating in an EAP, you can help your employees cope with and resolve their personal issues and come to work more focused.

HealthPartners EAP can help:

- Assist your company in the diagnosis, counsel and/or referral of troubled employees to the appropriate care
- Provide a quick response to employee problems to help the employee return to an acceptable level of productivity
- Reduce the need for terminating, hiring and training by helping employees resolve problems before termination is necessary
- Save your company time and money

* *Services administered by AffinityCare, Inc.*

- Companies spend over 5 percent of their payroll on costs associated with absenteeism.
- Personal and interpersonal factors are linked to 65-80 percent of all terminations.
- If 5 percent of your employees used an EAP, your potential monetary savings could be 3.45 percent of payroll for reduced absenteeism and improved productivity.

Achieve℠

EAP services for employees

EAP *by phone*

Employees can call for confidential support for emotional, family/personal, and work-related issues.

Our EAP phone line features:

- Unlimited access to a licensed counselor 24 hours/day, 7 days/week, 365 days/year.
- Assistance finding a local mental health provider, financial consultant, or even a legal advisor.
- Support for managers dealing with tough on-the-job issues.

EAP *Online*

HealthPartners EAP provides assistance that's just a click away, on topics such as:

- Addiction and Recovery
- Anger Management
- Balancing Work and Family
- Depression
- Divorce
- Financial Debt
- Grief and Loss
- Parenting
- Stress
- And more

Managers looking for solutions to work issues can access these topics and more online:

- Legal Issues
- Performance Feedback
- Diversity
- Motivating Your Staff
- Sexual Harassment

EAP Services for employers

HealthPartners EAP offers Work/Life Seminars that allow you to bring current topics and information to employees right in the workplace. When needed, Critical Incident Stress Management services are available to help you deal with major accidents/injuries, natural disasters, grief and loss, and other workplace traumas. In addition, robust quarterly reporting shows how your EAP dollars are being used and provides data to help you determine where additional employee training and education might be needed.

Is an EAP worth the expense?

Up to 20 percent of a company's employees may not be working to full capacity because they don't receive the help they need. Problems add up — quickly — when it comes to lost time, lost productivity and lost revenue. The real question isn't "Is an EAP worth the money?" but rather, "Can you afford to be without an EAP?"

Ready to learn more?

Contact your broker, consultant or HealthPartners sales representative today.

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HealthPartners® *Achieve*℠

Corporate Influenza Prevention Program

Catching the flu bug in any organization means lost work days and more doctor visits for employees — and lost productivity and rising health care costs for employers. HealthPartners Corporate Influenza Prevention program offers an easy way to stop the flu before it starts spreading in your company.

Convenient and easy to implement

For maximum convenience, we come to you! In partnership with our vaccine vendors, we work with you to schedule the place (at one location or all your sites), date and time. Plus, we consult with you from initial planning through completion of the flu shot clinic to ensure a smooth and successful program.

Who may receive the flu shot?

You can choose to offer the program to your HealthPartners covered employees, HealthPartners covered employees *and* their dependents, or to all employees. An employee who receives HealthPartners coverage from a spouse/significant other through a different employer group is also eligible to participate. Children must be at least nine years old; and for children under 18, a guardian must sign the consent form.

(continued on back)

Each year an average employer group with 1,000 employees would have an average of 100 people (10%) coming down with the flu. This translates to 280 lost work days and $39,788 paid in non-productive wages.

— *Economic Analysis of Influenza Vaccine and Antiviral Treatment for Healthy Working Adults,* Annals of Internal Medicine, 2002; 137:225-231

Achieve℠

Best of all, it's free for HealthPartners members!

- For your HealthPartners members and their covered dependents, the flu shot clinic is a covered benefit.
- For plans that require a copay, HealthPartners has waived the copay.
- We can also work with you to offer a program for all employees, including those not covered by HealthPartners. The cost range for nonmembers is approximately $20-$30 per person.

Here's how it works

Simply complete an Employer Registration form and email, mail or fax it to HealthPartners Worksite Health department. Worksite Health Department. You can find the form on HealthPartners Employer Web site.

You also need to designate a contact person. Our vendor will work with your contact to schedule dates and times for the flu shot clinic(s). You will need to provide necessary supplies (tables, chairs, and wastebaskets) for the nurses.

HealthPartners will send your contact a program packet including instructions, CDC information sheets, posters and registration/consent forms. You can distribute the registration/consent forms to employees either before or on the date of the clinic.

On the day of the clinic, your employees will need to fill out the employee registration and consent forms and will need to supply their HealthPartners member number to ensure coverage. If they don't have this information, employees must provide their birth date and Social Security number.

Minimum requirements

Some flu vaccine vendors have a minimum shot requirement per clinic site. For example, for three separate sites, or different times scheduled at the same site, each individual site and/or time has the minimum shot requirement. That means you may be charged the minimum shot requirement and/or a one-time fee whether the specified number of employees participates or not. This will be addressed during your planning process.

Flu shots make sense

Our Influenza Prevention program offers you a convenient, cost-effective way to protect the health of your employees — and to prevent influenza from catching on in your company.

Ready to learn more?

Contact HealthPartners Worksite Health department at (952) 883-7574, or call your broker, consultant or HealthPartners sales representative today.

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HealthPartners® *Achieve*℠

Healthy Discounts

HealthPartners Healthy Discounts provide your employees with extra perks that promote healthy lifestyles — at no additional cost to you! The benefits? Happier, healthier employees who are more productive and loyal to your company — plus a chance for you to reduce cost trends by encouraging physical activity and healthy choices in your employee population.

Here's how it works

Your employees who are HealthPartners members simply show their HealthPartners ID card to participating retailers for money-saving Healthy Discounts on exercise equipment, classes, snowboard and ski equipment, spa and wellness services and much more.

Weight Watchers

- $10 off a three-month subscription to Weight Watchers Online. To learn more, visit: www.weightwatchers.com/cs/healthpartners
- A $10 discount on *At Home* kits
- Local meeting coupons discount on weekly meetingfee and waived registration fee

Penn Cycle

- HealthPartners members get 10% off the regular price of any bike accessories or clothing, and $15 off the regular price on bike tune-ups

(continued on back)

The HealthPartners Research Foundation found that employees who are physically fit are more productive and absent less often.

— *Journal of Organizational and Environmental Medicine;* Volume 46, Number 1, January 2004)

Achieve℠

Erik's Bike Shop

- 10% off all snowboards and snowboard-related accessories, parts and clothing

Professional Karate Studios

- $10 per month off any regularly priced program
- Participating Minnesota locations are Blaine, Cambridge, Coon Rapids, Elk River and Rogers

2nd Wind Exercise Equipment

- HealthPartners members get the maximum discount available on exercise equipment at every 2nd Wind store (does not include spas or spa accessories).
- HealthPartners members receive one free in-home personal training session with purchase of $500 or more (for members with home addresses in Twin Cities and other select locations)

Hoigaards

Discounts on the following:

- 10% off recreational kayaks
- 10% off heart rate monitors
- 15% off camelbak hydration systems
- 15% off cross country skis and ski equipment
- 20% off a ski or snowboard tune-up
- 20% off a bicycle tune-up

Solimar Wellness Spa

- Full-service wellness, health and day spa providing services that support health and healing for body, mind, and spirit. See healthpartners.com for participation instructions.
- A variety of discounts are available on different services, including spa services, classes and special events, wig consultations and services and more.

Albertville Premium Outlets

- Obtain a current Albertville Premium Outlet VIP Coupon Book (normally a $5 value) for free.
- Contains discounts at a variety of Albertville Premium Outlet stores, including those with workout gear and athletic shoes.

Ready to learn more?

Contact your broker, consultant or HealthPartners sales representative today.

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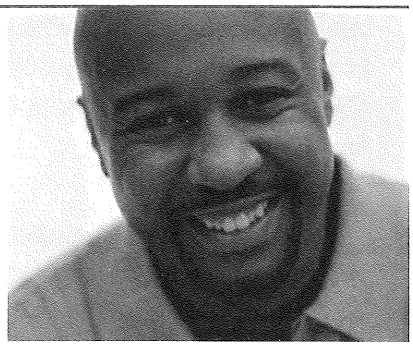
Worksite Health-e-Kit℠ Programs

Employee health improvement made easy and convenient



Now it's easy to reach out to your employees with on-site health improvement programs. HealthPartners Health-e-Kits make it simple for you to offer innovative programs on physical activity, healthy eating, stress and self-care that engage employees and address critical health issues.

The Health-e-Kit web site provides simple week-by-week directions that anyone in your organization can use to roll out an effective program. Included with the weekly directions are all the collateral materials necessary – just click and print. If you'd like, you can even add your organization's name to printed materials. The Health-e-Kit programs also provide all the tools needed to measure and document improvements in employee health attitudes, knowledge and behavior.

Inside a Health-e-Kit Program

The components of each Health-e-Kit program work together and build on one another for maximum impact. Each three-month program contains the following complementary program components:

- **The Score Card**
  Discover the policies and characteristics of the worksite environment that make it easier for employees

(continued on back)

A comprehensive review of more than two decades of increasingly sophisticated research shows that worksite health promotion programs are associated with long-term benefits of $3 to $8 for each dollar invested.

Journal of Health Promotion
2001; 15(5); 296-320

to make healthy choices. Suggestions from each Score Card can smooth the path for employees to make health behavior changes and can be implemented over time.

- **Motivational Messages**
  Employees see how healthy choices benefit them and they are motivated to make changes. Messages use humor and emotion to grab attention and encourage behavior change and increased program participation. The messages are provided in both poster and email format.
- **Newsletters**
  Each useful, engaging newsletter offers practical tips and strategies for making healthy choices. These professionally written and designed newsletters can be distributed by email or interoffice mail. Each newsletter is paired with an equally engaging email you can use when sending the newsletter as an email attachment.
- **Employee events and programs**
  These novel, all-employee events and programs target key health behaviors and give employees the opportunity to experience making healthy choices. Events target and reinforce behaviors such as taking the stairs, choosing healthy snacks and practicing stress management techniques.
- **Promotion strategies**
  Programs are only as good as their participation. Every event and program includes a complete promotional strategy designed for maximum impact.
  Promotional strategies include:
  - Timeline for promotion and program rollout
  - Innovative materials that grab attention
  - One-of-a-kind messages that put a new spin on healthy choices
- **Evaluation tools**
  Document your success with these evaluation tools. Included are:
  - An inviting employee evaluation survey
  - Reminders for maximum employee response
  - Easy to use tally
  - Evaluation summary template

Current Health-e-Kit Programs

- ***Satisfy***
  The *Satisfy* program provides employees with tasty and convenient ways to eat well.
- ***Unwind***
  The *Unwind* program provides employees with simple and powerful tools to relieve stress.
- ***Energize***
  The *Energize* program puts employees on the road to physical activity.
- ***Benefit: Get the best care when you need it***
  The *Benefit* program equips employees to benefit from appropriate and effective use of the health care system.

Ready to learn more?

Call your consultant, broker or HealthPartners sales representative today.

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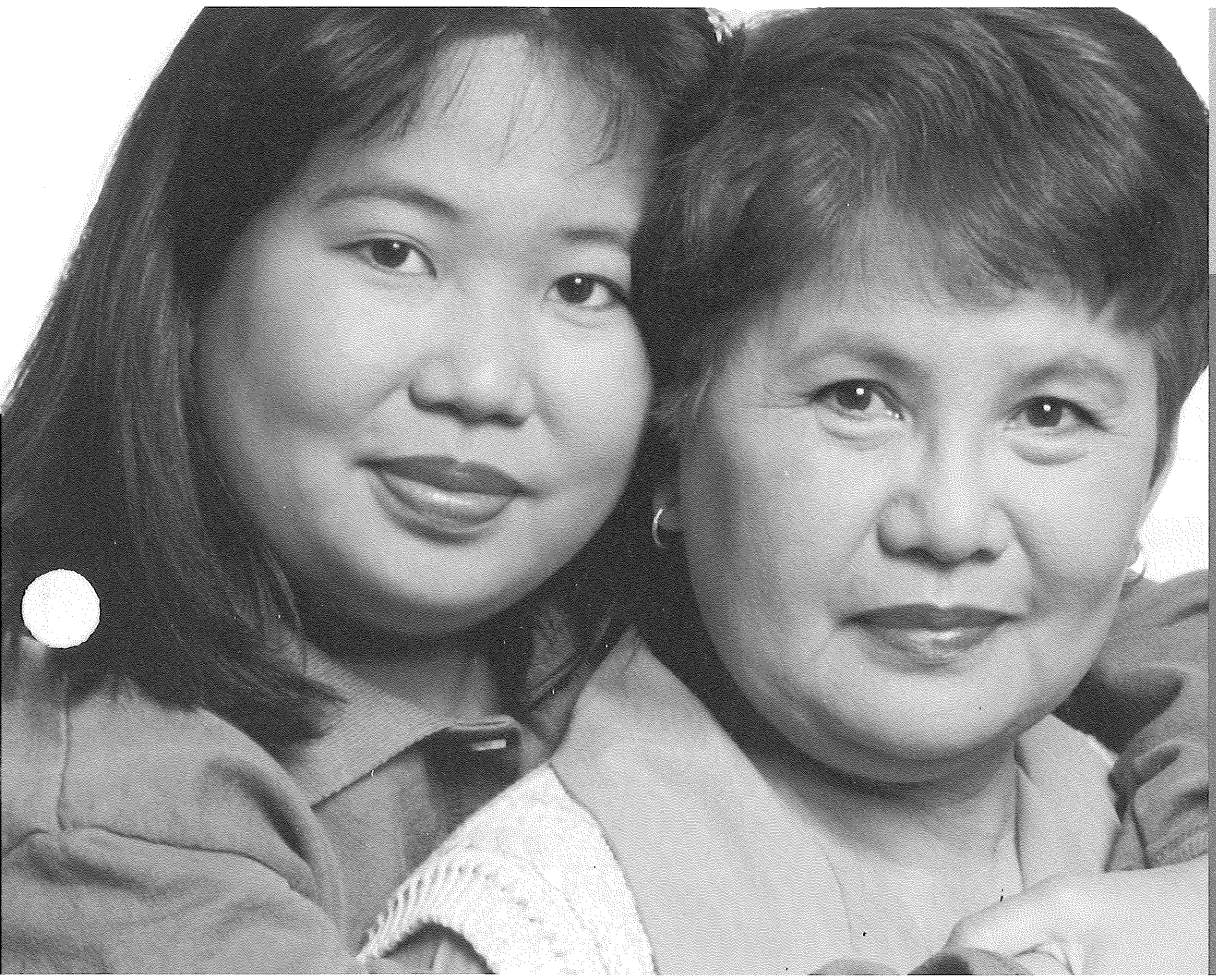
HealthPartners®
CareSpan℠

Helping you achieve the best possible health

Disease Management Programs

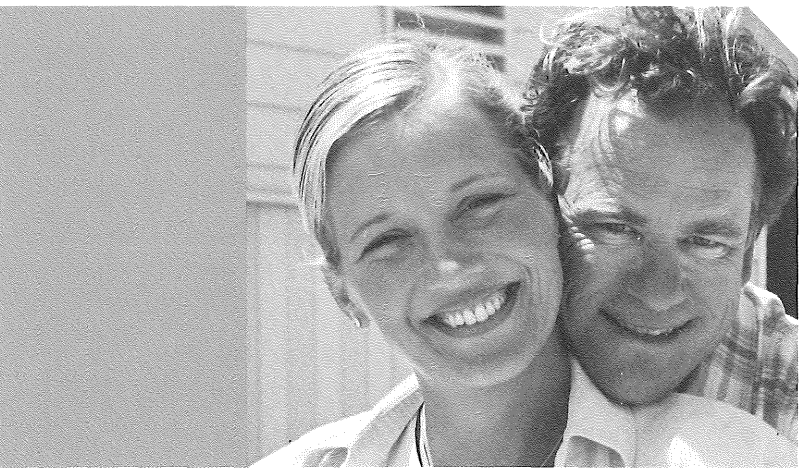


Our CareSpan℠ programs help you manage your condition for better health

If you have a chronic condition or disease that challenges your health and your peace of mind, our programs will help you take back control.

CareSpan programs help members with chronic diseases and conditions such as:

- Diabetes
- Heart failure
- Coronary artery disease
- Chronic obstructive pulmonary disease
- Asthma
- Obesity
- Kidney diseases
- Depression
- Behavioral health disorders
- Rare and chronic diseases:
  - Amyotropic lateral sclerosis (ALS)
  - Chronic idiopathic demyelinating polyneuropathy (CIDP)
  - Cystic fibrosis
  - Dermatomyositis
  - Gaucher's disease
  - Hemophilia
  - Multiple sclerosis
  - Myasthenia gravis
  - Parkinson's disease
  - Polymyositis
  - Rheumatoid arthritis
  - Sickle cell disease
  - Systemic lupus erythematosus
  - Systemic sclerosis



The HealthPartners CareSpan disease management programs help you manage your condition so you can achieve your best possible health. CareSpan services supplement your doctor's treatment by providing you with additional information and support between appointments to help you understand and manage your condition.

Here's how CareSpan works

HealthPartners provides personalized services and support to help you to take charge of your health and make positive lifestyle choices.

- Working with your doctor or health care provider, we will contact you and invite you to participate in the CareSpan program that's right for you.
- You'll receive a personalized welcome packet with helpful information about your CareSpan program and your condition.
- Depending on the severity of your condition, you'll be contacted by phone and work with a personal health manager who's familiar with your condition.
- Your health manager stays in touch to check on your progress and continues to provide you with information to manage your condition.
- We want to help you have the best health possible. So if you choose not to participate, you may be contacted again later and given the opportunity to work with our CareSpan programs.

CareSpan programs are provided by HealthPartners in partnership with HealthSuite Partners, Accordant Health Services and RMS.

Greg's Story

Greg visited his clinic and told his doctor that he:

- has diabetes
- was in severe pain from a knee injury, which limited his mobility
- had lost 19 pounds unexpectedly
- was feeling depressed
- had been missing work due to pain and lack of energy

An examination showed that his knee was infected and his diabetes was not under control. Due to his multiple health concerns, Greg's doctor referred him to HealthPartners CareSpan programs.

Sue, Greg's CareSpan health manager, wanted to help him in ways that wouldn't depress him further. She taught him self-treatments that he could do at home, which kept him out of the hospital, and reviewed with him educational materials on diet and blood sugar levels.

Sue also identified resources that could help him cope with his situation — from family members to a home care nurse — and she coordinated efforts with his providers. She kept in touch with Greg, following up after doctor appointments and offering advice and education.

With each doctor visit, Greg's condition continued to improve. His blood sugar levels normalized, his pain lessened, his weight returned to normal and his mobility improved.

In just four months, Greg was in better health and going to work regularly, thanks to the integrated care and support he received through CareSpan.

Depending on your disease and the level of severity, here are some of the services you may receive:

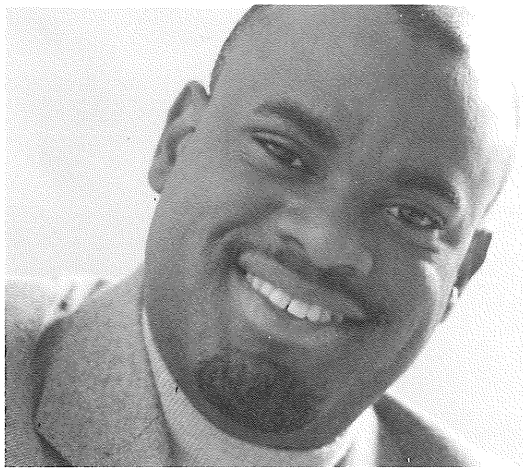
- Welcome letter and package
- Targeted educational materials
- Reminders for preventive services
- Nutritional counseling
- Behavior/lifestyle education
- Patient reports
- Satisfaction survey
- And more

There is no cost to you

There is no extra cost to eligible members to participate in CareSpan programs. We offer these programs to you as part of our ongoing effort to provide you with the best quality health care to help you improve your health.

Questions?

For questions about your HealthPartners coverage or other concerns, please call Member Services at the number on the back of your member identification card.



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CareSpan℠

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HP 450085 (12/04)

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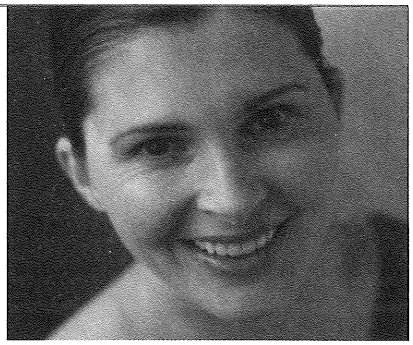
Achieve℠

With HealthPartners Frequent Fitness program, it pays to stay fit!



When you consider that two-thirds of Americans are overweight or obese, and that increasing physical activity by just 90 minutes a week can reduce health care costs, it's clear the time is right for Frequent Fitness from HealthPartners.

The Frequent Fitness program promotes regular, sustained athletic club participation by offering your employees an incentive to stay fit. Individuals simply join a participating health club, work out at least eight times a month, and they're rewarded for improving their health with monthly savings off their club membership fees. Healthier employees are absent less often and are more productive, which saves you money in the short term — and in the long run.

t's an affordable way to reward healthy choices.

If you're concerned about rising health care costs, health improvement programs like this are a great way to engage and reward employees. It's a win-win situation: employees are rewarded for improving their health, and it helps employers reduce health care costs.

In October 2003, the HealthPartners Research Foundation published the first research to provide evidence that increased physical activity can directly affect health care costs. The study found that older adults who increase their physical activity to 90 minutes a week could immediately reduce their health care costs by over $2,000 per year.

Achieve℠

Frequent Fitness basics

- **Workout requirement:** Each participant must work out — and have their health club membership card swiped to reflect usage of — at least eight times during the month to earn reimbursement for that month.
- **Eligible participants:** Adult (age 18+) HealthPartners members who have HealthPartners coverage. *Non-HealthPartners members included on a family or couples fitness membership are not eligible.*
- **Required from participant at program enrollment:** Copy of HealthPartners medical ID card.
- **Maximum participation per family:** A maximum of two individuals per household can participate in this program, regardless of whether the individuals are covered by the same HealthPartners health plan or not.
- **Participating area clubs:** For the most current listing, please visit *healthpartners.com.*

Ready to learn more?

Call your consultant, broker or HealthPartners sales representative today.

Some of our participating clubs include:

- Twin Cities and Western Wisconsin YMCAs
- Northwest Athletic Club
- Gold's Gym
- YWCA
- Flagship Athletic Club
- White Bear Swim & Racquet
- Calhoun Beach Club
- Eagan Community Center
- St. Cloud Area Family YMCA
- Regency Athletic Club and Spa
- The Grove Community Center
- Red Wing Family YMCA
- Eagan Community Center
- Alliance Fitness Center
- Rochester Area Family Y
- And many more!

Incentive program available to HealthPartners members of senior or individual plans and members of participating employers, age 18 years and older with a limit of two workout contract incentives per household. Some restrictions apply. See participating locations for incentive program details. HealthPartners reserves the right to modify or discontinue the program at any time.

HealthPartners®

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P.O. Box 1309
Minneapolis, MN 55440-1309
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HP450081 8/04

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Medica's Disease Management Programs

Medica presently offers disease management programs for more than 20 health conditions as part of its full-service benefits package to fully insured customers. These programs are also available to self-insured customers for an additional fee. The goals for these programs are to improve health, reduce any complications through early intervention and monitoring, and to improve satisfaction with health care services.

Disease Management program	Chronic conditions Served	Program features
Medica CorChoices℠ For common chronic conditions (In partnership with CorSolutions®, Inc.)	• Pediatric Asthma • Diabetes • Coronary Artery Disease • Congestive Heart Failure	• Level of care based on individual need • Contact by nurses or clinical specialists to assess, monitor and manage health conditions • Telephone access to registered nurses for answers about a specific condition 24 hours a day • Written communications including newsletters and educational brochures, with disease-specific articles and resources • Access to on-line health care information and health assessment tools. • Coordinate health care services with other care providers.
Medica AccordantCare™ For rare diseases (In partnership with Accordant Health Services, Inc.)	• Rheumatoid Arthritis • Multiple Sclerosis (MS) • Parkinson's Disease • Systemic Lupus Erythematosus (SLE) • Myasthenia Gravis • Sickle Cell Disease • Cystic Fibrosis (CF) • Hemophilia • Scleroderma • Polymyositis • Chronic Inflammatory Demyelinating Polyradiculoneuropathy (CIDP) • Amyotrophic Lateral Sclerosis (ALS) • Dermatomyositis • Gaucher Disease	
Health Advantage by Medica℠ A personalized depression-management program (In partnership with United Behavioral Health)	Depression or Depression/Anxiety Possible symptoms of depression may include: • Feeling down or hopeless • Little interest or pleasure in activities • Sleep changes • Appetite changes • Feeling tired or having little energy	

Continued =>

Helping Medica Members Lead Healthier Lives

Medica has teamed with best-in-class vendors to offer members, employers and health care professionals a more comprehensive approach to disease management.

Medica CorChoices

Access to the right care at the right time, based on individual needs

- Third party analysis revealed 3.61 Return on Investment after first year!
- Reduced ER visits and hospital admissions by eleven percent and twenty percent respectively during first year of program.
- Delivers customized and accessible resources based on individual needs. Resources include: www.medica.com/member resources/disease management for current information on specific chronic conditions, interactive tests and quizzes, nutrition information and advice; Voice Connections℠, a health library accessible by phone with unlimited, toll-free service; Nurse Connections℠, telephone access to registered nurses for answers about a condition 24 hours a day; and CorNews, a quarterly newsletter with disease-specific articles and resources.
- Provides education, motivation and assistance to help members manage chronic conditions that adversely affect their health and well being.
- CorSolutions is accredited by the National Committee for Quality Assurance (NCQA®).

Medica AccordantCare

Education, support and resources for managing 14 rare diseases

- Improves patient clinical outcomes and promotes a better quality of life. Offers education and support to empower members to self-manage their condition under the guidance and direction of a primary care provider or specialist.
- Reduces ER visits and hospital admissions due to severe symptoms.
- Delivers customized educational materials, preventive strategies, and support. Resources include a toll-free dedicated number for 24-hour access to nurses and a team of healthcare professionals, and customized educational materials, brochures and monthly newsletters.
- Monitors and reports on health status. Periodic nurse telephone contacts to complete personalized health evaluations that help members identify early warning signs of potential complications and learn preventive self-care strategies. Communication with health care providers alerts them to changes in a patient's health status and specific health needs that are deemed critical.
- Accordant Health Services, Inc., is NCQA-accredited.

Health Advantage by Medica

A personalized depression management program

- Provides education and support for members with depression or depression/anxiety so they can:
    - ➢ Better understand their condition.
    - ➢ Take an active role in managing their depression.
    - ➢ Improve adherence with their doctor's recommendations and treatment plan.
- Delivers a variety of member resources including regularly scheduled telephone calls and 24 hours access to trained clinical specialists, tailored educational mailings, and face to face home visits for selected members.
- Consultative support and educational resources for Primary Care Providers in the diagnosis and treatment of depression.

Information is available online at www.medica.com under "Medica Products" in "Value-Added Services." For more information about Medica's Disease Management programs, please contact your Medica Account Service Representative. For member-specific inquires, members may call 952-992-8460 or 1-888-365-8240.

1/06 M vers.

Dr. Anne Kelly

U Special Kids

Intensive Case Management

for

Children with Complex Medical Problems

Anne Kelly, M.D., M.P.H.

Division of General Pediatrics and Adolescent Health

Director, U Special Kids Program

U Special Kids

- Funded by the State of Minnesota
- 50 active cases
- Statewide, ethnic and income diversity
- Medicaid most common insurance
- Hospitalizations largest expenditure

U Special Kids

Critical components of success

- ***Low patient to team ratio*** allows intensive management,
- Targeting the ***right population*** - complex medical problems, recurrent hospitalizations for ***acute illnesses***,
- Up to date summary of critical information -"**SICK** ids"
- "Team care" for ***whatever***...*we work for families to get their child's needs met,*
- Recognizing and treating ***food allergies***, ***nutritional deficiencies,***
- Improve "**gut health**" and behaviors, sleep improve.

Intensive and Expensive Medical Conditions

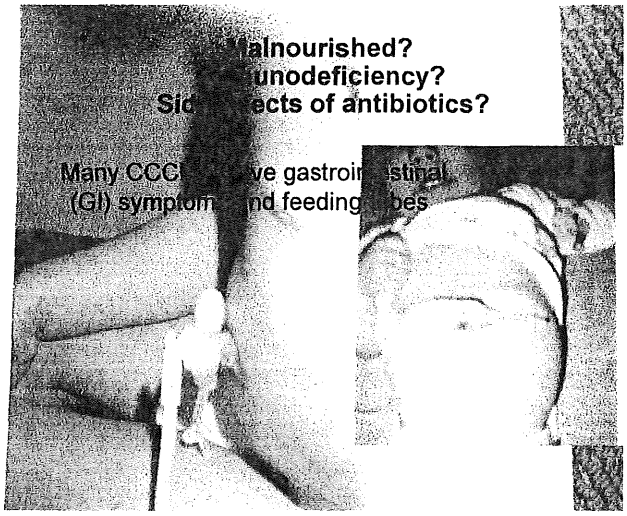
- One year in intensive care unit $$$$$$$$$$
- 20 different specialists $$
- Medications, infections, hospitalizations $$$$$
- OT, PT, speech, ABA, home care $$$$
-
- Private InsuranceHospitalizations
- Medical AssistanceTherapies, Home Care

U Special Kids

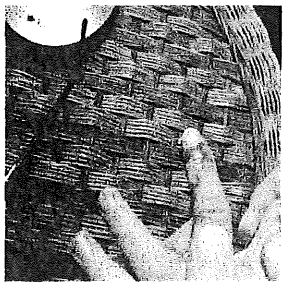
Complex surgical, medical and behavioral problems

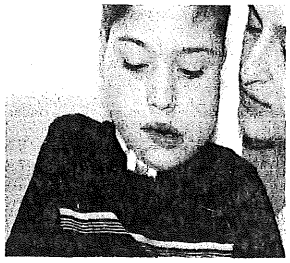
Malnourished? Immunodeficiency? Side effects of antibiotics?

Many CCC[illegible]ve gastrointestinal (GI) symptoms and feeding tubes



Other Evidence of Immunodeficiency





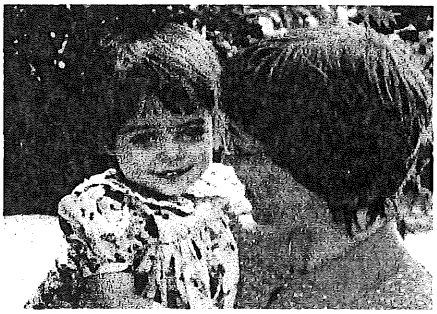
Growing Children can be Malnourished

- ***A Regular Cast of*** *Suspicious* ***Characters***
- Sensitivity to cow's milk
- Chronic antacid suppression "the purple pill"
- Recurrent antibiotics
- Poor quality diet
- Environmental toxins - mold, pesticides, mercury

U Special Kids
Non-Identical Twins with
Cow's Milk Protein Hypersensitivity

Expensive workups for rare disorders:
Suspicions of Munchausen by proxy

Expensive workups for difficult to diagnose disorders



Growing but not healthy

Intensive management
Nutritional and complimentary supplements improve health

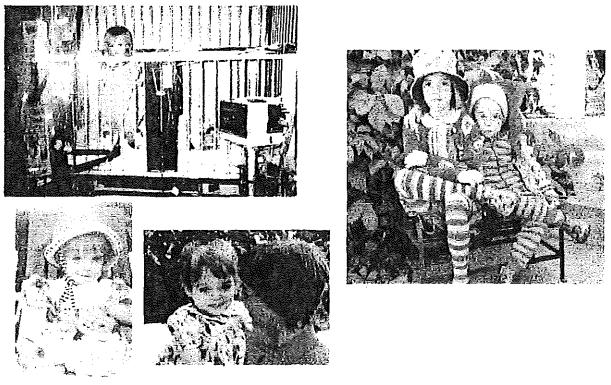
- Nutritional deficiencies,
- Complications of chronic treatments,
- Unrecognized allergies and immunodeficiencies,
- Behavioral problems and sleep disorders,

"SICKids"
Nutritional and Complimentary Medicine
A good investment

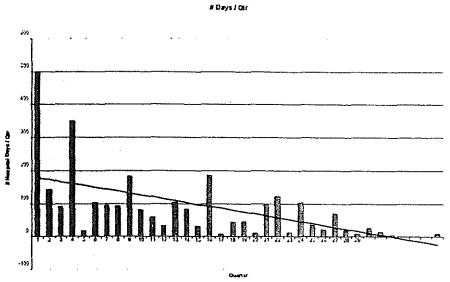
Intensive management
Nutritional and complimentary supplements improve health

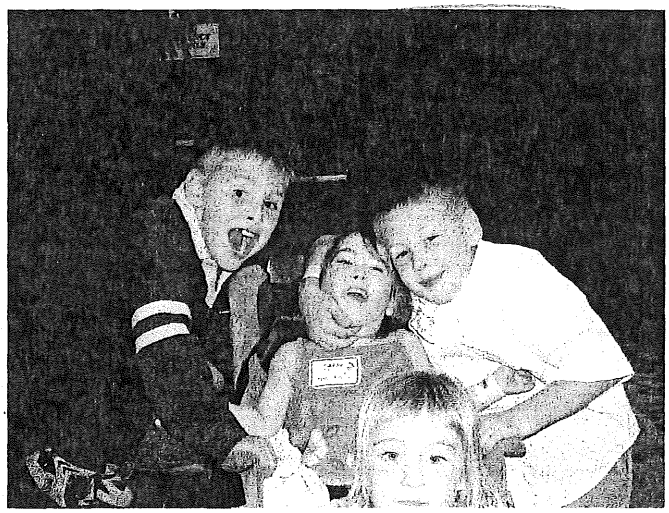
- Hypo-allergenic formula
- Probiotics- lactobacillus
- Omega 3 - essential fatty acids; ***Cod liver oil***
- B vitamins, Zinc, Mg
- Melatonin for sleep
- Organic foods - reduce artificial sugars, dyes, fats
- Eliminate environmental toxins - pesticides, mold, lake fish, tuna fish

Integrative Medicine
Long term benefits



Integrated Medicine for Complex Medical Conditions
A Good Investment





FACT SHEET OF NATUROPATHIC MEDICINE

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President, Minnesota Association of Naturopathic Physicians (MNANP)
Phone: 651-222-4111
FAX 651-222-8758
Email wellspringclinic@msn.com
Website www.helenhealynd.com

MNANP is the affiliate organization of the American Association of Naturopathic Physicians (AANP)

Websites to check out:

MNANP www.mnanp.org
AANP www.naturopathic.org

Currently there are 23 naturopathic doctors in Minnesota who graduated from 4-year naturopathic medical schools, accredited and recognized by the U.S. Department of Education.

Most Minnesota N.D.s maintain a license in one of the fifteen states that do license naturopathic doctors.

The majority of N.D.s in Minnesota are practicing in clinics with other practitioners of the healing arts. Additionally, one recent graduate has joined the University of Minnesota to do research on medicinal mushrooms and breast cancer, another is a member of U of M's Community Faculty, hosting medical students to observe patient consultations. Two N.D.s practice at the Natural Care Center at Woodwinds Health Campus, and three are on the faculty at The College of St. Catherine, teaching Herbology in the Masters of Arts in Holistic Health Studies.

As medical clinics move toward a more integrated approach to healthcare, we expect more N.D.s will be included. Once a bill is passed to license naturopathic doctors in Minnesota, we also expect an influx of graduates will move to the state, bringing their skills to bridge the gap between conventional and natural medicine perspectives.

Helen Healy

NATUROPATHIC MEDICINE IN TREATMENT OF DIABETES

DIET & LIFESTYLE COUNSELING TO PREVENT DIABETES IN AT-RISK PATIENTS

Knowler WC. Barrett-Connor E. Fowler SE. Hamman RF. Lachin JM. Walker EA. Nathan DM. Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin. New England Journal of Medicine. 346(6):393-403, 2002 Feb 7.

BACKGROUND: Type 2 diabetes affects approximately 8 percent of adults in the United States. Some risk factors--elevated plasma glucose concentrations in the fasting state and after an oral glucose load, overweight, and a sedentary lifestyle--are potentially reversible. We hypothesized that modifying these factors with a lifestyle-intervention program or the administration of metformin would prevent or delay the development of diabetes. METHODS: We randomly assigned 3234 nondiabetic persons with elevated fasting and post-load plasma glucose concentrations to placebo, metformin (850 mg twice daily), or a lifestyle-modification program with the goals of at least a 7 percent weight loss and at least 150 minutes of physical activity per week. The mean age of the participants was 51 years, and the mean body-mass index (the weight in kilograms divided by the square of the height in meters) was 34.0; 68 percent were women, and 45 percent were members of minority groups. RESULTS: The average follow-up was 2.8 years. The incidence of diabetes was 11.0, 7.8, and 4.8 cases per 100 person-years in the placebo, metformin, and lifestyle groups, respectively. The lifestyle intervention reduced the incidence by 58 percent (95 percent confidence interval, 48 to 66 percent) and metformin by 31 percent (95 percent confidence interval, 17 to 43 percent), as compared with placebo; the lifestyle intervention was significantly more effective than metformin. To prevent one case of diabetes during a period of three years, 6.9 persons would have to participate in the lifestyle-intervention program, and 13.9 would have to receive metformin. CONCLUSIONS: Lifestyle changes and treatment with metformin both reduced the incidence of diabetes in persons at high risk. The lifestyle intervention was more effective than metformin.

Uusitupa MI. Early lifestyle intervention in patients with non-insulin-dependent diabetes mellitus and impaired glucose tolerance. Annals of Medicine. 28(5):445-9, 1996 Oct.

Non-insulin-dependent diabetes mellitus (NIDDM) is preceded by impaired glucose tolerance (IGT) lasting for years before manifesting as overt hyperglycaemia. Both genetic and environmental factors contribute to the development of IGT and NIDDM. Obesity, physical inactivity and high-fat diet have been found to predict IGT and NIDDM. Therefore, a diet and exercise intervention from diagnosis of NIDDM could improve the treatment outcome and prognosis of patients with NIDDM. Furthermore, because subjects with IGT are at increased risk for diabetes and atherosclerotic vascular disease, it is reasonable to assume that in terms of reducing the incidence and longterm consequences of NIDDM an intervention at this phase is more effective than in overt diabetes. Although the nonpharmacological approach is generally accepted as the first-line treatment of NIDDM its efficacy has often been questioned. Therefore, it is important to carry out long-term controlled studies to find out to what extent lifestyle modification could improve the metabolic control and level of major cardiovascular risk factors known to be associated with poor outcome in NIDDM. This kind of study also gave relevant experience in planning studies aiming at primary prevention of NIDDM. One-year dietary and exercise intervention on newly diagnosed NIDDM patients in Kuopio, Finland resulted in a better metabolic control and a moderate reduction in cardiovascular risk factors as compared to the conventional treatment group. After the second year of follow-up only 12.5% in the intervention group were receiving oral antidiabetic drugs vs. 34.8% in the conventional treatment group. Weight reduction and a reduced use of saturated fats appeared to be the main determinants of successful treatment results. Good aerobic capacity was associated with an increase in HDL cholesterol. A multicentre primary prevention study on IGT patients

is continuing in Finland applying the same principles of intervention as used in the study on newly diagnosed NIDDM patients. Pilot results show that glucose tolerance can be improved by lifestyle changes.

DIET & LIFESTYLE COUNSELING TO IMPROVE GLYCEMIC CONTROL IN DIABETIC POPULATION
Nicholson AS. Sklar M. Barnard ND. Gore S. Sullivan R. Browning S. Toward improved management of NIDDM: A randomized, controlled, pilot intervention using a low fat, vegetarian diet. Preventive Medicine. 29(2):87-91, 1999 Aug.

OBJECTIVE: To investigate whether glycemic and lipid control in patients with non-insulin-dependent diabetes (NIDDM) can be significantly improved using a low fat, vegetarian (vegan) diet in the absence of recommendations regarding exercise or other lifestyle changes. METHODS: Eleven subjects with NIDDM recruited from the Georgetown University Medical Center or the local community were randomly assigned to a low-fat vegan diet (seven subjects) or a conventional low-fat diet (four subjects). Two additional subjects assigned to the control group failed to complete the study. The diets were not designed to be isocaloric. Fasting serum glucose, body weight, medication use, and blood pressure were assessed at baseline and biweekly thereafter for 12 weeks. Serum lipids, glycosylated hemoglobin, urinary albumin, and dietary macronutrients were assessed at baseline and 12 weeks. RESULTS: Although the sample was intentionally small in accordance with the pilot study design, the 28% mean reduction in fasting serum glucose of the experimental group, from 10.7 to 7.75 mmol/L (195 to 141 mg/dl), was significantly greater than the 12% decrease, from 9.86 to 8.64 mmol/L (179 to 157 mg/dl), for the control group ($P < 0.05$). The mean weight loss was 7.2 kg in the experimental group, compared to 3. 8 kg for the control group ($P < 0.005$). Of six experimental group subjects on oral hypoglycemic agents, medication use was discontinued in one and reduced in three. Insulin was reduced in both experimental group patients on insulin. No patient in the control group reduced medication use. Differences between the diet groups in the reductions of serum cholesterol and 24-h microalbuminuria did not reach statistical significance; however, high-density lipoprotein concentration fell more sharply (0.20 mmol/L) in the experimental group than in the control group (0.02 mmol/L) ($P < 0.05$). CONCLUSION: The use of a low fat, vegetarian diet in patients with NIDDM was associated with significant reductions in fasting serum glucose concentration and body weight in the absence of recommendations for exercise. A larger study is needed for confirmation.

Hanefeld M. Fischer S. Schmechel H. Rothe G. Schulze J. Dude H. Schwanebeck U. Julius U. Diabetes Intervention Study. Multi-intervention trial in newly diagnosed NIDDM. Diabetes Care. 14(4):308-17, 1991 Apr.

OBJECTIVE: In a randomized 5-yr multi-intervention trial, we tested the efficacy of intensified health education (IHE) in improving metabolic control and reducing the level of coronary risk factors and incidence of ischemic heart disease (IHD). RESEARCH DESIGN AND METHODS: Within the intervention group, the benefit of clofibric acid was evaluated in a double-blind study. One thousand one hundred thirty-nine newly diagnosed middle-aged (30- to 55-yr-old) patients with non-insulin-dependent diabetes mellitus (NIDDM) entered the study. They were classified as diet controlled after a 6-wk screening phase with conventional dietary treatment. During the follow-up, the control group ($n = 378$) was cared for at different diabetes outpatient clinics with a standardized surveillance. The intervention group ($n = 761$) had a structured IHE that included dietary advice, antismoking and antialcohol education, and ways to enhance physical activity. RESULTS: Randomly, 379 of the IHE patients received 1.6 g clofibric acid/day, and the others received placebo. IHE resulted in improved glucose control (adjusted fasting blood glucose) levels after 5 yr (control subjects 9.27 mM, IHE group 8.71 mM, and IHE plus clofibric acid group 8.60 mM, P less than 0.01). The better glycemic control was achieved with fewer antidiabetic drugs. After 5 yr, antidiabetic drugs were prescribed to 47% of the control subjects, 28% of the IHE group, and 34% of the IHE plus clofibric acid group (cutoff limit for drug application was

postprandial blood glucose of greater than or equal to 13.87 mM). The ratio of polyunsaturated to saturated fatty acids (0.26 vs. 0.40, P less than 0.01) and physical activity (174 vs. 327 scores, P less than 0.01) were increased, and blood pressure, tobacco, and alcohol consumption were significantly reduced by IHE. However, IHE had no effect on calorie intake, percentage of fat in the diet (45%), and body weight. The most important finding was the significant increase of blood cholesterol in all three groups (+0.47, +0.36, and +0.34 mM, respectively). Clofibric acid only prevented the increase of triglyceride levels (+0.56, +0.24, and +0.05 mM, respectively). The incidence rate per 1000 for myocardial infarction was 30.3 for control subjects, 53.6 for the IHE group, and 55.6 for the IHE plus clofibric acid group. The corresponding rates for IHD incidence were 90.9, 97.8, and 98.8, respectively. Men suffered more frequently from myocardial infarction, whereas women developed ECG criteria for IHD more frequently. Among the 35 cases of death, besides cardiovascular diseases, liver cirrhosis and neoplasia were the predominant causes. The death rate per 1000 in control subjects was 46.2, 30.6 in the IHE group, and 27 among patients with IHE plus clofibric acid. CONCLUSIONS: IHE was of substantial benefit for the control of glycemia, significantly diminished the need for antidiabetic drugs, and reduced a cluster of risk factors but had no effect on the control of blood lipids. This could be one major reason for the failure of IHE, effective lowering of blood pressure, and clofibric acid to prevent cardiovascular complications. Clofibric acid was only effective in reducing triglycerides.

SPECIFIC DIETARY MODIFICATIONS

Dietary Fats

Tanasescu M. Cho E. Manson JE. Hu FB. Dietary fat and cholesterol and the risk of cardiovascular disease among women with type 2 diabetes. *American Journal of Clinical Nutrition. 79(6):999-1005, 2004 Jun.*

BACKGROUND: Nutritional therapy is a cornerstone of diabetes management, but no epidemiologic studies have investigated the relation between specific dietary fatty acids and cholesterol and cardiovascular disease (CVD) risk among diabetic patients. OBJECTIVE: This study assessed the relation between specific dietary fatty acids and cholesterol and CVD risk among women with type 2 diabetes. DESIGN: Among 5672 women with type 2 diabetes from the Nurses' Health Study, diet was assessed prospectively and updated periodically. Relative risks of CVD were estimated from Cox proportional hazards analysis after adjustment for potential confounders. RESULTS: Between 1980 and 1998, we identified 619 new cases of CVD (nonfatal myocardial infarction, fatal coronary heart disease, and stroke). The relative risk (RR) of CVD for an increase of 200 mg cholesterol/1000 kcal was 1.37 (95% CI: 1.12, 1.68; P = 0.003). Each 5% of energy intake from saturated fat, as compared with equivalent energy from carbohydrates, was associated with a 29% greater risk of CVD (RR: 1.29; 95% CI: 1.02, 1.63; P = 0.04). The ratio of polyunsaturated to saturated fat (P:S) was inversely associated with the risk of fatal CVD. We estimated that replacement of 5% of energy from saturated fat with equivalent energy from carbohydrates or monounsaturated fat was associated with a 22% or 37% lower risk of CVD, respectively. CONCLUSIONS: A higher intake of cholesterol and saturated fat and a low P:S were related to increased CVD risk among women with type 2 diabetes. Among diabetic persons, replacement of saturated fat with monounsaturated fat may be more effective in lowering CVD risk than is replacement with carbohydrates.

Van Dam RM. Willett WC. Rimm EB. Stampfer MJ. Hu FB. Dietary fat and meat intake in relation to risk of type 2 diabetes in men. *Diabetes Care. 25(3):417-24, 2002 Mar.*

OBJECTIVE: To examine dietary fat and meat intake in relation to risk of type 2 diabetes. RESEARCH DESIGN AND METHODS: We prospectively followed 42,504 male participants of the Health

Professionals Follow-Up Study who were aged 40-75 years and free of diagnosed diabetes, cardiovascular disease, and cancer in 1986. Diet was assessed by a validated food frequency questionnaire and updated in 1990 and 1994. During 12 years of follow-up, we ascertained 1,321 incident cases of type 2 diabetes. RESULTS: Intakes of total fat (multivariate RR for extreme quintiles 1.27, CI 1.04-1.55, P for trend=0.02) and saturated fat (1.34, 1.09-1.66, P for trend=0.01) were associated with a higher risk of type 2 diabetes. However, these associations disappeared after additional adjustment for BMI (total fat RR 0.97, CI 0.79-1.18; saturated fat 0.97, 0.79-1.20). Intakes of oleic acid, trans-fat, long-chain n-3 fat, and alpha-linolenic acid were not associated with diabetes risk after multivariate adjustment. Linoleic acid was associated with a lower risk of type 2 diabetes in men <65 years of age (RR 0.74, CI 0.60-0.92, P for trend=0.01) and in men with a BMI <25 kg/m(2) (0.53, 0.33-0.85, P for trend=0.006) but not in older and obese men. Frequent consumption of processed meat was associated with a higher risk for type 2 diabetes (RR 1.46, CI 1.14-1.86 for > or = 5/week vs. <1/month, P for trend <0.0001). CONCLUSIONS: Total and saturated fat intake were associated with a higher risk of type 2 diabetes, but these associations were not independent of BMI. Frequent consumption of processed meats may increase risk of type 2 diabetes.

Lichtenstein AH. Schwab US. Relationship of dietary fat to glucose metabolism. *Atherosclerosis. 150(2):227-43, 2000 Jun.*

The relationship between dietary fat and glucose metabolism has been recognized for at least 60 years. In experimental animals, high fat diets result in impaired glucose tolerance. This impairment is associated with decreased basal and insulin-stimulated glucose metabolism. Impaired insulin binding and/or glucose transporters has been related to changes in the fatty acid composition of the membrane induced by dietary fat modification. In humans, high-fat diets, independent of fatty acid profile, have been reported to result in decreased insulin sensitivity. Saturated fat, relative to monounsaturated and polyunsaturated fat, appears to be more deleterious with respect to fat-induced insulin insensitivity. Some of the adverse effects induced by fat feeding can be ameliorated with omega-3 fatty acid. Epidemiological data in humans suggest that subjects with higher intakes of fat are more prone to develop disturbances in glucose metabolism, type 2 diabetes or impaired glucose tolerance, than subjects with lower intakes of fat. Inconsistencies in the data may be attributable to clustering of high intakes of dietary fat (especially animal fat) with obesity and inactivity. Metabolic studies suggest that higher-fat diets containing a higher proportion of unsaturated fat result in better measures of glucose metabolism than high-carbohydrate diet. Clearly, the area of dietary fat and glucose metabolism has yet to be fully elucidated.

Dietary Fiber Intake

Schulze MB. Liu S. Rimm EB. Manson JE. Willett WC. Hu FB. Glycemic index, glycemic load, and dietary fiber intake and incidence of type 2 diabetes in younger and middle-aged women. *American Journal of Clinical Nutrition. 80(2):348-56, 2004 Aug.*

BACKGROUND: Increasing evidence suggests an important role of carbohydrate quality in the development of type 2 diabetes. OBJECTIVE: Our objective was to prospectively examine the association between glycemic index, glycemic load, and dietary fiber and the risk of type 2 diabetes in a large cohort of young women. DESIGN: In 1991, 91249 women completed a semiquantitative food-frequency questionnaire that assessed dietary intake. The women were followed for 8 y for the development of incident type 2 diabetes, and dietary information was updated in 1995. RESULTS: We identified 741 incident cases of confirmed type 2 diabetes during 8 y (716 300 person-years) of follow-up. After adjustment for age, body mass index, family history of diabetes, and other potential confounders, glycemic index was significantly associated with an increased risk of diabetes (multivariate relative risks for quintiles 1-5, respectively: 1, 1.15, 1.07, 1.27, and 1.59; 95% CI: 1.21, 2.10; P for trend = 0.001). Conversely, cereal fiber intake was associated with a decreased risk of diabetes (multivariate relative risks for quintiles 1-5, respectively: 1, 0.85, 0.87, 0.82, and 0.64; 95% CI: 0.48, 0.86; P for trend = 0.004). Glycemic load was not significantly associated with risk in the overall cohort (multivariate relative risks

for quintiles 1-5, respectively: 1, 1.31, 1.20, 1.14, and 1.33; 95% CI: 0.92, 1.91; P for trend = 0.21). CONCLUSIONS: A diet high in rapidly absorbed carbohydrates and low in cereal fiber is associated with an increased risk of type 2 diabetes.

Tabatabai A. Li S. Dietary fiber and type 2 diabetes. *Clinical Excellence for Nurse Practitioners. 4(5):272-6, 2000 Sep.*

This article addresses the current theory, research, and implications of dietary fiber in the management of type 2 diabetes mellitus (DM; non-insulin-dependent DM). Dietary fiber shows promise in the management of type 2 DM. The inclusion of sufficient dietary fiber in a meal flattens the postprandial glycemic and insulinemic excursions and favorably influences plasma lipid levels in patients with type 2 DM. Water-soluble fiber appears to have a greater potential to reduce postprandial blood glucose, insulin, and serum lipid levels than insoluble fiber. Viscosity of the dietary fiber is important; the greater the viscosity, the greater the effect. Possible mechanisms for metabolic improvements with dietary fiber include delay of glucose absorption, increase in hepatic extraction of insulin, increased insulin sensitivity at the cellular level, and binding of bile acids. Patients with type 2 DM should increase their dietary fiber intake to 20 to 35 g/d and be aware of the considerations when increasing fiber intake. The nurse practitioner is in an ideal position to promote dietary fiber intake in such patients.

Chandalia M. Garg A. Lutjohann D. von Bergmann K. Grundy SM. Brinkley LJ. Beneficial effects of high dietary fiber intake in patients with type 2 diabetes mellitus. *New England Journal of Medicine. 342(19):1392-8, 2000 May 11.*

BACKGROUND: The effect of increasing the intake of dietary fiber on glycemic control in patients with type 2 diabetes mellitus is controversial. METHODS: In a randomized, crossover study, we assigned 13 patients with type 2 diabetes mellitus to follow two diets, each for six weeks: a diet containing moderate amounts of fiber (total, 24 g; 8 g of soluble fiber and 16 g of insoluble fiber), as recommended by the American Diabetes Association (ADA), and a high-fiber diet (total, 50 g; 25 g of soluble fiber and 25 g of insoluble fiber), containing foods not fortified with fiber (unfortified foods). Both diets, prepared in a research kitchen, had the same macronutrient and energy content. We compared the effects of the two diets on glycemic control and plasma lipid concentrations. RESULTS: Compliance with the diets was excellent. During the sixth week, the high-fiber diet, as compared with the sixth week of the ADA diet, mean daily preprandial plasma glucose concentrations were 13 mg per deciliter [0.7 mmol per liter] lower (95 percent confidence interval, 1 to 24 mg per deciliter [0.1 to 1.3 mmol per liter]; P=0.04) and mean median difference, daily urinary glucose excretion 1.3 g (0.23; 95 percent confidence interval, 0.03 to 1.83 g; P= 0.008). The high-fiber diet also lowered the area under the curve for 24-hour plasma glucose and insulin concentrations, which were measured every two hours, by 10 percent (P=0.02) and 12 percent (P=0.05), respectively. The high-fiber diet reduced plasma total cholesterol concentrations by 6.7 percent (P=0.02), triglyceride concentrations by 10.2 percent (P=0.02), and very-low-density lipoprotein cholesterol concentrations by 12.5 percent (P=0.01). CONCLUSIONS: A high intake of dietary fiber, particularly of the soluble type, above the level recommended by the ADA, improves glycemic control, decreases hyperinsulinemia, and lowers plasma lipid concentrations in patients with type 2 diabetes.

Low Glycemic Index Diet

Rizkalla SW. Taghrid L. Laromiguiere M. Huet D. Boillot J. Rigoir A. Elgrably F. Slama G. Improved plasma glucose control, whole-body glucose utilization, and lipid profile on a low-glycemic index diet in type 2 diabetic men: a randomized controlled trial.

OBJECTIVE: To determine whether a chronic low-glycemic index (LGI) diet, compared with a high-glycemic index (HGI) diet, has beneficial effects on plasma glucose control, lipid metabolism, total fat mass, and insulin resistance in type 2 diabetic patients. RESEARCH DESIGN AND METHODS: Twelve type 2 diabetic men were randomly allocated to two periods of 4 weeks of an LGI or HGI carbohydrate diet separated by a 4-week washout interval, in a crossover design. RESULTS: The LGI diet induced lower postprandial plasma glucose and insulin profiles and areas under the curve than after the HGI diet. At the end of the two dietary periods, the 7-day dietary records demonstrated equal daily total energy and macronutrient intake. Body weight and total fat mass were comparable. Four-week LGI versus HGI diet induced improvement of fasting plasma glucose ($P < 0.01$, Delta changes during LGI vs. HGI), HbA(1c) ($P < 0.01$), and whole-body glucose utilization measured by the euglycemic-hyperinsulinemic clamp ($P < 0.05$). LGI diet induced a decrease in fasting plasma total and LDL cholesterol (Delta changes LGI vs. HGI, $P < 0.01$), free fatty acids ($P < 0.01$), apolipoprotein B, and plasminogen activator inhibitor 1 activity. CONCLUSIONS: Only 4 weeks of an LGI diet was able to improve glycemic control, glucose utilization, some lipid profiles, and the capacity for fibrinolysis in type 2 diabetes. Even if changes in glycemic control were modest during the 4-week period, the use of an LGI diet in a longer-term manner might play an important role in the treatment and prevention of diabetes and related disorders.

Wolever TM. Jenkins DJ. Vuksan V. Jenkins AL. Wong GS. Josse RG. Beneficial effect of low-glycemic index diet in overweight NIDDM subjects. *Diabetes Care. 15(4):562-4, 1992 Apr.*

OBJECTIVE--To determine whether low-glycemic index (GI) diets have clinical utility in overweight patients with non-insulin-dependent diabetes mellitus (NIDDM). RESEARCH DESIGN AND METHODS--Six patients with NIDDM were studied on both high- and low-GI diets of 6-wk duration with metabolic diets with a randomized crossover design. Both diets were of similar composition (57% carbohydrate, 23% fat, and 34 g/day dietary fiber), but the low-GI diet had a GI of 58 compared with 86 for the high-GI diet. RESULTS--Small and similar amounts of weight were lost on both diets: 2.5 kg on high-GI diet and 1.8 kg on low-GI diet. On the low-GI diet, the mean level of serum fructosamine, as an index of overall blood glucose control, was lower than on the high-GI diet by 8% (P less than 0.05), and total serum cholesterol was lower by 7% (P less than 0.01). CONCLUSIONS--In overweight patients with NIDDM, reducing diet GI improves overall blood glucose and lipid control.

SPECIFIC NUTRITIONAL SUPPLEMENTATION

Chromium

Rabinovitz H. Friedensohn A. Leibovitz A. Gabay G. Rocas C. Habot B. Effect of chromium supplementation on blood glucose and lipid levels in type 2 diabetes mellitus elderly patients. *International Journal for Vitamin & Nutrition Research. 74(3):178-82, 2004 May.*

Intervention trials have shown the beneficial effects of chromium supplementation in type 2 diabetes (non-insulin-dependent diabetes mellitus). This study investigated the effects of chromium picolinate on elderly diabetic patients within a rehabilitation program. Thirty-nine diabetic subjects, average age 73 years (18 males and 21 females), undergoing rehabilitation following stroke or hip fracture, were recruited to participate in this study. An additional 39 diabetic patients constituted the control group. Along with standard treatment for diabetes, the study group received 200 microg of chromium twice a day for a three-week period. Blood samples, dietary intake, and anthropometric data were collected prior to and post-intervention. Throughout the study period, participants received a diet of approximately 1500 kcal/day. Significant differences in the fasting blood level of glucose compared to the baseline (190 mg/dL vs 150 mg/dL, $p < 0.001$) were found at the end of the study. HbA1c also improved from 8.2% to 7.6% ($p < 0.01$). Total cholesterol was also reduced from 235 mg/dL to 213 mg/dL ($p < 0.02$). A trend

towards lowered triglyceride levels was also observed (152 mg/dL vs 136 mg/dL). We conclude that, in this population of elderly, diabetic patients undergoing rehabilitation, dietary supplementation with chromium is beneficial in moderating glucose intolerance. In addition, chromium intake appears to lower plasma lipid levels.

Preuss HG. Anderson RA. Chromium update: examining recent literature 1997-1998. *Current Opinion in Clinical Nutrition & Metabolic Care. 1(6):509-12, 1998 Nov.*

Trivalent chromium is an essential nutrient required for sugar and fat metabolism. The majority of people eating typical Western diets consume less than the upper limit of the estimated safe and adequate daily dietary intake, which is set at 50-200 micrograms per day. Insufficient chromium intake is associated with signs and symptoms similar to those seen in diabetes and cardiovascular diseases. The efficacy of chromium in the general population relates to its prevention of deficiency or a reduction in the risk of chronic diseases. It is possible that doses above the estimated safe and adequate daily dietary intake are necessary for the treatment of certain chronic disease states. In a study performed in China, the use of 1000 micrograms of chromium per day (five times above the upper limit of the estimated safe and adequate daily dietary intake) was highly effective in relieving many of the symptomatic manifestations of type 2 diabetes mellitus, including a return of the HbA1C levels into the normal range. Most recent evidence strongly supports the conclusion that there is little fear of toxic reactions from chromium consumption. In addition to type 2 diabetes mellitus, chromium supplementation may be useful to direct overall weight decrements specifically towards fat loss with the retention of lean body mass and to ameliorate many manifestations of aging.

Alpha Lipoic Acid

Evans JL. Goldfine ID. Alpha-lipoic acid: a multifunctional antioxidant that improves insulin sensitivity in patients with type 2 diabetes. *Diabetes Technology & Therapeutics. 2(3):401-13, 2000.*

Alpha-Lipoic acid (LA) is a disulfide compound that is produced in small quantities in cells, and functions naturally as a co-enzyme in the pyruvate dehydrogenase and alpha-ketoglutarate dehydrogenase mitochondrial enzyme complexes. In pharmacological doses, LA is a multifunctional antioxidant. LA has been used in Germany for over 30 years for the treatment of diabetes-induced neuropathy. In patients with type 2 diabetes, recent studies have reported that intravenous (i.v.) infusion of LA increases insulin-mediated glucose disposal, whereas oral administration of LA has only marginal effects. If the limitations of oral therapy can be overcome, LA could emerge as a safe and effective adjunctive antidiabetic agent with insulin sensitizing activity.

Orzechowski A. Justification for antioxidant preconditioning (or how to protect insulin-mediated actions under oxidative stress). *Journal of Biosciences. 28(1):39-49, 2003 Feb.*

Insulin resistance is characterized by impaired glucose utilization in the peripheral tissues, accelerated muscle protein degradation, impaired antioxidant defenses and extensive cell death. Apparently, both insulin and IGF-1 at physiological concentrations support cell survival by phosphatidylinositol 3 kinase-dependent and independent mechanisms. Postprandial hyperglycemia and hyperinsulinemia are found in insulin resistance, which accompanies the so-called noninsulin dependent diabetes mellitus (diabetes type 2). Evidence also indicates that increased susceptibility of muscle cells and cardiomycoytes to oxidative stress is among the harmful complications of insulin resistance and diabetes. Limited knowledge showing benefits of preconditioning with anti- oxidants (vitamin C, E, a-lipoic acid, N-acetylcysteine) in order to protect insulin action under oxidative stress prompted the author to discuss the theoretical background to this approach. It should be stressed that antioxidant preconditioning is relevant to prevention of both diabetes- and insulin resistance-associated side-effects such as low viability and cell deletion.

Furthermore, antioxidant conditioning promises to provide higher efficacy for clinical applications in myoblast transfer therapy and cardiomyoplasty.

Coenzyme Q10

Hodgson JM. Watts GF. Playford DA. Burke V. Croft KD. Coenzyme Q10 improves blood pressure and glycaemic control: a controlled trial in subjects with type 2 diabetes. *European Journal of Clinical Nutrition. 56(11):1137-42, 2002 Nov.*

OBJECTIVE: Our objective was to assess effects of dietary supplementation with coenzyme Q10 (CoQ) on blood pressure and glycaemic control in subjects with type 2 diabetes, and to consider oxidative stress as a potential mechanism for any effects. SUBJECTS AND DESIGN: Seventy-four subjects with uncomplicated type 2 diabetes and dyslipidaemia were involved in a randomised double blind placebo-controlled 2x2 factorial intervention. SETTING: The study was performed at the University of Western Australia, Department of Medicine at Royal Perth Hospital, Australia. INTERVENTIONS: Subjects were randomly assigned to receive an oral dose of 100 mg CoQ twice daily (200 mg/day), 200 mg fenofibrate each morning, both or neither for 12 weeks. MAIN OUTCOME MEASURES: We report an analysis and discussion of the effects of CoQ on blood pressure, on long-term glycaemic control measured by glycated haemoglobin (HbA(1c)), and on oxidative stress assessed by measurement of plasma F2-isoprostanes. RESULTS: Fenofibrate did not alter blood pressure, HbA(1c), or plasma F2-isoprostanes. There was a 3-fold increase in plasma CoQ concentration (3.4+/-0.3 micro mol/l, P<0.001) as a result of CoQ supplementation. The main effect of CoQ was to significantly decrease systolic (-6.1+/-2.6 mmHg, P=0.021) and diastolic (-2.9+/-1.4 mmHg, P=0.048) blood pressure and HbA(1c) (-0.37+/-0.17%, P=0.032). Plasma F2-isoprostane concentrations were not altered by CoQ (0.14+/-0.15 nmol/l, P=0.345). CONCLUSIONS: These results show that CoQ supplementation may improve blood pressure and long-term glycaemic control in subjects with type 2 diabetes, but these improvements were not associated with reduced oxidative stress, as assessed by F2-isoprostanes.

Lamson DW. Plaza SM. Mitochondrial factors in the pathogenesis of diabetes: a hypothesis for treatment. *Alternative Medicine Review. 7(2):94-111, 2002 Apr.*

A growing body of evidence has demonstrated a link between various disturbances in mitochondrial functioning and type 2 diabetes. This review focuses on a range of mitochondrial factors important in the pathogenesis of this disease. The mitochondrion is an integral part of the insulin system found in the islet cells of the pancreas. Because of the systemic complexity of mitochondrial functioning in terms of tissue and energetic thresholds, details of structure and function are reviewed. The expression of type 2 diabetes can be ascribed to a number of qualitative or quantitative changes in the mitochondria. Qualitative changes refer to genetic disturbances in mitochondrial DNA (mtDNA). Heteroplasmic as well as homoplasmic mutations of mtDNA can lead to the development of a number of genetic disorders that express the phenotype of type 2 diabetes. Quantitative decreases in mtDNA copy number have also been linked to the pathogenesis of diabetes. The study of the relationship of mtDNA to type 2 diabetes has revealed the influence of the mitochondria on nuclear-encoded glucose transporters and the influence of nuclear encoded uncoupling proteins on the mitochondria. This basic research into the pathogenesis of diabetes has led to the awareness of natural therapeutics (such as coenzyme Q10) that increase mitochondrial functioning and avoidance of trans-fatty acids that decrease mitochondrial functioning.

Omega-3 Fatty Acids

Tapsell LC. Gillen LJ. Patch CS. Batterham M. Owen A. Bare M. Kennedy M. Including walnuts in a low-fat/modified-fat diet improves HDL cholesterol-to-total cholesterol ratios in patients with type 2 diabetes. *Diabetes Care. 27(12):2777-83, 2004 Dec.*

OBJECTIVE: The aim of this study was to examine the effect of a moderate-fat diet inclusive of walnuts on blood lipid profiles in patients with type 2 diabetes. RESEARCH DESIGN AND METHODS: This was a parallel randomized controlled trial comparing three dietary advice groups each with 30% energy as fat: low fat, modified low fat, and modified low fat inclusive of 30 g of walnuts per day. Fifty-eight men and women, mean age 59.3 +/- 8.1 years, started the trial. Dietary advice was given at baseline with monthly follow-up and fortnightly phone calls for support. Body weight, percent body fat, blood lipids, HbA1c, total antioxidant capacity, and erythrocyte fatty acid levels were measured at 0, 3, and 6 months. Data were assessed by repeated-measures ANOVA with an intention-to-treat model. RESULTS: The walnut group achieved a significantly greater increase in HDL cholesterol-to-total cholesterol ratio (P=0.049) and HDL (P=0.046) than the two other treatment groups. A 10% reduction in LDL cholesterol was also achieved in the walnut group, reflecting a significant effect by group (P=0.032) and time (P=0.036). There were no significant differences between groups for changes in body weight, percent body fat, total antioxidant capacity, or HbA1c levels. The higher dietary polyunsaturated fat-to-saturated fat ratio and intakes of omega-3 fatty acids in the walnut group were confirmed by erythrocyte biomarkers of dietary intake. CONCLUSIONS: Structured "whole of diet" advice that included 30 g of walnuts/day delivering substantial amounts of polyunsaturated fatty acid improved the lipid profile of patients with type 2 diabetes.

Thorsdottir I. Hill J. Ramel A. Omega-3 fatty acid supply from milk associates with lower type 2 diabetes in men and coronary heart disease in women. *Preventive Medicine. 39(3):630-4, 2004 Sep.*

BACKGROUND: Omega-3 fatty acids may prevent type 2 diabetes and coronary heart disease (CHD). We investigated these fatty acids in Nordic cow's milk and whether their supply from milk associates with type 2 diabetes prevalence and CHD mortality in the Nordic countries. METHODS: Samples (N = 84) of consumers' milk were collected in five Nordic countries four times during 1 year. Fatty acids were analyzed using gas chromatography. Fatty acids supply from milk fat was calculated using national food balance sheets. RESULTS: The omega-3 fatty acids content was higher and omega-6 fatty acid content was lower in Icelandic milk when compared with milk from other Nordic countries. Type 2 diabetes prevalence in men correlated inversely with the supply of omega-3 fatty acids and eicosapentaenic acid, but positively with omega-6/omega-3 ratio in milk. CHD mortality in women correlated inversely with the supply of eicosapentaenic acid but positively with the omega-6/omega-3 ratio. CONCLUSIONS: Milk fatty acids content can depend upon the origin of the milk. The higher supply of omega-3 fatty acids from milk might explain the lower type 2 diabetes prevalence and CHD mortality in Iceland compared to the other Nordic countries.

Magnesium

Huerta MG. Roemmich JN. Kington ML. Bovbjerg VE. Weltman AL. Holmes VF. Patrie JT. Rogol AD. Nadler JL. Magnesium deficiency is associated with insulin resistance in obese children. *Diabetes Care. 28(5):1175-81, 2005 May.*

OBJECTIVE: Magnesium deficiency has been associated with insulin resistance (IR) and increased risk for type 2 diabetes in adults. This study was designed to determine whether obese children exhibit serum or dietary magnesium deficiency and its potential association with IR. RESEARCH DESIGN AND METHODS: We studied 24 obese nondiabetic children (BMI > or =85th percentile) and 24 sex- and puberty-matched lean control subjects (BMI <85th percentile). We measured serum magnesium, indexes of insulin sensitivity, dietary magnesium intake (using a food frequency questionnaire), and body composition (by air displacement plethysmography). RESULTS: Serum magnesium was significantly lower in obese children (0.748 +/- 0.015 mmol/l, means +/- SE) compared with lean children (0.801 +/- 0.012 mmol/l) (P = 0.009). Serum magnesium was inversely correlated with fasting insulin (r(s) = -0.36 [95% CI -0.59 to -0.08]; P = 0.011) and positively correlated with quantitative insulin sensitivity check index (QUICKI) (0.35 [0.06-0.58]; P = 0.015). Dietary magnesium intake was significantly lower in

obese children (obese: 0.12 +/- 0.004 vs. lean: 0.14 +/- 0.004 mg/kcal; P = 0.003). Dietary magnesium intake was inversely associated with fasting insulin (-0.43 [-0.64 to -0.16]; P = 0.002) and directly correlated with QUICKI (0.43 [0.16-0.64]; P = 0.002). CONCLUSIONS: The association between magnesium deficiency and IR is present during childhood. Serum magnesium deficiency in obese children may be secondary to decreased dietary magnesium intake. Magnesium supplementation or increased intake of magnesium-rich foods may be an important tool in the prevention of type 2 diabetes in obese children.

Lopez-Ridaura R. Willett WC. Rimm EB. Liu S. Stampfer MJ. Manson JE. Hu FB. Magnesium intake and risk of type 2 diabetes in men and women. *Diabetes Care. 27(1):134-40, 2004 Jan.*

OBJECTIVE: To examine the association between magnesium intake and risk of type 2 diabetes. RESEARCH DESIGN AND METHODS: We followed 85,060 women and 42,872 men who had no history of diabetes, cardiovascular disease, or cancer at baseline. Magnesium intake was evaluated using a validated food frequency questionnaire every 2-4 years. After 18 years of follow-up in women and 12 years in men, we documented 4,085 and 1,333 incident cases of type 2 diabetes, respectively. RESULTS: After adjusting for age, BMI, physical activity, family history of diabetes, smoking, alcohol consumption, and history of hypertension and hypercholesterolemia at baseline, the relative risk (RR) of type 2 diabetes was 0.66 (95% CI 0.60-0.73; P for trend <0.001) in women and 0.67 (0.56-0.80; P for trend <0.001) in men, comparing the highest with the lowest quintile of total magnesium intake. The RRs remained significant after additional adjustment for dietary variables, including glycemic load, polyunsaturated fat, trans fat, cereal fiber, and processed meat in the multivariate models. The inverse association persisted in subgroup analyses according to BMI, physical activity, and family history of diabetes. CONCLUSIONS: Our findings suggest a significant inverse association between magnesium intake and diabetes risk. This study supports the dietary recommendation to increase consumption of major food sources of magnesium, such as whole grains, nuts, and green leafy vegetables.

Vitamin C

Armstrong AM. Chestnutt JE. Gormley MJ. Young IS. The effect of dietary treatment on lipid peroxidation and antioxidant status in newly diagnosed noninsulin dependent diabetes. *Free Radical Biology & Medicine. 21(5):719-26, 1996.*

Increased lipid peroxidation and reduced antioxidant status may contribute to the development of complications in diabetes. The aim of this study was to assess the effects of dietary treatment of noninsulin-dependent diabetes on these parameters. Twenty patients with newly diagnosed noninsulin-dependent diabetes were recruited along with 20 age, sex, and smoking-status-matched control subjects. Dietary intake was assessed by food frequency questionnaire and 24-h dietary recall and blood collected for biochemical analyses before and 2 months after dietary treatment was initiated. Carbohydrate, fat, and protein intake fell in patients following dietary advice. Among micronutrients, intakes of vitamins C, E, and A, carotene, selenium, copper, zinc, and iron were similar in patients and controls. Vitamin C intake in patients rose following dietary advice (44.6 +/- 11.7 vs. 49.5 +/- 5.5 mg/d, p < .05), while there was no change in intake of other micronutrients. Fasting plasma glucose in diabetic subjects fell from 13.6 +/- 1.1 mmol/l at recruitment to 9.7 +/- 1.1 mmol/l after diet (p < .01), and this was accompanied by a fall in hemoglobin Alc from 7.44 +/- 0.67% to 5.91 +/- 0.57% (p < .01). Serum malondialdehyde was higher in patients than controls at T0 (2.39 +/- 0.55 mumol/l vs. 1.48 +/- 0.33; p < .01), and fell following diet to 1.42 mumol/l (p < 0.01). Ascorbate was lower in patients than controls (1.27 +/- 2.9 mumol/k vs. 41.4 +/- 9.3; p < .01) at baseline and rose after diet to 27.8 +/- 6.4 (p < .01). beta-Carotene also rose after diet in patients (0.13 +/- 0.04 mumol/l vs. 0.17 +/- 0.04; p < 0.05), as did lipid corrected alpha-tocopherol (4.39 +/- 1.09 mumol/mmol cholesterol vs. 5.16 +/- 1.18; p < .05). Reduced lipid peroxidation and improved antioxidant status may be one mechanism by which dietary treatment contributes to the prevention of diabetic complications.

Sinclair AJ. Taylor PB. Lunec J. Girling AJ. Barnett AH. Low plasma ascorbate levels in patients with type 2 diabetes mellitus consuming adequate dietary vitamin C. *Diabetic Medicine. 11(9):893-8, 1994 Nov.*

Low ascorbate concentrations in diabetes may be secondary to inadequate dietary vitamin C intake or may relate to the varied metabolic roles of the vitamin. To determine whether inadequate dietary intake is a factor we calculated daily vitamin C intakes using both a vitamin C questionnaire and a 4-day food diary in a group of 30 patients with Type 2 diabetes (mean age 68.8 +/- 6.9 yr, 17M/13F) and in 30 community controls (mean age 68.0 +/- 5.5 yr, 12M/18F)). Measures of plasma glucose, serum fructosamine, and plasma ascorbic and dehydroascorbic acid were obtained from 20 subjects in each group. There was no significant difference in daily vitamin C intake between the two groups using both methods: food diary, 61.4 +/- 28.3 (patients) vs 69.5 +/- 33.4 (controls) mg; questionnaire, 54.0 +/- 28.9 (patients) vs 65.0 +/- 30.9 (controls) mg. Vitamin C intake derived from both methods was significantly correlated ($p < 0.001$). Plasma ascorbate (30.4 +/- 19.1 mumol l-1) and dehydroascorbate (27.6 +/- 6.4 mumol l-1) levels were significantly lower in patients vs in controls (68.8 +/- 36.0 and 31.8 +/- 4.8 mumol l-1, respectively), $p < 0.0001$ and $p < 0.01$. Plasma ascorbate levels were significantly correlated with vitamin C intake derived from the food diary ($p < 0.01$) and questionnaire ($p < 0.01$) methods in the diabetic group only. Low ascorbate levels in diabetes appears to be a consequence of the disease itself and not due to inadequate dietary intake of vitamin C. A short vitamin C questionnaire is a convenient and reliable estimate of vitamin C intake.

Antioxidants

Montonen J. Knekt P. Jarvinen R. Reunanen A. Dietary antioxidant intake and risk of type 2 diabetes. *Diabetes Care. 27(2):362-6, 2004 Feb.*

OBJECTIVE: The intake of antioxidants was studied for its ability to predict type 2 diabetes. RESEARCH DESIGN AND METHODS: A cohort of 2,285 men and 2,019 women 40-69 years of age and free of diabetes at baseline (1967-1972) was studied. Food consumption during the previous year was estimated using a dietary history interview. The intake of vitamin C, four tocopherols, four tocotrienols, and six carotenoids was calculated. During a 23-year follow-up, a total of 164 male and 219 female incident cases occurred. RESULTS: Vitamin E intake was significantly associated with a reduced risk of type 2 diabetes. The relative risk (RR) of type 2 diabetes between the extreme quartiles of the intake was 0.69 (95% CI 0.51-0.94, P for trend = 0.003). Intakes of alpha-tocopherol, gamma-tocopherol, delta-tocopherol, and beta-tocotrienol were inversely related to a risk of type 2 diabetes. Among single carotenoids, beta-cryptoxanthin intake was significantly associated with a reduced risk of type 2 diabetes (RR 0.58, 95% CI 0.44-0.78, $P < 0.001$). No association was evident between intake of vitamin C and type 2 diabetes risk. CONCLUSIONS: This study supports the hypothesis that development of type 2 diabetes may be reduced by the intake of antioxidants in the diet.

Ylonen K. Alfthan G. Groop L. Saloranta C. Aro A. Virtanen SM. Dietary intakes and plasma concentrations of carotenoids and tocopherols in relation to glucose metabolism in subjects at high risk of type 2 diabetes: the Botnia Dietary Study. *American Journal of Clinical Nutrition. 77(6):1434-41, 2003 Jun.*

BACKGROUND: The role of antioxidants in the pathogenesis of type 2 diabetes is uncertain. OBJECTIVE: We evaluated cross-sectional relations of dietary intakes and plasma concentrations of antioxidants with glucose metabolism in a high-risk population. DESIGN: The subjects were 81 male and 101 female first- and second-degree, nondiabetic relatives of patients with type 2 diabetes. Antioxidant intake data were based on 3-d food records. Subjects taking supplements containing beta-carotene or

alpha-tocopherol were excluded. Plasma antioxidant concentrations were measured by HPLC. By using multiple linear regression analysis and adjusting for demographic, anthropometric, and lifestyle covariates, we studied whether dietary and plasma alpha- and beta-carotene, lycopene, and alpha- and gamma-tocopherol were related to fasting and 2-h concentrations of glucose and nonesterified fatty acids during an oral-glucose-tolerance test, to the homeostasis model assessment index of insulin resistance, and to measures of beta cell function (incremental 30-min serum insulin concentration during an oral-glucose-tolerance test and first-phase insulin secretion during an intravenous-glucose-tolerance test). RESULTS: In men, dietary carotenoids were inversely associated with fasting plasma glucose concentrations ($P < 0.05$), plasma beta-carotene concentrations were inversely associated with insulin resistance ($P = 0.003$), and dietary lycopene was directly related to baseline serum concentrations of nonesterified fatty acids ($P = 0.034$). In women, dietary alpha-tocopherol and plasma beta-carotene concentrations were inversely and directly associated, respectively, with fasting plasma glucose concentrations ($P < 0.05$). In both sexes, cholesterol-adjusted alpha-tocopherol concentrations were directly associated with 2-h plasma glucose concentrations ($P < 0.05$). CONCLUSION: The data suggest an advantageous association of carotenoids, which are markers of fruit and vegetable intake, with glucose metabolism in men at high risk of type 2 diabetes.

Fenugreek

Gupta A. Gupta R. Lal B. Effect of Trigonella foenum-graecum (fenugreek) seeds on glycaemic control and insulin resistance in type 2 diabetes mellitus: a double blind placebo controlled study. *Journal of the Association of Physicians of India. 49:1057-61, 2001 Nov.*

OBJECTIVES: To evaluate the effects of Trigonella foenum-graecum (fenugreek) seeds on glycemic control and insulin resistance, determined by HOMA model, in mild to moderate type 2 diabetes mellitus we performed a double blind placebo controlled study. METHODS: Twenty five newly diagnosed patients with type 2 diabetes (fasting glucose < 200 mg/dl) were randomly divided into two groups. Group I (n=12) received 1 gm/day hydroalcoholic extract of fenugreek seeds and Group II (n=13) received usual care (dietary control, exercise) and placebo capsules for two months. RESULTS: At baseline both the groups were similar in anthropometric and clinical variables. Oral glucose tolerance test, lipid levels, fasting C-peptide, glycosylated haemoglobin, and HOMA-model insulin resistance were also similar at baseline. In group 1 as compared to group 2 at the end of two months, fasting blood glucose (148.3 +/- 44.1 to 119.9 +/- 25 vs. 137.5 +/- 41.1 to 113.0 +/- 36.0) and two hour postglucose blood glucose (210.6 +/- 79.0 to 181.1 +/- 69 vs. 219.9 +/- 41.0 to 241.6 +/- 43) were not different. But area under curve (AUC) of blood glucose (2375 +/- 574 vs 27597 +/- 274) as well as insulin (2492 +/- 2536 vs. 5631 +/- 2428) was significantly lower ($p < 0.001$). HOMA model derived insulin resistance showed a decrease in percent beta-cell secretion in group 1 as compared to group 2 (86.3 +/- 32 vs. 70.1 +/- 52) and increase in percent insulin sensitivity (112.9 +/- 67 vs 92.2 +/- 57) ($p < 0.05$). Serum triglycerides decreased and HDL cholesterol increased significantly in group 1 as compared to group 2 ($p < 0.05$). CONCLUSIONS: Adjunct use of fenugreek seeds improves glycemic control and decreases insulin resistance in mild type-2 diabetic patients. There is also a favorable effect on hypertriglyceridemia.

Madar Z. Abel R. Samish S. Arad J. Glucose-lowering effect of fenugreek in non-insulin dependent diabetics. *European Journal of Clinical Nutrition. 42(1):51-4, 1988 Jan.*

The effect of fenugreek on postprandial glucose and insulin levels following the meal tolerance test (MTT) was studied in non-insulin dependent diabetics (NIDDM). The addition of powdered fenugreek seed (15 g) soaked in water significantly reduced the subsequent postprandial glucose levels. The plasma insulin also tended to be lower in NIDDM given fenugreek but without a statistical difference. Fenugreek had no effect on lipid levels 3 h following the MTT. Fenugreek may have a potential benefit in the treatment of NIDDM.

Helen Healy

Naturopathic Medicine in the Treatment of Hypertension

DIET & NUTRITION

Rankins J. Sampson W. Brown B. Jenkins-Salley T. Dietary Approaches to Stop Hypertension (DASH) intervention reduces blood pressure among hypertensive African American patients in a neighborhood health care center. *Journal of Nutrition Education & Behavior. 37(5):259-64, 2005 Sep-Oct.*

The purpose of this study was to pilot-test DASH-Dinner with Your Nutritionist, a university-neighborhood health care center intervention to promote the Dietary Approaches to Stop Hypertension (DASH) diet. Study participants were low-income African American adults (N = 82) with poorly controlled blood pressure. Six groups, each consisting of 12 to 15 participants taking antihypertensive medications, met for 1 to 2 hours per week for 8 weeks. The intervention followed constructs of Social Cognitive Theory and featured dinners based on the DASH diet plan. Blood pressure was significantly lowered ($P < .05$) among participants who missed no more than 2 of 8 sessions. Extension of the DASH-Dinner model could improve blood pressure control among low-income hypertensive African Americans and reduce health disparities.

Zimmerman E. Wylie-Rosett J. Nutrition therapy for hypertension. *Current Diabetes Reports. 3(5):404-11, 2003 Oct.*

A contemporary approach to hypertension and prevention are covered in this article. It contains important information for clinicians, such as hypertension management, metabolic syndrome issues, lifestyle behavioral management, nutrient issues, weight loss treatments (ie, medications and surgical procedures), the role of physical activity, and pharmacologic treatment. The Dietary Approaches to Stop Hypertension (DASH) trial eating plan is discussed at length, as well as information from recent trials on hypertension, prevention, and treatment.

Appel LJ. Lifestyle modification as a means to prevent and treat high blood pressure. *Journal of the American Society of Nephrology. 14(7 Suppl 2):S99-S102, 2003 Jul.*

High BP is one of the most important and common risk factors for atherosclerotic cardiovascular disease and renal disease. The contemporary approach to the epidemic of elevated BP and its complications involves pharmacologic treatment of hypertensive individuals and "lifestyle modification," which is beneficial for both nonhypertensive and hypertensive persons. A substantial body of evidence strongly supports the concept that lifestyle modification can have powerful effects on BP. Increased physical activity, a reduced salt intake, weight loss, moderation of alcohol intake, increased potassium intake, and an overall healthy dietary pattern, termed the Dietary Approaches to Stop Hypertension (DASH) diet, effectively lower BP. The DASH diet emphasizes fruits, vegetables, and low-fat dairy products and is reduced in fat and cholesterol. Other dietary factors, such as a greater intake of protein or monounsaturated fatty acids, may also reduce BP but available evidence is inconsistent. The current challenge to health care providers, researchers, government officials, and the general public is developing and implementing effective clinical and public health strategies that lead to sustained lifestyle modification.

REDUCING SIDE EFFECTS & INTERACTIONS WITH PRESCRIPTION DRUGS

TREATING HYPERTENSION WITH NUTRITIONAL SUPPLEMENTS, BOTANICAL MEDICINE & STRESS REDUCTION

Natural Diuretics

Natural Vasodilators

Natural Anti-Hypertensive Antioxidants

Brighenti F. Valtuena S. Pellegrini N. Ardigo D. Del Rio D. Salvatore S. Piatti P. Serafini M. Zavaroni I. Total antioxidant capacity of the diet is inversely and independently related to plasma concentration of high-sensitivity C-reactive protein in adult Italian subjects. *British Journal of Nutrition. 93(5):619-25, 2005 May.*

Inflammation, a risk factor for cardiovascular disease, is associated with low plasma levels of antioxidant vitamins. In addition to vitamins, other antioxidants modulate the synthesis of inflammatory markers in vitro and contribute to the total antioxidant capacity (TAC) of a diet. However, the relationship between dietary TAC and markers of inflammation has never been evaluated in vivo. We investigated the relationship between dietary TAC and markers of systemic (high-sensitivity C-reactive protein (hs-CRP), leucocytes) and vascular (soluble intercellular cell adhesion molecule-1) inflammation in 243 non-diabetic subjects. General Linear Model (GLM) analysis showed a significant (P=0.005) inverse relationship between hs-CRP and quartiles of energy-adjusted dietary TAC, even when recognized modulating factors of inflammation, namely alcohol, fibre, vitamin C, alpha-tocopherol, beta-carotene, BMI, waist circumference, HDL-cholesterol, hypertension, insulin sensitivity and plasma beta-carotene, were included in the model as covariates (P=0.004). The relationship was stronger for subjects with hypertension (P=0.013 v. P=0.109 for normotensive individuals). Among dietary factors, TAC was significantly higher (5.3 (sd 3.0) v. 4.9 (sd 2.7) mmol Trolox/d; P=0.026) in subjects with low plasma hs-CRP (range: 0.0-4.1 mg/l) than in subjects with high plasma hs-CRP (range: 4.2-27.8 mg/l). We conclude that dietary TAC is inversely and independently correlated with plasma concentrations of hs-CRP and this could be one of the mechanisms explaining the protective effects against CVD of antioxidant-rich foods such as fruits, whole cereals and red wine. This could be of particular significance for subjects with high blood pressure.

Rodrigo R. Passalacqua W. Araya J. Orellana M. Rivera G. Homocysteine and essential hypertension. *Journal of Clinical Pharmacology. 43(12):1299-306, 2003 Dec.*

The authors examined the available clinical and experimental data supporting the view that homocysteine, an alternative risk factor of cardiovascular disease, may play a role in the pathogenesis of essential hypertension. The mechanism of this disease has not been elucidated, but it may be related to impairment of vascular endothelial and smooth muscle cell function. Therefore, the occurrence of endothelial dysfunction could contribute to alterations of the endothelium-dependent vasomotor regulation. Elevated homocysteinemia diminishes the vasodilation by nitric oxide, increases oxidative stress, stimulates the proliferation of vascular smooth muscle cells, and alters the elastic properties of the vascular wall. Thus, homocysteine contributes to elevate the blood pressure. Also it is known that elevated plasma levels of homocysteine could lead to oxidant injury to the endothelium. The correction of elevated homocysteinemia by administration of vitamins B12 and B6 plus folic acid, could be a useful adjuvant therapy of hypertension.

Alpha Lipoic Acid (ALA)

Wollin SD. Jones PJ. Alpha-lipoic acid and cardiovascular disease. *Journal of Nutrition. 133(11):3327-30, 2003 Nov.*

Alpha-lipoic acid (ALA) has been identified as a powerful antioxidant found naturally in our diets, but appears to have increased functional capacity when given as a supplement in the form

of a natural or synthetic isolate. ALA and its active reduced counterpart, dihydrolipoic acid (DHLA), have been shown to combat oxidative stress by quenching a variety of reactive oxygen species (ROS). Because this molecule is soluble in both aqueous and lipid portions of the cell, its biological functions are not limited solely to one environment. In addition to ROS scavenging, ALA has been shown to be involved in the recycling of other antioxidants in the body including vitamins C and E and glutathione. Not only have the antioxidant qualities of this molecule been studied, but there are also several reports pertaining to its blood lipid modulating characteristics, protection against LDL oxidation and modulation of hypertension. Therefore, ALA represents a possible protective agent against risk factors of cardiovascular disease (CVD). The objective of this review is to examine the literature pertaining to ALA in relation to CVD and describe the most powerful actions and potential uses of this naturally occurring antioxidant. Despite the numerous studies on ALA, many questions remain relating to the use of ALA as a supplement. There is no consensus on dosage, dose frequency, form of administration, and/or preferred form of ALA. However, collectively the literature increases our understanding of the potential uses for supplementation with ALA and identifies key areas for future research.

Coenzyme Q10

Pettit FH. Harper RF. Vilaythong J. Chu T. Shive W. Reversal of statin toxicity to human lymphocytes in tissue culture. *Drug Metabolism & Drug Interactions. 19(3):151-60, 2003.*

Hydroxymethylglutaryl-CoA reductase inhibitors (statins) are widely used to inhibit biosynthesis of cholesterol in individuals with elevated serum levels of this risk factor for cardiovascular disease. We find that statins are toxic to human lymphocytes in cell culture at concentrations less than 0.1 microg/ml. Addition of their own plasma reverses this toxicity in some, but not all, individuals. Addition of coenzyme Q10 (CoQ10) with plasma is more effective than plasma alone in reversing toxicity in some individuals. Apparently, two factors are required to reverse the cellular toxicity of statins: CoQ10 and a plasma factor found in a subset of individuals. These observations may provide the basis for a method to assess individual susceptibility to statin toxicity and to predict which individuals may benefit from supplements of CoQ10.

Sarter B. Coenzyme Q10 and cardiovascular disease: a review. *Journal of Cardiovascular Nursing. 16(4):9-20, 2002 Jul.*

This article provides a comprehensive review of 30 years of research on the use of coenzyme Q10 in prevention and treatment of cardiovascular disease. This endogenous antioxidant has potential for use in prevention and treatment of cardiovascular disease, particularly hypertension, hyperlipidemia, coronary artery disease, and heart failure. It appears that levels of coenzyme Q10 are decreased during therapy with HMG-CoA reductase inhibitors, gemfibrozil, Adriamycin, and certain beta blockers. Further clinical trials are warranted, but because of its low toxicity it may be appropriate to recommend coenzyme Q10 to select patients as an adjunct to conventional treatment.

Vitamin E

Tucker JM. Townsend DM. Alpha-tocopherol: roles in prevention and therapy of human disease. *Biomedicine & Pharmacotherapy. 59(7):380-7, 2005 Aug.*

Alpha-tocopherol, one of the eight isoforms of vitamin E, is the most potent fat-soluble antioxidant known in nature. For years, it was thought that alpha-tocopherol only functioned as a scavenger of lipid peroxyl radicals, specifically, oxidized low-density lipoprotein (oxLDL), thereby serving as a chief antioxidant for the prevention of atherosclerosis. In recent years, the many roles of alpha-tocopherol have been uncovered, and include not only antioxidant functions,

but also pro-oxidant, cell signaling and gene regulatory functions. Decades of clinical and preclinical studies have broadened our understanding of the antioxidant vitamin E and its utility in a number of chronic, oxidative stress-induced pathologies. The results of these studies have shown promising, albeit mixed reviews on the efficacy of alpha-tocopherol in the prevention and treatment of heart disease, cancer and Alzheimer's disease. Future studies to uncover cellular and systemic mechanisms may help guide appropriate clinical treatment strategies using vitamin E across a diverse population of aging individuals.

Hawthorne

Gavagan T. Cardiovascular disease. *Primary Care; Clinics in Office Practice. 29(2):323-38, vi, 2002 Jun.*

The primary care physician is in a position to advise patients on the efficacy of alternative and complementary therapies as they relate to cardiovascular diseases. Anti-oxidant vitamin supplementation has not been shown to be efficacious in decreasing cardiovascular events. N-3 fatty acids appear to be beneficial in secondary prevention of cardiovascular events but their use in primary prevention is not clear. Adoption of vegetable-based diets, including whole grains, can be recommended to decrease cardiovascular events, lower cholesterol and help lower blood pressure. For patients with hypercholesterolemia, cholestin, a red-yeast rice supplement, has been shown to be effective. Garlic supplements may have some mild cholesterol-lowering effect, but this effect is not significant enough to recommend clinically. Herbal therapies with hawthorn and ubiquinone (Q10) are of possible benefit in congestive heart failure. An integrated program of rigorous diet, exercise and stress reduction in motivated patients with cardiovascular disease may have value as an alternative to cardiovascular medications and surgical interventions.

Schroder D. Weiser M. Klein P. Efficacy of a homeopathic Crataegus preparation compared with usual therapy for mild (NYHA II) cardiac insufficiency: results of an observational cohort study. *European Journal of Heart Failure. 5(3):319-26, 2003 Jun.*

OBJECTIVES: To compare the efficacy of the homeopathic Crataegus preparation Cralonin for non-inferiority to standard treatment for mild cardiac insufficiency. METHODS: Multicentre non-randomised cohort study in patients aged 50-75 years in New York Heart Association class II. Patients received Cralonin (n=110) or ACE inhibitor/diuretics (n=102) for 8 weeks. To adjust for confounding by baseline factors, populations were stratified according to propensity score. After adjusting, there were no statistically significant differences between treatment groups. Treatment efficacy was assessed on 15 variables. A stringent non-inferiority criterion for the upper limit of the 97.5% one-sided confidence interval of the treatment difference was set to 0.2x the standard deviation (S.D.). RESULTS: Both treatment regimens improved scores on most variables studied, with the greatest effect on double product after exercise (average score reduction 15.4% with Cralonin vs. 16.0% for the control group). Stringent non-inferiority of Cralonin was demonstrated on 7 variables. Medium-stringent (0.5xS.D.) non-inferiority was indicated by 13 variables (exceptions: systolic blood pressure (BP) during exercise and diastolic BP at rest; for these, differences between treatments were not significant). Both treatments were well tolerated. CONCLUSION: The Crataegus-based preparation Cralonin is non-inferior to usual ACE inhibitor/diuretics treatment for mild cardiac insufficiency on all parameters except BP reduction.

L-Carnitine

Koh SG. Brenner DA. Korzick DH. Tickerhoof MM. Apstein CS. Saupe KW. Exercise intolerance during post-MI heart failure in rats: prevention with supplemental dietary propionyl-L-carnitine. *Cardiovascular Drugs & Therapy. 17(1):7-14, 2003 Jan.*

Exercise capacity in patients with several types of cardiovascular disease can be improved with dietary carnitine, or carnitine derivatives. Mechanisms underlying this improvement remain largely unknown in part due to a lack of animal models of cardiac pathology in which carnitine derivatives improve exercise tolerance. Our goal was to evaluate the ability of propionyl-L-carnitine (PLC) to improve exercise tolerance in a rat model of exercise intolerance. Fischer 344 rats were followed after either a moderate size MI (n = 22) or sham MI surgery (n = 14). Starting 10 days post-surgery 10 of the MI and 7 of the sham rats received 100 mg/kg/day PLC in drinking water, which increased plasma and LV total l-carnitine concentrations 15-23% ($p < 0.05$). Rats were followed longitudinally until a statistically significant decrease in exercise capacity occurred in one of the groups, at which time all rats were sacrificed for study of the isolated perfused hearts. At 12-weeks post-MI exercise capacity had decreased 16 +/- 7% ($p < 0.05$) in the MI group, but remained within 3% of baseline in the MI group that received PLC and the sham groups. Both MI groups exhibited the same degree of LV dilation, decrease in fractional shortening, and blunting of the response to isoproterenol. We conclude that supplemental dietary PLC attenuates the exercise intolerance that occurs secondary to post-MI heart failure in rats, but that this beneficial effect is not attributable to altered LV remodeling, an improved response to beta-adrenergic stimulation, or increased skeletal muscle citrate synthase activity.

Arsenian MA. Carnitine and its derivatives in cardiovascular disease. Prog Cardiovasc Dis. 40(3):265-86, 1997 Nov-Dec.

Carnitine and its derivative propionyl-L-carnitine are endogenous cofactors which enhance carbohydrate metabolism and reduce the intracellular buildup of toxic metabolites in ischemic conditions. The carnitines have been, and are being used in a spectrum of diseases including multiple cardiovascular conditions. These include angina, acute myocardial infarction, postmyocardial infarction, congestive heart failure, peripheral vascular disease, dyslipidemia, and diabetes. Most published data on carnitine, propionyl-L-carnitine, and other carnitine congeners are favorable but the clinical trials have been relatively small. In currently used doses, these substances are virtually devoid of significant side effects.

Omega-3 PUFAs

Siddiqui RA. Shaikh SR. Sech LA. Yount HR. Stillwell W. Zaloga GP. Omega 3-fatty acids: health benefits and cellular mechanisms of action. *Mini-Reviews in Medicinal Chemistry. 4(8):859-71, 2004 Oct.*

Epidemiological evidence has established that ingestion of long-chain polyunsaturated omega-3 fatty acids (omega-3 PUFAs), abundant in fish oils, have profound effects on many human disorders and diseases, including cardiovascular disease and cancer. Here we briefly review the dietary recommendations and the food sources that are naturally enriched by these fatty acids. There are also a number of products including eggs, bread, and cereals available to supplement omega-3 fatty acid dietary intake. Some of these supplements are proposed to aid different pathological conditions. While the beneficial effects of omega-3 fatty acids can no longer be doubted, their molecular mechanism of action remains elusive. Without question, the action of omega-3 fatty acids is complex and involves a number of integrated signaling pathways. This review focuses on one of the possible cellular mechanisms by which the omega-3 PUFAs, docosahexaenoic acid (DHA) and eicosapentaenoic acid (EPA), may function. Studies with cancer cells suggest that DHA induces cell cycle arrest and apoptosis by activating protein phosphatases, leading to dephosphorylation of retinoblastoma protein (pRB). Protein phosphatases are also involved with the protein Bcl2, which regulates the release of cytochrome c from mitochondria, and eventually, activation of the apoptotic enzyme caspase 3.

Engler MB. Vascular effects of omega-3 fatty acids: possible therapeutic mechanisms in cardiovascular disease. *Journal of Cardiovascular Nursing. 8(3):53-67, 1994 Apr.*

Dietary consumption of omega-3 polyunsaturated fatty acids (PUFAs) found in seafood and fish oils is associated with a decrease in coronary heart disease and overall cardiovascular mortality. Omega-3 PUFAs exert a number of physiologic effects, including relaxation of vascular smooth muscle, lowering of blood pressure, interference in phosphatidylinositol signaling, a reduction in platelet aggregation and growth factors, a decrease in atherogenic lipoproteins, a reduction in thrombotic factors, alterations in eicosanoid metabolism, a decrease in platelet and macrophage activating factors, and an increase in thrombolytic substances. These factors may provide a therapeutic means of reducing cardiovascular disease. This article reviews the vascular effects of omega-3 PUFAs and discusses the hypolipidemic, antihypertensive, antiatherosclerotic, antiinflammatory, and antithrombotic actions of the omega-3 PUFAs.

Potassium, Magnesium & Calcium

Whelton PK. He J. Potassium in preventing and treating high blood pressure. Seminars in Nephrology. 19(5):494-9, 1999 Sep.

Our objective was to assess the effects of supplementation with oral potassium on blood pressure (BP) in humans, using pooled analysis of randomized, controlled trials. Results from 33 randomized, controlled trials (2,609 participants) in which potassium supplementation was the only difference between the intervention and control conditions were used. Information on sample size, duration, study design, potassium dose, participant characteristics, and treatment results was independently obtained by the authors using a standardized protocol. The findings from each trial were pooled after weighting the results for individual studies by the inverse of its variance. Using a random-effects model, potassium supplementation was associated with a significant reduction in mean (95% confidence interval) systolic and diastolic BP of -4.44 (range, -2.53 to -6.36) and -2.45 (range, -0.74 to -4.16) mm Hg, respectively. After exclusion of a trial with extreme results, potassium supplementation was still associated with a significant reduction in mean (95% confidence interval) systolic and diastolic BP of -3.11 (range, -1.91 to -4.31) and -1.97 (range, -0.52 to -3.42) mm Hg, respectively. The BP effects of potassium administration appeared to be enhanced in studies where participants were concurrently exposed to a high intake of sodium. Increased potassium intake should be included as a recommendation for prevention and treatment of hypertension, especially in those who are unable to reduce their intake of sodium.

Motoyama T. Sano H. Fukuzaki H. Oral magnesium supplementation in patients with essential hypertension. *Hypertension. 13(3):227-32, 1989 Mar.*

To elucidate the effects of magnesium on high blood pressure, a 4-week study of oral magnesium supplementation (MgO 1 g/day) was conducted in 21 outpatients with uncomplicated essential hypertension. During the study, blood pressure and intraerythrocyte sodium concentration decreased significantly, and the erythrocyte ouabain-sensitive 22Na efflux rate constant (Kos) and intraerythrocyte magnesium concentration both increased. Serum triglyceride and free fatty acid concentrations were reduced. Furthermore, the elevation in Kos significantly and positively correlated with both the increase in intraerythrocyte magnesium concentration and the decrease in mean blood pressure. There was a significant inverse correlation between the prestudy Kos and the decrease in mean blood pressure. In addition, when patients were divided according to their overall decrease in mean blood pressure, the prestudy intraerythrocyte sodium concentration was significantly higher in patients with a mean blood pressure decrease of more than 7 mm Hg than

that of patients whose mean blood pressure decrease was less than 7 mm Hg. These results suggest that oral magnesium supplementation may lower blood pressure through the activation of a cell membrane sodium pump and may reduce serum lipid concentration. It also suggests that the lower the prestudy Kos or the higher the prestudy intraerythrocyte sodium concentration, the more effective the oral magnesium treatment is in lowering blood pressure. Therefore, we concluded that appropriate oral magnesium intake might be effective as a nonpharmacological treatment for essential hypertension.

Combined Supplements

DeBusk RM. Dietary supplements and cardiovascular disease. Curr Atheroscler Rep. 2(6):508-14, 2000 Nov.

Consumer use of dietary supplements has increased considerably in recent years, and interest in using supplements to treat or prevent chronic diseases such as cardiovascular disease is particularly high. This review examines several popular dietary supplements used for cardiovascular disease, their likely points of intervention, and what is known to date about their efficacy and safety.

Commissioner Lindeman

Health Care Purchasing Authority

January 31, 2006
Prepared by MN Dept of Employee Relations
For the Health Care Solutions Series Joint Committee Meeting

Overview

- Presenting today:
  - Highlights of two recent reports to the Legislature
    - Health Care Purchasing Authority (HCPA) -- Executive Summary
    - Preliminary Report on a Secure Benefit Set for the Public Employees Insurance Program (PEIP) -- Executive Summary

Health Care Purchasing Authority (HCPA) legislation

- Statutory authority and requirements:
  - Minnesota Session Laws 2005, Chapter 156, Article 2, Section 47
- "Health Care Purchasing Authority" (HCPA)
  - Purpose: Unified strategy and joint purchasing of health care services for the state of Minnesota
  - "Secure benefit set"

Agency charges and authorizations

- Report on HCPA formation
- May form HCPA
- Dept. of Employee Relations (DOER) may expand PEIP offerings, including "secure benefit set"

State agencies participating

- Department of Employee Relations (DOER)
  - In consultation with Commissioners of:
    - Health
    - Human Services
    - Labor and Industry
    - Corrections
    - Commerce
    - Administration
  - Also: MN Comprehensive Health Association (MCHA)

HCPA Study methods

- Health cabinet meetings and discussions
- Interagency staff meetings and discussions
- Individual staff and commissioner meetings
- Review of previous reports, studies, models, examples
- Contacts with other state health care purchasing entities and policy experts
- Consulting with DOER actuaries
- Meetings, conferences, etc. (local, state, national)

HCPA Backdrop – Converging interests, challenges

- Scope, complexity, and enormous expense of health care
- Variation in quality and value

"...between the health care we now have and the health care we could have lies not just a gap, but a chasm."

- Institute of Medicine's (IOM) "Crossing the Quality Chasm"

Converging interests, challenges (cont.)

- More than driving volume discounts
- Key challenge is to buy smarter
  - Greater transparency
  - Align incentives
- Coordination, consistent reinforcing messages to the market
  - Governor's Health Cabinet
  - Smart Buy Alliance

Impacts of recent efforts

- Quality measurement "triple play"
  - Health Plans – "eValue8"
  - Clinic groups – "MN Community Measurement"
  - Hospitals – "Adverse events"
- Clearinghouse: www.Minnesotahealthinfo.org
- "Best in class" and value-based purchasing
  - Tiered arrangements (e.g., Advantage) + quality measures
  - "Bridges to Excellence" program and other initiatives
- Reduced, streamlined reporting and regulation

HCPA Options

- Continuum of possible options
- Vary by
  - Mechanisms or approaches
  - Level of Government restructuring and reorganization
  - Potential impacts and benefits
  - Practicality

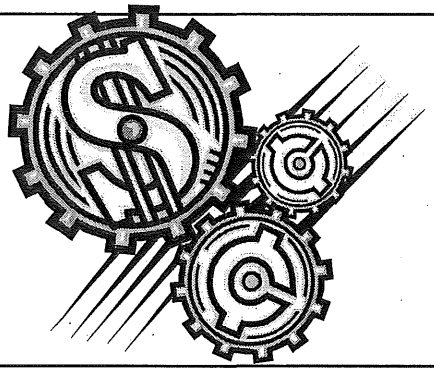
Illustrative HCPA Options

Name	D. "Functionally focused" HCPA	C. "Interactive" HCPA	B. "Utility" HCPA	A. New Cabinet Level Agency
Description	Like "C", but focused on narrow set of objectives	Agencies coordinate to adopt best practices. Similar to Governor's Health Cabinet	Single new clearinghouse of expertise to advise, guide agencies	All state health care purchasing integrated into new agency
Pros	Engages agencies, uses existing authority, resources.Avoids "mission creep"	Engages agencies, uses existing authority, resources	Single source of expert review and guidance to keep efforts in synch	- Eliminates agency "silos" - Single, direct path to the Governor
Cons	Does not eliminate "silos" Based on voluntary cooperation and consensus	Does not eliminate "silos" Based on voluntary cooperation and consensus	Potentially limited staffing, resources, potential limited impact	- Significant restructuring, requiring time, energy, resources - Creates another bureaucracy

Maximum strength medicine...

- Same strong Rx for state health care purchasing as proposed for health care supply chain
  - High expectations and goals
  - Rapid adoption of innovations
  - Transparency and accountability for results
  - Consequences for poor performance

Shift Gears for a Moment



Secure Benefit Set

- Part of HCPA legislation
  - DOER commissioner
    - May expand range Public Employer Insurance Program (PEIP) offerings
    - Offerings may include secure benefit set
      - Preventive care, prescription drugs, catastrophic coverage
        - » Meet needs of persons such as elderly, disabled, those with chronic conditions
      - Evidence-based guidelines for purchasing decisions and coverage designs

Again, converging interests, developments

- Increasing costs of health insurance
- Traditional "All or nothing" choices
  - Erosion of employer based coverage and growth of the uninsured
    - Small groups
    - Part-time, contract workers
- New products, new approaches
  - Wal-Mart, "HR Policy Association", Aetna, UnitedHealth Group, others

Illustrative 2005 average costs of health insurance (PPO-national)

	Single (Employee Only)	Family
Annual	$4150	$11,090
Monthly	$346	$924
Employee Share	$51/Mo.	$226/Mo.

Source: Kaiser/HRET Survey of Employer-Sponsored Health Benefits, 2005.

Secure Benefit

- DOER study undertaken as part of preliminary planning for possible PEIP options
  - Reviewed other reports and examples
  - Met with state staff and Health Care Guidelines Workgroup
  - Worked with DOER consulting actuaries, Deloitte Consulting

Public Employees Insurance Program (PEIP)

- Voluntary pool for local units of government
- Administered by DOER
- Available since late 1980's
- Typically small, or very small public sector employers
- Array of products – HMO, comprehensive major medical, HSA-compliant
  - Range of premium prices and employer contributions
    - Based on product chosen, experience of group, employer contribution levels
- Currently provides health coverage for approx. 94 groups, over 1700 employees

Challenging secure benefit set balancing act

- "Basic" health benefits
  - that are less costly than most typical benefit designs currently being offered
- Provide individuals with protection from financial catastrophe due to high medical expenses, and
- Provide access to needed medical services and health care proven to be effective to maintain and improve health

Examples of some approaches, interests to reduce benefits costs

- Reductions, exemptions from benefit mandates
- Benefit caps, limits, exclusions
- More individual cost share
  - Monthly premium
  - At point of service
  - Based on risk factors (e.g., charge smokers more, nonsmokers less)

More examples of some approaches, interests to reduce benefits costs

- Subsidy
  - Explicit
  - Implicit
- Discounts
  - Not insurance
- New approaches, models
  - Tiering
  - Pay for Performance, Centers of excellence
  - Consumer Driven Health Plans (HRA, HSA, Etc.)

Illustrative "benefits space"

Annual costs (single)							
$500	$1000	$1500	$2000	$2500	$3000	$3500	$4000
Discount cards							
	Limited benefit plans (caps, exclusions)						
	High deductible plans			High deductible plans with savings account			
						Traditional plans	

Case Studies/Sample Plans

- Selected several types of benefits plans
- Examined costs for several populations
- Used DOER experience to develop estimated costs for sample plans
  - –Plan designs and estimated premium costs are for discussion only
  - –Estimated costs developed on a employee only basis as well as a employee plus dependents basis.

What can you get for the money?

Brief summary of preliminary modeling

Monthly single premium range	Typical Features
$50 - $100	Little or no inpatient coverage; No Prescription drug (Rx) coverage, Little or no office visit coverage, Annual caps
$100 - $150	As above (slightly improved), No Rx, and/or High deductibles and coinsurance
$150 - $200	Inpatient covered, deductibles and coinsurance, No prescription drug coverage
$200 - $250	Inpatient covered, deductibles and coinsurance, Rx coverage (middle of range and above)
$250 - $300	More like traditional plans, with more cost sharing

Next steps

- Continue to explore options for lower cost insurance products to be available through PEIP
- In particular, DOER plans to:
  - Explore Advantage-like arrangements, that could be available through PEIP

Next steps (cont.)

- More fully develop and analyze the business case for a secure benefit set through PEIP
- Meet with and discuss benefits design issues with PEIP-eligible public employers and stakeholders
- Continue to monitor the health care market and to identify other innovative health benefit designs and options

David Haugen

Health Care Purchasing Authority (HCPA)

Executive Summary

December 15, 2005
Minnesota Department of Employee Relations

Health Care Purchasing Authority

Executive Summary

I. Introduction

Minnesota Session Laws 2005, Chapter 156, Section 47, requires the Commissioner of the Minnesota Department of Employee Relations (DOER), in consultation with other state agencies, to report to the Minnesota Legislature on the creation of a "Health Care Purchasing Authority" (HCPA) responsible for "all state purchasing of health care." The study legislation also allows state agencies to enter into interagency agreements regarding formation of the HCPA.

This report is being submitted in compliance with the statute. It describes several options for the creation of an HCPA, for review and consideration by the Legislature and to contribute to additional dialog on the topic of Health Care Purchasing Authority (HCPA) and related health care reform.

The HCPA study legislation also includes a number of additional provisions regarding the HCPA itself. These provisions have been addressed within the scope of the study charge, recognizing the need for pending legislative review and response to this report regarding the initial step of creating a HCPA.

One such HCPA-specific requirement is that the HCPA define a "secure benefit set" providing coverage for preventive care, prescription drugs, and catastrophic coverage. The HCPA legislation authorizes the secure benefits set to be made available to public sector employers through an existing voluntary health insurance pooling arrangement known as the Public Employees Insurance Program (PEIP), as well as to others in the future. DOER administers PEIP and is forwarding a report on the secure benefits set concept under separate cover to provide information and to facilitate discussion of the secure benefit concept as part of the broader legislative consideration of the HCPA.

II. Study Methods

As required by the study statute, DOER met with commissioners and staff of the following state agencies: Health; Human Services; Labor and Industry; Corrections; Commerce; and Administration. In addition, DOER met with the Commissioner and staff of the Department of Finance and the Director of the Minnesota Comprehensive Health Association.

The interagency effort produced a series of inventories of current state purchasing activities, purchasing functions and support, and health care quality measurement and quality assurance activities. These inventories were important to better understand the scope of state health care involvement and to help in exploring possible new connections and synergies. The interagency dialog also provided a forum for the exchange of views, expertise, and real-world experience as well as a sounding board for ideas and options. In addition, the study included reviews of other related studies and reports, contacts and meetings with other counterparts and experts, and participation in both local and national relevant conferences. DOER also met with its contracted actuarial and benefits consultants, Deloitte Consulting LLP, regarding the secure benefit concept.

III. Study Backdrop and Focus

A number of challenges and developments form an important backdrop to the study and have shaped and focused it, including:

- Continuing concerns about high and rising health care costs, despite some recent moderation in rates of cost growth;
- A broad, national awareness of massive underperformance of the US health care system, marked by variable and sometimes poor quality, with a growing call for significant restructuring of how health care is delivered and paid for;
- Recent efforts and developments in Minnesota's health care market and in state government to address the problems above through greater transparency of health care costs and quality, and through efforts to align and reinforce incentives to bring about desired change and improvements.

Given this backdrop, the HCPA study legislation makes important references to achieving "unified", "joint", and coordinated health care purchasing by state government. To date, these objectives have often been considered in terms of pooling various state groups -- such as state employees, enrollees of public programs like Medicaid, and others – to gain leverage in negotiating discounts with health care providers, and for achieving administrative cost savings through economies of scale.

However, in practice it is often difficult to implement such pooling arrangements because of differences in the covered populations and different federal and state regulations that may apply. There may also be differences in administrative and service delivery system requirements, with differing organizational or operational expertise and capabilities, and varying competing demands and responsibilities. Cost savings may be relatively low or temporary, or may accrue largely from cost shifts to other groups with less leverage, such as small employers and persons purchasing individual coverage. Rarely will such strategies alone lead to the large scale changes now called for in well-known, well-received national studies such as the national Institute of Medicine's 2001 landmark report, *Crossing the Quality Chasm: A New Health System for the 21st Century*.[1]

Crossing the Quality Chasm, and an equally well-known predecessor report, *To Err Is Human: Building a Safer Health System,* documented significant shortcomings in the American health care system. *Crossing the Quality Chasm* concluded that "Health care harms patients too frequently and routinely fails to deliver its potential benefits. Indeed, between the health care that we now have and the health care that we could have lies not just a gap, but a chasm." The report stressed that bridging the chasm demands "a fundamental, sweeping redesign of the entire health care system" that will "require changing the structures and processes of the environment in which health care professionals and organizations function."

Crossing the Quality Chasm also stressed that health care purchasing and payment practices need to be redesigned to help create incentives for change. The report recommended building "stronger incentives for quality enhancement" and payment methods that:

> *"provide an opportunity for providers to share in the benefits of quality improvement, provide an opportunity for consumers and purchasers to recognize quality differences in*

[1] Crossing the Quality Chasm: A New Health System for the 21st Century (2001), IOM. An online version of the report is available at the National Academies Press website at http://www.nap.edu/books/0309072808/html/. Citations from *Crossing the Quality Chasm* used in this HCPA executive summary report are from a shortended .pdf summary listed as "PDF Brief" at http://books.nap.edu/catalog/10027.html.

health care and direct their decisions accordingly, align financial incentives with the implementation of care processes based on best practices and the achievement of better patient outcomes, and enable providers to coordinate care for patients across settings and over time."

As a result of many inherent limitations of a primarily discount-driven or price-driven strategy, and because the HCPA legislation itself does not specify such a strategy, this study has focused on the broader issue of bringing about more fundamental and sustainable changes in health care. As detailed in *Crossing the Quality Chasm*, the hallmarks of a better, more cost-effective, higher quality health care system include:

- greater transparency of health care costs and quality to aid decision making and improvement; and
- aligning incentives to ensure that the health care system is accountable for greater results and value.

In practice, this means an HCPA capable not only of exerting its collective purchasing "muscle", but more importantly, exercising a new level of "brainpower" that is information rich, incentives-oriented, and quality and outcomes focused. The ideal Health Care Purchasing Authority would be one in which the whole is greater than the sum of the parts, acting together in well planned, well choreographed movements to bring about the reforms described in *Crossing the Quality Chasm*.

The State has a unique opportunity and can play a valuable role in helping achieve the system reforms envisioned in *Crossing the Quality Chasm*. It is a major health care purchaser and market force, directly purchasing on behalf of more than 780,000 residents, or approximately one in seven Minnesotans – at annual costs totaling more than $4 billion. Two primary components of state health care purchasing in particular, health benefits for state employees and their families, and public programs such as Medicaid and MinnesotaCare, have unique potential to catalyze change.

State public program health expenditures are a major, rapidly growing, visible budget item receiving considerable legislative, consumer, taxpayer, and media attention. Public program decisions and operations affect virtually all health care providers and a significant cross-section of all Minnesotans statewide. State employee health benefits are also not only a significant budget expenditure in their own right, but have historically been a source of innovation that has attracted wide local and national attention and health market response. For example, the state employee health benefits program was an early example of the "managed competition" concept of offering employees choices of competing health plans, and recently received a national "Innovation in State Government" award for its introduction of a unique tiered benefit program.

Efforts to further coordinate state health care purchasing and bring about the other reforms outlined in *Crossing the Quality Chasm* through a HCPA will also need to consider changes already occurring in the market and in state government. Market pressures, increasing consumer and purchaser demand, and provider responses to concerns raised in *Crossing the Quality Chasm* and other related studies reports have had an impact. Minnesota has recently made important strides in providing greater transparency of health care costs and quality to consumers, purchasers, and health care providers. In the last year alone, important new standard, comparative measures of health care provider performance have provided a wealth of previously unavailable information on performance of Minnesota's health care system. Examples of recent health care measurement and reporting include: a public report on health plan performance, based on a new tool called "eValue8"; MN Community Measurement reports

on key quality indicators of performance of clinic systems representing over 700 clinics around the state; and public reporting of "Adverse Events" at Minnesota hospitals.

At the same time, a Governor's Health Cabinet was recently formed to bring all state agencies with health care purchasing responsibilities together to identify best purchasing practices and ways of acting more in concert to align and reinforce incentives for delivering higher value health care. The concept was later broadened to include the private sector, with the formation of the "Smart Buy Alliance" comprised of public and private sector purchasers representing nearly sixty percent of Minnesotans, working together to adopt common strategies and practices to improve the value of health care received.

IV. Health Care Purchasing Authority Options and Approaches and Discussion

This study focused on developing options for legislative review and consideration regarding a Health Care Purchasing Authority to more fully coordinate and direct Minnesota state government's health care purchasing. It is important that the options be considered in line with the system reform objectives such as those outlined in *Crossing the Quality Chasm*, and with Minnesota's unique health care environment at this time.

A continuum of four types of options was developed to illustrate different approaches and various tradeoffs to creating a state Health Care Purchasing Authority. The options reflect divergent views and experiences, both within state government, and in the relevant literature and in practice. Some key variables and tradeoffs distinguishing the options include:

- The mechanisms or approaches used to coordinate and choreograph state health care purchasing;
- The amount of government restructuring and reorganization required;
- Anticipated costs, complexity, and time requirements of any changes;
- Perceived benefits and impacts; and,
- Feasibility and practicality of the options.

The four types of options with a number of respective perceived benefits and limitations are briefly summarized below. Each option would also have responsibilities for the development and availability of the "secure benefit concept" described in the study statute, and briefly noted above.

Option A – A new "cabinet level agency" HCPA

Some argue that in order to accomplish a truly integrated and coordinated model of state health care purchasing, with similar goals and incentives for maximum system response, requires a single new overarching cabinet-level agency with responsibility for all state health care purchasing policy and management of operations. Under this scenario, state government would be restructured to bring most or all existing state purchasing responsibilities and activities together "under one roof", with a single new management and oversight.

As envisioned, the new agency and its management would have wide-ranging state health care purchasing responsibilities for most or all state covered populations, ranging from state employees to public program enrollees to state correctional system inmates and others. The new agency would centralize and directly administer most or all aspects of:

- Setting specifications and objectives in contracting with providers and vendors;
- Contract and performance management;

- Design and implementation of administrative systems and support;
- Data and information processing, and analysis;
- Health care quality and performance strategies and measures; and,
- Purchasing support (e.g., actuarial, legal, data-analytic, and other services, whether provided internally or by contracts).

It could also potentially have responsibility for overseeing and administering most or all:
- Billing and enrollment system(s);
- Member information, communications, and support system(s); and,
- Claims adjudication and payment.

Perceived benefits
- Eliminates existing agency and program-based health care purchasing "silos"
- Ensures more uniformity of state purchasing policy and operations
- Eliminates or streamlines redundant activities to achieve administrative savings
- Creates a single, direct path to the Governor and a more direct chain of accountability for activities and results

Perceived limitations
- Requires significant restructuring
    - Initial estimates of movement of 80-400 state staff, depending on scope and activities of new agency
    - Considerable cost for reorganization
        - Facilities
        - Communications and IT technical infrastructure
        - Personnel issues
        - Communications and relationships with stakeholders
    - Considerable time and energy to reconfigure
        - Upwards of 1-2 years
        - Ability to focus on purchasing improvements and incentives for system-wide change during changeover period?
    - Would create another bureaucracy
        - Guarantees that new agency perform more efficiently or effectively than other bureaucracies?

Option B: "Utility" HCPA

This option assumes a much more limited, targeted reorganization and creation of a special health care purchasing "utility" function. The new utility function would serve as a central clearinghouse of high level technical and professional expertise to help guide and advise other state agency purchasing functions. In concept, the utility would be developed to both recommend best purchasing practices, as well as to review and work with agencies regarding purchasing activities to be consistent with best practices and overall state-wide health care purchasing goals. The utility is not viewed as an independent cabinet-level agency, but a special resource within an existing agency. The utility would likely have an executive director for management and relations with other senior staff and agency heads, as well as eight to ten senior level staff with specializations in areas of medical director, analyst, actuary, quality and performance measurement, and other disciplines.

Perceived benefits

- Agencies with purchasing responsibilities would have a single source of review, expertise, and guidance to help keep their efforts aligned with overall goals and strategies
- Little time-consuming or costly reorganization
- Potential to eliminate or streamline some redundant activities and achieve some administrative savings

Perceived limitations

- Limited staffing and resources – potentially limited ability to respond to agency needs
- Potentially limited ability to directly influence agency purchasing practices and strategies and to establish compliance with overall goals and objectives

Option C: Interactive HCPA

Option C is analogous to the current Governor's Health Cabinet. It would provide a vehicle for bringing state agencies with health care responsibilities together as a special standing group to collectively develop and implement health care purchasing strategies of broader interest. Under the existing Governor's Health Cabinet arrangement, the Governor has named one agency head to chair a special sub-cabinet made up of the existing agencies with health care responsibilities. The group meets on a regular basis, or is convened at the call of the chair or as otherwise needed, to identify best purchasing practices, and strategies and opportunities to implement the best practices in concert. Participating agency heads also draw upon and bring together agency staff and outside resources as in-kind support to the effort. The Health Cabinet is also engaged in similar broader efforts with private sector counterparts through the Smart Buy Alliance.

The Health Cabinet has provided forums and a vehicle for stakeholders to meet with and communicate directly with the state's key health care purchasers and regulators. It has created a single clearinghouse for health care quality and cost information for use within state government and the general public. With the Smart Buy Alliance, it has called for health plan participation in a standard, comparable measure of health plan performance known as eValue8, which was completed and made available in a report to the public. It has also called for and supported other forms of recent standard, comparable, public disclosure of health care provider performance, including Adverse Event reporting of hospital-based adverse patient events and MN Community Measurement reports on performance of clinic systems representing over 700 Minnesota clinics.

Perceived Benefits

- Engages existing agency heads with expertise and authority in state health care purchasing and regulation in mutual problem solving and arriving at more uniform and cohesive purchasing strategies
- Uses existing resources
- Potential to eliminate or streamline some redundant activities and achieve some administrative savings
- Does not require reorganization or restructuring
- Can generally act based on existing authority and organization

Perceived Limitations

- Does not eliminate agency and program silos
- Based on voluntary cooperation, shared efforts, consensus among agencies

- Resources are limited to those currently available and in use for other purposes and priorities as well

Option D: Functionally focused HCPA

This option envisions a set of working relationships similar to those in the "Interactive" model above, but would be specifically focused only on a limited, pre-selected, specific set of high priority functions or desired changes and improvements. For example, the rise of obesity and diabetes-related conditions is rapidly reaching epidemic proportions and is affecting all state health care programs and purchasing. The functionally focused version of an HCPA would draw together agency heads with health care responsibilities to develop and implement common approaches aimed at greater diabetes awareness, prevention, improved treatment, and better outcomes. A similar type of emphasis might be to foster and accelerate the use of interoperable health Information Technology (health IT), to reduce errors in patient care, provide up-to-date patient information to aid diagnosis and treatment, and to reduce burdensome, expensive paperwork and administrative hassle factors throughout the health care system.

Perceived Benefits
- Engages existing agency heads with expertise and authority in state health care purchasing and regulation in mutual problem solving and arriving at more uniform and cohesive purchasing strategies
- Maintains tight focus on highly visible, high priority areas
    - Helps avoid "mission creep" and having too many objectives and insufficient time or resources to accomplish them
    - Limited, targeted focus easier to communicate, engage with stakeholders and the public
    - Performance of HCPA is easier to assess if targets are limited, narrow, focused
- Uses existing resources
- Potential to eliminate or streamline some redundant activities and achieve some administrative savings
- Does not require reorganization or restructuring
- Can generally act based on existing authority and organization

Perceived Limitations
- Does not eliminate agency and program silos
- Based on voluntary cooperation, shared efforts, consensus among agencies
- Resources are limited to those currently available and in use for other purposes and priorities as well

Discussion

The options above were provided to help illustrate an array of possible Health Care Purchasing Authority structures and relationships. Based on the work of national groups like the national Institute of Medicine, and its landmark *Crossing the Quality Chasm* report, key determinants of success in any HCPA option will be the degree to which any restructured, refocused state health care purchasing:
- Leads to greater transparency and accountability for health care costs and outcomes;
- Identifies, aligns, and reinforces the correct incentives to bring about maximum improvements in patient care and outcomes in the shortest time.

None of the options alone can guarantee success in reaching these goals. For example, the "Single Agency" option (Option A above) offers the advantage of bringing all the component parts together under a single line-authority leadership structure to help ensure that the parts are working in tandem for maximum impact. However, as discussed above, creating such an entity would likely require considerable time, effort, and expense. During its formation, attention and resources may be less available to address the underlying root problems of poor health care performance. Establishing line authority back to a single designated agency head for all state health care purchasing will be only as effective as the individual links in the chain and the agency leader. As many corporations have recently seen, from car manufacturers to airlines, even the best, strongest line-authority structures and leaders are often not sufficient to survive or manage the type of sea change considered necessary in health care.

The converse – working within existing agency structures and responsibilities – provides opportunities to coordinate already available resources and staff to quickly "hit the ground running." However, this arrangement is more ad hoc than the creation of a new single agency HCPA, and questions remain as to how such a model would remain cohesive and on track in the face of changing priorities, personnel, and budgets.

Regardless of the HCPA option selected, it will be important that the same standards and expectations desired for the health care industry and health care supply chain – for transparency and accountability, and for correctly aligned and reinforcing incentives to bring about maximum performance improvement – be developed and applied to state health care purchasing as well. The state's success in rapidly addressing one of its largest, fastest growing budget areas to the benefit of all Minnesotans may ultimately be less a function of the way an HCPA is organized and structured, and more determined by:

- High expectations and goals;
- The degree to which there is faster adoption of innovations already proven to work in other agencies or sectors;
- Demands for transparency and accountability for the state's performance as a health care purchaser, with standard, comparable measurement and reporting of progress toward goals; and,
- Consequences for poor performance in reaching goals, such as budget and other implications.

These are many of the same types of tools and incentives that are needed to help reduce health care costs and improve quality. Minnesota state government can most effectively position itself to help achieve these goals if it too takes some of the same strong medicine.

David Haugen

Preliminary Report on a Secure Benefit Set for the Public Employees Insurance Program (PEIP)

Executive Summary

December 15, 2005
Minnesota Department of Employee Relations

Preliminary Report on a Secure Benefit Set for the Public Employees Insurance Program (PEIP)

Executive Summary

I. Introduction and Context

The Problem

Already high and rising health care costs are making health coverage unaffordable for many and eroding employer-based health insurance. Employers, especially smaller firms, may be dropping health insurance for employees, scaling back on the coverage available, and/or requiring that employees pay more. Increasing health care costs, reflected in higher monthly insurance premiums and out-of-pocket payments when services are provided, are also significant issues for the self-employed and others without access to employer-based coverage.

The design of most traditional third party health insurance can be a factor in the costs and erosion of current health coverage. Despite a recent proliferation of new product offerings, most health insurance is still quite comprehensive, often presenting employers and individuals with only an "all or nothing" choice: either to purchase expensive insurance products covering a wide array of medical services, often with relatively modest direct consumer payments, or to receive nothing – no health coverage.

In response to concerns about rising health insurance costs, and to address the "all or nothing" conundrum of existing insurance options, a number of efforts are underway to develop and market lower cost health benefits and products. Major employers such as Wal-Mart, and a coalition of over 50 large employers known as the "HR (Human Resources) Policy Association," have attracted recent national attention with news that they will be offering new types of health packages for employees, specifically in attempts to provide lower cost alternatives to conventional employer-sponsored health coverage. Major insurers and health plans such as UnitedHealth Group and Aetna have announced new products with lower monthly premiums. Many states and other organizations are also examining new health coverage products and offerings.

Purpose and scope of this report

This report is a preliminary exploration of the concept of a "secure benefit set" to help address the issues above. It is being undertaken as part of requirements and authorizations of Minnesota Session Laws 2005, Chapter 156, Section 47, which require the Commissioner of the Minnesota Department of Employee Relations (DOER), in consultation with other state agencies, to report to the Minnesota Legislature on the creation of a "Health Care Purchasing Authority" (HCPA) responsible for "all state purchasing of health care." A report has been submitted under separate cover for review and consideration by the Legislature describing several options for the creation of an HCPA, and to contribute to additional dialog on the topic of a Health Care Purchasing Authority and related health care reform.

The HCPA study legislation includes several provisions related to the design and availability of a "secure benefit set", including:

- Authorization for the DOER commissioner to make available a secure benefit set to public sector employers through an existing voluntary health insurance pooling arrangement administered by DOER, known as the Public Employees Insurance Program (PEIP)[1].
- Three other HCPA-specific provisions, including:
    - That the HCPA "convene a panel of health care policy experts and health care providers, to establish a process to select evidence-based guidelines ... and implement an integrated approach using these guideline for purchasing decisions and coverage designs;"
    - That it define a "secure benefit set" providing coverage for preventive care, prescription drugs, and catastrophic coverage that also takes into account the needs of special populations, including persons who are elderly or disabled and persons with chronic conditions; and
    - That it prepare a report and plan for public employers, nursing homes and other long term care providers, and individuals to purchase the secure benefit set through the HCPA.

DOER is exploring the secure benefit set concept for PEIP and is submitting this preliminary report as part of that exploration and planning process. It is hoped that this information will also facilitate discussion of the secure benefit concept as part of the broader legislative consideration of the Health Care Purchasing Authority.

The secure benefit set is not further described in the HCPA legislation. However, the current context for this issue suggests interest in a benefit set that is "secure" both in the sense of being less costly, while at the same time providing access to needed care and financial protection. While such a benefit set could possibly take many forms, there are a variety of converging interests in the design and availability of:

- "Basic" health benefits that are less costly than most typical benefit designs currently being offered;
- Benefits that provide individuals with protection from financial catastrophe due to high medical expenses; and
- Benefits that provide access to needed medical services and health care proven to be effective to maintain and improve health.

II. Study Methods

As part of its planning to offer a secure benefit set through the Public Employees Insurance Program (PEIP), DOER:

- Reviewed other relevant reports, studies, and private and public sector examples of new and emerging health benefit designs;
- Met with state agency staff and the Health Care Guidelines Workgroup, an interdisciplinary workgroup of health policy experts and health care providers that advised the Minnesota

[1] The Public Employees Insurance Program (PEIP) is a voluntary statewide health-dental-life insurance pool authorized by Minnesota Statutes § 43A.316 that has been in operation since the late 1980s. The program provides Minnesota's public employers, including counties, cities, townships, and school districts, with the option to purchase a package of benefits for their employees and retirees, and their dependents. Individually tailored health plans allow each employer group to choose the amount of deductibles and coverage levels paid. Employee eligibility and employer contributions are determined by each employer group, most often through collective bargaining. PEIP currently serves 102 total public employer groups and approximately 2,085 enrolled employees.

Department of Health in 2004 and 2005 on how best to encourage the use of evidence-based guidelines by providers and consumers. The Health Care Guidelines Workgroup submitted a report on the topic, "Recommendations on Systems Improvements to Advance Evidence-Based Health Care" to the Legislature in January, 2005.

- Worked with DOER's consulting actuaries, Deloitte Consulting LLP, in reviewing the secure benefit set concept and examples of alternative benefits designs for PEIP, and in preliminary modeling and pricing of a continuum of example design options.

III. Current Health Benefits Costs

A useful starting point in discussions of a secure benefit set is current health care coverage and costs. Information on current average employer-based health insurance premiums is provided in the table below, based on the results of an annual, large, national survey of employer health benefits by the Henry J. Kaiser Family Foundation/Health Research and Educational Trust (Kaiser/HRET).[2]

2005 Kaiser/HRET Survey:
Average employer-based health insurance premiums

Type of Coverage	Average 2005 Monthly Total Health Insurance Premium Rates*	Average 2005 Annual Total Health Insurance Premium Rates*
Single (employee only)	$314 to $346 per month	$3,767 to $4,150 per year
Family	$833 to $924 per month,	$9,979 to $11,090 per year

(*average premium costs vary by type of plan: e.g., conventional, HMO,PPO, POS.)

At these costs, medical benefits are generally comprehensive with coverage for at least most major categories of services such as preventive care, inpatient hospital and outpatient care, doctor's office visits, lab, radiology, and other services. Patients and families have out-of-pocket maximums that limit their out-of-pocket exposure, and unlimited or very high annual limits on the total benefits that will be provided. However, the average total annual premium costs cited above for employer-based family health coverage are now more than the annual earnings of individuals working full-time at minimum wage, and are more than many persons' mortgage, car, education, or other traditional major payments.

Because employers typically contribute to premium costs, however, the employee portion of monthly premium costs is much lower than the total cost. According to the 2005 Kaiser/HRET survey, the average employee share of single monthly premiums is $51 per month, and $226 per month for family coverage. Although the dollar amount contributed by employees has risen substantially in the last few years, employee contributions as a share of the total premium have been stable at 16% and 26% for single and family coverage, respectively.

Employers typically offer health benefits designs that generally require some forms of cost sharing at the point services are delivered. The Kaiser/HRET survey report indicates that the average point-of-service cost share for employees in 2005 is $323 for annual first dollar

[2] A description of the survey and its results is available online at http://www.kff.org/insurance/7315/index.cfm.

deductibles, with $15 to $20 copays per doctor office visit, and $10 to $35 copays for each prescription drug.

While the average out-of-pocket costs faced by covered individuals are typically much lower than the actual cost of services, or the portion paid by their employer, they can be significant for lower income individuals and/or persons with high or persistent medical expenses. In addition, the cost sharing requirements for some consumers may be much more than the average. However, the averages above also indicate the level at which individuals are generally required to pay directly out-of-pocket, which may be instructive in considerations of price points that individuals or employers may consider acceptable under alternative health insurance product designs and pricing.

IV. Benefit Design Issues

While there are many efforts underway to develop and introduce health insurance options other than the current "all or nothing" standard of coverage, the solution is difficult, complex, and elusive. A combination of health benefits meeting broad, sometimes varying definitions of affordability, personal financial protection, health needs and value is strikingly difficult to achieve. In practice, there are many issues and trade-offs to consider, including:

- There are often no agreed-upon definitions of terms such as "catastrophic" or "affordable", which can also vary greatly depending on individual situations. In addition, "preventive" and "catastrophic" coverage represent important ends of the health care spectrum, but do not address important components in the middle of the spectrum that can result in significant costs and greatly affect health outcomes.

- The challenge of achieving more affordable, attractive health benefit designs is further confounded by the fact that a relatively small number of persons will have high medical expenses in a given period, while most will have few or possibly even none. This so-called "80-20" rule, in which roughly 20% of an insured population accounts for 80% of its costs, often makes it even more difficult to find a single insurance design that will meet the needs of all. Some persons will value preventive and primary care services intended to maintain generally healthy people in reasonable health, while others with serious illness or chronic conditions will value access to a wide array of state of the art services and care. Health status is also not static, and changes over time, as do employment and incomes, assets and accumulated wealth, and family status.

- Excluding or limiting coverage, or increasing the share of costs borne by consumers, can lower monthly premium costs but may come at a price to many individuals and payers, and the health care system.
    - Benefit costs and exclusions or limitations may result in needed care not being accessed when it is timely and most cost-effective, resulting in higher subsequent health care costs. Less comprehensive insurance packages may not provide desired levels of protection to avoid financial catastrophe due to severe illness or injury.
    - Health care costs that are not covered by insurance may contribute to higher uncompensated care costs paid for by other health care users, or higher public program costs if ultimately covered by public programs.
    - Concerns have been raised that a proliferation of lower cost insurance arrangements with limited coverage may "crowd out" other more comprehensive insurance

arrangements, resulting in fewer, more expensive insurance options for persons with high health care needs.

- While benefit designs with coverage limitations can be problematic, they may offer more-affordable insurance alternatives that meet important needs of many persons, especially those who cannot afford more traditional comprehensive coverage. They have the potential to provide better options for many than the current "all or nothing" choices which generally prevail, under which many are receiving nothing.
    - More limited coverage, while not as comprehensive as most insurance products currently marketed, can still provide not only individual financial protection and access to medical services, but may also help reduce uncompensated care and public program costs associated with uninsured persons.

- Determining health benefit levels may involve competing objectives and philosophies. For example, one approach to defining benefits is to identify the range of needed services to meet health needs, and then to determine the costs and prices of coverage to provide the services. This represents the traditional approach to health insurance. An alternative approach is to determine levels of insurance costs or prices that are considered feasible for broad groups of users, and then to determine what could be purchased or provided at a given price.

- Some promising alternatives and possible approaches to improving health care quality and reducing health benefit costs may be difficult to implement directly at this time on a large scale to result in near term savings.

  For example, in its 2005 report to the Legislature, the Health Care Guidelines Work Group noted:

  "While Minnesota and the United States have committed health care professionals who deliver excellent care under most circumstances, there is widespread evidence that there is substantial room for improvement in the delivery of health care services. ...Physicians and researchers have been working over the course of the past several decades to objectively and scientifically examine which care delivery models and methods work best for certain types of conditions and for the average patient under normal circumstances. The more widespread use of "evidence-based medicine" and the acceleration in the use of "best clinical practice" can improve patient care, provide better patient outcomes, and has the potential of lowering health care costs."[3]

  In its report, the Work Group also recommended a number of steps to facilitate the development and use of evidence-based medicine and best clinical practices. Many of the recommended steps are being undertaken. Conceptually, a further step that could be considered is a version of a "secure benefit set" that covered only scientifically proven medical practice. Such a strategy would provide coverage for important forms of medical care and treatment, and promote continued development and application of evidence-based medicine. However, at present there is good scientific evidence for only relatively limited amounts of medical practice. While it is important to acknowledge and foster higher quality health care and evidence-based practice, developing a secure benefit set that covers only currently scientifically proven practice would also be limited, leaving potentially large gaps and questions about coverage.

[3] "Recommendations on Systems Improvements to Advance Evidence-Based Health Care," Report to the Legislature, Minnesota Department of Health, 2005

- However, even while some desired innovations or changes in benefit design are difficult to achieve at this time, there may be other alternatives and related strategies that could be considered. For example, an additional option to support development and use of scientifically-based health care guidelines is to explore ways to increasingly identify and reward "best in class providers" or limited "high value networks" of health care providers that deliver high quality care according to scientifically based guidelines.

  Provider rewards and incentives could take a variety of potential forms, including benefit designs with higher levels of benefit for accessing services through the designated networks or best in class providers. Another approach that could also be used in combination with those above, would be the use of "tiered" arrangements in which health care providers are placed into tiers based on their performance. Each tier is differentiated from the others through benefit differentials such as copays or deductibles that vary according to the tier of the provider that is selected for care. The current state employee health benefits program, Advantage, uses a tiered arrangement, which is briefly described in more detail later in this report.

- Finally, an important new issue in alternative health benefit designs or insurance products is information and assistance to employers, consumers, and others to help them make fully informed, wise choices. Because lower cost insurance arrangements may have limits or exclusions that are difficult to identify, understand or evaluate, it will be important to provide clear consumer disclosures of any coverage limits or exclusions. Clear scenarios should be provided to illustrate potential out-of-pocket costs and financial exposure.

V. Examples of approaches being used to introduce lower cost coverage alternatives

To date, a number of approaches and tools are being explored and or have recently been implemented as part of less expensive health insurance alternatives. Several common approaches, as well as some salient issues and trade-offs of the approaches, are briefly summarized below and help illustrate the issues described above.

Reductions, exemptions from state benefit mandates

This approach exempts some types of insurance from having to cover some or all benefits mandated in state statutes. In theory, elimination of mandates reduces the medical services and treatments that must be covered, resulting in lower premiums. However, in practice, researchers have found that mandated benefits are often in demand and would frequently be offered voluntarily, especially by larger employers, reducing the overall cost savings associated with mandate-free plans. For the most part, the mandate-free or limited mandate plans have not reduced costs to arrive at significantly lower price points and have not sold well in the market. [4]

[4] Minnesota currently has 26 "benefit mandates" that insurers must cover. According to a recent study, mandated benefits account for approximately 13% of total private health insurance premiums in Minnesota. However, most of the cost is due to mandated maternity coverage, which accounts for 6% of premiums. In many instances the mandates are generally accepted and researchers estimate that most would be offered voluntarily. The greatest difference is in the small group market, where approximately only 8.5% of the nearly 13% of costs of current mandates would be covered on a voluntary basis. While the potential reduction in premium costs due to mandated benefits are estimated to be greatest in the small group market, at 4.3% , the small group market is currently only 15% of the total Minnesota private health insurance market. As a result, elimination of mandated benefits was

Benefit caps, limits, exclusions

Insurance exclusions or limits can make premiums more affordable and still provide important levels of insurance protection. However, they come at a price for individuals who need the services that are limited or not covered. Consumers may also not be fully aware of the implications of insurance limits, or prepared to pay for uncovered expenses.

- Examples:
    - Annual caps on total benefit that will be paid (e.g., $50,000 or $100,000 maximum benefit)
    - Exclusions of types of services
        - e.g., No coverage for certain types of services, such as prescription drugs, inpatient services, chemical dependency, chiropractic, others
    - Limits – maximum daily, per visit, or annual limits
        - e.g., maximum limits on amounts that will be paid per day of inpatient hospitalization; coverage of only up to a certain amount for doctor's office visits or preventive care or prescription drugs.

Greater individual cost share

Increasing the individual's share of monthly premium costs, and/or the individual's cost at the point of service help keep employers' costs lower in order to offer health coverage and make contributions to employee coverage. However, this approach raises costs to consumers, including costs when services are provided that consumers may not have anticipated or budgeted.

Beyond the issue of who pays, there are also issues of the impact of greater consumer cost share on consumer behavior. Conventional, comprehensive health coverage with relatively low cost sharing for consumers is often believed to insulate them from the true costs of health care, leading to over-consumption of care, increasing demand for medical services, and contributing to health care cost escalation. Advocates of greater consumer cost sharing point out that if consumers were more directly aware of and engaged in paying health care costs, they will likely use fewer services and/or consider less expensive treatment alternatives when available. However, there are also concerns that it may be difficult for many consumers to shop effectively when they are ill or injured; that information needed for good decision making may be unavailable; and that consumers may be "penny wise" but "pound foolish" in not appropriately seeking care when needed, but then incurring even greater costs for more serious episodes of care later.

- Examples:
    - Increased monthly premium
    - Increased point of service costs such as deductibles, copays, and coinsurance
    - Variable pricing based on risk factors (e.g., charge smokers more, nonsmokers less)

---

found to have relatively small impact in the overall Minnesota private insurance market, with an overall premium reduction averaging 1.3%.

In 1999, Minnesota created a three-year pilot program allowing insurers with less than 3% of total state market share to market insurance policies exempt from state benefit mandates except maternity coverage. Two insurers filed plans to offer the mandate-free policies, but later rescinded the plans when cost differences were not viewed as significant. More recently, legislation passed in 2005 allows any health plan to offer products that do not conform to state benefit mandates, with the exception of maternity coverage. As of the end of 2005, no insurers had yet submitted filings to offer such plans.

- While controversial, some employers are factoring certain health risks and behaviors, such as smoking, into pricing of premium rates and out of pocket expenses, charging smokers more but nonsmokers less.

Subsidies

A variety of direct and indirect subsidies have been made available to reduce health care costs for individuals, especially low income persons. While subsidies reduce costs for their recipients, the subsidies must be paid for through some means, raising costs to others. At the same time, subsidies may only further obscure the true costs of health care and health insurance.

Examples:

- Direct subsidies
  - There are many examples of direct means-tested subsidies to lower the costs of health insurance for individuals, including the state's MinnesotaCare program. (MinnesotaCare also includes benefit limits described above, especially on inpatient care, to reduce premium costs and to prevent "crowd out" of other forms of insurance that are already being paid for in the market.)
- Indirect subsidies
  - For example, the State of New York through the "Healthy New York" program, covers ninety percent of an individual's annual intermediate health costs greater than $5000 and less than $75,000. This form of state provided reinsurance represents an indirect subsidy intended to lower the cost of coverage for individuals and small employers. Minnesota has a similar reinsurance program for "purchasing alliances" (Minnesota Statutes § 256.956), but its impact has been very small due to low enrollment.

Discounts

Discounting arrangements are not insurance, but simply discounts off retail prices that consumers would otherwise pay for health care services. Initially often developed and promoted as tools to aid consumers without prescription drug coverage to obtain less expensive prescription drugs, discount arrangements are being widely marketed for many health care services.

While much less expensive than conventional insurance, discount cards do not provide the financial protection or access to health care services of conventional insurance. However, it should be observed that discounts are an important component of health insurance plans. Even services which might not be covered by a limited benefit plan due to caps or limitations would still receive the benefit of the health plan's discount, providing some relief to the consumer.

New approaches, models

Employers, providers, government, and others are actively exploring new benefit designs and value-based purchasing arrangements to reduce health care costs and improve the quality and value of health care expenditures. Some examples include:

- *Tiered benefit designs*, in which health care providers are placed into tiers based on their performance. The tiers can be differentiated for consumers on the basis of premium differentials and/or different costs at the point of service to encourage consumers to access less costly, higher quality providers.

  The State of Minnesota employee health benefit plan, known as Advantage, is one example of a tiered program in practice. Advantage serves the more than 115,000 employees and

family members of the State Employee Group Insurance Program (SEGIP). It places primary care clinics available to state employees into one of four cost levels, based on their risk-adjusted cost of delivering care and as negotiated in collective bargaining. Advantage members may then choose any primary care clinic that is available, but they pay higher copays, deductible, and coinsurance for more costly choices. In addition, during the recent annual open enrollment for employees, links were provided in open enrollment materials to the MN Community Measurement website, which provides information on how over 50 different clinic systems, representing more than 700 clinics, compared on quality.

Advantage gives consumers choices and information that they have never had before, while creating new market pressures and incentives for health care providers to deliver efficient, high value care. As a result, Advantage costs did not increase this year, and the program received a competitive "Innovation in State Government" award from the Council of State Governments.

- *Pay for Performance, Centers of Excellence*. A number of employers are exploring value-based purchasing concepts to reward high performing health care providers, including special pay for performance initiatives such as the "Bridges to Excellence" program, and others. Others are examining and adopting Centers of Excellence programs to identify "best in class" care delivery and to reward it through special payment rewards and/or increased patient volume.

- *High deductible, "Consumer Driven Health Plans" coupled with savings accounts*. Under these arrangements, insurance products are offered with high deductibles but lower premiums, coupled with special savings accounts that can be used to pay for services for which the deductible applies, or for other services that may not be part of conventional health insurance offerings. In some cases, remaining balances in the savings accounts can be rolled over from one year to the next, creating incentives to access and use care carefully so as not to use up the value of the health care savings account.

Many of these new approaches are being rapidly deployed and adopted in the health care market. For example, the recent Medicare Modernization Act, which established prescription drug coverage for Medicare, also created Health Care Savings Accounts (HSAs) used in conjunction with high deductible consumer driven health plans. Such consumer driven health plans are among the most rapidly growing types of new health coverage products. Tiered arrangements are in place for not only state employees, but have been recently announced by the state's major health plans for Minnesotans generally. Pay for performance models and initiatives are being adopted both nationally and locally.

VI. Examples of relative pricing of various benefit design alternatives

To provide further perspective on health care benefit options and tradeoffs, an illustrative "benefits space" with relative price ranges of different benefit alternatives is provided below. For example, health care discount cards are often available in a range of prices, depending on the size of the discounts and the array of applicable products and services. Typically, discount cards are often priced in the range of $50 per month ($600 per year) or even much less, for single persons. At the other end of the spectrum are traditional employer based health plans, averaging over $300 per month for single coverage, or over $3600 per year.

Relative Pricing of Various Benefit Design Alternatives

<table>
<tr><th colspan="8">Annual costs (single)</th></tr>
<tr><th>$500</th><th>$1000</th><th>$1500</th><th>$2000</th><th>$2500</th><th>$3000</th><th>$3500</th><th>$4000</th></tr>
<tr><td>Dis-count cards</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td></td><td colspan="5">Limited benefit plans with benefit caps, exclusions)</td><td></td><td></td></tr>
<tr><td></td><td colspan="3">High deductible plans</td><td colspan="4">High deductible plans with savings account</td></tr>
<tr><td></td><td></td><td></td><td></td><td></td><td></td><td>Traditional, existing plans</td><td></td></tr>
</table>

DOER's consulting actuaries at Deloitte Consulting LLP further explored the range of costs and tradeoffs above by comparing several types of benefit designs recently introduced into the market. For the purpose of this comparison, prices of several types of recently available health insurance products were calculated using the experience of the state employee group as an initial proxy for possible PEIP experience. The pricing estimates were preliminary, and intended only for illustrative purposes. The pricing estimates were then compared across ranges of monthly premium levels for single (employee only) coverage, to illustrate what different premium amounts might buy. The relative levels of coverage and costs of the comparison are summarized below.

Monthly single premium range	Some Typical Features and Plan Design
$50 - $100	• Little or no inpatient coverage • No prescription drug coverage • Little or no office visit coverage • Annual caps and limits (e.g., maximum annual benefit payout of $100,000)
$100 - $150	• Limited inpatient coverage (capped payments per day, or subject to high coinsurance) • No prescription drug coverage • Deductibles and coinsurance • Some annual caps and limits (e.g., maximum annual benefit payout of $50,000)
$150 - $200	• Inpatient covered, subject to coinsurance • No prescription drug coverage • Deductibles, coinsurance • Some annual caps and limits (e.g., maximum annual benefit payout of $50,000 - $100,000)
$200 - $250	• Inpatient covered, subject to coinsurance • Some limited prescription drug coverage (at mid to high end of range) • Deductibles, coinsurance • Some annual caps and limits (e.g., maximum annual benefit payout of $50,000 - $100,000)
$250 - $300	• More like traditional health benefit plans • Coinsurance and deductibles • No annual caps or limits • Copays for prescription drugs in some cases

As shown above, the lower the monthly premium cost, the fewer the covered services and the greater the consumer cost share at the time services are delivered. In particular, at monthly premium prices below $150-$200 per month, it is difficult to cover significant categories of services such as inpatient care and prescription drugs. Both these categories are often key to caring for persons with complex or chronic conditions, and important components of both preventive and catastrophic coverage called for in the HCPA study legislation regarding secure benefits.

Preliminary Conclusion/Observation

In attempting to develop a secure benefit set, the more affordable the plan, the less secure the coverage for the individual. Defining "catastrophic coverage" in an acceptable manner is a key element in developing an affordable plan. If the definition could be limited to $50,000 per individual, the affordability index is significantly increased. In a typical population, this would meet the needs of a high percentage of participants. However, a small percentage would exceed the maximum limit placing a significant financial burden on the participant or ultimately, the health care providers. Setting the limit higher moves the projected cost of coverage into the cost range of traditional plans. A second key element is defining "preventive coverage." Left to the definition assigned by most traditional health plans, it would cover a relatively small number of services. Many would argue that in the context of a limited benefit plan scenario that it should

be expanded to include treatment for conditions, which left undertreated will lead to catastrophic cases (e.g., diabetes, asthma, heart conditions). Finally, balancing some minimal level of initial care to enable early diagnosis of conditions against limiting benefits to hold down cost becomes the third element to consider. These issues will need to be further explored, discussed, and debated as the secure benefit set is developed.

VII. Next Steps and Opportunities

Current levels of comprehensive health benefits and coverage have helped provide those with such coverage access to a wide range of medical services and financial security but at high and growing costs. In the absence of other alternatives, many employers and individuals are faced with "all or nothing" health insurance coverage alternatives. Many are no longer able to afford current levels of coverage and costs.

DOER will continue to build on this preliminary planning to explore options for lower cost insurance products to be available through PEIP. In particular, DOER plans to:

- Capitalize on the success of its tiered arrangement for state employees, known as Advantage, by exploring similar arrangements that could be available through PEIP.

- More fully develop and analyze the business case for a secure benefit set available through PEIP, especially in relation to:
    - Insurance choices and arrangements otherwise available to PEIP-eligible groups;
    - Intrinsic choices and trade-offs among benefit design alternatives;
    - Impacts on PEIP, including potential changes in the number and type of groups who may become part of PEIP, as well as related staffing, reserving, and other PEIP administrative and management issues;
    - Overall costs and benefits of any changes.

- Meet with and discuss benefits design issues with PEIP-eligible public employers and stakeholders;

- Continue to monitor the health care market and to identify other innovative health benefit designs and options.

Jacob I. Mirman, MD, CCH
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Argument for Inclusion of Homeopathy in Avian Flu Pandemic Planning.

A. The Disease

- According to public health officials a "super-flu" pandemic is likely to occur at some point.
- All evidence indicates that it may be lethal, similar to the 1918 pandemic

B. Conventional Treatment

- Vaccine does not exist yet, and it may take many months to make enough to immunize the US population once it is initially produced.
- There are no effective conventional drugs.
- Our level of preparedness is not much better than it was in 1918-1919 pandemic, when 500,000 Americans and over 50 million people world-wide died of the flu.

C. Homeopathy

- Historical evidence suggests that Homeopathy is supremely effective in epidemic disease.
- Available clinical research is supportive.
- Practitioner and patient experience is overwhelmingly supportive.
- Homeopathic medications are cheep and easily available.
- Minnesota Homeopathic Association is standing by to provide all possible assistance to public health officials, including first responder training and hospital based professional support.

Conclusion: Homeopathy must be further investigated by public health officials for possible inclusion in the pandemic planning. We have very little to lose, and possibly a lot to gain.

Historical data, research and other information regarding Homeopathy in influenza may be found at **www.HomeopathyForFlu.com**

PRESENTATIONS ON HOMEOPATHY BY

JACOB I. MIRMAN, M.D.

Homeopathic Medical Clinic

Homeopathy ♦ www.demystify.com
Weight Management ♦ www.getslimforlife.com

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- Professional Course in Homeopathy
  C.M.P. Homeopathic College and Homeopathic Research & Charities
  Bombay, India
  11/91- 04/92
- The Long Course
  Faculty of Homeopathy
  London, England
  10/90- 04/91
- Residency-Primary Care Internal Medicine
  Illinois Masonic Medical Center
  Chicago, IL
  06/87- 06/90
- Degree: MD
  University of Minnesota Medical School
  Minneapolis, MN
  07/83-06/87
- Degree: BA in Chemistry
  University of Minnesota
  Minneapolis, MN
  09/79- 06/83

MEDICAL LICENSURE - Minnesota

MEDICAL BOARDS

- Diplomate of American Board of Internal Medicine
- Diplomate of National Board of Medical Examiners

HOMEOPATHIC CERTIFICATION

- DHt (Diplomate of American Board of Homeotherapeutics, 07/14/97)
- CCH (Certified in Classical Homeopathy, The Council for Homeopathic Certification, 03/1/97)
- CTHom (Certified Trained Homeopath, ESSH School of Homeopathy,

05/12/96)
- MHom (Master Homeopath, ESSH School of Homeopathy, 11-1-04)
- DNBHE (Diplomate of National Board of Homeopathic Examiners,12/30/93)
- MFHom (Member of Faculty of Homeopathy, Royal London Homeopathic Hospital, 04/25/91)
- RSHom(NA) (Registered with Society of Homeopaths of North America, Dec. 2003)

OTHER CERTIFICATION

- U.S. Civil Surgeon (certified by the INS to perform physical exams on new immigrants)

PROFESSIONAL INVOLVEMENT

- Registrar of Minnesota Homeopathic Association
- Provost of ESSH School of Homeopathy

EMPLOYMENT

- Private Practice 5/92- Present
- Texa-Tonka Health Care Associates (part-time) 2/93-Present
- Camden Physicians, Inc. (part-time) and private practice 05/92- 02/93
- Group Health, Inc. 05/90- 10/91

PUBLICATIONS

- *Demystifying Homeopathy: A Concise Guide to Homeopathic Medicine*
- Numerous articles for a variety of publications

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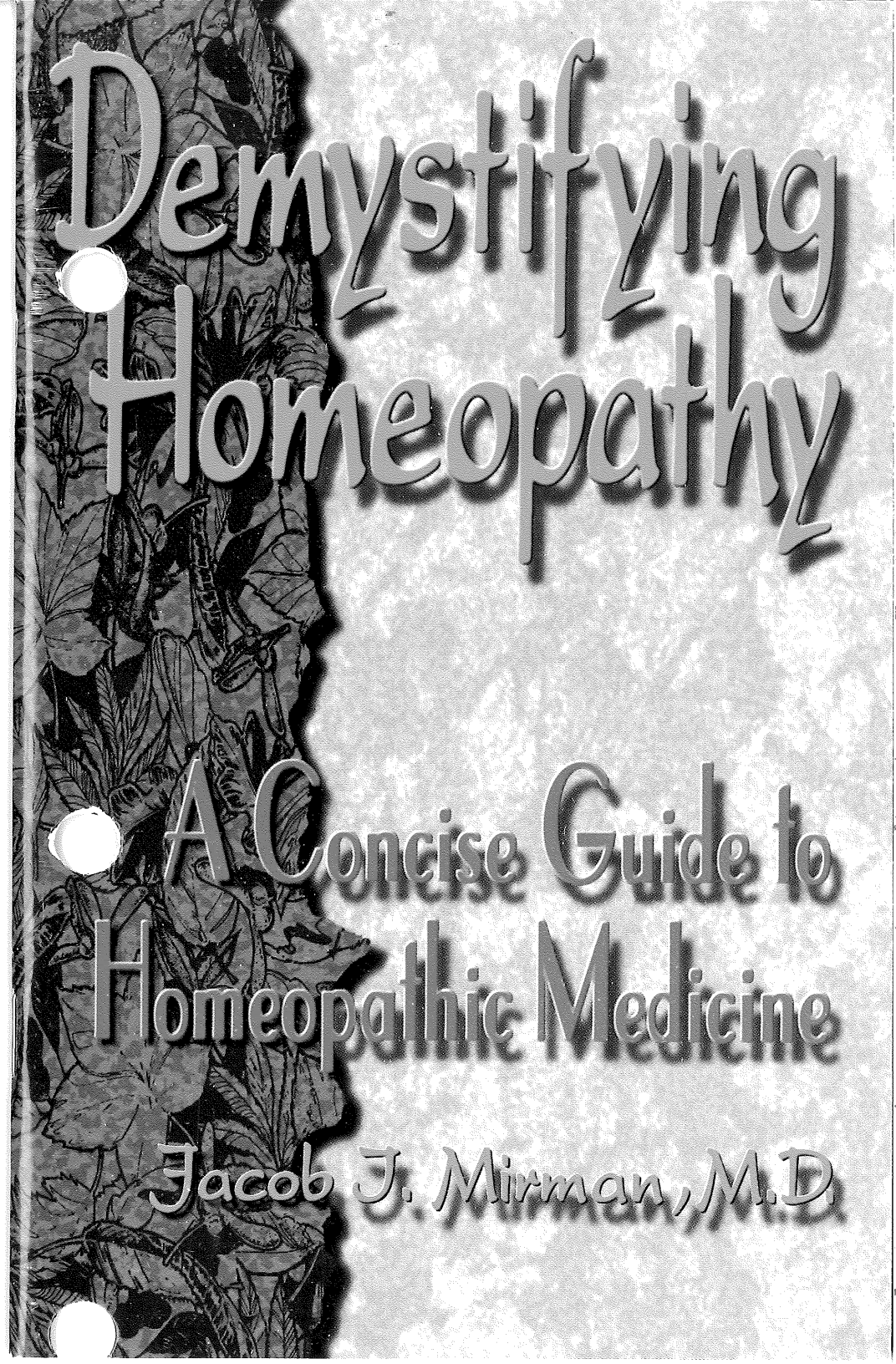
Demystifying Homeopathy
A Concise Guide to Homeopathic Medicine
Jacob J. Mirman, M.D.

"Open your heart with a jest, and let your heart laugh a little; then become serious."
Talmud

o ... what is homeopathy? Here's how some people responded o this question:

- "It's that health freak medicine using vitamins and mineral supplements."
- "It's organic herbs."
- "Never heard of it."
- "It's where they use some kind of strange machines."
- "A form of treatment using suggestion and placebos."

Though creative, none of these answers is correct. Actually, homeopathy is the best kept secret in medicine today. While conventional medicine definitely has its place, it can't match homeopathy in its effectiveness against human suffering. So why don't more doctors practice it? The answer is simple. First of all, it makes no sense to a "rational" mind—that is, at first glance. Second, it's much more difficult to practice than conventional medicine; most doctors will only dabble in it a bit and therefore don't get good results. Finally, if you want to do it well, you have to take your time and see eight patients a day, nstead of forty, and that's hard on the wallet.

Since I began my practice, I've searched for a concise booklet that would explain homeopathy to new and prospective patients. Having never found it, I realized that I would have to write it. Here it is. It is directed at lay people just curious about the subject, as well as doctors and scientists. One thing I know from experience: when somebody tells me they know what homeopathy is, they are usually wrong. I hope you find my explanation helpful.

DEMYSTIFYING HOMEOPATHY
A Concise Guide to Homeopathic Medicine

"Nicely written and well stated - clinical and intellectual balance."
Bernie Siegel, MD
Author

"It was a wonderful, concise, clear and informative little book. I believe it was the best explanation of homeopathy I have seen. Nice job."
William D. Manahan, MD
Author

"A thoughtful and poignant introduction to homeopathy. Demystifies one of the World's great healing systems."
Dr. Michael A. Schmidt
Author

"Anyone who is interested in explaining what homeopathy is will be able to glean another viewpoint from this book."
Julian Winston
Homeopathy Today

"Good book. Good price. The best small book explaining homeopathy to come around."
Melanie Grimes
Resonance

"This is not only the truth, - it is finally, the *whole* truth..."
Iain Marrs
American Homeopath

"I challenge you to find a more concise explanation of homeopathy anywhere."
Tim Miejan
The Edge

"I predict that this remarkable little book will change many lives."
Audrey DeLaMarte
T.C. Wellness

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I would like to express my appreciation to the following people:

To my wife, Julia, for sharing her creative ideas, supporting me in every aspect of my life and patiently enduring endless conversations regarding homeopathy.

To Tracy Whartman, for putting the finishing touches on the second edition.

To Carol Hamilton, whose enthusiasm, dedication and editing made the second and third edition possible.

To all the colleagues, whose input helped me fine-tune this edition to make it more reflective of the general opinions held by the members of the profession. Special thanks to Valerie Ohanian who took time from her busy practice to review this edition and suggest the necessary changes.

Demystifying Homeopathy
A Concise Guide to Homeopathic Medicine
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Dedicated to
Tom Stowell, ND
who showed me the light

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*"You thought, as a boy, that a mage is one who can do anything. So I thought, once. So did we all. And the truth is that as a man's real power grows and his knowledge widens, ever the way he can follow grows narrower: until at last he chooses nothing, but does only and wholly what he **must do** ..."*

Ursula K. LeGuin

MY CONVERSION: ACCEPTING THE IMPOSSIBLE

When I began medical school at the University of Minnesota, I was convinced that the common medical practice of our time, allopathic medicine, was the only method of healing worth considering. Still, I attended the meetings sponsored by the Humanistic Health Committee to introduce medical students to alternative therapies. That way, I would at least know what alternatives were available. The committee invited practitioners in acupuncture, applied kinesiology, chiropractors, rolfers, Trager therapists, psychic healers and others. Some of these presentations seemed credible; others did not. But when a homeopath lectured, I was outraged! It made absolutely no sense! I was certain that anyone who practices something so ridiculous must be a complete idiot or a crook, though this gentleman didn't appear to be either. The whole concept sounded so improbable, it fired up my curiosity. I knew I'd have to investigate it further, if only to disprove it.

I got a homeopathic first aid book and a few remedies and waited for a suitable trial case. I didn't have to wait long. My grandmother suffered from mild, but frequent, anxiety attacks. Since immigrating to the United States, she couldn't find the tincture of valerian she always used in Russia. When she had her next anxiety episode, I gave her Aconite 6X from my homeopathic kit and told her it was valerian. She gladly took it and calmed down immediately. Of course, I assumed the result was only a demonstration of the placebo effect (the power of suggestion). Just thinking she was getting valerian calmed her. So, I set out to prove this assumption by giving her a placebo the next time she became anxious. It looked and tasted exactly the same, and I was surprised when it didn't produce the expected calming result. So once again I gave her Aconite and she calmed

down. Since then, she has used bottles and bottles of the stuff and it always helps.

Since I was a child, I dreamed of doing magic. I wondered what it would be like to have special powers like my heroes in fairy tales, and later, in science fiction stories. Using this homeopathic remedy on my grandmother felt very close! I gave her something that couldn't possibly work and yet it produced a significant reproducible effect. I was hooked; I just hadn't realized it yet.

My final and irrevocable conversion to homeopathy took place in 1985, when my father developed what appeared to be a case of an autoimmune disease. He had severe muscle pains, sweats, a fever, weight loss and a very high sedimentation rate (130), indicating severe inflammation somewhere in the body. He was admitted to Mount Sinai Medical Center in Minneapolis after having been ill for about a month. He had a complete workup, but after ten days, the diagnosis was still uncertain. He was still getting worse and, by this time, was bedridden. Steroids were the suggested treatment. Instead, my father saw a doctor who treated him homeopathically, and he improved dramatically. He was almost pain free the next day. Within a month, all his other symptoms resolved, and his sedimentation rate came down to 10.

My father's case convinced me to investigate this system of therapy more closely. I researched the literature and sat in with several homeopathic doctors. I became so impressed with homeopathy, I decided to study it myself. Once I finished my residency in Internal Medicine, I studied homeopathy as comprehensively as I could, which took me all over the world. When I returned to the United States, I started my homeopathic practice while also working part time as a conventional internist. I soon realized that although conventional approaches can definitely be of some use, nothing can come close to the effectiveness of homeopathic medicine. I now only use allopathic medicine either as a palliative (that is, to help deal with symptoms temporarily, while homeopathy takes effect), or in the rare case when homeopathy would not be appropriate.

"... a scientist must ... be absolutely like a child. If he sees a thing, he must say that he sees it, whether it was what he thought he was going to see or not. See first, think later, then test. But always see first, otherwise you will only see what you are expecting. Most scientists forget that."

Douglas Adams
So Long and Thanks for All the Fish

HISTORY OF HOMEOPATHY: DOUBT BREEDS TRUTH

No discussion of homeopathy is complete without the story of its founder, Dr. Samuel Hahnemann (1755—1843). Hahnemann graduated from medical school in 1779, started his practice, and soon became disillusioned with the prevailing beliefs and practices of his time. Hahnemann was taught, as were all doctors of his time, that disease was due to an overabundance of one of the body's fluids or "liquors" and that treatment consisted of draining these excesses. The most accessible "liquor" was blood and it was drained profusely. There were many variations in technique, but the goal was always the same—drain as much blood as possible[1]. Doctors advocated drawing blood until no more came from the vein. Children were supposed to be bled until four-fifths of their blood was drained. Other "liquors" were drained through a variety of purging methods including large doses of laxatives and emetics. All sorts of poisons, such as arsenic and mercury, were also used. Mercury, for example, was thought to effectively treat syphilis and was administered until the patient experienced copious salivation (which we recognize now as a symptom of severe mercury poisoning). From our perspective, any compassionate physician should have rebelled against such outrageous treatment of patients, but Hahnemann's colleagues followed what they were taught, not knowing any better. They did their job to the best of their ability and with the best methods known at the time.

Is it so different now? Many contemporary doctors give children antibiotics for any minor cold, a practice that eventually destroys the immune system. These doctors, too, think this is the best

way to treat disease. They are honest, hardworking people who practice medicine as they were taught. You might be inclined to defend contemporary practices by pointing out that antibiotics do work and quickly. But bloodletting also often helped in the short run. Over time of course, frequent bloodletting and poisoning made people chronically ill, as antibiotics do when used without moderation.

Hahnemann had a sharp and probing intelligence, and he refused to trust anyone or anything simply at face value. His writings indicate that, unlike his colleagues, Hahnemann was not blinded by unquestioning faith in his professors. He rebelled against prevailing practices and openly criticized those who followed them. His writings were so full of contempt for his contemporaries, that he was soon regarded as the embodiment of the devil himself. Lacking trustworthy alternatives he could offer his patients, Hahnemann simply quit medicine altogether. He worked as a chemist, and to provide additional income for his growing family, he translated books. It was through this secondary occupation that Hahnemann eventually stumbled upon homeopathy. He translated a book written by a popular doctor of the time that discussed the use of cinchona bark (quinine) in the treatment of malaria. The author suggested that the bitterness of the substance produced the curative effect. This didn't satisfy Hahnemann's skeptical mind. He added a critical commentary to the translation, stating that he could easily list several substances even more bitter in taste that did nothing to help a patient with malaria.

Apparently not satisfied with mere criticism, Hahnemann experimented on himself by taking a large dose of cinchona. He developed a fever, sweats, body pains and other symptoms similar to those of malaria. These symptoms lasted some time before he recovered.

Hahnemann formulated a hypothesis: cinchona appears to cure malaria because it produces malaria-like symptoms in healthy people. He proceeded to test other substances, taking them himself, giving them to his hapless family and anyone else brave enough to visit his house, and carefully recorded the symptoms produced. If malpractice suits were common then, Hahnemann might never have developed homeopathy.

Hahnemann started seeing patients again. He administered substances that produced in healthy people the same symptoms

for which the patient sought treatment. These patients improved enough to remove any doubt about the validity of his hypothesis.

The Latin phrase *Similia similibus curentur* defines the one and only principle of homeopathy: "**Let likes be cured by likes.**" This is all homeopathy is. A homeopathic physician's goal is to find a substance that produces in a healthy person the same symptoms the patient suffers from. He or she gives the patient that substance and watches the "magic." And what magic it is!

Homeopathy was brought to the United States by the students of Hahnemann in mid-18th century. It became an immediate success and by the end of the century there were thousands of practicing homeopaths in this country. The New School enjoyed its popularity until the beginning of 20th century. This is when the modern drug companies started coming out with new drugs which were quite effective and easily administered. It became easier to prescribe aspirin than to take a comprehensive case to find a good homeopathic remedy. Most homeopaths took the easy route, and the science of homeopathy declined to the point of virtual non-existence.

A handful of faithful practitioners kept homeopathy going until it was again recognized for its virtues in the 1970s. Homeopathy is now enjoying a strong comeback. There are presently several colleges in this country training quality homeopathic practitioners. There are also a number of homeopathic clinics sprouting up all over the world. I must say, it's a great time to be a homeopath!

"Never accept a drink from a urologist."

Erma Bombeck's Father

PROVING: SICKENING THE WELL TO HEAL THE SICK

Hahnemann's practice of testing substances on healthy people to determine their specific symptom pictures is called "proving." Hahnemann proved around 100 substances during his career. His students and followers continued the process, and approximately two thousand substances have been proven in this fashion. Because homeopathic practitioners didn't always know what to prove, all kinds of unlikely substances found their way into our Materia Medica books, the collection of information on remedy pictures. Some of the most unlikely are our most valuable remedies today. Homeopathic remedies come from plant, animal and mineral sources. Some of them are strong poisons, some are inert substances in their crude form. When properly prepared a (process that will be discussed in the next chapter), they lose their toxic potential and acquire the ability to heal.

An extreme example of an unlikely substance becoming a powerful homeopathic medicine is Pyrogenium. This substance is derived from raw meat that is left in the sun until it rots. If a healthy person ate this meat, he or she would develop severe symptoms: diarrhea, vomiting, fevers with foul smelling sweat, restlessness, body aches. In short, he or she would feel, well, rotten.

A patient who has not ingested rotten meat, but has these symptoms for some other reason, will be helped by Pyrogenium. Of course, a homeopathic practitioner would not recommend eating rotten meat. Pyrogenium is prepared in the standard homeopathic way, which is discussed in the next chapter.

We don't often see patients with typhoid or other intestinal conditions that cause such symptoms. Nevertheless, while working for a local HMO a few years ago, I saw a fifty-year-old man who had developed a "cold" that just wouldn't go away. He had constant fevers, foul smelling sweats, restlessness, terrible mouth odor and other symptoms associated with Pyrogenium. It had already been three weeks, and he was not getting better. I

even gave him a strong antibiotic but, as I feared, it didn't alleviate the symptoms. The man had influenza, a viral condition, so of course, antibiotics couldn't help. I tried them only out of desperation. I considered admitting him to the hospital and ran some blood tests in preparation. In the meantime, I asked him to go to the store that sells homeopathic remedies and buy Pyrogenium 30c. I doubted it would help, but it couldn't hurt! He was to take three granules every two hours and report to me in two days.

Two days passed and his blood test results came back. One look at them made me shiver. It seemed the virus had affected his red blood cells. They were hemolyzing (decomposing), and hemoglobin, the normal constituent of red blood cells, was spilling into the blood and trying to come through his kidneys to be eliminated in his urine. In the process, the hemoglobin had plugged the kidney's delicate filtering mechanism and early signs of kidney shutdown were already apparent in the results. The patient was definitely headed for close monitoring in an intensive care unit. He would have to get vigorous intravenous hydration and could end up on dialysis.

A few hours after I read the results, the patient came in. Before I could say anything he told me, "Doc, I feel thirty percent better." He looked a little better too. I didn't know what to say. He wasn't supposed to be improving; he should have felt worse and possibly stopped producing urine. He defied the rules, so I decided to defy mine and wait a bit longer. After all, I was treating a patient, not a statistic on some report. Still, I drew blood for more tests.

Another two days passed, and the latest blood test results showed a slight improvement. The patient came in and said, "Doc, it's working. I'm seventy percent better now." He continued his steady improvement and the blood abnormalities resolved as well. He was completely well in a couple of weeks.

A week later he came back for an urgent visit for an acute gout attack in one of his joints. This development made me even happier. He'd had these gout attacks previously and a temporary return of old symptoms in the face of overall improvement is the best sign we can see (a phenomenon I'll explain in the Payment chapter).

I advised him to take a pain reliever for pain and eventually, the gout attack resolved on its own. I saw him a few months later

when he invited me to a car demolition derby where he was one of the drivers. Needless to say, at this time he was completely well. This case illustrates a classic response to a well-chosen homeopathic remedy. We don't always see such textbook cases, but they are by no means uncommon.

"Be wary of strong drink. It can make you shoot at tax collectors—and miss."

Robert A. Heinlein
Time Enough for Love

REMEDY PREPARATION: THE LESS WHISKEY YOU DRINK, THE DRUNKER YOU GET

How can a homeopathic practitioner get away with giving patients a substance like rotten meat? Even in the days when bloodletting was common practice, Hahnemann recognized that giving poisonous substances in crude form caused side effects. Treating syphilis with mercury, even if it fitted the patient's case perfectly, still caused mercury poisoning. Hahnemann attempted to avoid side effects by decreasing the doses and discovered that not only did the side effects diminish as the doses decreased, but the effectiveness of the remedy actually increased.

After experimenting for years, Hahnemann finally arrived at the method of preparation used today. The effectiveness of this method cannot be accounted for by present day science, and this is the major stumbling block to widespread acceptance of homeopathy. However, once you are willing to set this apparent inconsistency aside, you see dramatic results.

Preparing homeopathic remedies involves serial dilutions and shaking of the product between dilutions. After several dilutions, the initial substance is essentially washed out and cannot be chemically detected in the final product. For instance, one of the lower potencies, 30c, is a serial dilution of 1 to 100 made thirty times, which yields a final product diluted 10^{60} times from the initial substance (that's 10 with 60 zeros after it!). Of course, this is far beyond Avogadro's number of 6.0×10^{23}. Therefore, the chance of finding a single molecule of the initial substance in the final product is zero for all practical purposes. These preparations are referred to as submolecular.

30c is a low potency and homeopaths commonly use dilutions such as 1M ($10^{2,000}$), 10M ($10^{20,000}$), or 50M ($10^{100,000}$). While it makes no sense whatsoever in light of present day science, in practice, **the higher the dilution, the stronger and longer lasting the effect.**

Now you can see why the rotten meat did not make my patient sicker. None of it was left in the medicine! It seems ridiculous, which is why I thought the homeopath who gave the presentation in medical school was either crazy or a crook. The idea that sub-molecular preparations could have any effect insulted my rational mind. It still does, but what can I say ... it works. I try to be pragmatic in these situations. I knew it would do no harm, so I tried it. When I saw that it worked, I couldn't turn back.

There have been attempts to explain this phenomenon. For example, Dr. W. A. Tiller[2] of Stanford University approached this subject from the standpoint of theoretical physics. His article seems too complicated for my simple mind, but some readers might find it informative. This is the only in-depth scientific explanation of which I am aware. Other available explanations are more metaphysical and are the topic of the next chapter.

"This is much too deep for me."
Leo Rosten
An epitaph he wrote for his tombstone

PHILOSOPHY: EXPLAINING THE UNEXPLAINABLE

The concepts at the heart and soul of homeopathy are not grounded in science, or, at least not the science we know. Nevertheless, effective practice of homeopathy is impossible without a thorough understanding of them. With the help of this philosophy, a practitioner can properly evaluate a case, find the remedy, and know how not to be distracted. It is the result of two hundred years of thought and combines elements of religious philosophy with practical observation.

We start with the concept of Vital Force. It is probably that something whose edges we can photograph with the Kirlian process. It animates our physical body (hence, it is called *animus* in Latin). The Chinese call it Chi. It controls all of the body's natural processes and preserves balance. When it becomes inactive, we die.

In homeopathic philosophy, the Vital Force is seen as elemental and indivisible, which means it reacts as a whole to any irritant. If an irritant is strong enough, it can produce a stable derangement of the Vital Force, which we call disease. Because the Vital Force is elemental, it can sustain only one kind of derangement (disease) at a time. Such a derangement may somehow dull the ability of the Vital Force to recognize what's wrong and that, in turn, causes a chronic illness. Although the Vital Force may have the power to throw off such an illness, it may fail to do so because it lacks perception of the problem. Vital Force is essential to our being, so when it is not well, we feel the symptoms on all levels.

Homeopathic remedies directly affect the Vital Force. Because the Vital Force perceives a homeopathic remedy as a disease-producing irritant, and because the irritant is strong enough, it stirs the Vital Force into action to repel it. If the disease state produced by the remedy is similar to the disease we're trying to treat, the Vital Force recognizes the similarity and, in repelling the remedy irritant, it also repels the disease. In effect, we give the Vital Force a glimpse of itself in a mirror. Because only one

disease can be active within the Vital Force at any given time, only one remedy is necessary to cure it.

Even patients who appear to have several diseases such as asthma, gastritis, headaches, rash and depression need only one remedy. All of these "diseases" are but symptoms of one central disturbance existing within the Vital Force.

In *The Spirit of Homeopathy*, Dr. Rajan Sankaran explains thi with a metaphor of a pole that has several vines growing and wrapping around it. Even though we may not be able to see the pole itself, we know it is there because without it, the vines would fall to the ground. We can remove one vine, then another and yet another, until we think we've removed them all, but they'll grow right back and will continue to grow back as long as the pole remains in place to support them.

Here the pole represents the central disturbance within the Vital Force, and the vines represent our "diseases." By observing the shape of the vines on the pole (the minute individual characteristics of the patient's symptoms), we can ascertain the shape of the pole itself (the general characteristics of the inner disturbance). We then find a remedy that causes a similar derangement in a healthy person. This remedy is administered in homeopathic form and triggers the Vital Force into action. The Vital Force then removes the disturbance (the pole), and all the individual "diseases" get cured.

For those of you who are scientifically minded, I like the analogy using Einsteinian physics. Einstein came up with a theory explaining the time disturbances that would happen during nea light speed travel long before such travel could take place. Using this analogy, homeopathy is like near light speed travel, already happening. We can observe the effects but can't explain them. We now need another Einstein to come up with the explanation. Of course, if such an explanation were to materialize, it would radically change our understanding of the universe and the newly evolved science would be to present day science as Einsteinian physics was to Newtonian physics of yesteryear.

"Somewhere, something incredible is waiting to be known."
Carl Sagan

FROM THEORY TO PRACTICE: THE MAGIC IN ACTION

The practice of homeopathic medicine is often a lengthy process. Most homeopaths spend an hour or two with a patient on the first visit. The initial evaluation involves mainly taking the patient's history and a minimal physical examination. Practitioners gather information to understand the patient as completely as possible. First we note all the symptoms of the presenting complaint in great detail. We ask what makes the complaint better or worse, what time of day (down to the hour) it is the worst, what seems to bring it on, and whether it is associated with any other symptoms, especially if the connection doesn't seem to make any sense. Then we want to understand the patient's general physical makeup: whether he is usually cold or hot, how he sweats, what foods he craves, and so on. A major portion of the interview is devoted to understanding the patient's psyche. Since most physical disease is caused by inappropriate reaction to stress that builds tension and is therefore released in the form of symptoms, a homeopath must understand this aspect of the patient in depth. A keen understanding of what drives the patient, what particular things the patient finds stressful and how he or she reacts to these stresses, holds the key to finding that patient's cure.

Once the data is collected, the essence of the remedy may be clear and the prescription is given. More commonly, however, we must "repertorize." To repertorize, a practitioner refers to a repertory, a cross reference of all the symptoms in the Materia Medica. You may recall that the Materia Medica lists various remedies and their characteristic symptoms as seen in provings. There are several Materia Medica books written by different authors. Besides the proving symptoms, they also include those symptoms cured with these remedies in the author's practice.

The homeopath uses the repertory to find those remedies that have in their picture all the symptoms that are significant in the patient's case. There are usually very few remedies that have all the significant symptoms. Then the practitioner refers back to the Materia Medica to determine which remedy will fit the patient best. This is a tedious process, although computer programs to

assist the practitioner have been developed in the last few years. Even with computer assistance, however, only a skilled practitioner can determine which symptoms are significant.

Once a remedy is selected, it may be given in one dose or in a series of doses. Patients are always scheduled for a follow-up visit anywhere from two days to two months later. These follow-ups are very important. They allow the practitioner to evaluate the response to the remedy administered. The patient is not in a position to make this judgment. A patient may feel better and decide he or she is cured, or the patient may feel worse and decide the remedy is not working. Either judgment may be completely inappropriate. An apparent improvement may not be moving in the right direction; an apparent worsening may be a therapeutic aggravation. Only the practitioner can evaluate the case objectively, always keeping Hering's Law of Cure in mind (the explanation of Hering's Law is in the next chapter).

Typically, for chronic conditions, I see a patient for a follow-up in about a month. During that follow-up visit we decide if the remedy is correct. If it is, we continue with it and the next follow-up is usually in two to three months. If the remedy was wrong, we note the symptoms again, I select a new remedy and schedule another follow-up in a month.

Some Illustrative Cases: By the time my son was three and a half, we had moved 6 times across 3 continents as I pursued my studies. When he turned three, we were staying in Bombay, India. All of this moving was starting to have a negative effect on him. He was fearful and clinging desperately to his mother. Whenever my wife would leave the room, he would scream at the top of his lungs.

After taking the case, I gave him Stramonium 1M (Remember, this is 10^{2000} dilution. There is definitely *nothing* of the original substance left in the preparation). Stramonium is a poisonous plant which, when given to healthy people, causes overwhelming feelings of fear, something like what a child would feel if left alone in the woods with wild beasts. It is not difficult to see why he would be so terrified when you consider his state of mind at the time of the prescription. The remedy produced a remarkable change. Within two days after the dose (he was given only one dose) he allowed my wife to leave him in the room alone. He

then began exploring the house, going up to the second floor, going outside, etc. He even began talking to strangers.

Another intriguing case was a woman in Bombay. She was suffering from aches and pains diagnosed as fibromyalgia. Even before taking the case formally I was able to observe her at home. One incident struck me. Her refrigerator once broke and she asked me where to go to have it fixed. This was a bit unusual, as she was the native and I the foreigner. She just did not feel capable of taking care of it herself. Later, when I took her case she told me she was rather shy and didn't like to go to parties for fear of looking stupid and being laughed at. She received Baryta Carbonica 1M. This is carbonate of barium, the stuff we drink when we have our stomachs x-rayed. When taken in homeopathic form, this stuff produces a feeling of being stupid, incapable and dependent. These patients are usually very shy and fear they will be laughed at. Children requiring this remedy will often hide behind furniture while in the doctor's office. Within two weeks after the dose, this patient had no more pains. She has improved tremendously on all levels since then.

In both cases, the patients had feelings inappropriate to their situations. My son was afraid when there was nothing to be afraid of; the woman felt stupid when she was actually quite smart. This is what we look for when taking homeopathic cases: things that don't make sense or don't belong, reactions out of proportion to the situation, strange things. That's why the initial interview may seem so strange to some patients: it may appear that the doctor is not much interested in the patient's original complaint. On the contrary, we are very interested, but the appropriate remedy may be determined by other seemingly unrelated symptoms. Sometimes the clue is provided by a mental-emotional symptom, as in the case above. Sometimes it's a strange physical symptom. Once I cured a case of abdominal pains and indigestion, guided by the patient's strange predisposition to get sneezing attacks when exposed to bright sun. You just never know what will turn out to be the most important clue in the case.

Sometimes a clue is provided by a patient's dream. Dreams are where our feelings can often be seen most clearly, not clouded by the conscious mind. For example, I was treating a girl with asthma. When I could find no good clues in her case, I asked about dreams. She described quite a sad state of affairs. She was always alone in the dreams, there were no other people

there, neither her parents nor friends. She was very lonely there. She sounded quite sad when talking about it. This type of "orphan" feeling which is usually suppressed in the waking state but comes out clearly in dreams, is characteristic of Magnesia Carbonica (magnesium carbonate). One dose of 1M cured the girl of asthma and she became more cheerful.

Occasionally, knowledge of homeopathy may help a doctor deal with patients who don't even need a homeopathic remedy. Every doctor has seen numerous patients suffering from insomnia. Upon taking a more careful history, we discover that many of these patients drink a couple pots of coffee per day. To a homeopath, these patients are proving (see the chapter on proving) coffee and should cut its intake immediately. Of course, any reasonable physician will conclude that. Sometimes it is not so clear that a patient is experiencing a proving of some substance (you can also call it a side effect, or poisoning). One of my more interesting cases was a 95-year-old physician who was complaining of having very disturbing dreams. He would dream of finding himself in some strange place, unable to find his way home. This was the most peculiar symptom in his case. I looked it up in the repertory and found that Glonoinum (nitroglycerin) was one of the remedies listed. I reviewed the patient's medication list and saw that one of his daily medications was Nitrobid, a long acting nitrate preparation, similar to nitroglycerin. We replaced Nitrobid with another drug and the dream problem resolved.

"Truth is stranger than fiction because life doesn't give a damn about being plausible."
Leo Rosten

PAYMENT: THERE IS NO FREE LUNCH

Disease is a disturbance in the Vital Force that interferes with its ability to deal adequately with stress. Tension builds, and the Vital Force is unable to discharge it effectively. This tension causes disease symptoms. The goal of treatment is to trigger a reaction in the Vital Force so that it recognizes its problem and acts to diffuse the tension. Since tension may have been building for some time, other symptoms might appear as it gets diffused. These are usually symptoms we've had before. Hering's Law of Cure, which establishes the criteria for evaluating a healthy response, states that symptoms should appear and then disappear in the following order:

- from more to less important organs
- from center to periphery
- from top to bottom
- in the reverse order of their appearance in life

The main idea is that a disordered Vital Force spreads inner tension to the wrong places in the body. As the remedy brings more order, the pressure moves from more important organs to less important ones, and eventually leaves the body.

Another important concept is suppression. Homeopaths believe that if a symptom is suppressed by a treatment modality that is not directed at the center, more important organs may become affected. This happens, presumably, because an outlet for diffusion of tension is closed by the treatment and the Vital Force attempts to diffuse the tension elsewhere.

For example, steroid ointment is often prescribed for children with eczema. It is usually used over a long period of time to "heal" the rash and, in most cases, it does the job and everybody is happy. But such children often develop asthma a few years down the road. A dermatologist once told me that children often "grow out" of eczema and "into" asthma. Such children are said to have "atopic" tendency, and their doctors usually don't make

the connection between the use of steroids and the development of asthma.

But a homeopath looks at this case differently. The eczema is a result of a disturbance in the Vital Force. If it is suppressed by the steroids, we can expect some more serious disease to develop. So the asthma comes. When we treat a child homeopathically at this point, we expect the asthma to go away and the eczema to reappear for some time. The symptoms move from within outward (lung to skin), from the more important organ to the less important ones, and in reverse order of their appearance. If the child is not treated homeopathically and the asthma is suppressed with allopathic drugs, then in a few years, perhaps when the patient is twenty or thirty years old, the disease will deteriorate into something more serious yet, such as depression or migraine headaches. If treated at this time, the patient can be expected to pass through the asthma stage before getting the eczema back. When old symptoms return, they must not be suppressed with local treatment. **The Vital Force must not be interfered with when it is attempting to bring the disease out to the periphery; otherwise, the progress of the treatment is halted, and any gains made may disappear.**

For example, a fifty-year-old man came to me for treatment of depression and insomnia. After the remedy, he started sleeping much better. At the same time he developed a rash in his groin. He'd had a similar rash in the past, and, as a matter of fact, still had some of the cream he'd used to treat it. Without a second thought, he used the cream. The rash promptly disappeared, and so did his improved sleep pattern. We were back to square one. I explained these concepts and gave him another dose of the remedy. Luckily for him, it worked again and both the sleep and the rash came back. This time he didn't suppress it and put up with the itching for a few months. He made quite remarkable improvements in his mental health and the rash eventually resolved as well. This case is not unusual. I've seen this kind of reaction many times. That's why we homeopaths watch so closely for suppression.

The return of old symptoms can be seen as payment for getting better. When such a reaction happens, I usually ask the patient one question: "Is this worth the improvement or would you rather

have the original symptoms back?" Most patients find the improvement in their general well being so good, they're willing to tolerate a minor aggravation. It would be easy enough to reverse the case by using allopathic drugs, but my patients usually choose to wait it out.

"Be careful about reading health books. You may die of a misprint."
Mark Twain

SAFETY: DON'T PLAY WITH FIRE

A major misconception about homeopathy is that it is natural medicine that can never do any harm. It is true that homeopathy can heal gently and without side effects, but the treatment in most cases must be directed by a trained practitioner who knows how to avoid the pitfalls. I can't stress this enough. Homeopathy is a very powerful, deep-acting form of therapy. Its effects are more profound and longer lasting than those of any modern-day allopathic drugs. The longer I practice homeopathy, the more respect I gain for its power and the more cautious I become in its use.

We often say that homeopathic remedies are perfectly adopted for home use. Homeopathic first aid kits are widely available. I would not disagree. However, because this method of healing is so powerful, it is a good idea to learn as much as you can before using it on your own. See the **Further Reading** chapter at the end of this booklet for the suggestions.

Sometimes, when used inappropriately, homeopathic remedies may cause problems. These are rare but anybody planning to use homeopathic remedies at home must be aware of the possible complications and know how to avoid them.

We know that homeopathic remedies may aggravate a pre-existing condition. This is usually comparatively mild and brief. Nevertheless, in some cases, even a mild aggravation can be very serious. This must be considered especially in people with week Vital Force, such as the elderly and patients with severe chronic diseases.

For example, people with coronary artery disease have cholesterol deposits blocking the arteries that supply their heart muscle. In advanced cases they experience chest pains with even mild exertion. Coronary arteries have a tendency to spasm around obstructions and this can cause more pain and, if prolonged, a heart attack. An otherwise correct homeopathic remedy given in **too high** of a potency **for the particular patient** could produce an aggravation by causing spasm around the obstruction. A point to remember here is that the choice of the potency is always individualized and what is low for one patient may be high for another. A qualified professional will know what is appropriate in a particular case. Somebody treating such a patient at home may not know the difference and cause more trouble than they are ready for.

Another way a homeopathic remedy could cause harm is by producing a proving. This happens if a remedy is repeated too frequently and for too long, even in low potencies, especially if a patient is particularly sensitive to the remedy. The symptoms of the remedy may start appearing (as in a proving), and the patient may get quite ill. Many professional homeopaths do administer remedies in repeated doses, but they know what to watch out for. Any qualified professional homeopath should be able to recognize a proving immediately and adjust the treatment before any serious problems occur. This situation is similar to when a conventional drug produces side effects and the doctor must make changes in the treatment. Home prescribers may not always recognize the problem if they are lulled into complacency by the commonly held mistaken belief that everything natural is always safe.

Combination homeopathic remedies may cause harm in a different way. This approach creates confusion in the Vital Force and, while occasionally helping in the short run, it may cause serious health consequences in the future. You will find practitioners that would disagree with this statement, but given my education and experience I believe it to be correct. Since the jury is still out on this question, I suggest, if you are considering using over the counter combination remedies, to limit the use to no longer than a couple of days, just in case I am right. Personally, I would never use any of these preparations in my practice. This also goes for the "homeopathic weight loss patches" currently flooding the market.

In conclusion, if you are planning to use homeopathic remedies at home, first learn as much as you can; stick to lower potencies, especially in the beginning; treat only acute self limiting conditions like colds and flues; treat only generally healthy people; don't change remedies frequently; and above all, always remember your limitations and ask for proper professional help whenever you have any doubt. Then, by all means, go ahead and you too will make a miracle from time to time.

"It is always ours to question why, and never to just do and die."

This is a twisted version of a rather famous quote. It is unknown just who twisted it first.

QUESTIONS AND ANSWERS

Q. What kind of diseases can be treated with homeopathy?

A. As I have mentioned elsewhere in this booklet, Homeopathy treats the root cause of all symptoms, not specific diseases as described by conventional doctors. However, people suffering from constellations of symptoms defined as specific diseases by the allopaths, such as diabetes, asthma, duodenal ulcer and many others, may want to know if their particular problem is likely to resolve with homeopathic treatment. While everyone can benefit from homeopathic treatment regardless of their presenting complaint, some conditions are more likely to resolve then others. The conditions most likely to resolve are those in which there is no irreversible pathology. For example, asthma and emphysema are conditions involving the lungs, and while very different in their specific effect on the lungs, they present with very similar symptoms of wheezing and air hunger. Asthma is an active, inflammatory process and the lungs can heal from its effects once the patient's Vital Force is cured. Homeopathy can be very effective in getting rid of asthma. Emphysema, on the other hand, is a degenerative process that permanently destroys the lung tissue. Homeopathy can sometimes make an emphysema patient feel a little better as far as their lungs are concerned, but in most cases it can't reverse the effects of emphysema. A good homeopath may be able to give you an opinion regarding whether your specific condition is likely to resolve with the treatment. However, please keep in mind that it is the whole person we are treating, not just the presenting complaint.

Q. What interferes with homeopathic treatment?

A. First and foremost on the list of things that can interfere with a homeopathic remedy's effectiveness are strong suppressive drugs like steroids and immunosuppressants. Since birth control pills suppress the natural cycle, they too can interfere with a

remedy. Camphor oil tends to antidote the action of the remedies, as can some types of dental work. Coffee (decaf or regular) may interfere in some cases.

A strong shock, either emotional or physical, such as being injured in a motor vehicle accident or grieving the death of a close relative can interfere with the effectiveness of a homeopathic remedy.

Q. What about all those homeopathic combination remedies widely available today, like "Flu", "Sinus", Headache", "PMS", etc.?

A. First of all, they are not homeopathic because they are not individually prescribed. A patient with a headache may get one of about a thousand remedies, and it will be different for every headache sufferer. Yes, potentized drugs are used in these combinations, but it does not make them homeopathic.

Next, when numerous potentized drugs are used at one time, the Vital Force gets confused. Keep in mind that each remedy has a certain disease state associated with it. If one presents the Vital Force with several disease states all at the same time, the Vital Force gets mixed messages. If used for any length of time, these combination remedies may confuse the Vital Force to the point of no return. When I get these "confused" cases in my practice it is very hard to find a good remedy for them. Then, when the remedy is found, it takes ten fold more time for the remedy to work. In my opinion, its much healthier to take Tylenol for your headaches, decongestant for your sinuses and antihistamine for your insomnia (all in moderation of course), then to use homeopathic combination remedies.

Q. Do homeopaths use electronic equipment for diagnosis?

A. Some practitioners who call themselves homeopaths do. But to a classical prescriber these practitioners are not, strictly speaking, homeopaths. They use homeopathic remedies in a non-homeopathic way. The same goes for those practitioners who inject the remedies. There may be value in these approaches, but they probably shouldn't be called homeopathy. In classical teaching, a patient should either ingest (eat) or inhale (sniff) the remedy.

Q. Is homeopathy the same as herbal medicine? Is it a combination of herbs, diets, vitamins and counseling?
A. No, though this can be confusing, as some practitioners do get involved in both homeopathy and nutritional counseling. My personal philosophy is that as you improve in your health, your body will desire healthy food. When my patients request assistance with their diets, I refer them to a nutritionist who is properly trained in that specialty.

Regarding herbs, they are, strictly speaking, allopathic drugs. In homeopathy, drugs are chosen according to the principle of similarity (like cures like). In conventional or allopathic medicine, drugs are chosen on the principle of opposite (a drug must have action opposite to that of the disease). For example, a narcotic lessens a patient's sensitivity to pain, so it can be used if a person is experiencing pain. An expectorant makes one's respiratory tract secrete more mucus, so it can be used when cough is too dry. These effects can be achieved by either natural drugs, like herbs, or synthetic drugs, like most conventional medications. Conceptually, there is little difference between the two approaches. One must realize that no chronic condition could be cured by this method. The most one can hope for is palliation, or temporary improvement. However, sometimes this is all that is desired, and if one chooses to use an allopathic approach to treat a condition, a drug that is the most effective and has the least side effects should be chosen, whether herbal or synthetic.

It is possible to use herbs in a homeopathic way as well, but practitioners who do this well are very hard to find, and such a practice is very poorly standardized. Most herbalists are allopathic.

Q. What is the best remedy for hay fever, headache, flu, diarrhea, depression, etc.?
A. There is no such remedy. Homeopathic remedies are not chosen on such indications.

Q. Will I have to be on a homeopathic remedy for the rest of my life?
A. No, you will only be on a remedy until you achieve the desired state of health.

Q. Are all homeopaths medical doctors? How do I find a good homeopath?
A. No. In fact, I would not base my choice of a homeopath on the appearance of MD or DO after their name. My personal homeopath has initials RSHom (Registered with Society of Homeopaths). These initials are certified by the North American Society of Homeopaths exclusively for "non-licensed" practitioners. This title carries a lot of weight. The best way to find a good practitioner is to get referred to one by a happy patient. If you don't know anybody seeing a good homeopath, call the practitioners in the area and inquire if they are classical and how much time they allow for the first visit. If they are combination prescribers (non-classical) or schedule less then one hour I would be skeptical. It is possible for a very advanced practitioner to spend less time on the first interview, but most of us require at least an hour to get a good case history. Personally, I schedule two hours for my new patients. One way to find a good homeopath is by calling a homeopathic study group in your area and asking them. They would be very happy to refer you. A study group in your area can be found in the referral list put out by the National Center for Homeopathy @ (703) 548-7790

Q. What do all those letters mean?
A. Many homeopaths have different initials after their names. These are usually titles awarded by different homeopathic boards and schools. Because homeopathic education and certification in the US have not been standardized yet there are several groups certifying their members. Any certification, of course, speaks only of the particular homeopath's ability to satisfy the particular board's minimum competency requirements and may not reflect the practitioner's true level of mastery.
Here are some of the titles you may find:
DHt (Diplomate of Homeotherapeutics): Given by the American Institute of Homeopathy to medical doctors passing their exam. The AIH is the oldest organization of physicians in the US, predating the AMA. In fact, the AMA was originally founded in response to the threat perceived by the allopathic (conventional) doctors of the time, from homeopaths forming a national organization.
DHANP (Diplomate of Homeopathic Academy of Naturopathic Physicians): As the name implies, this is a title similar to DHt given by the naturopathic board.

DNBHE (Diplomate of National Board of Homeopathic Examiners): This one may sound a bit misleading. It is awarded by a group of chiropractic homeopathic educators to practitioners passing their exam.

MFHom (Member of the Faculty of Homeopathy): Given by the Faculty of Homeopathy, the British equivalent of the AIH, to doctors passing their exam. This title is recognized by medical authorities throughout European Community and other countries having historical ties to the United Kingdom. The Faculty runs a fairly intensive educational program attracting doctors from all over the world.

FFHom (Fellow of the Faculty of Homeopathy): Awarded to doctors holding the title of MFHom and showing certain extra achievement, particularly in the area of homeopathic education.

RSHom(NA) (Registered with Society of Homeopaths (North America)): Given by NASH (North American Society of Homeopaths). NASH accepts only non-licensed practitioners as members and this title signifies the practitioner's passing of membership requirements which include demonstrating proficiency in classical homeopathy. This title was originally modeled on RSHom of Great Britain.

CCH (Certified in Classical Homeopathy): Given by CHC (Council for Homeopathic Certification), a fairly new board trying to unite all these different groups under a common umbrella. This title certifies that the practitioner, regardless of their licensure status, passed a minimum competency exam in classical homeopathy. The interesting new twist added by this board is a medical portion of the exam required for all non-medically licensed applicants. This is the first attempt in modern history of homeopathy in this country to make sure the practitioner possesses a certain minimum of conventional medical knowledge in addition to proficiency in homeopathy.

CTHom (Certified Trained Homeopath): This is a diploma given by ESSH School of Homeopathy in Flagstaff, AZ, to students demonstrating a certain degree of mastery in classical homeopathy. I have a heavy personal bias in favor of this title. I believe its bearers are some of the best homeopaths available. However, this should in no way diminish the importance of other titles mentioned above. There are other titles given by other groups, some probably very good, but having no personal familiarity with them I will not mention them here.

Q. Will my insurance pay for homeopathy?

A. I have been told that some insurance companies are coming around. However, be sure to call regarding your specific policy before you get treatment to verify coverage. If your homeopath is an MD or DO and your policy allows you to see that doctor—you may be reimbursed according to plan rules.

Q. What are the different kinds of homeopathy?

A. There are two major schools of homeopathy in the world today: classical homeopathy, which I've described here, and pluralist homeopathy. Classical homeopathy is also called Hahnemannian or unicist. Its main principle is to use one remedy at a time to address the whole person. The pluralist approach uses several remedies simultaneously. It is prevalent in France and is used by some practitioners in this country. Pluralist homeopathy is generally frowned upon by classical prescribers who believe that it is difficult enough to find the one right remedy and follow its effect on the patient. Therefore, giving several remedies at once makes it impossible to determine which of them is causing the change in the patient's condition. We are also concerned about the possible deleterious effect on the Vital Force that may be produced by such prescribing, but as I have mentioned elsewhere, the jury is still out on this one.

Q. Has homeopathy been put through scientific testing?

A. When I tell my doctor colleagues about homeopathy, they always want to see some "hard data." In the medical world this usually takes the form of studies. Such studies are carried out in a "double-blind, placebo-controlled" fashion. This means that two groups of people take either an active drug or a sugar pill that looks the same. The pills are administered by a third party and neither the researcher nor the patient know what anybody is taking until the code is broken. The results of these studies really help address the issue of whether the drug is indeed effective or a placebo effect is occurring. The studies I quote in the appendix show that the submolecular dilutions used in homeopathy really do produce significant effect on living beings, both humans and animals. Science can't explain homeopathy yet, but it is really immaterial as long as we can demonstrate that it works.

Q. Are homeopathic remedies all natural?
A. If you haven't read the entire book, this answer may not make sense to you. The point is, who cares what the remedies are, if the healing is natural. The remedies don't really have any effect on the body other than to trigger the Vital Force to react. Once it reacts, healing takes place from within, directed by the Vital Force. That is, we heal ourselves, and that is the most natural kind of healing.

If you still insist on the answer—most are indeed, natural. Whether this should prompt you to use homeopathy is another question. You should decide to use it for *completely* different reasons. Here are some examples of homeopathic remedies:

Mineral Source:
Arsenicum Album (white oxide of arsenic)
Silica (sand)
Graphites (lead from "fine English pencil")
Sulphur (elemental sulphur)
Aurum (gold)
Argentum nitricum (silver nitrate)
Petroleum (petroleum)
Hydrogen (hydrogen gas)
Mercurius vivus (mercury)

Plant Source:
Rhus toxicodendron (poison ivy)
Conium maculatum (poison hemlock)
Chamomilla (daisy)
Thuja occidentalis (arbor vitae)
Carbo vegetabilis (vegetable charcoal)
Phytolacca decandra (poke-root)
Urtica urens (stinging nettle)
Lilium tigrinum (tiger lily)

Animal Source:
Crotalus horridus (venom of rattle snake)
Pyrogenium (rotten meat)
Lac caninum (dog's milk)
Lyssin (saliva of rabid dog)
Tarentula Hispanica (tarantula, tincture of the living spider)
Apis mellifica (honey-bee, tincture of the whole bee)

And then there are other things I don't care to mention as an unaware reader might have an inclination to vomit. Of course, all of these things are natural and therefore good for you, right? Right!, but only if well prescribed and given in the appropriate homeopathic form, and not because they are natural.

Q. Is homeopathy safe in pregnancy?
A. This is a hard one. It probably is, but as with all healing modalities, one has to be very careful. One always has to weigh the risk of treatment vs. non-treatment. If the mother has a certain clear state that definitely needs treatment, there is a strong chance that she will give this state to the baby if untreated, and it may be a good idea to treat them both at the same time and for the price of one—but very carefully, and only when the remedy is very clearly indicated.

"Get your facts first, and then you can distort them as much as you please."

Mark Twain

APPENDIX

Quadruple — Blind (Editorial), *The Lancet*, April 22 1989, p. 914.4

Complete Text

Can blind discussion remove bias from the reader? Take a trial in which 149 general practitioners entered 487 patients with an influenza-like syndrome into a randomized double-blind comparison of active treatment and matching placebo, both given sublingually.[1] The first dose was supervised, the other four doses were taken on the following mornings and evenings. 478 of the entered patients (98.2%) met the admission criteria (5 out of 242 patients in the active treatment group and 4 out of 245 placebo patients were ineligible). At admission the groups were similar in age and proportion with severe illness. The patients recorded their rectal temperature morning and evening and whether they still had any or all of five cardinal symptoms within forty-eight hours of the start of treatment. The recovery rates were 39/228 (17.1%) in the active treatment group and 24/234 (10.3%) in the placebo group (P=0.03,X^2). The relative risk of recovery was 1.67 (95% confidence interval [CI] 1.1-2.7). The difference in the proportion of patients who recovered was 6.8% (95% CI 0.6-13.0%). Logistic regression showed that several potential confounders did not substantially alter the effect of active treatment (odds ratio 1.9, 95% CI 1.1-3.4; P=0.02). Age and severity at admission were significantly associated with recovery: younger patients and those with mild or moderate illness recovered better, as might be expected. All the patients were asked about the effectiveness of their therapy, and more expressed favourable judgments about the active treatment (61% *vs.* 49%, P=0.02). Use of other symptom-relieving drugs for pain, fever, cough, or coryza and use of antibiotics were not confounders; in fact, more patients in the placebo group used compounds to relieve pain or fever. Can the trial be criticized more than the authors do already? There might have been

[1] Ferley JP, Zmirou D, D'Adhemar D, Balducci F. "A Controlled Evaluation of a Homeopathic Preparation in the Treatment of Influenza-like Syndromes." *Br F Clin Pharmacol* 1989;27:329-35.

imbalances between the general practitioners in their recruitment of patients: every participating doctor should have entered 4-6 patients, to give a total of at least 596 cases. Also, data on 16 eligible patients were not analyzed for efficacy. There were only four unsupervised doses, but compliance was not reported. Finally side-effects in both groups were not recorded or reported. The authors are restrained in their discussion "The effect was modest ... but nevertheless is of interest". *A 7% difference in efficacy as defined would be a respectable proportion in most drug trials*[2]. Now let the code be broken—the active treatment was a homeopathic preparation.

Ferley, J.P., A Controlled Evaluation of Homeopathic Preparation in the Treatment of Influenza-like Syndromes, *British Journal of Clinical Pharmacology*, 1989, 27, pp. 329-335.

1. A controlled clinical trial was conducted to assess the effectiveness of a homeopathic preparation in the treatment of influenza-like syndromes.
2. 237 cases received the test drug and 241 were assigned to placebo. Patients recorded their rectal temperature twice a day, and the presence or absence of five cardinal symptoms (headache, stiffness, lumbar in articular pain, shivers) along with cough, coryza and fatigue.
3. Recovery was defined as a rectal temperature less than 37.5°C and complete resolution of the five cardinal symptoms.
4. The proportion of cases who recovered within 48 h of treatment was greater among the active drug group than among the placebo group (17.1% against 10.3%, *P*=0.03).
5. The result cannot be explained given our present state of knowledge, but it calls for further rigorously designed clinical studies.

Reilly, D.T., Is Homeopathy a Placebo Response? Controlled Trail of Homeopathic Potency, with Pollen in Hay Fever as a Model, *The Lancet*, October 18, 1986, pp. 881-886.

The hypothesis that homeopathic potencies are placebos was tested in a randomized, double-blind, placebo-controlled trial. The study model chosen compared the effects of a homeopathic preparation of mixed grass pollens with placebo in 144 patients

[2] My emphasis.

with active hay fever. The homeopathically treated patients showed a significant reduction in patient and doctor assessed symptom scores. The significance of this response was increased when results were corrected for pollen count and the response was associated with a halving of the need for antihistamines. An initial aggravation of symptoms was noted more often in patients receiving the potency and was followed by an improvement in that group. No evidence emerged to support the idea that placebo action fully explains the clinical responses to homeopathic drugs.

Day, C.E.I., Control of Stillbirths in Pigs Using Homeopathy, *International Journal for Veterinary Homeopathy*, Vol. 1, No. 2, October 1986, pp. 26-28.

The author tested Caulophyllum C30 for its effect against stillbirth in a herd of pigs. Ten sows received Caulophyllum C30 prior to farrowing; ten sows received no treatment (control). Stillbirth rate was over 20, 8% in the control and 10, 3% in the treated group. These results are statistically significant.

Fisher, P., Effect of Homeopathic Treatment on Fibrositis (Primary Fibromyalgia), *British Medical Journal*, 1989, 229, pp. 365-6.

Fibrositis (primary Fibromyalgia) is a controversial condition but is becoming increasingly accepted. It is difficult to treat. We showed that the homeopathic medicine *Rhus toxicondendron* 6c was effective for a selected subgroup of patients with fibrositis. The improvement in tenderness, which is the best discriminator of fibrositis, was particularly distinct. The improvement experienced by our patients while receiving active treatment was at least as great as that reported for any other treatment that has been assessed double blind.

Kleijnen, J., Clinical Trials of Homeopathy, *British Medical Journal*, 1991, 302, 216-23.

Objective—To establish whether there is evidence of the efficacy of homeopathy from controlled trials in humans.

Design—Criteria based meta-analysis. Assessment of the methodological quality of 107 controlled trials in 96 published reports found after an extensive search. Trials were scored using a list of predefined criteria of good methodology, and the outcome of the trials was interpreted in relation to their quality.

Setting—Controlled trials published world wide.

Main outcome measures—Results of the trials with the best methodological quality. Trials of classical homeopathy and several modern varieties were considered separately.

Results—In 14 trials some form of classical homeopathy was tested and in 58 trials the same single homeopathic treatment was given to patients with comparable conventional diagnoses. Combinations of several homeopathic treatments were tested in 26 trials; isopathy was tested in nine trials. Most trials seemed to be of very low quality, but there were many exceptions. The results showed a positive trend regardless of the quality of the trial or the variety of homeopathy used. Overall, of the 105 trials with interpretable results, 81 trials indicated positive results whereas in 24 trials no positive effects of homeopathy were found. The results of the review may be complicated by publication bias, especially in such a controversial subject as homeopathy.

Conclusions—At the moment, the evidence of clinical trials is positive but not sufficient to draw definitive conclusions because most trials are of low methodological quality and because of the unknown role of publication bias. This indicates that there is a legitimate case for future evaluation of homeopathy, but only by means of well performed trials.

Gibson, R.G., Homeopathic Therapy in Rheumatoid Arthritis: Evaluation by Double-Blind Clinical Therapeutic Trial, *British Journal of Clinical Pharmacology*, 1980, 9, pp. 453-459.

1. Twenty-three patients with rheumatoid arthritis on orthodox first-line anti-inflammatory treatment plus homeopathy were compared with a similar group of twenty-three patients on orthodox first-line treatment plus an inert preparation.
2. There was a significant improvement in subjective pain, articular index, stiffness and grip strength in those patients receiving homeopathic remedies, whereas there was no significant change in the patients who received placebo.
3. Two physicians were involved in prescribing for the patients and there were no significant differences in the results which they obtained.
4. No side effects were observed with the homeopathic remedies.

Jacobs, J. et al, Treatment of Acute Childhood Diarrhea with Homeopathic Medicine: A Randomized Clinical Trial in Nicaragua, *Pediatrics*, Vol. 93, No. 5, May 1994, pp. 719-725.

Objective—Acute diarrhea is the leading cause of pediatric morbidity and mortality world-wide. Oral rehydration treatment can prevent death from dehydration, but does not reduce the duration of individual episodes. Homeopathic treatment for acute diarrhea is used in many parts of the world. This study was performed to determine whether homeopathy is useful in the treatment of acute childhood diarrhea.

Methodology—A randomized double-blind clinical trial comparing homeopathic medicine with placebo in the treatment of acute childhood diarrhea was conducted in Leon, Nicaragua, in July 1991. Eighty-one children aged 6 months to 5 years of age were included in the study. An individualized homeopathic medicine was prescribed for each child and daily follow-up was performed for 5 days. Standard treatment with oral rehydration treatment was also given.

Results—The treatment group had a statistically significant ($P<.05$) decrease in duration of diarrhea, defined as the number of days until there were less than three unformed stools daily for 2 consecutive days. There was also a significant difference ($P<.05$) in the number of stools per day between the groups after 72 hours of treatment.

Conclusions—The statistically significant decrease in the duration of diarrhea in the treatment group suggests that homeopathic treatment might be useful in acute childhood diarrhea. Further study of this treatment deserves consideration.

Reilly, D., et. al, Is Evidence for Homeopathy Reproducible?, *The Lancet*, 1994; 344: pp. 1601-06

We tested under independent conditions, the reproducibility of evidence from two previous trials that homeopathy differs from placebo. The test model was again homeopathic immunotherapy.

Twenty-eight patients with allergic asthma, most of them sensitive to house-dust mite, were randomly allocated to receive either oral homeopathic immunotherapy to their principal allergen or identical placebo. The test treatments were given as a complement to their unaltered conventional care. A daily visual analogue scale of overall symptom intensity was the outcome measure. A difference in visual analogue score in favour of

homeopathic immunotherapy appeared within one week of starting treatment and persisted for up to 8 weeks (P=0.003). There were similar trends in respiratory function and bronchial reactivity tests.

A meta-analysis of all three trials strengthened the evidence that homeopathy does more than placebo (P=0.0004). Is the reproducibility of evidence in favour of homeopathy proof of its activity or proof of the clinical trial's capacity to produce false-positive results?

Linde, K., et all, Are the clinical effects of homeopathy placebo effects? A meta-analysis of placebo-controlled trials, *The Lancet* , 1997; 350: pp.834-43

Background Homeopathy seems scientifically implausible, but has widespread use. We aimed to assess whether the clinical effect reported in randomized controlled trials of homeopathic remedies is equivalent to that reported for placebo.

Methods We sought studies from computerized bibliographies and contacts with researchers, institutions, manufacturers, individual collectors, homeopathic conference proceedings, and books. We included all languages. Double-blind and/or randomized placebo-controlled trials of clinical conditions were considered. Our review of 186 trials identified 119 that met the inclusion criteria. 89 had adequate data for meta-analysis, and two sets of trials were used to assess reproducibility. Two reviewers assessed study quality with two scales and extracted data for information on clinical condition, homeopathy type, dilution, "remedy", population, and outcomes.

Findings The combined odds ratio for the 89 studies entered into the main meta-analysis was 2.45 (95% CI 2.05, 2.93) in favor of homeopathy. The odds ratio for the good-quality studies was 1.66 (1.33, 2.08), and that corrected for publication bias was 1.78 (1.03, 3.10). Four studies on the effects of a single remedy on seasonal allergies has a pooled odds ratio for ocular symptoms at 4 weeks of 2.03 (1.51, 2.74). Five studies on postoperative ileus had a pooled mean effect-size-difference of -0.22 standard deviations (95 % CI -0.36, -0.09) for flatus, and -0.18 SDs (-0.33, -0.03) for stool (both $p<0.05$).

Interpretation The results of our meta-analysis are not compatible with the hypothesis that the clinical effects of homeopathy are completely due to placebo. However, we found insufficient evidence from these studies that homeopathy is clearly efficacious for any single clinical condition. Further, research is warranted provided it is rigorous and systematic.

END NOTES

1. Harris L. Coulter, *Divided Legacy: The Conflict Between Homeopathy and the American Medical Association.* (Berkeley, CA: North Atlantic Books, 1973).

2. William A Tiller, Ph.D., "Towards a Scientific Rationale of Homeopathy," *Journal of Holistic Medicine*, Vol. 6, No. 2, Fall 1984, (Human Sciences Press), pp. 130-147.

3. James Tyler Kent, *Lectures on Homeopathic Materia Medica*, (New Delhi: Homeopathic Publications, 1920), page number 3.

Leo Rosten's, *Carnival of Wit*, (New York City, NY: Penguin Books). This is where many of the quotes come from.

Further Reading

Dooley, Timothy, MD, ND:
Homeopathy: Beyond Flat Earth Medicine
Timing Publishers, San Diego, CA, ISBN 1-886893-00-4
This is a great book! It discusses essentially the same subjects as my book, but in a different way. Some people seem to relate better to Tim's presentation than to mine. I highly recommend this book.

Panos, Maesimund B., MD and Heimlich, Jane: ***Homeopathic Medicine at Home***
J.P. Tarcher, Inc., Los Angeles, CA, ISBN 0-87477-195-1
This book is for those who would like to dabble in homeopathy a bit. It will give you the guidelines for prescribing for acute conditions, like injuries, flues, earaches, etc. This book is well written and easy to understand. But be careful! Stick to low potencies, prescribe only when indications are very clear, and don't change remedies often!

Vithoulkas, George: ***The Science of Homeopathy***
Grove Press, Inc., New York, NY, ISBN 0-394-17560-3
As the title implies, we are getting more serious here. This is a definitive work on homeopathic philosophy and practice.

Hahnemann, Samuel: ***The Organon of Medicine***
J.P. Tarcher, Inc., Los Angeles, CA, ISBN 0-87477-223-0
This is the source. This is where it starts and this is where we always come back to when in doubt. This is the homeopath's bible. It is not to be read lightly, but studied, preferably under direction of a good teacher.

Coulter, Harris L.: ***Divided Legacy: The Conflict Between Homeopathy and the American Medical Association***
North Atlantic Books and Homeopathic Educational Services Berkeley, CA , ISBN 0-913028-96-7
This is for history buffs. This book traces the complete history of homeopathy in the United States: from the beginning in the mid-1800s, through the height of popularity, and down through the decline at the turn of the 20th century.

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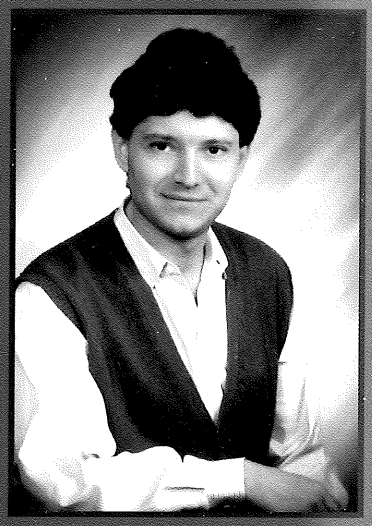

Dr. Mirman's mission in life is to make classical homeopathy recognized as a major medical specialty by the medical community while maintaining the quality of its practice through certification of all practitioners by reputable homeopathic boards.
Dr. Mirman lives with his wife and two children in Minneapolis, Minnesota.

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CLINICAL MEDICINE

By David B. Jewett, M. D., Department Editor

HOMEOPATHY IN INFLUENZA—A CHORUS OF FIFTY IN HARMONY

By W. A. Dewey, M. D., University of Michigan

In a plant of 8,000 workers we had only one death. The patients were not drugged to death. Gelsemium was practically the only remedy used. We used no Aspirin and no vaccines. —Frank Wieland, M. D., Chicago.

Absence of the customary drugging was also an element of the remarkable success in this plant.—Burton Haseltine, M. D., Chicago.

There is one drug which directly or indirectly was the cause of the loss of more lives than was influenza itself. You all know that drug. It claims to be Salicylic acid. Aspirin's history has been printed. Today you don't know what the sedative action of Salicylic acid is. It did harm in two ways. Its indirect action came through the fact that Aspirin was taken until prostration resulted and the patient developed pneumonia.—Frank L. Newton, M. D., Somerville, Mass.

I did not lose a single case of influenza; my death rate in the pneumonias was 2.1%. The salycilates, including Aspirin and Quinine, were almost the sole standbys of the old school and it was a common thing to hear them speaking of losing 60% of their pneumonias.—Dudley A. Williams, M. D., Providence R. I.

Three hundred and fifty cases and lost one, a neglected pneumonia that came to me after she had taken one hundred grains of Aspirin in twenty-four hours.—Cora Smith King, M. D., Washington, D. C.

Dean W. A. Pearson of Philadelphia collected 26,795 cases of influenza treated by homeopathic physicians with a mortality of 1.05%, while the average old school mortality is 30%.

My low death rate at Camp Lee was due entirely to the fact that I avoided the use of Aspirin absolutely. I was complimented by the chief medical officer as having the lowest death rate in the hospital. After the medical chief had noted the effect of Aspirin on the blood and the results which I was having in using Homeopathy he discouraged the use of Aspirin and the death

I treated 455 cases of influenza and 26 cases of pneumonia with no deaths. Remedies: Gelsemium, Bryonia, Epis, etc. —T. G. Barnhill, M. D., Findlay, Ohio.

The importance of homeopathic remedies has been emphasized; 24 out of 42 cases who used vaccines had influenza and there were 8 cases of pneumonia—so vaccines as a prophylactic failed.—W. L. Love, M. D., Brooklyn.

Eleven men reported 3,600 cases with 6 deaths. My records show 750 cases with one death. Gelsemium, Bryonia and Eupatorium were the remedies chiefly.—F. A. Swartwout, M. D., Washington, D. C.

The more Aspirin, Codein, Dobell's solution and other extra-homeopathic remedies used the slower the recovery.—James W. Ward, M. D., San Francisco.

The mortality rate in a camp was for pneumonia 25.8%. The lieutenant in charge was persuaded to discontinue Aspirin, Digitalis and Quinine and the mortality dropped speedily to 15% with no medicine whatever. This was in one ward. Whereupon it was ordered in other wards and the mortality dropped to 15% with no medicine.—W. A. Pearson, M. D., Philadelphia.

I treated 618 cases and had 5 deaths. Three of these had had allopathic treatment.—R. S. Faris, M. D., Richmond, Va.

One physician in a Pittsburgh hospital asked a nurse if she knew anything better than what he was doing, because he was losing many cases. "Yes, Doctor, stop Aspirin and go down to a homeopathic pharmacy, and get homeopathic remedies." The Doctor replied: "But that is Homeopathy." "I know it, but the homeopathic doctors for whom I have nursed have not lost a single case."—W. F. Edmundson, M. D., Pittsburgh.

It is a rare thing for pneumonia to develop if a good homeopathic physician is called during the first 24 hours of an attack of influenza. An appalling death rate comes from the baneful results of large doses of Aspirin, salicylates and opium preparations.—A. H. Grimmer, M. D., Chicago.

Murphy, of Lansing, Michigan, treated 325 cases of influenza in a camp where the mortality had been 20%, while the mortality under his homeopathic treatment was less than 3%.—W. H. Wilson, M. D., Chicago.

I have treated 1,000 cases of influenza. I have the records to show my work. I have no losses. Please give all credit to Homeopathy and none to the Scotch-Irish-American!—T. A. McCann, M. D., Dayton, Ohio.

rate came down very rapidly after that ruling.—Carleton A. Harkness, M. D., Chicago.

In Hahnemann Hospital of San Francisco, homeopathic remedies acted in a curative way while, with some other forms of treatment, the result was only palliative.—Laura A. Hurd, M. D., San Francisco.

Fifteen hundred cases were reported at the Homeopathic Medical Society of the District of Columbia with but fifteen deaths. Recoveries in the National Homeopathic Hospital were 100%.—E. F. Sappington, M. D., Philadelphia.

I attended over one hundred cases without any fatalities. I never deviated from the homeopathic remedy. I never gave Aspirin. One case that was loaded with Aspirin before I saw him, referred to me from an old school physician, died. This epidemic should encourage us to renewed faith in Homeopathy. —G. H. Wright, M. D., Forest Glen, Md.

The German Aspirin has killed more people than the German bullets killed.—C. J. Loizeaux, M. D., Des Moines, Iowa.

I remember Acetanilid in the epidemic of 1889 and its fatalities. In this epidemic I knew that Aspirin and the coal tar products would kill more people than the disease itself and it has so proved. One old school physician told me that he had gotten wise to the fact that Aspirin was killing his patients and that he had stopped using it and was relying on homeopathic and eclectic remedies.—E. B. Finney, M. D., Lincoln, Neb.

Thirty physicians in Connecticut responded to my request for data. They reported 6,602 cases with 55 deaths, which is less than 1%. In the transport service I had 81 cases on the way over. All recovered and were landed. Every man received homeopathic treatment. One ship lost 31 on the way.—H. A. Roberts, M. D., Derby, Conn.

Homeopathy saved patients with influenza and pneumonia, ill luck always followed the coal tar derivatives, Aspirin especially.—W. H. Hanchett, M. D., Omaha, Neb.

Through the International Hahnemannian Association I have collected over 17,000 cases of influenza with a mortality of 4%. —G. B. Stearns, M. D., New York.

I had 300 cases and one death; one good homeopathic doctor had 275 cases and no deaths. I am health officer of my city. One old school man had 294 cases and reported 15 deaths. Aspirin and Iodized lime were the remedies used by the old school.—H. H. Crum, M. D., Ithaca, N. Y.

In the month of October, 1918, I treated, in round numbers, 200 cases of influenza without a death.—W. R. Andrews, M. D., Mannington, W. Va.

Dr. M. I. Boger of Portsmouth, N. H., treated 331 cases with 2 deaths. Dr. G. G. Bascom of Lake Wilson, Minn., 300 cases with no deaths.—E. C. Price, M. D., Baltimore.

The word Homeopathy stands for so much that is good and true and useful in the medicinal therapy of the year of our Lord 1919.—O. S. Haines, M. D., Philadelphia.

I have treated 267 cases of influenza. No deaths.—A. B. Hawes, M. D., Bridgewater, S. D.

In one month treated 65 cases of influenza with one death and that in a tubercular case.—F. C. Thornhill, M. D., Alma, Mich.

One of the principal druggists of Montreal told Dr. T. A. McCann that they had lost 900 patients from influenza. Being asked what drug they used most he replied that Aspirin was used more than all other drugs combined. The directions were to take a 5-grain tablet every three hours, but more took ten grains every three hours. Comment is unnecessary.

Seventy-six cases developed in the Children's Home without any complicating pneumonia or death. Most of the cases were on Bryonia and Gelsemium, which seemed to be successful in carrying them through to complete recovery.—J. G. Dillon, M. D., Fargo, N. D.

It has been my experience that Gelsemium was most always the first remedy and served the purpose well in early conditions. —E. B. Hooker, M. D., Hartford, Conn.

I had a package handed to me containing 1,000 Aspirin tablets, which was 994 too many. I think I gave about a half dozen. I could find no place for it. My remedies were few. I almost invariably gave Gelsemium and Bryonia. I hardly ever lost a case if I got there first, unless the patient had been sent to a drug store and bought Aspirin, in which event I was likely to have a case of pneumonia on my hands.—J. P. Huff, M. D., Olive Branch, Ky.

Aspirin and the other coal tar products are condemned as causing great numbers of unnecessary deaths. The omnipresent Aspirin is the most pernicious drug of all. It beguiles by its quick action of relief of pain, a relief which is but meretricious. In several cases Aspirin weakened the heart, depressed the vital forces, increased the mortality in mild cases and made conva-

lescence slower. In all cases it masks the symptoms and renders immeasurably more difficult the selection of the curative remedy. Apparently Aspirin bears no curative relation to any disease and it ought to be prohibited.—Guy Beckly Stearns, M. D., New York.

One thousand eclectic physicians were asked to name the remedies most useful in influenza and in pneumonia. Over 75% named Aconite and Bryonia in pneumonia.—Lloyd Brothers, Cincinnati.

Experimental research conducted in the Hygienic Laboratory, Washington, D. C., failed to show any evidence in favor of vaccine in pneumonia. "Imagine such a confession relative to our own well-tried remedies, Gelsemium, Rhus tox., Eupatorium, etc., whose indications are fixed, definite, unchangeable and permanent."—Homeopathic Recorder, October, 1920.

In the Public Health service in New Mexico among the Mexican population chiefly Veratrum viride, Gelsemium and Bryonia were introduced and excellent results followed their use in influenza. No cases died under homeopathic medication.—C. E. Fisher, M. D., Chicago.

The reasons why children fared better than adults in the influenza epidemic were, first, they were seen earlier by the physician; second, they were not drugged with "sure cures"; third, they were not filled up with Aspirin; fourth, they were put to bed; and fifth, they were given the proper remedy and had a fine chance.—Dr. J. P. Cobb, Chicago.

All of the people under my care who died of influenza had of their own accord taken Aspirin before I saw them.—W. P. Best, M. D., Indianapolis.

There may be some hearts that can withstand Aspirin; there may be some hearts that can withstand influenza; but there are no hearts that can withstand both Aspirin and influenza.—Dr. Taylor, Philadelphia.

Gelsemium does not depress the heart and is superior to Aspirin and other coal tar derivatives in all particulars for La Grippe.—J. A. Munk, M. D., Los Angeles.

Many patients had been advised to take Aspirin as a prophylactic against influenza and influenza pneumonia. One lady had taken 240 grains in 48 hours. She was sent to the hospital diagnosed as scarlet fever because of the red spots on her body. Many cases who came to the hospital (Haynes Memorial) were filled up with Aspirin, Codein, Morphine and Digitalis. Men in government work praised our hospital for its homeopathic treat-

ment in influenza. They do not all agree, however, but they have a feeling in Boston that we have a wonderful treatment for influenza.—Samuel Clement, M. D., Boston.

During the "flu" period almost every victim got his Aspirin. Almost everybody believed in it because it relieved his distress and "couldn't do him any harm." The result was that thousands died who might have lived had they been willing to bear discomfort for a little while. They died like flies around a plate of poison although "science" did all that could be done to "save" them.—A. F. Stevens, M. D., St. Louis.

We treated over 300 cases of influenza among the members of the Student Army Training Corps with no deaths. Gelsemium, Bryonia and Ferum phosphoricum were the leading remedies. Only in those cases having had Aspirin was convalescence delayed and pneumonia produced.—C. B. Stouffer, M. D., Ann Arbor.

In some 150 cases treated in the first "Flu" epidemic Gelsemium and Bryonia were the chief remedies. Very few had pneumonia, none that I treated from the beginning. Only one died under my care, a man of sixty, having had asthma and brought into our Minnesota climate in the midst of a severe winter, a truly septic pneumonia.—Wm. E. Leonard, M. D., Minneapolis.

I treated approximately 50 cases of influenza, had two pneumonias, one in a pregnant woman. All recovered. Remedies Gelsemium, Bryonia and Rhus, chiefly.—Wm. Boericke, M. D., San Francisco.

I treated over 100 cases of influenza and pneumonia, lost two cases, one who had taken Aspirin for a week when pneumonia developed before I was called; the other a very malignant case with very high temperature from the onset. Remedies: Gelsemium, Eupatorium, Bryonia, etc.—C. P. Bryant, M. D., Seattle.

I treated approximately 500 cases which included much pneumonia, lost two cases; never used Aspirin nor permitted it to be used. Chief drugs used were Belladonna, Gelsemium, Sticta for the throat symptoms, Mercurius, Natrum muriaticum and Kali muriaticum—A. B. Palmer, M. D., Seattle.

A permanent international association for the prevention of tuberculosis, composed of representatives of all nations signatory to the League of Nations covenant and of the United States, was formed, October 19th, at an international antituberculosis conference in Paris. The first meeting will be held in the fall of 1921 at London.

Homeopathy for Influenza

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When the flu strikes. Think Homeopathy! Its time has come ...

by Sally Tamplin B.Ed (Hons.) DSH, MARH CMT

It would seem that we are living in an age of increasing disaster and chaos. In the aftermath of hurricane Katrina and the earthquake in Asia we are now contemplating the possibility of a flu pandemic. Indeed it would appear that the latest avian flu threat is a hot topic; the newspapers, television and radio broadcasts are continuously informing us every day the about the increasing number of people who may succumb to this virus and there has been some discussion about the effectiveness and shortage of anti viral medicines. Health experts warn that the Bird Flu vaccine may come too late, it could take six months to manufacture adequate vaccine stocks and current stocks may be useless because the flu virus has mutated. Clearly some people are beginning to panic. In the light of this current situation I felt it necessary to update and rewrite this article which was originally published a few years ago.

Over many centuries medical practitioners have always noted that in any epidemic there are always a number of people, who despite exposure, never seem to get sick. These people seem to have stronger constitutions and are less susceptible. Unfortunately, many of us have weaker constitutions, and we are asking ourselves what we can do to keep the flu at bay this year. For most of us if we do get sick it is not likely to be a life-threatening problem, there will simply be the inconvenience of a few days off work or school. However, there are growing numbers of people who are immune compromised and for them an encounter with the predicted avian flu may land them in hospital or prove to be life threatening. The current press is speculating that hospitals will be overwhelmed and that many people will die.

During the 1918 influenza pandemic fifty million people died worldwide, much more than those struck down by bullets in the trenches of wartime France. Scientific evidence indicates this was an avian influenza that managed to mutate and infect the human population. It was young people, in the prime of their life, 25 -34 years of age, which were most severely affected; they appeared to have no immunity and succumbed to a pneumonia that would kill within days. It was not uncommon for someone physically strong and in good health to get up feeling well in the morning and by bedtime they would be dead.

As a homeopath and Executive Director of The Minnesota Homeopathic Association, one of my main priorities is to inform the general public about this wonderfully effective system that can help the body to heal quickly and without the toxic side effects of conventional medications. However, few people understand the principles and practice of homeopathy. Most people that I encounter at my public speaking engagements confuse homeopathy with herbalism. Homeopathic remedies come from different sources and although many are derived from plants there are a number of remedies that come from the animal and mineral kingdoms. The FDA regulates the manufacture of all homeopathic remedies sold within the United States.

The interesting point about these remedies is that they are made in a way that renders them so dilute that in most cases there is nothing of the original substance in the pill. As a result of this process there is no danger of toxic substances building up in the body and producing unwanted side effects. Homeopathy is probably the safest type of medicine that you will ever find. Many people say that homeopathy must work

because of the placebo effect. The truth is that no one has been able to explain exactly how the remedies work but for the past twenty years or so veterinary medicine has contributed to the development of homeopathy. It has shown that this system of healing works on animals that are unaware of what they are taking. There has been at least three large scale double – blind placebo –controlled trials to treat people with flu or influenza – like syndrome. Each of these large scale studies were conducted by independent researchers, and a treatment is considered proven when at least three independent studies verify positive results.

I have a nine year-old dachshund that took a turn for the worse a few years ago. He developed a right-sided herniated disc and suddenly his back legs became paralyzed. The prognosis was extremely poor for him. I gave him a homeopathic remedy specific to this problem for over a period of three months. I am delighted to say that according to the vet he made a 98% recovery and now he always wants to play tag and go for a long walk when I get home from work.

I know that homeopathy works and I get to witness its miraculous results every day in my professional practice. Only yesterday, the grandmother of a young boy who I have been helping with severe behavioral and ADD problems for the past year, looked me in the eye and announced that I have given her back her life and that of her grandson. It doesn't get any better than this!

Homeopathic remedies are prescribed according to the **Law of Similars.**This law states, **"That which makes sick shall heal."** This means that the symptoms caused by an overdose of a substance are the symptoms that can also be cured by a small dose of that same substance. As an example, we know that when we cut up an onion most people experience an acrid runny nose, soreness in the throat and stinging runny eyes. A homeopath will prescribe ***Allium Cepa***, this is the homeopathic remedy made from the onion for the individual who has a cold and a sore throat with these symptoms. Therefore, homeopathy uses remedies prepared from natural substances that are similar to the illness in contrast to conventional or allopathic medicine, which treats and often suppresses the patient's symptoms with large amounts of drugs, which then have the opposite effect.

A well chosen remedy acts as a signal, which energizes or stimulates the body's self healing powers, mobilizing the defense systems and working on all aspects of the body - mental, emotional and physical. Homeopathic literature, both past and present, documents cases, sometimes of severe pathology, that have been cured or significantly helped by homeopathy.

The Flu Pandemic of 1918 – 1919: Homeopathy – the beacon of light

Since its discovery two hundred years ago, homeopathy has provoked much controversy, criticism, acclaim and impassioned support. It is interesting to note that during the 1918 flu pandemic large numbers of people sought homeopathic care and were restored to good health; in numerous cases their lives were saved. This was a time when homeopathy truly won its laurels and was a beacon of light to so many. If an influenza victim was seen as soon as symptoms began to develop and a good homeopathic remedy was given their life was spared and they went on to make an excellent recovery. The only patients whom homeopathic doctors tended to lose were people who presented late into their illness, usually with pneumonia, and often drugged by large toxic doses of aspirin.

The flu pandemic of 1918 – 1919 was devastating and it was about as deadly as the Black Death. People who lived through it reported that someone who was up and well in the morning could be dead by the evening. 50 million people died world wide and 548,000 in the USA alone. From information recorded and published by these doctors we know that homeopathy was highly successful and in most cases only one or two homeopathic remedies were needed. They were referred to as the "genus

epidemicus" and became known through careful observation of the flu cases that were brought to the attention of the homeopathic community.

In an article published in the ***Journal of the American Institute of Homeopathy*** in 1921 Dean W.A.Pearson of Philadelphia collected 26,795 cases of influenza treated by homeopathic physicians with only a mortality rate of 1.05%, while the average conventional medical approach had a mortality rate of 30%. Dr Frank Wieland of Chicago says that in a plant of 8,000 workers there was only one death, the patients were not drugged with the conventional medicines of the time and no vaccines were used. Most workers were given just one homeopathic remedy, *Gelsemium.* Dr.T.A Mc Cann from Dayton. Ohio wrote: ***"I have treated 1,000 cases of influenza. I have the records to show my work. I have no losses. Please give all credit to homeopathy."***Dr.W.F Edmundson of Pittsburg related how one physician in a Pittsburg hospital asked a nurse if she knew anything better than what he was doing, because he was losing so many cases. The nurse replied, ***"Yes, Doctor, stop aspirin and go down to the homeopathic pharmacy and get homeopathic remedies, as the homeopathic doctors for whom I have nursed have not lost a single case."***1500 cases were reported to the Homeopathic Medical Society of the District of Colombia with only 15 deaths. Recoveries in the National Homoeopathic Hospital were 100%.*

A homeopathic remedy is prescribed upon the ***totality of an individual's symptoms*** taken from the mental, emotional and the physical levels. The homeopathic Materia Medica has well over 3,500 remedies. There is no one remedy that is specific to the flu because individuals will manifest symptoms in different ways that are unique to them. The most important point to remember about homeopathy is that it ***treats the individual***.

I have selected a number of the more common homeopathic remedies that have proved to be useful in influenza outbreaks. Sadly, homeopathy is not well known and all of the homeopathic hospitals of this past era in The United States have closed their doors. However, we do have a thriving, passionate homeopathic community right here in The Twin Cities and in many other locations in The United States. The old wisdom and knowledge of this past age still lies in the hands of a few practitioners who are always able and willing to share with our community. **In the event of an influenza pandemic this knowledge may mean the difference between your life and your death.**

Please read the remedy picture carefully and select the one, which seems to fit the picture of the individual whom you are caring for. The remedies can be purchased from local health food stores, Twin City Co - ops, Byerly's and Lund's stores, Mastels in St Paul, Present Moment Books and Herbs in Minneapolis and from mail order homeopathic pharmacies. Generally they are available to the public in low potencies.

- I would recommend that you purchase either 12c or 30c potencies but whatever potency is available will suffice.
- The remedy comes in the form of small sugar pills that are easily dissolved on the tongue. Do not eat or drink approximately 15 –30 minutes before and after the dose.
- **The doses can be repeated frequently in an acute illness but as soon as symptoms improve it is very important to stop the remedy.**
- If you select a remedy and take several doses but there is no improvement, review the symptoms and select another remedy that seems to fit the current picture.

- **Usually the most important symptoms are how the individual feels mentally and emotionally. Consider what things make the individual feel better or worse. Pay attention to the strong and unique symptoms of the patient and match these up with the characteristic symptoms known for the homeopathic remedy.**

- It is important to only take one remedy at a time.

- Children, adults and senior citizens can safely use homeopathic remedies, they are not intrinsically harmful but they are powerful and must be treated with care and respect. Store the remedies in a cool, dark place away from strong smells.

- The remedies can be safely used in conjunction with conventional medication; there is no known interaction.

- It is extremely important to work in conjunction with your licensed health care provider if symptoms are causing concern. When the patient's condition requires serious conventional treatment, homeopathy often helps to speed up the healing process and it can enable a reduction in the dosages of conventional drugs and decrease the unwanted side effects.

Prevention is the best remedy.

No one wants to be sick over the coming winter months; the obvious precautions are to look after ourselves which means good nutrition, regular exercise and an appropriate amount of sleep. Washing the hands regularly helps to reduce the spread of infection, and if sickness strikes it is better to stay at home and to use a handkerchief or tissues. The homeopathic remedy **Influenzinum** can be used as a preventative **for the regular flu** that comes around annually. It can be taken once a month during the flu season and more often if contact is made with someone suffering from the flu. Many homeopathic pharmacies make it fresh from that year's flu vaccine. Some homeopaths say that it is more effective than the conventional flu shot and without any side effects. Studies in England and India between 1968 and 1970 using homeopathic **Influenzinum** as a preventative showed that this remedy was highly effective at preventing the flu.However; please note that **Influenzinum** will not be effective at preventing an avian flu epidemic. Chicken Bird flu is an ever mobile and changing virus; there are over 20 different mutations.Boiron's ***Oscillococcinum*** or Dolisos'***Dolivaxil*** can be taken at the very beginning of feeling ill before any symptoms have developed, before you even know that its flu. Take 2 or three doses, 4 to 8 hours apart.

If the flu does strike your household here are some useful remedies to have on hand:

- **Aconite: Flu with great restlessness and worry**.

  This remedy is useful if the flu ***symptoms came on very suddenly***, especially after exposure to a dry, cold wind, infection or from an emotional shock or fright. There is a high fever, sore throat and ***feeling of great worry and fear***. The individual is very ***restless*** and they feel better in the fresh air. They are worse in a warm room, in the evening or at night, when exposed to tobacco smoke or hearing music.

- **Arnica: Flu with a feeling of soreness, as if bruised internally and externally**

  Arnica is our main remedy that we think of in times of acute trauma, accident and

injury. People in an ***Arnica*** state usually send onlookers and helpers away saying, "***I'm fine, there's nothing wrong with me***," when usually its quite evident to the observer that they are very sick or injured. They will probably complain that the bed feels too hard and fear someone approaching and touching their body because it is so sore. They may desire sour drinks and alcohol.

- **Arsenicum: Flu with great restlessness and anxiety**

This remedy is useful when an acute illness affects the nervous system. The patient will be extremely restless and anxious, they may express a ***fear of death*** and ***do not want to be left alone.*** They will be very ***chilly***, their face is pale and will have an anxious expression and their pains are ***burning in nature***, feeling like hot needles and are better with hot applications. They will be thirsty but only able to drink in small sips and are ***generally worse between 1 and 2am .Vomiting and/or diarrhea are extremely common Arsenicum symptoms***

- **Baptisia: Flu with high fever and a feeling of being bruised all over.**

This remedy is useful for ***flu that comes on suddenly*** and the individual feels bruised and sore all over, ***the body and limbs feel as if they are scattered and all in bits***. There is profuse sweating with a high fever and an intense thirst. The face is dull red in color and ***people who need this remedy look dazed and sluggish as if they may fall asleep at any time.*** This remedy is also for gastric flus with vomiting and diarrhea.

- **Belladonna: Flu with a high fever, face is red and pupils dilated.**

This remedy is useful when a very ***high fever comes on suddenly*** usually as a result of exposure to infection or from the head getting cold, wet, or overheated. The face is flushed and bright red, the throat is sore, the eyes are wide and staring and the pupils dilated, ***there is possible confusion and delirium***. The individual feels better when they stand or sit upright and in a warm room. They are worse from any noise or bright light or movement. They are worse from lying down and at night and symptoms tend to affect the right side of their body.

- **Bryonia: Flu with a severe, throbbing headache, wants to be left alone.**

This remedy is useful for a flu that ***comes on slowly,*** they ache all over and the remedy tends to be characterized by a violent headache that is made worse by coughing or by even slightly moving the eyes. The headache feels better if firm pressure is applied and they can sleep. There is dehydration and a need to drink lots of fluids at infrequent intervals. ***They feel very irritable, and want to be left alone and at home. They may be worrying about financial problems***. They feel worse from any excitement, noise, touch, movement or bright light, from eating and coughing and at around 3am and 9pm.

- **Eupatorium Perfoliatum: Flu with a feeling that the bones are broken.**

This remedy is for the most terrible of all flus. ***The pains are so severe that it actually feels as if the bones are broken.*** The muscles ache and feel sore and bruised. The individual moans and groans and everything hurts. They feel worse for any kind of movement. They have a bursting headache and sore eyes. There is a lot of sneezing, the nose is runny, the chest is sore and coughing makes the head hurt. These people want ice-cold water although it brings on violent chills in the small of the back. They don't sweat much but when they do they feel better except for the head.

- **Gelsemium: Flu with chills and paralytic weakness.**

This tends to be the number 1 flu remedy. In contrast to Aconite, Baptisia and Belladonna the ***symptoms of Gelsemium come on slowly*** after exposure to infection or as a result of ***worrying about a forthcoming task or event such as a public speaking engagement***. There is a sore throat and chills, which run up and down the spine. They may have a splitting headache, which is better after urinating. There is a general feeling of fatigue, the legs feel weak and shaky and they just want to lie in bed. The eyelids are droopy, the head feels heavy and they may have double vision. There is pain felt in the bones. Although they may have a fever they do not sweat and they are not thirsty. They feel better in the fresh air, when moving around and bending forward. They feel worse in the early morning and last thing at night, in the sun, and when exposed to tobacco smoke.

- **Mercurius solubilis**: **Flu with fever and copious offensive perspiration that brings no relief.**

People in this state will also have ***very bad breath***, they have more salivation than normal and they are extremely thirsty.

- **Nux Vomica: Flu with great irritability and over sensitivity**

People in a ***Nux Vomica*** state are ***highly sensitive***; they easily become irritable, impatient, angry and easily offended. They are very chilly and want to be warmly wrapped up, they are very sensitive to light, noise and odors and often they will be constipated with frequent ineffectual urging or a sense of incompletion.

- **Rhus Toxicodendron: Flu that comes on in damp cold weather with much stiffness and restlessness.**

People in a ***Rhus Tox*** state are extremely ***restless***, they want to be on the move all of the time, there is a lot of ***aching and stiffness in the joints*** which is worse on first starting to move and after sitting or lying down for a while. The pains ease up a bit after movement and then return again and require them to go and rest. They may be anxious, weepy, worse at night and have a red triangular tip to their tongue.

It is interesting to note that in the 1918 – 1919 flu pandemic homeopathic ***Gelsemium*** and ***Bryonia*** were the most commonly indicated remedies.

Never well since the flu?

Sometimes people get over a bout of the regular flu but never feel that they have completely recovered. If this is the case consider using the remedy **Influenzinum**. A single dose of the 30c potency is usually all that is required to rectify the situation. You may also consider consulting a professional homeopath.

There are many remedies that can be self-prescribed for minor ailments and in a first aid situation; in acute cases a well-chosen homeopathic remedy acts quickly and well. Homeopathy also has an excellent track record of being able to help more chronic conditions from ADD, ADHD and chronic fatigue syndrome to asthma, excema, allergies and ear infections to name just a few. If you are impressed with the results of homeopathy consider seeing a professional homeopath. If you or a loved one is suffering from a chronic health problem it generally takes the considerable expertise of a professional homeopath to find a suitable remedy and to manage the case. There is a strong professional and well qualified homeopathic community right here in the Twin Cities as well as an excellent school of homeopathy, The North Western Academy.

Please be aware that our best line of defense in any epidemic situation

is to have a healthy body that is well balanced and able to live in harmony with our surroundings. People in a balanced state of health don't get sick or if they do they are able to make a quick recovery and are easily able to throw off the invading bacteria or viral infection. In the twilight of his life Louis Pasteur declared that the germ is nothing, but the constitution of the person is everything. History has shown us that pandemics occur approximately every 30 – 40 years.

Will you be ready?

Sally Tamplin comes from the UK; she is a graduate of The School of Homeopathy in England and is a member of The Alliance of Registered Homeopaths (UK). She is Executive Director of the Minnesota Homeopathic Association.

Sally's homeopathic consulting business, Alternative Horizons LLC, is based in Richfield and she shares an office with Jacob Mirman MD, a homeopathic physician. If you would like to find out more about Alternative Horizons or The Homeopathic Medical Clinic please call: 612 - 836 – 1424.

**Extracts taken from, "The Faces of Homeopathy, an illustrated history of the first 200 years" by Julian Winston. Great Auk publishing, Tawa, New Zealand.*

Demystifying Homeopathy

Dedicated to Tom Stowell, N.D.,who showed me the light

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"Get your facts first, and then you can distort them as much as you please."
Mark Twain

APPENDIX

Quadruple – Blind (Editorial), *The Lancet,* April 22, 1989, p. 914.4 Complete Text

Can blind discussion remove bias from the reader? Take a trial in which 149 general practitioners entered 487 patients with an influenza-like syndrome into a randomized double-blind comparison of active treatment and matching placebo, both given sublingually. The first dose was supervised, the other four doses were taken on the following mornings and evenings. 478 of the entered patients (98.2%) met the admission criteria (5 out of 242 patients in the active treatment group and 4 out of 245 placebo patients were ineligible). At admission the groups were similar in age and proportion with severe illness. The patients recorded their rectal temperature morning and evening and whether they still had any or all of five cardinal symptoms within forty-eight hours of the start of treatment. The recovery rates were 39/228 (17.1%) in the active treatment group and 24/234 (10.3%) in the placebo group ($P=0.03, X^2$). The relative risk of recovery was 1.67 (95% confidence interval [CI] 1.1-2.7). The difference in the proportion of patients who recovered was 6.8% (95% CI 0.6-13.0%). Logistic regression showed that several potential confounders did not substantially alter the effect of active treatment (odds ratio 1.9, 95% CI 1.1-3.4; P=0.02). Age and severity at admission were significantly associated with recovery: younger patients and those with mild or moderate illness recovered better, as might be expected. All the patients were asked about the effectiveness of their therapy, and more expressed favourable judgments about the active treatment (61% *vs* 49%, P=0.02). Use of other symptom-relieving drugs for pain, fever, cough, or coryza and use of antibiotics were not confounders; in fact, more patients in the placebo group used compounds to relieve pain or fever. Can the trial be criticized more than the authors do already? There might have been imbalances between the general practitioners in their recruitment of patients: every participating doctor should have entered 4-6 patients, to give a total of at least 596 cases. Also, data on 16 eligible patients were not analyzed for efficacy. There were only four unsupervised doses, but compliance was not reported. Finally side-effects in both groups were not recorded or reported. The authors are restrained in their discussion "The effect was modest ... but nevertheless is of interest". *A 7% difference in efficacy as defined would be a respectable proportion in most drug trials.* Now let the code be broken–the active treatment was a homeopathic preparation.

Ferley, J.P., A Controlled Evaluation of Homeopathic Preparation in the Treatment of Influenza-like Syndromes, *British Journal of Clinical Pharmacology*, 1989, 27, pp. 329-335.

1. A controlled clinical trial was conducted to assess the effectiveness of a homeopathic preparation in the treatment of influenza-like syndromes.

2. 237 cases received the test drug and 241 were assigned to placebo. Patients recorded their rectal temperature twice a day, and the presence or absence of five cardinal symptoms (headache, stiffness, lumbar in articular pain, shivers) along with cough, coryza and fatigue.

3. Recovery was defined as a rectal temperature less than 37.5° C and complete resolution of the five cardinal symptoms.

4. The proportion of cases who recovered within 48 h of treatment was greater among the active drug group than among the placebo group (17.1% against 10.3%, *P*=0.03).

5. The result cannot be explained given our present state of knowledge, but it calls for further rigorously designed clinical studies.

Reilly, D.T., Is Homeopathy a Placebo Response? Controlled Trail of Homeopathic Potency, with Pollen in Hayfever as a Model, *The Lancet*, October 18, 1986, pp. 881-886.

The hypothesis that homeopathic potencies are placebos was tested in a randomized, double-blind, placebo-controlled trial. The study model chosen compared the effects of a homeopathic preparation of mixed grass pollens with placebo in 144 patients with active hayfever. The homeopathically treated patients showed a significant reduction in patient and doctor assessed symptom scores. The significance of this response was increased when results were corrected for pollen count and the response was associated with a halving of the need for antihistamines. An initial aggravation of symptoms was noted more often in patients receiving the potency and was followed by an improvement in that group. No evidence emerged to support the idea that placebo action fully explains the clinical responses to homeopathic drugs.

Day, C.E.I., Control of Stillbirths in Pigs Using Homeopathy, *International Journal for Veterinary Homeopathy*, Vol. 1, No. 2, October 1986, pp. 26-28.

The author tested Caulophyllum C30 for its effect against stillbirth in a herd of pigs. Ten sows received Caulophyllum C30 prior to farrowing; ten sows received no treatment (control). Stillbirth rate was over 20, 8% in the control and 10, 3% in the treated group. These results are statistically significant.

Fisher, P., Effect of Homeopathic Treatment on Fibrositis (Primary Fibromyalgia), *British Medical Journal*, 1989, 229, pp. 365-6.

Fibrositis (primary Fibromyalgia) is a controversial condition but is becoming increasingly accepted. It is difficult to treat. We showed that the homeopathic medicine *Rhus toxicondendron* 6c was effective for a selected subgroup of patients with fibrositis. The improvement in tenderness, which is the best discriminator of fibositis, was particularly distinct. The improvement experienced by our patients while receiving active treatment was at least as great as that reported for any other treatment that has been assessed double blind.

Kleijnen, J., Clinical Trials of Homeopathy, *British Medical Journal*, 1991, 302, 216-23.

Objective–To establish whether there is evidence of the efficacy of homeopathy from controlled trials in humans.

Design–Criteria based meta-analysis. Assessment of the methodological quality of 107 controlled trials in 96 published reports found after an extensive search. Trials were scored using a list of predefined criteria of good methodology, and the outcome of the trials was interpreted in relation to their quality.

Setting–Controlled trials published world wide.

Main outcome measures–Results of the trials with the best methodological quality.

Trials of classical homeopathy and several modern varieties were considered separately.

Results–In 14 trials some form of classical homeopathy was tested and in 58 trials the same single homeopathic treatment was given to patients with comparable conventional diagnoses. Combinations of several homeopathic treatments were tested in 26 trials; isopathy was tested in nine trials. Most trials seemed to be of very low quality, but there were many exceptions. The results showed a positive trend regardless of the quality of the trial or the variety of homeopathy used. Overall, of the 105 trials with interpretable results, 81 trials indicated positive results whereas in 24 trials no positive effects of homeopathy were found. The results of the review may be complicated by publication bias, especially in such a controversial subject as homeopathy.

Conclusions–At the moment, the evidence of clinical trials is positive but not sufficient to draw definitive conclusions because most trials are of low methodological quality and because of the unknown role of publication bias. This indicates that there is a legitimate case for future evaluation of homeopathy, but only by means of well performed trials.

Gibson, R.G., Homeopathic Therapy in Rheumatoid Arthritis: Evaluation by Double-Blind Clinical Therapeutic Trial, *British Journal of Clinical Pharmacology*, 1980, 9, pp. 453-459.

1. Twenty-three patients with rheumatoid arthritis on orthodox first-line anti-inflammatory treatment plus homeopathy were compared with a similar group of twenty-three patients on orthodox first-line treatment plus an inert preparation.

2. There was a significant improvement in subjective pain, articular index, stiffness and grip strength in those patients receiving homeopathic remedies, whereas there was no significant change in the patients who received placebo.

3. Two physicians were involved in prescribing for the patients and there were no significant differences in the results which they obtained.

4. No side effects were observed with the homeopathic remedies.

Jacobs, J. et al, Treatment of Acute Childhood Diarrhea with Homeopathic Medicine: A Randomized Clinical Trial in Nicaragua, *Pediatrics*, Vol. 93, No. 5, May 1994, pp. 719-725.

Objective–Acute diarrhea is the leading cause of pediatric morbidity and mortality world-wide. Oral rehydration treatment can prevent death from dehydration, but does not reduce the duration of individual episodes. Homeopathic treatment for acute diarrhea is used in many parts of the world. This study was performed to determine whether homeopathy is useful in the treatment of acute childhood diarrhea.

Methodology–A randomized double-blind clinical trial comparing homeopathic medicine with placebo in the treatment of acute childhood diarrhea was conducted in Leon, Nicaragua, in July 1991. Eighty-one children aged 6 months to 5 years of age were included in the study. An individualized homeopathic medicine was prescribed for each child and daily follow-up was performed for 5 days. Standard treatment with oral rehydration treatment was also given.

Results–The treatment group had a statistically significant ($P<.05$) decrease in duration of diarrhea, defined as the number of days until there were less than three unformed stools daily for 2 consecutive days. There was also a significant difference ($P<.05$) in the number of stools per day between the groups after 72 hours of treatment.

Conclusions–The statistically significant decrease in the duration of diarrhea in the treatment group suggests that homeopathic treatment might be useful in acute childhood diarrhea. Further study of this treatment deserves consideration.

Reilly, D., et. al, Is Evidence for Homeopathy Reproducible?, *The Lancet*, 1994; 344: pp. 1601-06

We tested under independent conditions, the reproducibility of evidence from two previous trials that homeopathy differs from placebo. The test model was again homeopathic immunotherapy.

Twenty-eight patients with allergic asthma, most of them sensitive to house-dust mite, were randomly allocated to receive either oral homeopathic immunotherapy to their principal alergen or identical placebo. The test treatments were given as a complement to their unaltered conventional care. A daily visual analogue scale of overall symptom intensity was the outcome measure. A difference in visual analogue score in favour of homeopathic immunotherapy appeared within one week of starting treatment and persisted for up to 8 weeks (P=0.003). There were similar trends in respiratory function and bronchial reactivity tests.

A meta-analysis of all three trials strengthened the evidence that homeopathy does more than placebo (P=0.0004). Is the reproducibility of evidence in favour of homeopathy proof of its activity or proof of the clinical trial's capacity to produce false-positive results?

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A controlled evaluation of a homoeopathic preparation in the treatment of influenza-like syndromes

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1 A controlled clinical trial was conducted to assess the effectiveness of a homoeopathic preparation in the treatment of influenza-like syndromes.

2 237 cases received the test drug and 241 were assigned to placebo. Patients recorded their rectal temperature twice a day, and the presence or absence of five cardinal symptoms (headache, stiffness, lumbar and articular pain, shivers) along with cough, coryza and fatigue.

3 Recovery was defined as a rectal temperature less than 37.5° C and complete resolution of the five cardinal symptoms.

4 The proportion of cases who recovered within 48 h of treatment was greater among the active drug group than among the placebo group (17.1% against 10.3%, $P = 0.03$).

5 The result cannot be explained given our present state of knowledge, but it calls for further rigorously designed clinical studies.

Keywords homoeopathy influenza clinical trial

Introduction

Few clinical trials have been performed to evaluate homoeopathic therapy (Aulas, 1985; Reilly *et al.*, 1986). This situation is largely due to the rationale of homoeopathic prescription by which the precise nature of the treatment is adapted to the specific symptoms of a patient suffering from a given disease. The treatment is based on the 'similimum' principle, using infinitesimal concentrations of drugs which have the ability to induce, in healthy individuals, symptoms similar to those presented by sick persons. Although a regular feature of homoeopathic treatment is that two patients who have the same disease are liable not to benefit from the same treatment, a school of thought soon developed (Finella, 1877) that certain diseases, especially some acute diseases, could be treated with substances or drug mixtures tailored to the disease characteristics alone.

Homoeopathic physicians are far from reaching agreement about such drugs, which would be prescribed without taking account of the particular symptoms of each patient. Nevertheless, these drugs are gaining popularity among large sections of the medical profession and among the public who buy them over-the-counter.

These preparations provide the opportunity to design conventional trials in a way that has not so far been possible with regular 'unitarian' drugs.

The following experiment deals with a drug of the former category. Its action on the treatment of influenza and influenza-like syndromes was evaluated. It is a homoeopathic preparation currently on the market, made of a highly diluted autolysate of animal organs.

Methods

Study design

The trial was implemented with the participation of general practitioners of the Rhône-Alpes region in France (regional capital: Lyon). Most of them were not homoeopathic clinicians. Patients included in the study were chosen from

those who attended with influenza-like syndromes and who agreed to participate in the experiment after a formal briefing. The treatment allocation of active drug or placebo was made on a randomized double-blind basis. For the final evaluation a second visit to the physician's practice was planned for a week later.

Admission criteria

To be eligible patients had to be 12 years old and over, to suffer from an influenza-like syndrome defined by the association of a rectal temperature equal to or above 38° C, and at least two of the following symptoms: headache, stiffness, lumbar and articular pain, shivers. The first manifestation had to have occurred less than 24 h before entry.

Patients with immune deficiency or local infection were not included. Also excluded were those who had had immunization against influenza or who were under treatment either for depression or for stimulation of immunity.

Patients were asked not to take any drug for pain or fever during the 48 h following entry or, if they should do so, to record this use along with any use of antibiotics.

Study period

The definition of influenza-like syndrome was entirely clinical, and it was decided to undertake the experiment during an influenza epidemic. Two sources of information on the occurrence of such an epidemic were used. One was the national computer network set up by the 'Institut National de la Santé et de la Recherche Médicale' (Research on Biomathematics and Biostatistics Unit) and the 'Direction Générale de la Santé' of the Health Ministry (Valleron *et al.*, 1986; Direction Générale de la Santé, 1987b). This network then included about 300 sentinel practices scattered across the country (of which 23 were in the study region). It allows the weekly surveillance of the incidence of influenza-like syndromes at a national and regional level. It also publishes the results of identification tests on respiratory viruses made through the two National Reference Laboratories (South and North of France).

The second information source was a local network of 12 sentinel practices monitored for the purpose of the study (Figure 1).

The A H1N1 influenza virus was isolated in the study region 7 days after the study managers issued the instruction to start including patients in the experiment. Enrolment continued after the epidemic period, but 71% of all cases were entered during the peak of the epidemic. The study managers decided to include no further patients when it became apparent that the epidemic had ended. The main concern was to restrict the trial to those cases that were most likely to be cases of influenza.

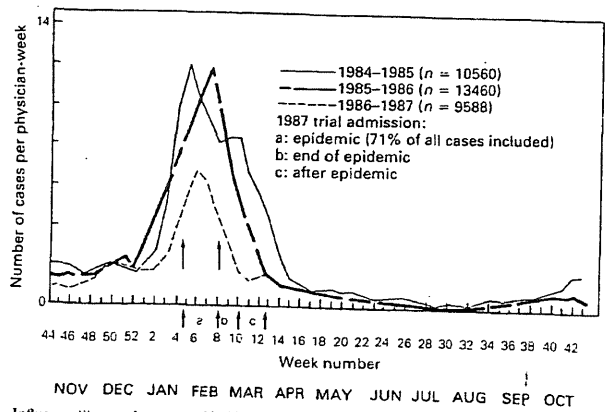

Figure 1 Influenza-like syndromes notified by the sentinel physicians between 1984 and 1987 through the National Computer Network on transmitted diseases: national data and trial admission period (Source: Direction Générale de la Santé, 1987b).

The homoeopathic preparation

The drug is commercialized under the trademark Oscillococcinum® by Boiron Laboratories. It is made of *Anas Barbariae Hepatis* and *Cordis Extractum* HPUS 200 C.

It is presented as granules (200 granules per dose). The vehicle is made of lactose and saccharose. The placebo, whose presentation was identical, was made of lactose and saccharose alone.

The standard treatment dispensed is one box containing five doses. The first dose was administered sublingually at the medical practice; the remaining four were taken on the following mornings and evenings. The doses were dispensed with a code number which was identified only after analysis of the data. Allocation of the active drug and placebo was balanced in every eight boxes. Each physician had to enrol between four and six patients.

Study diaries and monitoring

For 1 week patients noted morning and evening their temperature and the presence or absence of the five cardinal symptoms. Cough, coryza and fatigue were also recorded along with any use of medications or any side effects. Finally they were asked to make their own record of how effective they found the treatment to be.

Evaluation criteria

Recovery was defined as a rectal temperature less than 37.5° C and complete resolution of the five cardinal symptoms. Persistence of cough, coryza or fatigue was accepted. The main evaluation criteria set prior to data analysis were the recovery rate within 48 h of treatment (i.e. proportion of patients who had recovered within 48 h), and the time trend of this rate, as this gives insight into the consistency of the observed effect. Additional criteria were also examined e.g. the patients' judgement on the effectiveness of the treatment and whether any additional drug was taken.

Statistical analysis

Comparison of percentages were performed using Pearson's χ^2. Adjustment for some identified or potential confounders was done by a Mantel-Haenszel procedure (Mantel, 1963) or by a multivariate logistic regression analysis. Crude data analysis was performed with a hand calculator using Rothman's programs (Rothman & Boice, 1984). Confidence interval estimation followed Miettinen's method (1976). The time trend analysis of the recovery rate (actuarial method) was performed with a logrank test (Mantel, 1966), if necessary adjusted for some cofactors (Dash package from the Dana Farber Institute, Harvard University, Boston, run on VAX-VMS).

Results

Comparability of the two groups and general features of illness

Of 487 cases entered 478 met the admission criteria. Table 1 shows that the two groups were reasonably similar. Nine cases were not included in the analysis because they were not eligible (temperature lower than 38° C, delay before entry of greater than 24 h, or the presence of less than two cardinal symptoms). Five had been assigned to the active drug group and four to the placebo group.

43% of the cases had fairly severe illnesses at the initial visit, with temperature ≥39° C and the presence of at least three out of the five

Table 1 Initial comparison between treatment groups

	Active drug	*Placebo*
Number eligible cases	237	241
Sex-ratio M/F	93/127 (0.73)	97/129 (0.75)
Age* (years)	33.7 (1.7)	35.1 (1.9)
Inclusion during the epidemic peak (%)	73.6	69.2
Delay*** < 12 h (%)	48.2	52.0
Temperature at inclusion* (°C)	38.9 (0.07)	38.8 (0.07)
Severe illnesses (%)**	43.8	42.1

* mean (mean deviate)
** at least three of the cardinal symptoms present and temperature ≥ 39° C
*** delay before inclusion

Table 2 Recovery rate within 48 h of treatment

	Active drug n = 228	Placebo n = 234
Recovered *n*	39	24
%	17.1	10.3

$\chi^2_1 = 4.60$; $P = 0.03$

cardinal symptoms. If the whole observation period is considered, 58% of the patients had all five cardinal symptoms.

The most common symptoms at inclusion were fever (100% greater than 38° C), fatigue (95%), muscle pain (92%), shivers (91%), and headache (89%). Three other symptoms were less frequent: lumbar pain (70%), coryza (59%), and cough (58%). The last two symptoms often occurred secondarily and were found at some time during the week of observation among 84% and 81% of cases.

Recovery rate within 48 h

Recovery rate within 48 h of treatment was greater in the group which received the active drug than in the placebo group (Table 2). The relative efficacy of the drug can be estimated by the ratio of the recovery rates in the two groups. This relative risk (RR) of recovery was 1.67 (95% CI 1.1–2.7, $P = 0.03$). The 'attributable fraction', which is the difference in the proportions of cases who recovered within 48 h, was 6.8% (95% CI 0.6–13%). The proportion of recoveries related to the active drug was greatest 36 h after treatment at 39.6% (95 CI 4–62%).

Some parameters which were potential confounders of the association between the drug effect and recovery were included as covariates in a multivariate logistic regression model, as binary variables: age (< 30 years; ≥ 30), period of entry (during the epidemic, after the epidemic), delay before treatment administration (< 12 h or 12–24 h after onset of symptoms), severity of the syndrome (moderate: < 39° C, two symptoms; intense: ≥ 39° C, three + symptoms), use of symptomatic drugs (against fever, pain, inflammation, cough or coryza) during the first 48 h (yes, no), antibiotic therapy (yes, no). Controlling for these covariates did not alter substantially the effect of the drug, which remained significant (OR = 1.9, 95% CI 1.1–3.4; $P = 0.02$). (In this setting, the Odds-Ratio (OR) is a reasonably good approximation of the relative risk). Interaction terms were tested and dropped from the model. In addition to the drug two other parameters showed significant association with recovery, namely age and severity of the syndrome at admission. Tables 3 and 4 give insight into these effects, showing that drug efficacy seems greater among younger patients (67.6% of recoveries within 48 h were related to the drug [95% CI 29–85%]), and when the syndrome was mild or moderate (the proportion of recovery related to the active drug was then 51.6% [95% CI 20–70%]).

Table 3 Recovery within 48 h according to age and treatment group

Age (years)	*Recovery*	*Active drug*	*Placebo*	*Efficacy (RR* and P value)*
12–29	Yes	21 (25.0%)	6 (8.1%)	3.1
	No	63	68	$P < 0.01$
30 +	Yes	13 (10.6%)	11 (8.4%)	1.3
	No	110	120	$P = 0.56$

Mantel-Haenszel $\chi^2_1 = 5.82$; $P = 0.01$; $RR_{MH} = 2.06$ [1.1 – 3.4] Heterogeneity $\chi^2_1 = 2.46$; $P = 0.12$

Table 4 Recovery within 48 h, according to severity of syndrome and treatment group

Severity of syndrome*	*Recovery*	*Active drug*	*Placebo*	*Efficacy (RR and P value)*
Severe	Yes	7 (7.1%)	8 (8.2%)	0.9
	No	91	90	$P = 0.80$
Mild to moderate	Yes	31 (24.6%)	16 (11.9%)	2.1
	No	95	119	$P < 0.01$

Mantel-Haenszel $\chi^2_1 = 4.64$, $P = 0.02$; $RR_{MH} = 1.72$ [1.1 – 2.8]; Heterogeneity $\chi^2_1 = 2.29$; $P = 0.13$

* See definition in text.

Time trend of the recovery rate

Figure 2 (upper part) illustrates the actuarial analysis of the recovery trend between the treatment groups. A log-rank test with stratification on age confirmed the preceding result, showing nearly-significant efficacy of the drug over the whole 1 week observation period (RR = 1.2 [95% CI 1.0–1.4], $P = 0.07$). Most cases recovered before the end of the week after entry. It is no surprise, therefore, that the recovery curves get closer by the end of the observation period, thus lessening the difference between the two treatment groups.

Complementary evaluation criteria

More patients in the placebo group did use adjuvant drugs for pain or fever (50.2% against 40.7%, $P = 0.04$) during the first 48 h. Other symptomatic drugs against cough or coryza were equally used in both groups (39.4% among placebo cases against 37.7%; the same held true for antibiotics (8.6% and 7.6%). It was not possible to compare the amount of analgesic and antipyretic drugs used in each group.

Finally, the number of patients who made favourable judgements on the efficacy of the treatment was greater among the active drug group (61.2% against 49.3%; $P = 0.02$).

Discussion

Patients with an influenza-like syndrome who received the homoeopathic preparation showed

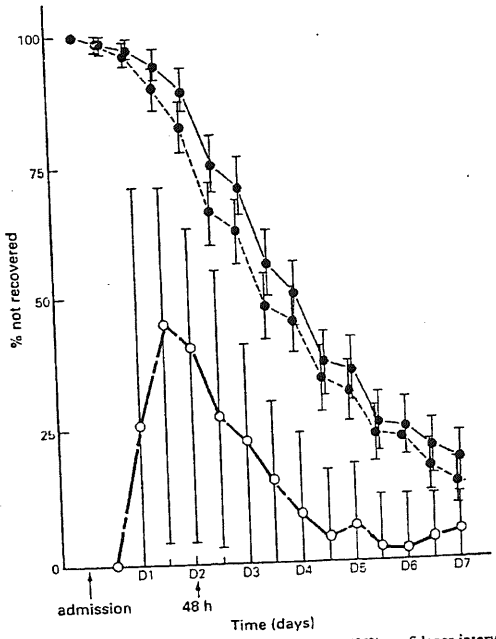

Figure 2 Actuarial recovery curve according to the treatment group (95% confidence interval) and proportion of recoveries related to the active drug (95% confidence interval). •——• placebo group, •---• active drug group, o—o % recoveries related to the active drug.

a greater early recovery rate than those who received placebo. This study sheds no light on the mode of action of this drug. Despite the use of terms such as 'attributable fraction' which have specific meaning in clinical epidemiology parlance, it would be unwise to claim that the study has demonstrated a cause and effect relationship between the drug and the recoveries. The positive effect of the homoeopathic preparation cannot be explained in our present state of knowledge, and thus calls for further investigation. The effect was modest (the increase in proportion of recoveries within 48 h was less than 7%), but nevertheless is of interest.

The patients were the main source of information in that they themselves recorded the clinical data twice a day. It might be suggested that physicians would have been more reliable observers. However due to the relative mildness of the disease studied, such an experiment could not be conducted in an institutional setting. Therefore, monitoring by physicians would have been incomplete and lacking in continuity. One consequence of this self-surveillance system is that the response rate might have been poor for some items. The proportion of unanswered questions was lower than 4.8% for the key questions which were used to assess recovery, but did reach 12% for some items of secondary importance. However, missing data were balanced between the two groups.

Another weakness stems from the choice of criteria for the influenza-like syndrome. The definition was purely clinical and probably lacked specificity. However the clinical picture was quite complete, with 58% of cases having all five symptom criteria during their illness, in addition to fever, and 81% having at least four of them. Moreover almost three out of four cases occurred during the peak of the influenza epidemic of the 1986–1987 winter. The conclusions do not differ whether the cases were collected during the epidemic period or afterwards, as demonstrated by the multivariate analysis.

The influenza virus A H1N1 was identified during this epidemic, which was of mild intensity. It was a variant of a strain that appeared in 1977 and which was analogous to an epidemic agent encountered between 1947 and 1957 (Direction Générale de la Santé, 1987a). Hence this virus mostly spread among people born after 1957 (i.e. less than 30 years old) (Hannoun & Lhillier, 1987). In consequence it is possible that many older patients included in the study suffered from syndromes that were caused by other viruses than the influenza virus. Respiratory syncitial virus was very active during the 1986–1987 winter in France (Hannoun & Lhillier, 1987). The partitioning of the data set into 'old' and 'young' cases, with 30 years as the threshold, was decided during the data analysis with the aim of testing age effect in reasonably similar sample sizes. It was not conditioned by any prior hypothesis as to the immune status of older patients. However as the drug was more effective among patients aged less than 30 years, one might speculate that the action of Oscillococcinum® was more specifically active against the influenza virus. Clearly further studies are required to examine this possibility.

One earlier study was conducted with a small sample size and with a rather wide definition of influenza infection (Gassinger *et al.*, 1981). It showed no evidence of an effect of a homoeopathic substance as compared with acetylsalicylic acid. Another trial used a definition of influenza-like syndrome which was similar to the present study but did not reveal any preventive effect of a homoeopathic complex (Ferley *et al.*, 1987). Our study did not aim to evaluate the homoeopathic approach as a whole, but to test a specific preparation.

While pharmacological studies have been published recently (Cazin *et al.*, 1987; Davenas *et al.*, 1987, 1988), conventional clinical trials published in the non-homoeopathic literature are exceptional (Reilly *et al.*, 1986). Reviews (Aulas *et al.*, 1985: Scofield, 1984) stress the weakness of most homoeopathy trials and underline the methodological difficulties of such an enterprise. This tends to enhance the suspicion of those who are detractors of this therapeutic approach. Although it may be enjoying a revival among sections of the population at large and among part of the medical profession, only rigorous clinical experiments will allow vindication of this approach.

The authors are indebted to the 149 general practitioners who collaborated in this study. They cannot all be named. A. Billette and N. Pontignat contributed to the trial organization and surveillance. F. Faris and E. Zogheib typed the manuscripts. They are very grateful to Gerald Moore for idiomatic revision of a first paper.

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Jerri Johnson

Access to Holistic Health Services in Minnesota

Access to complementary and alternative healers not licensed in the health care system has opened up. In 2000, the Minnesota legislature passed Statute 146A, creating the Office of Unlicensed Complementary and Alternative Health Care in the Department of Health. This was a ground-breaking, positive piece of legislation that has assured Minnesotans maximum options in health care.

Before MN 146A existed, many holistic healing services were being provided. However they were being provided under the chilling effect of potentially being in technical violation of the medical practices act. Statute 146A gives practitioners who comply an exemption to criminal charges of practice of medicine. It created an office in the Department of Health to have jurisdiction over unlicensed practitioners and to receive complaints and take action if necessary, including cease and desist and injunctive relief. It required unlicensed practitioners to give disclosure to their clients of their education and training.

Consumers and practitioners are enjoying the benefits of this statute because there is open communication between client and practitioner about the nature of the services, and there is an innovative and respectful environment surrounding these practices. The Client Bill of Rights has enhanced consumer education and is a wonderful asset to Minnesotans who use these services.

With this innovative solution, Minnesota now leads the country in providing consumers with the options they are seeking. According to National Health Freedom Action, there are now six states with laws that allow unlicensed natural health care practitioners to practice: **Minnesota, Rhode Island, California, Oklahoma, Louisiana, and Idaho.** Many more states have introduced legislation similar to Minnesota's and are going forward in 2006. National Health Freedom Action is working with many more states to educate state leaders on how to create environments in their states that maximize consumer options in these kinds of health care practices.

There is still a need for legislative change to allow licensed practitioners who wish to utilize alternative methods the flexibility to do so. Currently in Minnesota, licensed health care practitioners can not freely prescribe alternative treatments because their practice statutes require them to practice within the acceptable and prevailing minimum standards of care for their profession. If they use different approaches, they could lose their license.

But consumers are asking for holistic therapies, and many health professionals wish they had more latitude to administer them. Consumers are eager to access not only the unlicensed healers, but also those licensed practitioners who can offer their expertise in natural health methods. Legislation is needed to assure that practitioners need not fear the loss of their license if they do so.

Chiropractic
and Evidence Based Health Care

Gert Bronfort, DC, PhD
Research Professor

Director of the Neck and Back Research Program
Northwestern Health Sciences University, Minnesota

Outline of Presentation

- Chiropractic
- Evidence-based Recommendations regarding Cost Savings in Minnesota
- Scientific Evidence for the Clinical and Cost-Effectiveness of Chiropractic Care
- Evidence-based Health Care
- Policy Recommendation

Chiropractic

Chiropractic

- Chiropractors the third largest group of health care practitioners in the United States (> 60.000)
- An estimated 25 million Americans receive chiropractic care yearly
- Four years of professional education preceded by bachelor of science degree
- Chiropractors licensed in all states by state law
- Chiropractors used more often than any other alternative care providers in the US
- 95% of the care delivered is for musculoskeletal problems such is low back pain, neck pain, some forms of headache and peripheral joint problems

Evidence-based Recommendations regarding Cost Savings in Minnesota

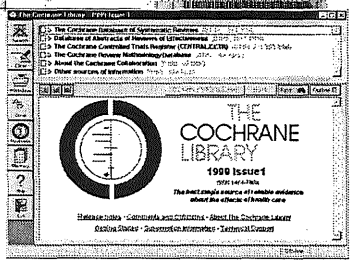
The Scientific Evidence

Using a systematic approach:

- Include all relevant evidence
- Evaluate the quality of the evidence
- Combine and summarize
- Make recommendations based on the preponderance of the scientific evidence

The Cochrane Collaboration

www.cochrane.org



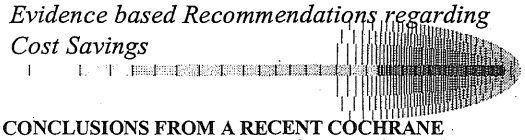
International non-profit organisation that prepares, maintains, and disseminates the highest quality systematic up-to-date reviews of health care interventions.

The Health Care Services Study 2005
Evidence based Recommendations regarding Cost Savings

Examples of overuse of diagnostic procedures and treatments

- Coronary Angiography
- Antibiotic use
- Hysterectomy
- Arthroscopic knee surgery for arthritis
- MRI for back pain
- Spinal manipulation for low back pain

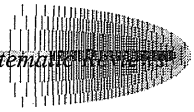
The Health Care Services Study 2005
Evidence based Recommendations regarding Cost Savings



- **CONCLUSIONS FROM A RECENT COCHRANE SYSTEMATIC REVIEW:** There is no evidence that spinal manipulation is superior to other standard treatments for patients with acute or chronic low back pain.
- *Neither is there any evidence that these therapies were superior to spinal manipulation.*
- ***The authors conclude that spinal manipulation is one of several effective treatment options.***

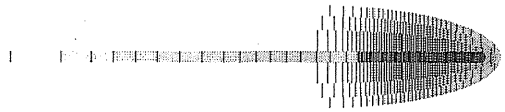
Spinal manipulative therapy for low-back pain Assendelft WJJ, et al

The Cochrane Database of Systematic Reviews



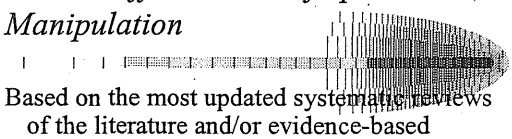
IMPLICATIONS:
The findings from this review **does not support** the notion that spinal manipulation for low back pain is an ineffective or inappropriately used treatment as suggested in the Minnesota Health Care Services Study.

The finding from this review therefore **should not form the basis for introducing policy and budget proposals** which would deny/reduce access to or payment for spinal manipulation for low back pain.



Scientific Evidence for the Clinical Effectiveness and Cost-Effectiveness of Chiropractic Care

Clinical effectiveness of Spinal Manipulation



Based on the most updated systematic reviews of the literature and/or evidence-based clinical guidelines:

- One of several effective treatment options for chronic and acute low back pain
- Some evidence for chronic neck pain but inclusive evidence for acute neck pain
- Effective for some patients in reducing chronic headache

Cost-effectiveness of Spinal Manipulation and Chiropractic Care

Based on randomized clinical trials and insurance claims data:

- Good evidence of cost-effectiveness of spinal manipulation/mobilization for low back pain and neck pain based on prospective randomized clinical trials in Europe
- Based on retrospective claims data in the US, there is evidence that access to managed chiropractic care alone or as part of integrated medical care reduces overall health care expenditures

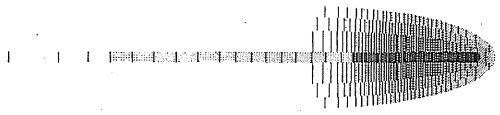
Evidence-based Health Care

What is Evidence-based Health Care?

- It's not "cookbook" care or rigid prescriptive clinical guidelines designed by policy makers
- The Evidence-based Health Care principle is a dynamic process that integrates

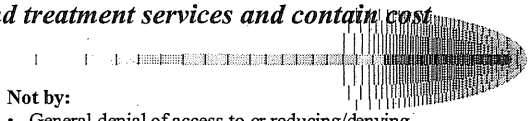
Scientific Evidence
+ Clinician Experience
+ Patient Preferences
Best Clinical Decisions

- The purpose is to promote quality patient-centered care



Policy Recommendation

How to counteract inappropriate use of diagnostic and treatment services and contain cost



Not by:

- General denial of access to or reducing/denying reimbursement of valid diagnostic procedures and effective treatments based on biased interpretation or selective reference to the scientific literature supporting inappropriate use.
- Arbitrary limits on numbers of treatment

But by:

- Mandating the introduction of Evidence-based Health Care
- Ensuring health care provider designed Best Practices (high quality care)
- Require public documentation of the use high quality care
- Rewarding the use of high quality cost-effective care

Thank You

Chiropractic: A Profession at the Crossroads of Mainstream and Alternative Medicine

William C. Meeker, DC, MPH, and Scott Haldeman, DC, PhD, MD, FRCP(C)

Chiropractic is a large and well-established health care profession in the United States. In this overview, we briefly examine the development of chiropractic from humble and contentious beginnings to its current state at the crossroads of alternative and mainstream medicine. Chiropractic has taken on many of the attributes of an established profession, improving its educational and licensing systems and substantially increasing its market share in the past two decades. The public increasingly uses chiropractic largely for spinal pain syndromes and appears to be highly satisfied with the results. Of all the so-called alternative professions, chiropractic has made the largest inroads into private and public health care financing systems and is increasingly viewed as an effective specialty by many in the medical profession. Much of the positive evolution of chiropractic can be ascribed to a quarter century–long research effort focused on the core chiropractic procedure of spinal manipulation. This effort has helped bring spinal manipulation out of the investigational category to become one of the most studied forms of conservative treatment for spinal pain. Chiropractic theory is still controversial, but recent expansion in federal support of chiropractic research bodes well for further scientific development. The medical establishment has not yet fully accepted chiropractic as a mainstream form of care. The next decade should determine whether chiropractic maintains the trappings of an alternative health care profession or becomes fully integrated into all health care systems.

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For author affiliations and current addresses, see end of text.

Chiropractic is the largest, most regulated, and best recognized of the professions that have traditionally functioned outside of mainstream medical institutions and, in the new lexicon, have fallen into the category of "complementary and alternative medicine." It is unique in the United States as the most widely disseminated indigenous U.S. system of healing. Its steadily increasing acceptance and use by the public and payers indicate that chiropractic is no longer the "marginal" or "deviant" profession it was once considered to be (1). According to surveys of patients seeking alternative care, chiropractors are used more often than any other alternative provider group (2), and the satisfaction with chiropractic care is very high (3, 4). The number of chiropractors is growing: The current number of 60 000 is expected to reach 100 000 by 2010 (5).

Although some observers suggest that the profession may be entering the health care mainstream (6, 7), chiropractic remains a young profession; in 1995, it celebrated its 100th anniversary. Until the mid-1970s, chiropractic was considered to be outside mainstream medicine, often an outcast, and most chiropractors viewed themselves as differing in philosophy and practice from other health care practitioners (8). During the past two decades, there has been a marked change in the manner in which chiropractic is viewed, not only by mainstream medical practitioners (9) and institutions (10, 11) but also by members of the profession itself (12). Examining the factors that led to this change in attitude and the legitimization of chiropractic as a method of treatment and as a profession, as well as the conflicting emotional discussion that has accompanied these changes, is an interesting and informative exercise in health care sociology (13). The changes in the chiropractic (and medical) profession are, however, still in the transitional phase, and the acceptance and even the future role of chiropractic in the overall health care system remain controversial (14, 15).

The Origins and History of Chiropractic

Chiropractors have designated 18 September 1895, when Daniel David Palmer reportedly gave his first spinal adjustment, as the origin of the chiropractic profession; however, spinal manipulation is one of the oldest and most widely practiced healing methods. References to spinal manipulation, and even the term *subluxation*, can be traced back as far as Hippocrates and Galen (16), and manual and manipulative procedures have been depicted in the art and writings of most ancient cultures. Although manipulation has been part of orthopedic medical practice for centuries, most nonmedical practitioners of spinal manipulation in the 19th century were

"bonesetters" who had learned their skills primarily by apprenticeship and observation (17).

The early and middle years of chiropractic were dominated by charismatic and authoritarian figures who often disagreed with one another. Many of the early schisms around the theory and scope of practice from this period still exist in some form (9, 17). Daniel David Palmer, who originally practiced as a lay magnetic healer, is credited with professionalizing the practice of spinal manipulation. He integrated popular natural health and scientific models of the day to present a unique theory of chiropractic. He did this by incorporating the concept of an inherent healing ability of the body, which he named "innate intelligence," into concepts drawn from contemporary knowledge about anatomy and physiology. He eschewed the use of drugs and surgery as unnatural invasions to the body and focused on what he perceived as normalizing the function of the nervous system as the key to health (17).

From the beginning, chiropractors understood that professional self-regulation and independent legal status were crucial to survival. This stormy history of the first century of chiropractic includes many milestones on the march to professionalization, some of which are listed in Table 1. Although chiropractic originated in the United States (the primary training ground and theoretical inspirational source for chiropractors), it took less than 10 years for chiropractors to immigrate and begin practice in other countries. In 1923, the province of Alberta in Canada became the first jurisdiction to license chiropractic outside of the United States; in 1939, the canton of Zürich in Switzerland was the first to license the profession outside of North America. Today, chiropractors are licensed and regulated in many countries throughout the world (18) and are permitted to practice in most countries, pursuant to general law.

Table 1. **Events in the Historical Development of Chiropractic**

Year	Historical Milestones
1905	Minnesota is the first state to license chiropractic as an independent profession.
1922	California recognizes and licenses chiropractors.
1933	The U.S. Council of State Chiropractic Examiners is established with a mandate to provide unified standards for licensure. It is now the Federation of Chiropractic Licensing Boards.
1944	The Foundation for Chiropractic Education and Research is established and remains the profession's foremost agency for funding postgraduate training and research.
1963	The National Board of Chiropractic Examiners is established to create standardized examinations and promote consistency and reciprocity between state examining boards.
1974	Louisiana is the last state to grant licensure to chiropractors.
1974	The U.S. Council on Chiropractic Education is recognized by the U.S. Department of Education as the sole accrediting agency for schools of chiropractic.
1975	The U.S. National Institute of Neurological Diseases and Stroke convenes a multidisciplinary conference to examine the research status of "spinal manipulative therapy."
1976	*Journal of Manipulative and Physiological Therapeutics* is founded as a scientific peer-reviewed chiropractic journal and is indexed by the National Library of Medicine.
1987	The U.S. Supreme Court upholds a lower-court decision that finds the American Medical Association guilty of antitrust violations in its attempt to eliminate the chiropractic profession.
1994	The U.S. Agency for Health Care Policy and Research convenes an evidence-based consensus panel that rates spinal manipulation as an effective treatment for back pain.
1997	The Consortial Center for Chiropractic Research is established by a grant from the U.S. National Institutes of Health.

Chiropractic in Health Care

One indicator of chiropractic mainstreaming is the steadily increasing use by patients in the United States, which has tripled in the past two decades from about 3.6% according to a 1980 survey (19) to an estimated 11% according to a 1997 national random telephone survey (2). This translates to an estimated 190 million patient visits to chiropractors in a year, or about 30% of visits to all complementary and alternative practitioners (2). One recent survey of family physicians and chiropractors in North Carolina (20) found that two thirds of the medical physicians felt "moderately" or "very" informed about chiropractic. Furthermore, 65% admitted referring patients to chiropractors, and 98% of chiropractors made routine referrals to physicians.

Payments for chiropractic care historically came directly from patients' pockets until chiropractic services were included in Medicare in the 1970s. In the past few decades, chiropractic has been included in a substantial proportion of private and public insurance plans, all state workers-compensation systems, and all forms of managed care (including health maintenance organizations). More than 50% of health maintenance organizations and more than 75% of private health insurance plans now offer chiropractic services (21). Under order of the U.S. Congress, the military health care system has initiated a series of demonstration projects to investigate the feasibility of providing chiropractic care to military personnel.

CHIROPRACTIC TRAINING AND LICENSURE

From many proprietary schools hastily established during the first part of the 20th century, a stable number of chiropractic training institutions have emerged in the United States. Unlike in the United States, where all but one college are privately funded, chiropractic education in Australia, South Africa, Denmark, one college in Canada, and two in Great Britain is provided at established government-sponsored universities and colleges. Most colleges in the United States are accredited by the Council on Chiropractic Education, an agency certified by the U.S. Department of Education. Each college requires at least 4 academic years of professional education before students can qualify for licensure examinations. A minimum of 60 units of prescribed college-level courses (increasing to 90 units by 2002), mostly in the sciences, is required before admission to chiropractic college. Approximately 50% of students enter chiropractic training with a baccalaureate degree.

A recent study described U.S. chiropractic curricula as an average of 4820 classroom and clinical hours, with about 30% spent in the basic sciences and 70% in clinical sciences and internship (22). Medical school curricula average about 4670 hours with a similar breakdown. Compared with medical students, chiropractic students spend more hours in anatomy and physiology but fewer in public health. Both programs have similar hours in biochemistry, microbiology, and pathology. Chiropractic curricula provide relatively little instruction in pharmacology, critical care, and surgery but emphasize biomechanics, musculoskeletal function, and manual treatment methods. Medical education has more than twice as many hours in actual clinical experience but 1000 fewer hours in didactic and workshop-like clinical courses. All chiropractic colleges maintain busy training clinics that deliver chiropractic care in settings similar to typical chiropractic practice. Specialty training is available in 2- to 3-year postgraduate residency programs in radiology, orthopedics, neurology, sports, rehabilitation, and pediatrics. Coursework leads to eligibility for accredited specialty board competency examinations, which confer "diplomate" or "certified" status.

Forty-six states either recognize or require passage of examinations administered by the National Board of Chiropractic Examiners in the areas of basic science, clinical science, and clinical competency before granting a graduate a license to practice. Most states also require annual proof of continuing education credits for ongoing license renewal.

CHIROPRACTIC HEALTH CARE AND PRACTICE CHARACTERISTICS

Chiropractic is an evolving health profession with functions, values, traditions, and training institutions similar to those of other professions. As envisioned by its founder, chiropractic was to be a revolutionary system of healing based on the premise that neurologic dysfunction caused by "impinged" nerves at the spinal level was the cause of most "dis-ease" and that spinal manipulation (adjustment) removed the interference to a full and healthy expression of life. Modern chiropractic theory and practice have moved away from the original monocausal theory, and research is gradually redefining the nature of the discipline and its education. Many still think "chiropractic" is synonymous with "spinal manipulation," but as described below, this is only partially accurate. With the advent of the category "complementary and alternative medicine" (CAM), chiropractors themselves are divided about how to define the profession; many do not want to be termed CAM practitioners (23). Chiropractors have many of the attributes of primary care providers and often describe themselves as such (24). Others point out that chiropractic has more of the attributes of a limited medical profession or specialty, akin to dentistry or podiatry (1). This is an ongoing internal and external debate affected by dynamic health industry forces.

Spinal Manipulation: The Chiropractic Adjustment

The core clinical action that all chiropractors agree upon is spinal manipulation. Chiropractors much prefer the term spinal "adjustment," reflecting their belief in the therapeutic and health-enhancing effect of correcting spinal joint abnormalities. Dozens of adjusting "techniques" exist, and discussions about their relative merits make up much chiropractic academic discourse (25, 26). The procedure in its broadest definition describes application of a load (force) to specific body tissues with therapeutic intent. This load, which has traditionally been delivered by hand, can vary in its velocity, amplitude, duration, and frequency, as well as anatomic location, choice of levers, and direction of force.

Although "spinal manipulation" is traditionally as-

sociated with "chiropractic" (chiropractors deliver >90% of the manipulations in the United States [27]), chiropractors also provide many other treatments and counselling services. Physical therapies such as heat, cold, electrical methods, and rehabilitation methods are common (28, 29). Chiropractors usually suggest therapeutic exercises and general fitness recommendations to most patients, and give advice to many patients about nutrition, vitamins, weight loss, smoking cessation, and relaxation techniques (30). Many chiropractors use other forms of CAM, with emphasis on massage, acupressure, and mineral and herb supplements (23).

Chiropractic Case Mix

Studies confirm that most patients go to chiropractors for musculoskeletal problems: about 60% with low-back pain, and the remainder with head, neck, and extremity symptoms (28, 31). Approximately one third of all patients who seek professional care for low-back pain consult chiropractors in a primary health care role (32–34). Furthermore, about half of the patients seeking chiropractic care have chronic symptoms (31, 35). Only a small number, typically fewer than 2% to 5%, seek care for other conditions. Recent studies have also documented that a minor proportion of patients visit chiropractors for general health concerns, prevention, and a feeling of well-being; they often receive standard health advice, most often with regard to physical fitness and nutrition (35–37).

Diagnostic and Assessment Methods

The approach used in chiropractic training and practice for clinical diagnosis is similar to that of all health care disciplines: a history, physical examination, and specialty-specific assessments (25, 38). The Council on Chiropractic Education specifies that these basic clinical competencies must be taught in all accredited institutions, and chiropractors are expected to differentiate mechanical musculoskeletal problems from visceral abnormalities that may present with a similar clinical picture (29). Chiropractic practice guidelines developed by the profession rate history taking, physical examination, and periodic reassessments of progress as "necessary" attributes of good practice (39).

By using job analysis concepts, the National Board of Chiropractic Examiners has provided the most thorough description of chiropractic practice (28). Chiropractors rated "extremely important" the knowledge needed to arrive at a diagnosis on the basis of information gathered from a patient's history and physical, neurologic, and orthopedic examinations. In most states, chiropractors have the statutory right and obligation to render a medical diagnosis, especially within their scope of customary and legal practice. Patients with diagnoses not amenable to chiropractic care are routinely referred (20).

Chiropractors' use of advanced diagnostic tests is generally low, reflecting the typical nature of the musculoskeletal caseload (29). The main exception is plain-film radiography, which has been traditional in chiropractic ever since its development at the beginning of the 20th century. Much training time is spent on the technique and interpretation of musculoskeletal radiographs (22, 40, 41). In regard to radiographic examination, the job analysis survey indicated that chiropractors "frequently" obtain radiographs for new patients to determine abnormality; they "sometimes" obtain radiographs to determine instability or joint dysfunction; they "frequently" determine the possible site and nature of a manipulable subluxation; they "frequently" perform radiography on a patient whose condition is deteriorating or who is not responding to care; and they "rarely" obtain radiographs to monitor a patient's progress. Chiropractors consider knowledge of normal radiographic anatomy and of radiographic interpretation and diagnosis to be "extremely important" (28).

Indications for radiography are hotly debated in chiropractic circles, but use appears to be declining over time (42). The use of radiography may also vary substantially by geographic region. A practice-based study comparing chiropractic and physician practices for patients with back pain in Oregon found that 26% of patients of both provider groups had radiography (43). Carey and colleagues (4) found higher rates of use in North Carolina: 67% for chiropractors and 72% for orthopedists. Of note, since the inception of Medicare 30 years ago, chiropractors had been mandated to obtain radiographs in order to be reimbursed for care. Only after persistent legislative activity has this provision finally been changed (44).

The Chiropractic Clinical Encounter and Patient Perceptions

Chiropractors use the information from the case history and examination to ascertain the patient's state

of health and to form a diagnostic impression, with additional studies obtained as needed. Focal joint, muscle, and soft tissue examinations are usually performed to determine the potential utility of spinal manipulation and other interventions. These usually include palpation, assessing the range and quality of joint motion, and probing for tenderness and inflammation. On the basis of the findings, the chiropractor chooses a treatment plan and estimates prognosis. Essentially, patients may receive a trial of chiropractic care, be referred for co-management, or be referred to an appropriate specialist. The profession has developed detailed consensus guidelines for quality for most aspects of case management (39), and these are didactically and clinically modeled in accredited chiropractic institutions.

The clinical encounter tends toward a high-touch, low-technology health model with more concern for the person than the disease. Chiropractors believe in the inherent healing ability of the body and communicate the hope of healing to patients. Spinal manipulation and other forms of touching care require that a level of trust develop between the patient and the chiropractor. Repeated visits allow a relationship to flourish that is often used to communicate on a social and psychological level as well as about biological implications of care (45).

One recent essay opined that much of chiropractic's success and perhaps its most important contribution to health care might concern this patient–physician relationship (7). Analyses from anthropologic and sociologic perspectives have suggested that treatment by a chiropractor, especially for many patients with chronic pain, can generate a sense of understanding and meaning, an experience of comfort, an expectation of change, and a feeling of empowerment (46, 47). The hands-on and compassionate "can do" clinical behavior of the typical chiropractor seems to be concrete, reassuring, and immediately satisfying. Observational studies (3, 4) and randomized trials (48) leave little doubt that chiropractic patients are very satisfied with their management.

CHIROPRACTIC THEORY AND RESEARCH

Throughout the short history of chiropractic, the profession has had the difficult task of justifying a treatment partially rooted in quasi-mystical concepts to a skeptical mainstream medical and scientific community. Confounding this problem has been the fact that pain, especially chronic musculoskeletal pain, remains something of a scientific enigma (49). A 1975 National Institute of Neurological Diseases and Stroke conference, "Research Status of Spinal Manipulative Therapy," pointed out the lack of any substantial research to justify claims made by chiropractors or any other practitioner of manipulation (50); by doing so the conference galvanized a quarter century–long research effort.

Focus of Research

Two broad categories of research have been pursued: 1) clinical outcomes in randomized clinical trials and observational studies and 2) basic science efforts attempting to understand the biological mechanisms of spinal manipulation. For this report, we supplemented our own exhaustive reference collections of randomized clinical trials of spinal manipulation with additional searches of MEDLINE, MANTIS, CHIROLARS, and the Cochrane Collaboration Library. We tracked citations and manually searched relevant journals to verify that the list was as complete as possible. We made no attempt to find finished unpublished clinical trials or review non–English-language reports.

To date, at least 73 randomized clinical trials of a broadly defined spinal manipulation procedure can be found in the English-language literature. Most trials have been published in general medical and orthopedic journals (for example, *British Medical Journal, Journal of the American Medical Association, Spine*). Nineteen papers were published in the chiropractic peer-reviewed literature (for example, *Journal of Manipulative and Physiological Therapeutics*). Most first authors have medical degrees, and 23 papers were written by chiropractors. Authors did not necessarily publish in the literature of their profession. While publication bias cannot be ruled out, there is no evidence of it in this information.

Most of these studies have been conducted on patients with low-back, neck, and head pain, and a few have examined other conditions. The clinical trials include placebo-controlled comparisons, comparisons with other treatments, and pragmatic comparisons of chiropractic management with common medical management (Table 2).

Forty-three randomized trials of spinal manipulation for treatment of acute, subacute, and chronic low-back pain have been published. Thirty favored manipulation over the comparison treatments in at least a subgroup of patients, and the other 13 found no signif-

Table 2. **Results of Randomized, Controlled Trials of Spinal Manipulation**

Condition	Randomized, Controlled Trials, *n*	Results	References
Acute back pain	10	Positive	51–63
	3	Equivocal	
Subacute and chronic back pain	9	Positive	64–79
	6	Equivocal	
Mixed acute and chronic back pain	10	Positive	48, 80–94
	4	Equivocal	
Sciatica	1	Positive	95
Migraine headache	2	Positive	96–98
	1	Equivocal	
Muscle tension headache	4	Positive	99–103
	1	Equivocal	
Cervicogenic headache	1	Positive	104
Acute, subacute, chronic neck pain	4	Positive	72, 73, 91, 92, 105–113
	7	Equivocal	
Elbow pain	1	Positive	114
Dysmenorrhea	1	Positive	115, 116
	1	Equivocal	
Infantile colic	1	Positive	117
Enuresis	1	Equivocal	118
Asthma	2	Equivocal	119, 120
Premenstrual syndrome	1	Positive	121
Carpal tunnel syndrome	1	Equivocal	122
Hypertension	1	Positive	123, 124
	1	Equivocal	

icant differences. No trial to date has found manipulation to be statistically or clinically less effective than the comparison treatment. Eleven of the low-back pain trials included a placebo group; 8 of them showed an advantage to manipulation (125). Eleven randomized, controlled trials of spinal manipulation for neck pain have been conducted; 4 had positive findings and 7 were equivocal. Seven of 9 randomized trials of manipulation for various forms of headache were positive.

In most of the randomized, controlled trials of manipulation for musculoskeletal pain, the positive effect sizes appear to be clinically and statistically significant but not dramatic, leaving room for various interpretations. Systematic reviews and meta-analyses conducted in the early to mid-1990s made cautiously positive or equivocal statements about the effectiveness of manipulation for low-back pain, neck pain, and headache, and called for higher-quality studies (27, 125–129).

Using formal consensus processes, in 1995 the Quebec Task Force on Whiplash-Associated Disorders concluded that spinal manipulation had at least "weak cumulative evidence," and recommended that a short regimen of spinal manipulation may be used as a therapeutic trial for neck pain (130). In 1994, the U.S. Agency for Health Care Policy and Research similarly concluded that spinal manipulation was safe and effective for acute low-back pain, with a strength of evidence level of "B." This agency reviewed all clinical trials available at the time and found no other treatment to have stronger evidence, although nonsteroidal anti-inflammatory drugs received the same "B" rating (131).

A 1997 systematic review of manipulation for low-back pain concluded (132), in contrast to previous opinions (27, 128, 131), that evidence was sufficient to recommend manipulation for chronic back pain but that the evidence for acute back pain was weak. The most recent systematic review (133) used a slightly different method of analysis, taking into account study design, quality, and strength of evidence; these authors concluded that there was moderately strong evidence of a short-term benefit of manipulation for both acute and chronic back pain. They found insufficient evidence for or against the effectiveness of manipulation for sciatica. However, a recent trial found that manipulation for patients with sciatica related to disc herniation was better than chemonucleolysis in the short term and equivalent to that therapy at 12 months (95). A recent quantitative review found only equivocal evidence for the benefit of traction, exercise, and drug therapies for sciatica (134).

The heterogeneity of patients with spinal pain, the

Table 3. **Proposed Mechanisms of Spinal Manipulation**

Action	Mechanism (Reference)
Mechanical/anatomic	Alleviation of an entrapped facet joint inclusion or meniscoid that has been shown to be heavily innervated (138, 139)
Mechanical/anatomic	Repositioning of a fragment of posterior annular material from the intervertebral disc (139, 140)
Mechanical/anatomic	Alleviation of stiffness induced by fibrotic tissue from previous injury or degenerative changes that may include adaptive shortening of fascial tissue (141, 142)
Neurologic/mechanical	Inhibition of excessive reflex activity in the intrinsic spinal musculature or limbs and/or facilitation of inhibited muscle activity (143–145)
Neurologic/mechanical	Reduction of compressive or irritative insults to neural tissues (146)

lack of definitive diagnoses, and the indications in some trials that subgroups of patients appear to respond better to manipulation than others have further highlighted the need to understand the underlying physiologic and psychological mechanisms of pain and disability. The design of rigorous clinical experiments of treatment efficacy for approaches that include strong physician–patient interactions and "hands-on" therapy has been challenging, posing the question of a strong psychological effect of chiropractic treatment. Surprisingly, spinal manipulation is one of the most studied treatments for back pain (56, 132). All manipulation trials, however, have had to contend with design and execution weaknesses that need to be addressed in future studies.

The treatment of disorders not directly related to the musculoskeletal system by manipulation has been supported mainly by clinical experience and case reports. In the past few years, randomized clinical trials for primary dysmenorrhea (115, 116), hypertension (123, 124), chronic asthma (119, 120), enuresis (118), infantile colic (117), and premenstrual syndrome (121) have been completed, with variable results. Two systematic reviews, one on extant trials at the time (135) and a recent one on asthma sponsored by the Cochrane Collaboration (136), concluded that the results do not argue convincingly for or against the utility of spinal manipulation for these kinds of conditions.

Biological Rationale

Chiropractors direct spinal manipulation to a dysfunctional joint "lesion" known as a subluxation. This is characterized as a form of joint strain or sprain with clinically associated hypomobility, malalignment, local and referred pain, inflammation, and muscle tension (137). Subluxation in the chiropractic context primarily connotes a functional and not necessarily an anatomic entity. At least five mechanical and neurologic mechanisms have been proposed (Table 3).

Chiropractic theory has held that subluxation and manipulation can have important physiologic effects: increased range of joint motion (147, 148), changes in facet joint kinematics (149), increased pain tolerance (150), increased muscle strength (151), attenuation of α-motoneuron activity (152), enhanced proprioceptive behavior (153), and changes in β-endorphins (154) and substance P (155). A biomechanical picture of manipulation is beginning to emerge from studies on the forces involved and the resultant kinetics and kinematics (156, 157).

Risks of Spinal Adjustments and Manipulations

The topic of complications from spinal manipulation has been controversial (126, 158, 159). Nonserious side effects of manipulation may consist of localized discomfort, headache, or fatigue that resolves within 24 to 48 hours (160). The more serious reported complications are the cauda equina syndrome from lumbar manipulation and cerebrovascular artery dissection from cervical manipulation. The apparent rarity of these accidental events has made it difficult to assess the magnitude of the complication risk. No serious complication has been noted in more than 73 controlled clinical trials or in any prospectively evaluated case series to date.

Serious complications from lumbar spinal manipulation are extremely rare, estimated to be 1 case per 100 million manipulations (27). For cervical manipulation, the risk for a cerebrovascular accident has been calculated by various authors to range from 1 in 400 000 (161) to between 3 and 6 per 10 million manipulations (126). The figures have been primarily based on retrospectively collected single case reports (126, 158) and unsubstantiated practitioner surveys (161, 162). One retrospective cohort study examined the incidence of cerebrovascular accidents after manipulation (163). It covered the experience of 99% of the practicing chiropractors in Denmark from 1978 to 1988. During this 10-year period, five cases and one death were identified,

representing approximately one serious complication for every 1 million cervical manipulations. Unfortunately, there do not appear to be any specific risk factors for vertebrobasilar artery dissection after manipulation, and the cases might represent idiosyncratic events or the aggravation of arterial dissections in progress (159).

THE FUTURE

Significant challenges for conducting high-quality studies in the chiropractic profession continue to exist, but this is changing. The U.S. Health Resources and Services Administration's Chiropractic Demonstration Program was the first federal effort to facilitate collaborative research between chiropractic and medical institutions in 1994, and it continues to sponsor annual conferences designed to set research agenda (164). In 1997, the National Center for Complementary and Alternative Medicine initiated a research center, the Consortial Center for Chiropractic Research, at Palmer College of Chiropractic in Davenport, Iowa. It represents a collaboration of six chiropractic colleges and four state-supported universities.

Chiropractic has survived, and it has begun to embrace the values and behaviors of a mainstream health profession. In the past few decades, chiropractic has strengthened its educational system; initiated research that has validated spinal manipulation; increased its market share of satisfied patients; initiated collaborations with other disciplines in practice, research, and professional settings; and effectively used political, legislative, and legal measures to secure a role. Nevertheless, significant attitudinal and structural barriers to mainstream status still hinder chiropractic, and the advances of recent years may not be enough to ensure continuing progress in this direction.

Chiropractic still maintains some vestiges of an alternative health care profession in image, attitude, and practice. The profession has not resolved questions of professional and social identity, and it has not come to a consensus on the implications of integration into mainstream health care delivery systems and processes. In today's dynamic health care milieu, chiropractic stands at the crossroads of mainstream and alternative medicine. Its future role will probably be determined by its commitment to interdisciplinary cooperation and science-based practice.

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Review Article

Efficacy of spinal manipulation and mobilization for low back pain and neck pain: a systematic review and best evidence synthesis

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Abstract

BACKGROUND CONTEXT: Despite the many published randomized clinical trials (RCTs), a substantial number of reviews and several national clinical guidelines, much controversy still remains regarding the evidence for or against efficacy of spinal manipulation for low back pain and neck pain.
PURPOSE: To reassess the efficacy of spinal manipulative therapy (SMT) and mobilization (MOB) for the management of low back pain (LBP) and neck pain (NP), with special attention to applying more stringent criteria for study admissibility into evidence and for isolating the effect of SMT and/or MOB.
STUDY DESIGN: RCTs including 10 or more subjects per group receiving SMT or MOB and using patient-oriented primary outcome measures (eg, patient-rated pain, disability, global improvement and recovery time).
METHODS: Articles in English, Danish, Swedish, Norwegian and Dutch reporting on randomized trials were identified by a comprehensive search of computerized and bibliographic literature databases up to the end of 2002. Two reviewers independently abstracted data and assessed study quality according to eight explicit criteria. A best evidence synthesis incorporating explicit, detailed information about outcome measures and interventions was used to evaluate treatment efficacy. The strength of evidence was assessed by a classification system that incorporated study validity and statistical significance of study results. Sixty-nine RCTs met the study selection criteria and were reviewed and assigned validity scores varying from 6 to 81 on a scale of 0 to 100. Forty-three RCTs met the admissibility criteria for evidence.
RESULTS: Acute LBP: There is moderate evidence that SMT provides more short-term pain relief than MOB and detuned diathermy, and limited evidence of faster recovery than a commonly used physical therapy treatment strategy.
Chronic LBP: There is moderate evidence that SMT has an effect similar to an efficacious prescription nonsteroidal anti-inflammatory drug, SMT/MOB is effective in the short term when compared with placebo and general practitioner care, and in the long term compared to physical therapy. There is limited to moderate evidence that SMT is better than physical therapy and home back exercise in both the short and long term. There is limited evidence that SMT is superior to sham SMT in the short term and superior to chemonucleolysis for disc herniation in the short term. However, there is also limited evidence that MOB is inferior to back exercise after disc herniation surgery.
Mix of acute and chronic LBP: SMT/MOB provides either similar or better pain outcomes in the short and long term when compared with placebo and with other treatments, such as McKenzie therapy, medical care, management by physical therapists, soft tissue treatment and back school.

FDA device/drug status: not applicable.

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Acute NP: There are few studies, and the evidence is currently inconclusive.
Chronic NP: There is moderate evidence that SMT/MOB is superior to general practitioner management for short-term pain reduction but that SMT offers at most similar pain relief to high-technology rehabilitative exercise in the short and long term.
Mix of acute and chronic NP: The overall evidence is not clear. There is moderate evidence that MOB is superior to physical therapy and family physician care, and similar to SMT in both the short and long term. There is limited evidence that SMT, in both the short and long term, is inferior to physical therapy.
CONCLUSIONS: Our data synthesis suggests that recommendations can be made with some confidence regarding the use of SMT and/or MOB as a viable option for the treatment of both low back pain and NP. There have been few high-quality trials distinguishing between acute and chronic patients, and most are limited to shorter-term follow-up. Future trials should examine well-defined subgroups of patients, further address the value of SMT and MOB for acute patients, establish optimal number of treatment visits and consider the cost-effectiveness of care.

Keywords: Low back pain; Cervical vertebrae; Manipulation/orthopedic; Randomized controlled trials; Comparative study; Review literature; Meta-analysis; Chiropractic; Osteopathy medicine; Manipulation/spinal

Background context

More than 50 mostly qualitative, nonsystematic reviews have been published since 1979 addressing the role of spinal manipulation and mobilization in the treatment of back and neck pain (NP) [1]. A majority of these reviews, including most of the systematic reviews [2–7], have concluded that spinal manipulation is an efficacious treatment for low back pain (LBP) [1]. However, most reviews restricted their positive conclusions to patients with acute LBP [1].

A number of scales and checklists have been developed to assess the quality of randomized clinical trials (RCTs) [8]. In general, positive or negative trial outcomes have been accepted at face value without consideration of the magnitude of the differences among interventions. A shortcoming of this approach is exemplified by reevaluations of individual RCTs on the efficacy of spinal manipulation, where it was found that the data supported conclusions that were in conflict with those of the original publications [9].

Our reevaluation of the literature follows from a previous systematic review of reviews [1], in which the authors observed that the vast majority of the reviews of spinal manipulation for LBP were of inadequate methodological quality. Furthermore, the authors identified a need to develop standards of quality for systematic reviews in general, which was emphasized in an accompanying editorial by Moher and Olkin [10]. The methodology used in this review is intended as a step in that direction. Using a stringent best evidence synthesis method, we reviewed the literature and contrasted our findings with other recent systematic reviews on the efficacy of spinal manipulation and mobilization for back and neck pain [11,12].

Purpose

The purpose of this review is to reassess the efficacy of spinal manipulative therapy (SMT) and mobilization (MOB) for the management of LBP and NP, with special attention to applying more stringent criteria for study admissibility into evidence and for isolating the effect of SMT and/or MOB.

Methods

Data selection

SMT is defined as the application of high-velocity, low-amplitude manual thrusts to the spinal joints slightly beyond the passive range of joint motion [13]. MOB is defined as the application of manual force to the spinal joints within the passive range of joint motion that does not involve a thrust. A literature search for all RCTs evaluating the therapeutic efficacy of SMT and/or MOB for LBP and NP was performed accessing MEDLINE (1966 to end of 2002), Embase (1974 to end of 2002), CINAHL and the chiropractic reference systems CRAC and MANTIS. Articles in English, Danish, Swedish, Norwegian and Dutch reporting on randomized trials were identified by a comprehensive search of computerized and bibliographic literature databases. The search strategy was based on combinations of the main keywords: manipulation, spinal; low back pain; cervical vertebrae; manipulation/orthopedic, randomized controlled trials, comparative study, review literature, chiropract and osteopathy.

Study selection

Each study had to have 10 or more subjects receiving SMT and/or MOB to be included in this review. The main outcome measures had to be explicitly patient oriented (eg, patient-rated pain, global improvement, low back or neck disability, recovery time, work loss, medication use and functional health status). Additionally, citation tracking of

Cochrane review abstract and plain language summary

This is an abstract and plain language summary of a regularly updated, systematic review prepared and maintained by The Cochrane Collaboration. The full text of the review is available in *The Cochrane Library* (ISSN 1464-780X).

The Cochrane Database of Systematic Reviews 2006 Issue 1

Manipulation and mobilisation for mechanical neck disorders

Gross AR, Hoving JL, Haines TA, Goldsmith CH, Kay T, Aker P, Bronfort G, Cervical overview group

Plain language summary

People with neck pain as well as people with neck pain plus related headache that lasted at least one month, who received multimodal care that included exercises plus mobilisation [movement imposed onto joints and muscles] or manipulation [adjustments] reported greater pain reduction, improved ability to perform everyday activities and an increase in their perceived effects of treatment than those who received no treatment.

This review of 33 trials did not favour manipulation or mobilisation done alone or in combination with various other physical medicine agents. It was unclear if manipulation and mobilisation performed in combination were beneficial, but when compared to one another, neither was superior.

Abstract

Background

Neck disorders are common, disabling, and costly. The effectiveness of manipulation and mobilisation remains unclear.

Objectives

To assess whether manipulation and mobilisation, either alone or in combination with other treatments, relieve pain or improve function/disability, patient satisfaction, and global perceived effect in adults with mechanical neck disorders (MND).

Search strategy

Computerised bibliographic databases including CENTRAL, MEDLINE, EMBASE, MANTIS, CINAHL, and ICL, were searched without language restrictions from their respective starting dates to March 2002.

Selection criteria

The studies had to be randomised (RCT) or quasi-randomised and investigate the use of manipulation or mobilisation as a treatment for mechanical neck disorders.

Data collection and analysis

Two independent authors conducted citation identification, study selection, data abstraction, and methodological quality assessment. Using a random effects model, relative risk and standardised mean differences were calculated. The reasonableness of combining studies was assessed on clinical and statistical grounds. In the absence of heterogeneity, pooled effect measures were calculated.

Main results

Of the 33 selected trials, 42% were high quality trials. Single sessions of manipulation or multiple sessions (3 to 11 weeks) of manipulation or mobilisation, or manipulation and mobilisation showed a nonsignificant benefit in pain relief when assessed against placebo, control groups or other treatments for acute/subacute/chronic MNDs with or without headache. There was strong evidence of benefit favouring multimodal care over a waiting list control for pain reduction [pooled SMD -0.85 (95% CI: -1.20 to -0.50)], improvement in function [pooled SMD -0.57 (95% CI: -0.94 to -0.21)] and global perceived effect [SMD -2.73 (95% CI: -3.30 to -2.16)] for subacute/chronic MND with or without headache. The common elements in this care strategy were mobilisation and/or manipulation plus exercise. There was moderate evidence of no difference in effect when multimodal care was compared to various other treatments.

Authors' conclusions

Multimodal care has short-term and long-term maintained benefits for subacute/chronic MND with or without headache. The common elements in this care strategy were mobilisation and/or manipulation plus exercise. The evidence did not favour manipulation and/or mobilisation done alone or in combination with various other physical medicine agents; when compared to one another, neither was superior. There was insufficient evidence available to draw conclusions for neck disorder with radicular findings.

The added benefit of exercise needs to be further explored. Factorial design would help determine the active treatment agent (s) within a treatment mix. Phase II trials would help identify the

most effective treatment characteristics and dosages. Greater attention to methodological quality is needed.

This is an abstract and plain language summary of a regularly updated, systematic review prepared and maintained by The Cochrane Collaboration. The full text of the review is available in *The Cochrane Library* (ISSN 1464-780X).

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The Cochrane Database of Systematic Reviews 2006 Issue 1

Non-invasive physical treatments for chronic/recurrent headache

Bronfort G, Nilsson N, Haas M, Evans R, Goldsmith CH, Assendelft WJJ, Bouter LM

Plain language summary

Some non-invasive physical treatments may help prevent chronic/recurrent headaches.

Various physical treatments are often used instead of, or in addition to, medications to treat headaches. Evidence from controlled trials suggests that several non-invasive physical treatments may help prevent chronic/recurrent headaches. Spinal manipulation may be effective for migraine and chronic tension-type headache. Both spinal manipulation and neck exercises may be effective for cervicogenic headache. Weaker evidence suggests that other treatments may also be effective: pulsating electromagnetic fields and transcutaneous electrical nerve stimulation (TENS) for migraine, and therapeutic touch, cranial electrotherapy, TENS, and a combination of self-massage/TENS/stretching for tension-type headache. Although none of these treatments has conclusive evidence for effectiveness, all appear to be associated with little risk of serious adverse effects.

Abstract

Background

Non-invasive physical treatments are often used to treat common types of chronic/recurrent headache.

Objectives

To quantify and compare the magnitude of short- and long-term effects of non-invasive physical treatments for chronic/recurrent

headaches.

Search strategy

We searched the following databases from their inception to November 2002: MEDLINE, EMBASE, BIOSIS, CINAHL, Science Citation Index, Dissertation Abstracts, CENTRAL, and the Specialised Register of the Cochrane Pain, Palliative Care and Supportive Care review group. Selected complementary medicine reference systems were searched as well. We also performed citation tracking and hand searching of potentially relevant journals.

Selection criteria

We included randomized and quasi-randomized controlled trials comparing non-invasive physical treatments for chronic/recurrent headaches to any type of control.

Data collection and analysis

Two independent reviewers abstracted trial information and scored trials for methodological quality. Outcomes data were standardized into percentage point and effect size scores wherever possible. The strength of the evidence of effectiveness was assessed using pre-specified rules.

Main results

Twenty-two studies with a total of 2628 patients (age 12 to 78 years) met the inclusion criteria. Five types of headache were studied: migraine, tension-type, cervicogenic, a mix of migraine and tension-type, and post-traumatic headache. Ten studies had methodological quality scores of 50 or more (out of a possible 100 points), but many limitations were identified. We were unable to pool data because of study heterogeneity.

For the prophylactic treatment of migraine headache, there is evidence that spinal manipulation may be an effective treatment option with a short-term effect similar to that of a commonly used, effective drug (amitriptyline). Other possible treatment options with weaker evidence of effectiveness are pulsating electromagnetic fields and a combination of transcutaneous electrical nerve stimulation [TENS] and electrical neurotransmitter modulation.

For the prophylactic treatment of chronic tension-type headache, amitriptyline is more effective than spinal manipulation during treatment. However, spinal manipulation is superior in the short term after cessation of both treatments. Other possible treatment options with weaker evidence of effectiveness are therapeutic touch; cranial electrotherapy; a combination of TENS and electrical neurotransmitter modulation; and a regimen of auto-massage, TENS, and stretching. For episodic tension-type headache, there is evidence that adding spinal manipulation to massage is not effective.

For the prophylactic treatment of cervicogenic headache, there is evidence that both neck exercise (low-intensity endurance training) and spinal manipulation are effective in the short and long term when compared to no treatment. There is also evidence that spinal manipulation is effective in the short term when compared to massage or placebo spinal manipulation, and weaker evidence when compared to spinal mobilization.

There is weaker evidence that spinal mobilization is more effective in the short term than cold packs in the treatment of post-traumatic headache.

Authors' conclusions

A few non-invasive physical treatments may be effective as prophylactic treatments for chronic/recurrent headaches. Based on trial results, these treatments appear to be associated with little risk of serious adverse effects. The clinical effectiveness and cost-effectiveness of non-invasive physical treatments require further research using scientifically rigorous methods. The heterogeneity of the studies included in this review means that the results of a few additional high-quality trials in the future could easily change the conclusions of our review.

This is an abstract and plain language summary of a regularly updated, systematic review prepared and maintained by The Cochrane Collaboration. The full text of the review is available in *The Cochrane Library* (ISSN 1464-780X).

Cochrane review abstract and plain language summary

This is an abstract and plain language summary of a regularly updated, systematic review prepared and maintained by The Cochrane Collaboration. The full text of the review is available in *The Cochrane Library* (ISSN 1464-780X).

The Cochrane Database of Systematic Reviews 2006 Issue 1

Spinal manipulative therapy for low-back pain

Assendelft WJJ, Morton SC, Yu Emily I, Suttorp MJ, Shekelle PG

Plain language summary

There was little or no difference in pain reduction or the ability to perform everyday activities between people with low-back pain who received spinal manipulation and those who received other advocated therapies.

This review of 39 trials found that spinal manipulation was more effective in reducing pain and improving the ability to perform everyday activities than sham (fake) therapy and therapies already known to be unhelpful. However, it was no more or less effective than medication for pain, physical therapy, exercises, back school or the care given by a general practitioner.

Abstract

Background

Low-back pain is a costly illness for which spinal manipulative therapy is commonly recommended. Previous systematic reviews and practice guidelines have reached discordant results on the effectiveness of this therapy for low-back pain.

Objectives

To resolve the discrepancies related to the use of spinal manipulative therapy and to update previous estimates of effectiveness, by comparing spinal manipulative therapy with other therapies and then incorporating data from recent high-quality randomized, controlled trials (RCTs) into the analysis.

Search strategy

The Cochrane Central Register of Controlled Trials, MEDLINE, EMBASE and CINAHL were electronically searched from their respective beginning to January 2000, using the Back Group search strategy; references from previous systematic reviews were also screened.

Selection criteria

Randomized, controlled trials (RCT) that evaluated spinal manipulative therapy for patients with low-back pain, with at least one day of follow-up, and at least one clinically-relevant outcome measure.

Data collection and analysis

Two authors, who served as the authors for all stages of the meta-analysis, independently extracted data from unmasked articles. Comparison treatments were classified into the following seven categories: sham, conventional general practitioner care, analgesics, physical therapy, exercises, back school, or a collection of therapies judged to be ineffective or even harmful (traction, corset, bed rest, home care, topical gel, no treatment, diathermy, and minimal massage).

Main results

Thirty-nine RCTs were identified. Meta-regression models were developed for acute or chronic pain and short-term and long-term pain and function. For patients with acute low-back pain, spinal manipulative therapy was superior only to sham therapy (10-mm difference [95% CI, 2 to 17 mm] on a 100-mm visual analogue scale) or therapies judged to be ineffective or even harmful. Spinal manipulative therapy had no statistically or clinically significant advantage over general practitioner care, analgesics, physical therapy, exercises, or back school. Results for patients with chronic low-back pain were similar. Radiation of pain, study quality, profession of manipulator, and use of manipulation alone or in combination with other therapies did not affect these results.

Authors' conclusions

There is no evidence that spinal manipulative therapy is superior to other standard treatments for patients with acute or chronic low-back pain.

This is an abstract and plain language summary of a regularly updated, systematic review prepared and maintained by The Cochrane Collaboration. The full text of the review is available in *The Cochrane Library* (ISSN 1464-780X).

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1: Arch Intern Med. 2004 Oct 11;164(18):1985-92.

Related Articles, Links

Comment in:

- Arch Intern Med. 2004 Oct 11;164(18):1953-4.
- Arch Intern Med. 2005 Jun 13;165(11):1313-4; author reply 1314.

Comparative analysis of individuals with and without chiropractic coverage: patient characteristics, utilization, and costs.

Legorreta AP, **Metz RD**, **Nelson CF**, **Ray S**, **Chernicoff HO**, **Dinubile NA**.

Department of Health Services, UCLA School of Public Health, Los Angeles, Calif, USA. alegorreta@healthbenchmarks.com

BACKGROUND: Back pain accounts for more than $100 billion in annual US health care costs and is the second leading cause of physician visits and hospitalizations. This study ascertains the effect of systematic access to chiropractic care on the overall and neuromusculoskeletal-specific consumption of health care resources within a large managed-care system. METHODS: A 4-year retrospective claims data analysis comparing more than 700 000 health plan members with an additional chiropractic coverage benefit and 1 million members of the same health plan without the chiropractic benefit. RESULTS: Members with chiropractic insurance coverage, compared with those without coverage, had lower annual total health care expenditures ($1463 vs $1671 per member per year, P<.001). Having chiropractic coverage was associated with a 1.6% decrease (P = .001) in total annual health care costs at the health plan level. Back pain patients with chiropractic coverage, compared with those without coverage, had lower utilization (per 1000 episodes) of plain radiographs (17.5 vs 22.7, P<.001), low back surgery (3.3 vs 4.8, P<.001), hospitalizations (9.3 vs 15.6, P<.001), and magnetic resonance imaging (43.2 vs 68.9, P<.001). Patients with chiropractic coverage, compared with those without coverage, also had lower average back pain episode-related costs ($289 vs $399, P<.001). CONCLUSIONS: Access to managed chiropractic care may reduce overall health care expenditures through several effects, including (1) positive risk selection; (2) substitution of chiropractic for traditional medical care, particularly for spine conditions; (3) more conservative, less invasive treatment profiles; and (4) lower health service costs associated with managed chiropractic care. Systematic access to managed chiropractic care not only may prove to be clinically beneficial but also may reduce overall health care costs.

PMID: 15477432 [PubMed - indexed for MEDLINE]

1: Acupunct Electrother Res. 2004;29(1-2):73-82. Related Articles, Links

Acupuncture decreases neuropeptide Y expression in the hypothalamus of rats with Streptozotocin-induced diabetes.

Lee JD, Jang MH, Kim EH, Kim CJ.

Dept of Acupuncture and Moxibustion, College of Oriental Medicine, Kyung Hee University, Seoul, Korea.

It has been known that acupuncture has various effects such as analgesia, promotion of homeostasis, improvements in brain circulation, and rectification of internal disorders. Neuropeptide Y (NPY), a 36-amino-acid peptide, is known to increase appetite. In the present study, the effect of acupuncture stimulation at Zusanli (St.36) on NPY expression in the Streptozotocin (STZ)-induced diabetic rats was investigated via immunohistochemistry. Increased NPY expression was detected in both the Arcuate nucleus (ARN) and the Paraventricular nucleus (PVN) of the Hypothalamus in rats with in STZ-induced diabetes. Needling on Zusanli resulted in decreased NPY levels in both the ARN and PVN of diabetic rats. The present study shows that acupuncture suppressed NPY expression in the ARN and PVN of the Hypothalamus in STZ-induced diabetic rats, suggesting the possibility that acupuncture treatment is effective in curbing the hyperphagia of diabetes.

PMID: 15382790 [PubMed - indexed for MEDLINE]

All: 1 Review: 0

1: Wien Med Wochenschr. 2005 Sep;155(17-18):386-91.

Complementary/alternative medicine for hypertension: a mini-review.

Ernst E.

Complementary Medicine, Peninsula Medical School, Exeter, United Kingdom. Edzard.Ernst@pms.ac.uk

Many hypertensive patients try complementary/alternative medicine for blood pressure control. Based on extensive electronic literature searches, the evidence from clinical trials is summarised. Numerous herbal remedies, non-herbal remedies and other approaches have been tested and some seem to have antihypertensive effects. The effect size is usually modest, and independent replications are frequently missing. The most encouraging data pertain to garlic, autogenic training, biofeedback and yoga. More research is required before firm recommendations can be offered.

PMID: 16392435 [PubMed - in process]

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Currently, the full article is available in German.

When it is officially accepted in PubMed, it may be available in English.

Supporting Documents

I. Acupuncturist Fact Sheet – Minnesota Board of Medical Practice

ACUPUNCTURIST FACT SHEET

HISTORY

The Minnesota Legislature enacted a law in 1995 establishing a licensure system for acupuncturists. The Board of Medical Practice enforces the requirements of the acupuncturist licensure system and provides information to consumers and other interested persons.

ACUPUNCTURE ADVISORY COUNCIL

The Acupuncture Advisory Council was appointed by the Board of Medical Practice to advise the Board on issues regarding acupuncturist licensure standards, enforcement of the practice act, and complaint review. The Council is composed of seven members: four acupuncture practitioners, one physician who also practices acupuncture, one chiropractor who is certified by the National Certification Commission for Acupuncture and Oriental Medicine (NCCAOM), and one public member who has received acupuncture treatment as a primary therapy from a NCCAOM certified acupuncturist.

LICENSURE REQUIRED

It is unlawful for any person to engage in the practice of acupuncture without a valid license after June 30, 1997. Each licensed acupuncture practitioner shall conspicuously display the license in the place of practice. A person licensed under the Acupuncture Practice Act shall use the title of licensed acupuncturist or L.Ac. A unlicensed person are prohibited from using the words or letters licensed acupuncturist, Minnesota licensed acupuncturists or any other words, letters, abbreviations, or insignia indicating or implying that the person is an acupuncturist without a license issued under the Acupuncture Practice Act. Unlicensed persons holding themselves out as an acupuncturist are guilty of a misdemeanor. A student attending an acupuncture training program must be identified as a student acupuncturist.

EXEMPTIONS

The following persons are exempt from the acupuncture license requirement:

1. Physicians licensed in Minnesota
2. Osteopaths licensed in Minnesota
3. Chiropractors licensed in Minnesota
4. Persons studying in an acupuncture advisory council approved program providing their acupuncture practice is supervised by a licensed acupuncturist
5. A visiting acupuncturist practicing and teaching acupuncture within an instructional setting registered with the Minnesota higher education coordinating board. This person may practice without a license for up to one year, with two one-year extensions permitted.
6. A visiting acupuncturists whose sole purpose for visiting state if to provide a tutorial or workshop for 30 days or less per calendar year.

LICENSURE REQUIREMENTS

A. **General Licensure.** To establish eligibility for licensure, an applicant must be currently NCCAOM certified.

B. **Licensure by Reciprocity.** Applicant must have current and unrestricted license or certificate from another jurisdiction with requirements which meet or exceed Minnesota licensure requirements.

SCOPE OF PRACTICE

The scope of practice of acupuncturists includes, but is not limited to: 1) using Oriental medical theory to assess and diagnose a patient and 2) using Oriental medical theory to develop a plan to treat a patient. The acupuncturists must refer patients witt a potentially serious disorder to other health care practitioners. The acupuncturists shall request a consultation or written diagnosis from a licensed physician for patients with potentially serious disorders.

PRACTICE STANDARDS

Prior to treatment of a patient, an acupuncture practitioner shall ask whether the patient has been examined by a health care professional

CONTINUING EDUCATION

All licensed acupuncturists must provide evidence annually of one hour of continuing education in infection control, including blood borne pathogen diseases. Licensees issued an acupuncture license under the general requirements must provide documentation of current NCCAOM certification. Licensees issued an acupuncture license by reciprocity or by equivalency during transitional period must meet one-half the current NCCAOM professional development activity requirements.

RENEWAL CYCLE

Licensure must be renewed annually on or before June 30 of each year. Renewal notices are sent approximately 45 days prior to expiration. It is the acupuncturist's responsibility to keep the Board advised of their current address. The Board is obligated to mail the renewal application to the address on file. Failure to receive the renewal documents does not relieve acupuncturists of their renewal obligation.

INACTIVE LICENSURE STATUS

A license may be placed in formal inactive status upon application to the Board and payment of $50 fee and may be reactivated by licensee upon application to the Board.

The Board will cancel a license for nonrenewal if the license has not been renewed within two annual renewal cycles. Acupuncturists wishing to practice in Minnesota again once a license has been canceled for nonrenewal must obtain a new license by reapplying and fulfilling all requirements in existence at time of reapplication.

If any part of this Fact Sheet conflicts with the Minnesota rules or laws, the rules or laws take precedence. It is your responsibility to understand and comply with the regulations. Please call the Board offices if you have any questions.

12-5-2005

National Institutes of Health
Consensus Development Statement

ACUPUNCTURE

November 3-5, 1997

Revised Draft
11/5/97

This statement will be published as: Acupuncture. NIH Consens Statement 1997 November 3-5;15(5): in press. For making bibliographic reference to consensus statement no. 107 in the electronic form displayed here, it is recommended that the following format be used: NIH Consens Statement Online 1997 November 3-5 [cited year, month, day]; 15(5): in press.

NIH Consensus Statements are prepared by a nonadvocate, non-Federal panel of experts, based on (1) presentations by investigators working in areas relevant to the consensus questions during a 2-day public session; (2) questions and statements from conference attendees during open discussion periods that are part of the public session; and (3) closed deliberations by the panel during the remainder of the second day and morning of the third. This statement is an independent report of the consensus panel and is not a policy statement of the NIH or the Federal Government.

Contents

Introduction

Acupuncture is a component of the health care system of China that can be traced back for at least 2,500 years. The general theory of acupuncture is based on the premise that there are patterns of energy flow (Qi) through the body that are essential for health. Disruptions of this flow are believed to be responsible for disease. The acupuncturist can correct imbalances of flow at identifiable points close to the skin. The practice of acupuncture to treat identifiable pathophysiological conditions in American medicine was rare until the visit of President Nixon to China in 1972. Since that time, there has been an explosion of interest in the United States and Europe in the application of the technique of acupuncture to Western medicine.

Acupuncture describes a family of procedures involving stimulation of anatomical locations on the skin by a variety of techniques. The most studied mechanism of stimulation of acupuncture points employs penetration of the skin by thin, solid, metallic needles, which are manipulated manually or by electrical stimulation. The majority of comments in this report are based on data that came from such studies. Stimulation of these areas by moxibustion, pressure, heat, and lasers is used in acupuncture practice, but due to the paucity of studies, these techniques are more difficult to evaluate. Thus, there are a variety of approaches to diagnosis and treatment in American acupuncture that incorporate medical traditions from China, Japan, Korea, and other countries.

Acupuncture has been used by millions of American patients and performed by thousands of physicians, dentists, acupuncturists, and other practitioners for relief or prevention of pain and for a variety of health conditions. After reviewing the existing body of

knowledge, the U.S. Food and Drug Administration recently removed acupuncture needles from the category of "experimental medical devices" and now regulates them just as it does other devices, such as surgical scalpels and hypodermic syringes, under good manufacturing practices and single-use standards of sterility.

Over the years, the National Institutes of Health (NIH) has funded a variety of research projects on acupuncture, including studies on the mechanisms by which acupuncture may have its effects, as well as clinical trials and other studies. There is also a considerable body of international literature on the risks and benefits of acupuncture, and the World Health Organization lists a variety of medical conditions that may benefit from the use of acupuncture or moxibustion. Such applications include pre-vention and treatment of nausea and vomiting; treatment of pain and addictions to alcohol, tobacco, and other drugs; treatment of pulmonary problems such as asthma and bronchitis; and rehabilitation from neurological damage such as that caused by stroke.

To address important issues regarding acupuncture, the NIH Office of Alternative Medicine and the NIH Office of Medical Applications of Research organized a $2^1/_2$-day conference to evaluate the scientific and medical data on the uses, risks, and benefits of acupuncture procedures for a variety of conditions. Cosponsors of the conference were the National Cancer Institute, the National Heart, Lung, and Blood Institute, the National Institute of Allergy and Infectious Diseases, the National Institute of Arthritis and Musculoskeletal and Skin Diseases, the National Institute of Dental Research, the National Institute on Drug Abuse, and the Office of Research on Women's Health of the NIH. The conference brought together national and international experts in the fields of acupuncture, pain, psychology, psychiatry, physical medicine and rehabilitation, drug abuse, family practice, internal medicine, health policy, epidemiology, statistics, physiology, and biophysics, as well as representatives from the public.

After $1^1/_2$ days of available presentations and audience discussion, an independent, non-Federal consensus panel weighed the scientific evidence and wrote a draft statement that was presented to the audience on the third day. The consensus statement addressed the following key questions:

- What is the efficacy of acupuncture, compared with placebo or sham acupuncture, in the conditions for which sufficient data are available to evaluate?
- What is the place of acupuncture in the treatment of various conditions for which sufficient data are available, in comparison with or in combination with other interventions (including no intervention)?
- What is known about the biological effects of acupuncture that helps us understand how it works?
- What issues need to be addressed so that acupuncture may be appropriately incorporated into today's health care system?
- What are the directions for future research?

The primary sponsors of this meeting were the National Human Genome Research Institute and the NIH Office of Medical Applications of Research. The conference was

cosponsored by the National Institute of Diabetes and Digestive and Kidney Diseases; the National Heart, Lung, and Blood Institute; the National Institute of Child Health and Human Development; the NIH Office of Rare Diseases; the National Institute of Mental Health; the National Institute of Nursing Research; the NIH Office of Research on Women's Health; the Agency for Health Care Policy and Research; and the Centers for Disease Control and Prevention.

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1. What is the efficacy of acupuncture, compared with placebo or sham acupuncture, in the conditions for which sufficient data are available to evaluate?

Acupuncture is a complex intervention that may vary for different patients with similar chief complaints. The number and length of treatments and the specific points used may vary among individuals and during the course of treatment. Given this reality, it is perhaps encouraging that there exist a number of studies of sufficient quality to assess the efficacy of acupuncture for certain conditions.

According to contemporary research standards, there is a paucity of high-quality research assessing efficacy of acupuncture compared with placebo or sham acupuncture. The vast majority of papers studying acupuncture in the biomedical literature consist of case reports, case series, or intervention studies with designs inadequate to assess efficacy.

This discussion of efficacy refers to needle acupuncture (manual or electroacupuncture) because the published research is primarily on needle acupuncture and often does not encompass the full breadth of acupuncture techniques and practices. The controlled trials usually have only involved adults and did not involve long-term (i.e., years) acupuncture treatment.

Efficacy of a treatment assesses the differential effect of a treatment when compared with placebo or another treatment modality using a double-blind controlled trial and a rigidly defined protocol. Papers should describe enrollment procedures, eligibility criteria, description of the clinical characteristics of the subjects, methods for diagnosis, and a description of the protocol (i.e., randomization method, specific definition of treatment, and control conditions, including length of treatment, and number of acupuncture sessions). Optimal trials should also use standardized outcomes and appropriate statistical analyses. This assessment of efficacy focuses on high-quality trials comparing acupuncture with sham acupuncture or placebo.

Response Rate. As with other interventions, some individuals are poor responders to specific acupuncture protocols. Both animal and human laboratory and clinical experience suggest that the majority of subjects respond to acupuncture, with a minority not responding. Some of the clinical research outcomes, however, suggest that a larger

percentage may not respond. The reason for this paradox is unclear and may reflect the current state of the research.

Efficacy for Specific Disorders. There is clear evidence that needle acupuncture is efficacious for adult post-operative and chemotherapy nausea and vomiting and probably for the nausea of pregnancy.

Much of the research is on various pain problems. There is evidence of efficacy for postoperative dental pain. There are reasonable studies (although sometimes only single studies) showing relief of pain with acupuncture on diverse pain conditions such as menstrual cramps, tennis elbow, and fibromyalgia. This suggests that acupuncture may have a more general effect on pain. However, there are also studies that do not find efficacy for acupuncture in pain.

There is evidence that acupuncture does not demonstrate efficacy for cessation of smoking and may not be efficacious for some other conditions.

While many other conditions have received some attention in the literature and, in fact, the research suggests some exciting potential areas for the use of acupuncture, the quality or quantity of the research evidence is not sufficient to provide firm evidence of efficacy at this time.

Sham Acupuncture. A commonly used control group is sham acupuncture, using techniques that are not intended to stimulate known acupuncture points. However, there is disagreement on correct needle placement. Also, particularly in the studies on pain, sham acupuncture often seems to have either intermediate effects between the placebo and Ôreal' acupuncture points or effects similar to those of the Ôreal' acupuncture points. Placement of a needle in any position elicits a biological response that complicates the interpretation of studies involving sham acupuncture. Thus, there is substantial controversy over the use of sham acupuncture as control groups. This may be less of a problem in studies not involving pain.

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2. What is the place of acupuncture in the treatment of various conditions for which sufficient data are available, in comparison with or in combination with other interventions (including no intervention)?

Assessing the usefulness of a medical intervention in practice differs from assessing formal efficacy. In conventional practice, clinicians make decisions based on the characteristics of the patient, clinical experience, potential for harm, and information from colleagues and the medical literature. In addition, when more than one treatment is possible, the clinician may make the choice taking into account the patient's preferences. While it is often thought that there is substantial research evidence to support conventional medical practices; this is frequently not that case. This does not mean that

these treatments are ineffective. The data in support of acupuncture are as strong as those for many accepted Western medical therapies.

One of the advantages of acupuncture is that the incidence of adverse effects is substantially lower than that of many drugs or other accepted medical procedures used for the same conditions. As an example, musculoskeletal conditions, such as fibromyalgia, myofascial pain, and "tennis elbow," or epicondylitis, are conditions for which acupuncture may be beneficial. These painful conditions are often treated with, among other things, anti-inflammatory medications (aspirin, ibuprofen, etc.) or with steroid injections. Both medical interventions have a potential for deleterious side effects, but are still widely used, and are considered acceptable treatment. The evidence supporting these therapies is no better than that for acupucture.

In addition, ample clinical experience, supported by some research data, suggests that acupuncture may be a reasonable option for a number of clinical conditions. Examples are postoperative pain and myofascial and low back pain. Examples of disorders for which the research evidence is less convincing but for which there are some positive clinical reports include addiction, stroke rehabilitation, carpal tunnel syndrome, osteoarthritis, and headache. Acupuncture treatment for many conditions such as asthma, addiction, or smoking cessation should be part of a comprehensive management program.

Many other conditions have been treated by acupuncture; the World Health Organization, for example, has listed more than 40 for which the technique may be indicated.

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3. What is known about the biological effects of acupuncture that helps us understand how it works?

Many studies in animals and humans have demonstrated that acupuncture can cause multiple biological responses. These responses can occur locally, i.e., at or close to the site of application, or at a distance, mediated mainly by sensory neurons to many structures within the central nervous system. This can lead to activation of pathways affecting various physiological systems in the brain as well as in the periphery. A focus of attention has been the role of endogenous opioids in acupuncture analgesia. Considerable evidence supports the claim that opioid peptides are released during acupuncture and that the analgesic effects of acupuncture are at least partially explained by their actions. That opioid antagonists such as naloxone reverse the analgesic effects of acupuncture further strengthens this hypothesis. Stimulation by acupuncture may also activate the hypothalamus and the pituitary gland, resulting in a broad spectrum of systemic effects. Alteration in the secretion of neurotransmitters and neurohormones and changes in the regulation of blood flow, both centrally and peripherally, have been documented. There is also evidence that there are alterations in immune functions produced by acupuncture. Which of these and other physiological changes mediate clinical effects is at present unclear.

Despite considerable efforts to understand the anatomy and physiology of the "acupuncture points," the definition and characterization of these points remains controversial. Even more elusive is the scientific basis of some of the key traditional Eastern medical concepts such as the circulation of Qi, the meridian system, and the five phases theory, which are difficult to reconcile with contemporary biomedical information but continue to play an important role in the evaluation of patients and the formulation of treatment in acupuncture.

Some of the biological effects of acupuncture have also been observed when "sham" acupuncture points are stimulated, highlighting the importance of defining appropriate control groups in assessing biological changes purported to be due to acupuncture. Such findings raise questions regarding the specificity of these biological changes. In addition, similar biological alterations including the release of endogenous opioids and changes in blood pressure have been observed after painful stimuli, vigorous exercise, and/or relaxation training; it is at present unclear to what extent acupuncture shares similar biological mechanisms.

It should be noted also that for any therapeutic intervention, including acupuncture, the so-called "non-specific" effects account for a substantial proportion of its effectiveness, and thus should not be casually discounted. Many factors may profoundly determine therapeutic outcome including the quality of the relationship between the clinician and the patient, the degree of trust, the expectations of the patient, the compatibility of the backgrounds and belief systems of the clinician and the patient, as well as a myriad of factors that together define the therapeutic milieu.

Although much remains unknown regarding the mechanism(s) that might mediate the therapeutic effect of acupuncture, the panel is encouraged that a number of significant acupuncture-related biological changes can be identified and carefully delineated. Further research in this direction not only is important for elucidating the phenomena associated with acupuncture, but also has the potential for exploring new pathways in human physiology not previously examined in a systematic manner.

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4. What issues need to be addressed so that acupuncture may be appropriately incorporated into today's health care system?

The integration of acupuncture into today's health care system will be facilitated by a better understanding among providers of the language and practices of both the Eastern and Western health care communities. Acupuncture focuses on a holistic, energy-based approach to the patient rather than a disease-oriented diagnostic and treatment model.

An important factor for the integration of acupuncture into the health care system is the training and credentialing of acupuncture practitioners by the appropriate state agencies. This is necessary to allow the public and other health practitioners to identify qualified

acupuncture practitioners. The acupuncture educational community has made substantial progress in this area and is encouraged to continue along this path. Educational standards have been established for training of physician and non-physician acupuncturists. Many acupuncture educational programs are accredited by an agency that is recognized by the U.S. Department of Education. A national credentialing agency exists that is recognized by some of the major professional acupuncture organizations and provides examinations for entry-level competency in the field.

A majority of States provide licensure or registration for acupuncture practitioners. Because some acupuncture practitioners have limited English proficiency, credentialing and licensing examinations should be provided in languages other than English where necessary. There is variation in the titles that are conferred through these processes, and the requirements to obtain licensure vary widely. The scope of practice allowed under these State requirements varies as well. While States have the individual prerogative to set standards for licensing professions, harmonization in these areas will provide greater confidence in the qualifications of acupuncture practitioners. For example, not all States recognize the same credentialing examination, thus making reciprocity difficult.

The occurrence of adverse events in the practice of acupuncture has been documented to be extremely low. However, these events have occurred in rare occasions, some of which are life threatening (e.g., pneumothorax). Therefore, appropriate safeguards for the protection of patients and consumers need to be in place. Patients should be fully informed of their treatment options, expected prognosis, relative risk, and safety practices to minimize these risks prior to their receipt of acupuncture. This information must be provided in a manner that is linguistically and culturally appropriate to the patient. Use of acupuncture needles should always follow FDA regulations, including use of sterile, single-use needles. It is noted that these practices are already being done by many acupuncture practitioners; however, these practices should be uniform. Recourse for patient grievance and professional censure are provided through credentialing and licensing procedures and are available through appropriate State jurisdictions.

It has been reported that more than 1 million Americans currently receive acupuncture each year. Continued access to qualified acupuncture professionals for appropriate conditions should be ensured. Because many individuals seek health care treatment from both acupuncturists and physicians, communication between these providers should be strengthened and improved. If a patient is under the care of an acupuncturist and a physician, both practitioners should be informed. Care should be taken so that important medical problems are not overlooked. Patients and providers have a responsibility to facilitate this communication.

There is evidence that some patients have limited access to acupuncture services because of inability to pay. Insurance companies can decrease or remove financial barriers to access depending on their willingness to provide coverage for appropriate acupuncture services. An increasing number of insurance companies are either considering this possibility or now provide coverage for acupuncture services. Where there are State health insurance plans, and for populations served by Medicare or Medicaid, expansion

of coverage to include appropriate acupuncture services would also help remove financial barriers to access.

As acupuncture is incorporated into today's health care system, and further research clarifies the role of acupuncture for various health conditions, it is expected that dissemination of this information to health care practitioners, insurance providers, policymakers, and the general public will lead to more informed decisions in regard to the appropriate use of acupucture.

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5. What are the directions for future research?

The incorporation of any new clinical intervention into accepted practice faces more scrutiny now than ever before. The demands of evidence-based medicine, outcomes research, managed care systems of health care delivery, and a plethora of therapeutic choices makes the acceptance of new treatments an arduous process. The difficulties are accentuated when the treatment is based on theories unfamiliar to Western medicine and its practitioners. It is important, therefore, that the evaluation of acupuncture for the treatment of specific conditions be carried out carefully, using designs which can withstand rigorous scrutiny. In order to further the evaluation of the role of acupuncture in the management of various conditions, the following general areas for future research are suggested.

What are the demographics and patterns of use of acupuncture in the U.S. and other countries?

There is currently limited information on basic questions such as who uses acupuncture, for what indications is acupuncture most commonly sought, what variations in experience and techniques used exist among acupuncture practitioners, and whether there are differences in these patterns by geography or ethnic group. Descriptive epidemiologic studies can provide insight into these and other questions. This information can in turn be used to guide future research and to identify areas of greatest public health concern.

Can the efficacy of acupuncture for various conditions for which it is used or for which it shows promise be demonstrated?

Relatively few high-quality, randomized, controlled trials have been published on the effects of acupuncture. Such studies should be designed in a rigorous manner to allow evaluation of the effectiveness of acupuncture. Such studies should include experienced acupuncture practitioners in order to design and deliver appropriate interventions. Emphasis should be placed on studies that examine acupuncture as used in clinical practice, and that respect the theoretical basis for acupuncture therapy.

Although randomized controlled trials provide a strong basis for inferring causality, other study designs such as used in clinical epidemiology or outcomes research can also provide important insights regarding the usefulness of acupuncture for various conditions. There have been few such studies in the acupuncture literature.

Do different theoretical bases for acupuncture result in different treatment outcomes?

Competing theoretical orientations (e.g., Chinese, Japanese, French) currently exist that might predict divergent therapeutic approaches (i.e., the use of different acupuncture points). Research projects should be designed to assess the relative merit of these divergent approaches, as well to compare these systems with treatment programs using fixed acupuncture points.

In order to fully assess the efficacy of acupuncture, studies should be designed to examine not only fixed acupuncture points, but also the Eastern medical systems that provide the foundation for acupuncture therapy, including the choice of points. In addition to assessing the effect of acupuncture in context, this would also provide the opportunity to determine if Eastern medical theories predict more effective acupuncture points, as well as to examine the relative utility of competing systems (e.g., Chinese vs. Japanese vs. French) for such purposes.

What areas of public policy research can provide guidance for the integration of acupuncture into today's health care system?

The incorporation of acupuncture as a treatment raises numerous questions of public policy. These include issues of access, cost-effectiveness, reimbursement by state, federal, and private payors, and training, licensure, and accreditation. These public policy issues must be founded on quality epidemiologic and demographic data and effectiveness research.

Can further insight into the biological basis for acupuncture be gained?

Mechanisms which provide a Western scientific explanation for some of the effects of acupuncture are beginning to emerge. This is encouraging, and may provide novel insights into neural, endocrine and other physiological processes. Research should be supported to provide a better understanding of the mechanisms involved, and such research may lead to improvements in treatment.

Does an organized energetic system exist in the human body that has clinical applications?

Although biochemical and physiologic studies have provided insight into some of the biologic effects of acupuncture, acupuncture practice is based on a very different model of energy balance. This theory may provide new insights to medical research that may further elucidate the basis for acupuncture.

How do the approaches and answers to these questions differ among populations that have used acupuncture as a part of its healing tradition for centuries, compared to populations that have only recently begun to incorporate acupuncture into health care?

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Conclusions and Recommendations

Acupuncture as a therapeutic intervention is widely practiced in the United States. There have been many studies of its potential usefulness. However, many of these studies provide equivocal results because of design, sample size, and other factors. The issue is further complicated by inherent difficulties in the use of appropriate controls, such as placebo and sham acupuncture groups.

However, promising results have emerged, for example, efficacy of acupuncture in adult post-operative and chemotherapy nausea and vomiting and in post-operative dental pain. There are other situations such as addiction, stroke rehabilitation, headache, menstrual cramps, tennis elbow, fibromyalgia myofascial pain, osteoarthritis, low back pain, carpal tunnel syndrome, and asthma where acupuncture may be useful as an adjunct treatment or an acceptable alternative or be included in a comprehensive management program. Further research is likely to uncover additional areas where acupuncture interventions will be useful.

Findings from basic research have begun to elucidate the mechanisms of action of acupuncture, including the release of opioids and other peptides in the central nervous system and the periphery and changes in neuroendocrine function. Although much needs to be accomplished, the emergence of plausible mechanisms for the therapeutic effects of acupuncture is encouraging.

The introduction of acupuncture into the choice of treatment modalities that are readily available to the public is in its early stages. Issues of training, licensure, and reimbursement remain to be clarified. There is sufficient evidence, however, of acupuncture's value to expand its use into conventional medicine and to encourage further studies of its physiology and clinical value.

Consensus Development Panel, Speakers, Planning Committee, Conference Sponsors and Conference Cosponsers names have been left off for space considerations.

III. Research Summary – Acupuncture as Treatment for Diabetes Mellitus, Asthma and Hypertension, January 2005 including update

RESEARH SUMMARY
Acupuncture as Treatment for Diabetes Mellitus, Asthma and Hypertension
January 2005

Prepared by
Sher Demeter, L.Ac.
Minnesota College of Acupuncture and Oriental Medicine
Northwestern Health Sciences University
Mark S. McKenzie, L.Ac., Dean

Following the National Institutes of Health Consensus Conference on Acupuncture in 1997, a favorable climate for clinical research has prevailed. Although there is an impressive array of quality case studies regarding the clinical effects of acupuncture, there still remains a paucity of randomized controlled trials which remain the gold standard for clinical research.

From several disease conditions considered as part of the recent legislative analysis concerning best practices, we have restricted our review of research to hypertension, asthma and diabetes mellitus. We have focused on information presented in The Cochrane Database of Systematic Reviews for 2002 and 2003 for diabetes mellitus and asthma. Although no Cochrane Reviews are available for hypertension, we present recent findings generated from animal studies and highlight an ongoing NIH sponsored study at the University of California, Irvine.

Diabetes Mellitus

The most favorable studies and recommendations emerged for trials testing Chinese herbal medicines in the treatment of diabetes mellitus. Of the sixty-six randomized trials, involving 8,302 participants, sixty-nine different herbal medicines were tested to compare with placebo and hypoglycemic drugs, or tested to compare herbal medicines plus hypoglycemic drugs.(1)

The conclusions demonstrate that some herbal medicines show hypoglycemic effect in type 2 diabetes. Compared with placebo, six of the herbal medicines showed significant hypoglycemic response. Compared with several hypoglycemic drugs, seven herbal medicines demonstrated a significantly better metabolic control. In 29 trials that evaluated herbal medicines combined with hypoglycemic drugs, 15 different herbal preparations showed better effects than hypoglycemic drugs monotherapy. When combined with diet and behavior change, two herbal therapies showed better hypoglycemic effects than diet and behavior change alone. Additionally, no serious adverse effects from the herbal medicines were reported.

Currently, type 2 diabetes is the fourth leading cause of death in developed countries with a two fold excess mortality and two to four fold increased risk of coronary heart disease and stroke.(2) Because of the chronicity of diabetes, the quality of a patient's life will be profoundly affected, resources of social support systems will be strained, and large financial demands will be placed on the health care system.(3) Since the mechanism of action of herbal medicines involves regulating glycemic metabolism, decreasing cholesterol levels, increasing secretion of insulin and improving microcirculation, these medicines may provide another avenue of exploration in the treatment of diabetic patients.

Asthma

Research literature from China is replete with studies showing the effective management of asthma with acupuncture and herbal medicine and many journals cite case studies showing encouraging and positive results in the treatment of asthma with acupuncture and herbs. However, The Cochrane Database of Systematic Reviews states that there is not enough evidence to make recommendations about the value of acupuncture in asthma treatment. The reviewers note that some studies do report significant positive changes in subjective parameters and medication use, suggesting that some patients with asthma may benefit from acupuncture. However, due to fundamental differences between trials and inadequate data presentation, little of the data is suitable for meta-analysis. (4)

The reviewers conclude that there is an urgent need for appropriately designed trials. The methodological inconsistencies and problems encountered in the reviewed trials indicate that more pilot data should be acquired before proceeding to large scale randomized trials. Their final recommendation is that further research is needed to consider the complexities and different types of acupuncture.

Hypertension

The Susan Samueli Center for Integrative Medicine at UC Irvine (UCI) has received a $2 million, NIH sponsored grant for a five-year study to determine how acupuncture can help treat cardiovascular illnesses such as heart disease, hypertension and arrhythmias. This current research follows upon previous findings of animal research by practicing cardiologist, Dr. John Longhurst, current director of the UCI Medical Center. His studies have shown that acupuncture excites brain cells to release neurotransmitters that either inhibit or heighten cardiovascular activity. Release of opioid chemicals in the brain can reduce excitatory responses in the cardiovascular system. This reduction, in turn, can help to decrease the heart's activity and its need for oxygen, thereby lowering blood pressure and promoting healing for a number of cardiac ailments and arrhythmias. Longhurst states that:

> "[W]e're trying to show … that acupuncture can be an excellent complement to other medical treatments, especially for those treating the cardiac system. The Western world is waiting for a clear scientific basis

for using acupuncture, and we hope that this research ultimately will lead to the integration of ancient healing practices into modern medical treatment." (5)

Overview

From a viewpoint of research and analysis, there is considerable work to be done in the future. Information from the Cochrane Reviews suggest, first, that it is important to develop more pilot studies before progressing to larger randomized trials; and second, that is necessary to create appropriately designed models that will incorporate the complexities of Chinese medical diagnosis and treatment. The authors of this summary also believe that future studies may want to consider the range and implications of non-specific effects of treatment which may contribute to patient health and recovery.

Chinese medicine has an extensive history in other parts of the world. The Western public has become increasingly more interested in Chinese medicine in recent years, and utilization rates continue to grow. (6) While there is admittedly much research to be done regarding its effectiveness for a variety of ailments, it is a treatment approach that is worthy of serious consideration due to its minimal side effects and potential to benefit individuals with chronic, disabling and costly conditions.

References

(1) The Cochrane Database of Systematic Reviews 2002, Issue 3. Art. No.: CD003642.pub2.DOI: 10.1002/14651858.CD003642.pub2.)

(2) McKinlay J, Marceau L. US Public Health and the 21st Century: Diabetes Melliltus. Lancet 2000; 356:757-61.

(3) Alberti KM, Zimmet PZ. Definition, Diagnosis and Classification of Diabetes Melliltus and Its Complications. Part I: Diagnosis and Classification of Diabetes Mellitus. Provisional Report of a WHO Consultation. Diabetic Medicine 1998; 15:539-53.

(4) The Cochrane Database of Systematic Reviews 2003, Issue 3. Art. No.: CD000008.pub2.DOI: 10.1002/14651858.CD000008.pub2.)

(5) Press Release of the University of California, Irvine, February 4, 2004

(6) Eisenberg D. Davis R. Ettner S. Appel S. Wilkey S. Van Rompay M. Kessler R. Trends in Alternative Medicine Use in the US 1990-1997: Results of a Follow-up National Survey. JAMA, Nov 1998; 280: 1569-1575.

Update to RESEARH SUMMARY
Acupuncture as Treatment for Diabetes Mellitus, Asthma and Hypertension
January 2006

Prepared by
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A. Summary

While there is a vast body of Chinese literature addressing the effects of Chinese Medicine and acupuncture, there has been substantially less Western-based scientific research performed on these modes of care. This is changing however, as evidenced by recent increases in funding for Chinese Medicine and acupuncture studies by the National Center for Complementary and Alternative Medicine, and the attention being given to these therapies by the Cochrane Library. Much of the research in the areas of cardiovascular disease and diabetes are either only recently completed or underway; there is substantial work that needs to be completed before definitive results regarding efficacy of Chinese Medicine and acupuncture for these conditions are available.

B. Cochrane Library of Systematic Reviews

Several systematic reviews are currently underway assessing the body of scientific evidence regarding Chinese Medicine for the treatment of cardiovascular disease and diabetes including:

- Chinese medicinal herbs for acute myocardial infarction
- Traditional Chinese interventions for stable angina
- Puerarin for unstable angina
- Suxiao jiuxin wan for angina pectoris
- Huangqi preparations for unstable angina
- Tongxinluo capsule for acute stroke
- Shengmai (traditional Chinese herbal medicine) for heart failure
- Chinese herbal medicines for type 2 mellitus

Completed Reviews

1. Cochrane systematic review of acupuncture for acute stroke identified ten studies. Found that acupuncture appears safe, but larger, higher quality studies needed to assess benefit for the treatment of acute ischaemic or haemorrhagic stroke.

REFERENCE:

Acupuncture for acute stroke
SH Zhang, M Liu, K Asplund, L Li
The Cochrane Database of Systematic Reviews 2006 Issue 1

DOI: 10.1002/14651858.CD003317.pub2 This version first published online: 20 April 2005 in Issue 2, 2005

2. Cochrane systematic review of Chineses herbal medicines for non-insulin dependent diabetes found that some herbal medicines show hypoglycaemic effects in type 2 diabetes. However, these findings should be carefully interpreted due to the low methodological quality, small sample size, and limited number of trials. In the light of some positive findings, some herbal medicines deserve further examination in high-quality trials.

REFERENCE:

Chinese herbal medicines for type 2 diabetes mellitus
JP Liu, M Zhang, WY Wang, S Grimsgaard
The Cochrane Database of Systematic Reviews 2006 Issue 1

DOI: 10.1002/14651858.CD003642.pub2 This version first published online: 22 July 2002 in Issue 3, 2002

3. Cochrane systematic review of Ginkgo biloba extract (widely used in the treatment of acute ischaemic stroke in China) found no convincing evidence from trials of sufficient methodological quality to support the routine use of Ginkgo biloba extract to promote recovery after stroke. High-quality and large-scale randomized trials are still needed to test its efficacy.

REFERENCE:

Ginkgo biloba for acute ischaemic stroke
X Zeng, M Liu, Y Yang, Y Li, K Asplund
The Cochrane Database of Systematic Reviews 2006 Issue 1

DOI: 10.1002/14651858.CD003691.pub2 This version first published online: 19 October 2005 in Issue 4, 2005

C. NCCAM

The National Center for Complementary and Alternative Medicine of the National Institutes of Health has funded several clinical trials investigating acupuncture/Chinese medicine for a variety of conditions. These include two recently completed trials of acupuncture for hypertension and cardiovascular disease (results pending).

IV. Abstract - Stop Hypertension with the Acupuncture Research Program (SHARP) Pilot Trial

Stop Hypertension with Acupuncture Research Program (SHARP)

September 2001 - March 2005

Project Description - This pilot randomized controlled trial (RCT) (n=192) was designed to gather preliminary data regarding the efficacy of acupuncture for treating mild to moderate hypertension without the use of pharmacologic therapy. The New England Research Institute (NERI) is the organizational center for the study. Patients were stratified by antihypertensive medication history and allocated randomly to one of three acupuncture treatment groups, each delivered twice weekly for 6 weeks: 1) Standardized Acupuncture, 2) Individualized Acupuncture, or 3) Sham Acupuncture (Control group). All patients were diagnosed by non-treating acupuncturists using a TCM protocol, but only those in the Individualized group were treated accordingly. The primary endpoint was change in systolic BP, adjusted for baseline level, from baseline to 4 months post-randomization. In addition, use of conventional medical treatments was monitored in order to test whether acupuncture reduces the need to introduce or resume pharmacologic treatment. Changes in quality of life were also assessed and compared across treatment groups.

Current Status - Recruitment for this study is complete and data analysis is underway. A paper describing the design of the study has been published (see below), preliminary results have been presented at various conferences and manuscripts are currently undergoing peer-review at various journals.

Results: Mean blood pressure decreased 4.8/4.8 mm Hg from baseline; 42% of patients had blood pressures below 140/90 at 10 weeks without use of anti-hypertensives. However, the meanbaseline-adjusted decrease in systolic blood pressure at 10 weeks did not differ between subjects randomized to active (Individualized and Standardized) versus sham (Control) acupuncture (-4.78 vs. -4.45 mm Hg, p=0.89). Individualized (Ind) acupuncture subjects experienced the largest decrease in diastolic blood pressure (-6.12 mm Hg vs. -4.72 for Control patients), but the differences among the treatment groups were not significant (p=0.46). A trend toward greater improvement in diastolic blood pressure from 2 weeks to 10 weeks was observed in the patients randomized to Individualized treatments, suggesting that a longer series of treatments might have revealed greater treatment differences; however, the observed difference in trends were not significant (p=0.23). Stratifying the subjects by ages, race, obesity, history of antihypertensive use, or primary TCM diagnosis did not reveal any sub-groups of subjects for whom the benefits of TCM acupuncture differed significantly from sham acupuncture. Future trials will be required to evaluate potential benefits of TCM acupuncture under different treatment schedules, among different patient populations, as a complement to western or herbal treatment, or compared to alternative controls.

Publications:

1. Kalish LA, Buczynski B, Connell P, Gemmel A, Goertz C, Macklin E, Pian-Smith M, Stevens S, Thompson J, Valaskatgis P, Wayne P, Zusman, R. Stop Hypertension with the Acupuncture Research Program (SHARP): Clinical Trial Design and Screening Results. *Controlled Clinical Trials* 2004 Feb; 25(1):76-103.

2. Macklin EA, Buczyski B, Connell P, Pian-Smith M, Stevens S, Thompson J, Valaskatgis P, Wayne P, Zusman R. Results of the Stop Hypertension With Acupuncture Research Program (SHARP) Pilot Trial (Abstract). *J Alt Compl Med* ., 2004; 10(1): 214-215.

3. Macklin EA, Wayne PM, Pian-Smith M, Stevens S, Thompson J, Valaskatgis P, Zusman R. Results of the Stop Hypertension with the Acupuncture Research Program (SHARP): a randomized controlled clinical trial. Submitted to *Hypertension* .

Principle Investigator: Eric Macklin, PhD (New England Research Institute)

Collaborating Institutions - New England Research Institute, Massachusetts General Hospital

Funding Agency – NIH---Grant # U01AT 000210-03

Supporting Documents

V. *Abstract - Practical Management of Patients with Painful diabetic Neuropathy*

Cynthia F. Corbett, PhD, RN
From the Intercollegiate College of Nursing, Washington State University, Spokane.

Purpose

Painful diabetic neuropathy (PDN) has a significant impact on patients' quality of life, affecting sleep, mood, mobility, ability to work, interpersonal relationships, overall self-worth, and independence. The purpose of this article is to provide diabetes educators with current and essential tools for PDN assessment and management.

Methods

Medline and CINAHL database searches identified publications on the assessment and treatment of PDN. Identified research was evaluated, and information pertinent to diabetes educators was summarized.

Results

Recent advancements in assessment of neuropathic pain include identifying characteristics that distinguish between neuropathic and nonneuropathic pain. In the absence of treatment, research demonstrates that nerve damage may progress while pain diminishes. Many disease-modifying and symptom-management treatment options are available.

Conclusion

Good glycemic control is the first priority for both prevention and management of PDN. However, even with good glycemic control, up to 20% of patients will develop PDN. PDN recognition and assessment are critical to optimize management. Although several treatment modalities are available, few patients obtain complete pain relief. Recent advances in understanding the mechanisms underlying neuropathic pain should lead to better treatment and patient outcomes. Combination therapy, including nonpharmacologic modalities, may be required. Research evaluating the efficacy of combination therapy is needed. (Note: the following information was abstracted from the article.)

> "Acupuncture has successfully relieved PDN symptoms. In a 10-week uncontrolled study, 46 participants with PDN received up to 6 acupuncture treatment sessions(Ref 68). Improvement in pain was reported by 77% of the 44 participants who completed the study, and 21% reported symptom resolution. Many participants without resolution were able to reduce pain medication. Of the34 participants who had significant symptom relief, only 8 required further acupuncture for maintenance over the 52-week follow-up period. Walker (Ref 11) reported similar results among 40 PDN patients treated with acupuncture. Retrospective medical record evaluation showed that nearly 90% of those treated for 20 minutes once a week for 2 to 3 months reported improvements in pain, sleep, mobility, and mood. The first benefit reported by most participants was improved sleep. Walker also reported lasting benefits, with only "a few" patients requesting an extra treatment for recurring pain; in those cases, 1 treatment was generally sufficient to reduce recurrent symptoms. " *The Diabetes EDUCATOR* 532Volume 31, Number 4, July/August 2005

11. Walker S. A nurse-led acupuncture service for painful diabetic neuropathy: 2. J Diabetes Nurs. 2001;5:59-62.
68. Abuaisha BB, Costanzi JB, Boulton AJM. Acupuncture for thetreatment of chronic painful peripheral diabetic neuropathy: along-term study. Diabetes Res Clin Pract. 1998;39:115-121.

VI. Updated Research - Published Evidence-Based Research 2005-1994

Listing of published Evidence-based Research for Acupuncture and Oriental Medicine dating from 2005, back to 1993. Where available, links to the research or research abstracts are provided.

Undated Research:

Journal: Ultrasound in Medicare and Biology
Date:
Title: Tissue Displacements During Acupuncture Elastography Techniques
Authors: Langevin,H.M., Ophir,J.; Konofagou,E.E., Garro,B.S.; Badger,G.J.; Churchill,D.L.
Principal Investigator: Langevin, Helene M.
Grant number: R01-AT001121
Pub Med ID: n/a

2005 Research:

Journal: Annals of Internal Medicine
Date: April 19, 2005
Title: Acupuncture for the Treatment of Low Back Pain
Authors: Eric Manheimer, MS; Adrian White, MD, BM, BCh; Brian Berman, MD; Kelly Forys, MA; and Edzard Ernst, MD, PhD
Full Text

Journal: Scandinavian Journal of Gastroenterology
Date: 2005
Title: Acupuncture Accelerates Delayes Gastrointestinal Transit after Abdominal Surgery in Conscious Rats
Authors: Balestrini,J.L.; Tsuchida,D.; Fukuda,H.; Pappas,T.
Principal Investigator: Takahashi, Toku
Grant number: R21-AT001588
Pub Med ID: n/a

2004 Research:

Journal: Critical Pulmonary Medicine

Date: 2004

Title: Massage Therapy and Acupuncture for Children with Chronic Pulmonary Disease

Authors: Kemper,K.J.; McLellan, M.C.; Highfield,E.S.

Principal Investigator: Woolf, Alan D

Grant number: R25-AT000538

Pub Med ID: n/a

Journal: Journal of Alternative Therapies

Date: 2004

Title: Patient characteristics for outpatient acupuncture in Beijing, China.

Authors: Napadow; Kaptchuk, T.J.

Principal Investigator: Rosen, Bruce R.

Grant number: P01-AT002048

Pub Med ID: n/a

Journal: Pediatric Research

Date: 2004

Title: Predictors of Patient Referral to Acupuncture or Therapeutic Massage by Community Pediatric Practitioners

Authors: McLellan, M.; Highfield, E.; Kalish, L.; Woolf, A.D.

Principal Investigator: Woolf, Alan D

Grant number: R25-AT000538

Pub Med ID: n/a

Journal: Pediatric Research

Date: 2004

Title: Influence of an Inpatient Therapeutic Massage and Acupuncture (TMA) Consultative Service on the Attitudes of Pediatric Pulmonry Staff.

Authors: McLellan, M.; Highfield, E.; Kalish, L.; Woolf, A.D.

Principal Investigator: Woolf, Alan D

Grant number: R25-AT000538

Pub Med ID: n/a

Journal: Ultrasound in Medicine and Biology

Date: 2004

Title: Tissue Displacements During Acupuncture using Ultrasound Elastography Techniques

Authors: Langevin,H.M., Ophir,J.; Konofagou,E.E., Garra,B.S.; Badger,G.J.; Churchill,D.L.

Principal Investigator: Langevin, Helene M.

Grant number: R21-AT000300

Pub Med ID: n/a

Journal: Controlled Clinical Trials

Date: February 2004

Title: Stop Hypertension with the Acupuncture Research Program (SHARP): Clinical Trial Design and Screening Results.

Authors: Kalish, L.A., Buczynski, B.; Buczynski, B., Connell, P.; Gemmel, A., Goertz, C.; Macklin, E.A., Pian-Smith, M.

Principal Investigator: Macklin, Eric A.

Grant number: U01-AT000210

Pub Med ID: 14980754

Journal: Clinical Pediatrics

Date: May 2004

Title: Parental Perceptions of the Therapeutic Effect from Osteopathic Manipulation or Acupuncture in Children with Spastic Cerebral Palsy.

Authors: Duncan B; Barton L; Edmonds D; Blashill BM.

Principal Investigator: Ghishan, Fayez K.

Grant number: P50-AT000008

Pub Med ID: 15118778

Journal: Evidence-based Complementary and Alternative Medicine

Date: June 2004

Title: Neurobiology of Acupuncture: Toward CAM.

Authors: Ma, S.X.

Principal Investigator: Ma, Sheng-Xing

Grant number: R01-AT000450

Pub Med ID: 15257325

Journal: Pharmacology, Biochemistry, Behavior

Date: August 2004

Title: Electroacupuncture Combined with Indomethacin Enhances Antihyperalgesia in Inflammatory Rats.

Authors: Zhang RX; Lao L,; Wang X; Ren K

Principal Investigator: Berman, Brian M.Grant number: P50-AT000084

Pub Med ID: 15301937

Journal: Complementary Therapies in Medicine

Date: September 2004

Title: Availability of acupuncture in the hospitals of a major academic medical center: a pilot study.

Authors: Highfield, E.S.; Kaptchuk, T.J.; Ott, M.J.; Barnes, L.

Principal Investigator: Rosen, Bruce R.

Grant number: P01-AT002048

Pub Med ID: 14659382

Journal: Brain Research

Date: Sep 2004

Title: Involvement of Opioid Receptors in Electroacupuncture-Produced Anti-Hyperalgesia in Rats with Peripheral Inflammation.

Authors: Zhang,R.X.; Lao,L.; Wang,L.; Liu,B., Berman,B.M.

Principal Investigator: Berman, Brian M.

Grant number: P50-AT000084

Pub Med ID: 15312782

Journal: Annals of Internal Medicine

Date: December 21 2004

Title: Effectiveness of Acupuncture as Adjunctive Therapy in Osteoarthritis of the Knee

Authors: Berman, B.M.; Lao, L.; Langenberg, P.; Lee, W.L.

Principal Investigator: Berman, Brian M.

Grant number: U01-AT000171

Pub Med ID: 15611487

Journal: Annals of Internal Medicine

Date: December 21, 2004

Title: Acupuncture for the Treatment of Chronic Neck Pail (Full Title: Acupuncture versus Placebo for the Treatment of Chronic Mechanical Neck Pain. A Randomized, Controlled Trial

Authors: The authors are P. White, G. Lewith, P. Prescott, and J. Conway.

Text

2003 Research:

Journal: Techniques in Orthopaedics
Date: 2003
Title: Acupuncture for Pain Management of Osteoarthritis of the Knee
Authors: Markow,M.J.; Secor, E.R.
Principal Investigator: Secor, Eric
Grant number: F32-AT001569
Pub Med ID: n/a

Journal: Medical Acupuncture
Date: 2003
Title: The effect of acupuncture on the quality of life in chronic pain patients-A Prospective Outcome Measure.
Authors: Leung, A.Y.
Principal Investigator: Leung, Albert Y.
Grant number: K08-AT001695
Pub Med ID: n/a

Journal: Journal of Alternative and Complementary Medicine
Date: 2003
Title: Enhanced Nitric Oxide Concentrations and Expressions of Nitric Oxide Synthase in Acupuncture Points/Meridians
Authors: Ma, S.X.
Principal Investigator: Ma, Sheng-Xing
Grant number: R01-AT000450
Pub Med ID: 12804074

Journal: NeuroImage
Date: 2003
Title: The effect of acupuncture on peripheral neurosensory thermal threshold and the central nervous system.
Authors: Leung, A.Y.; Duann, J.R.; Jung, T.P., Lam, V.; Liu, T., Buxton, R.
Principal Investigator: Leung, Albert Y.
Grant number: K08-AT001695
Pub Med ID: n/a

Journal: Digestive Diseases and Sciences
Date: Jan 2003
Title: Neural Mechanism of Acupuncture-Induced Gastric Relaxations in Rats.
Authors: Tada,H.; Fujita,M.; Harris,M.Takahashi T.; Tatewaki,M., Pappas TN
Principal Investigator: Takahashi, Toku
Grant number: R21-AT001588
Pub Med ID: 12645791

Journal: Alternative Therapies in Health and Medicine
Date: Jan-Feb 2003
Title: Is Acupuncture Safe? A Systematic Review of Case Reports
Authors: Lao, L.; Hamilton, G.; Fu, J.; Berman, B.
Principal Investigator: Berman, Brian M.
Grant number: P50-AT000084
Pub Med ID: 12564354

Journal: Pharmacology Biochemistry and Behavior
Date: February 2003
Title: The Effect of Electroacupuncture as an Adjunct on Cyclosphosphamide-Induced Emesis in Ferrets
Authors: Lao, L.; Zhang, G.; Wong, R.; Carter, A.
Principal Investigator: Berman, Brian M.
Grant number: P50-AT000084
Pub Med ID: 12543236

Journal: Journal of Neurophysiology
Date: August 2003
Title: Nitric Oxide in the Gracile Nucleus Mediates Depressor Response to Acupuncture (ST36).
Authors: Chen,S.; Ma,S.X..
Principal Investigator: Ma, Sheng-Xing
Grant number: R01-AT000450
Pub Med ID: 12672780

Journal: Complementary Therapies in Medicine
Date: September 2003
Title: Availability of Acupuncture in the Hospitals of a Major Academic Medical Center: A Pilot Study.
Authors: Highfield,E.S.; Kaptchuck,T.J.; Ott,M.J.; Barnes,L.
Principal Investigator: Woolf, Alan D
Grant number: R25-AT000538 Pub Med ID: 14659382

Journal: American Journal of Physiology. Regulatory, Integrative and Comparative Physiology
Date: Oct 2003
Title: Dual Effects of Acupuncture on Gastric Motility in Conscious Rats.
Authors: Tatewaki M; Harris M; Uemura,K. , Takahashi,T.; Ueno,T., Pappas,T.N.
Principal Investigator: Takahashi, Toku
Grant number: R21-AT001588
Pub Med ID: 12959921

2002 Research

Journal: Acupuncture and Electro-Therapeutics Research, International Journal
Date: 2002
Title: Increased Neuronal Nitric Oxide Synthase Expression in the Gracile Nucleus Following Electroacupuncture Stimulation of Cutaneaous Hindlimb Acupoints
Authors: Ma, S.X.; Li, X.Y.
Principal Investigator: Ma, Sheng-Xing
Grant number: R01-AT000450
Pub Med ID: 12638736

Journal: Clinical Acupuncture and Oriental Medicine
Date: 2002
Title: Matching Acupuncture Cinical Study Designs to Research Questions
Authors: Sherman, K.J.; Lao, L.; MacPherson, J.; Lewith, G.
Principal Investigator: Berman, Brian M.
Grant number: P50-AT000084
Pub Med ID: n/a

Journal: Clinical Acupuncture and Oriental Medicine
Date: 2002
Title: The Clinical Evaluation of Traditional East Asian Systems of Medicine
Authors: MacPherson, H.; Sherman, K.; Hammerschlag, R.; Birch, S.
Principal Investigator: Berman, Brian M.
Grant number: P50-AT000084
Pub Med ID: n/a

Journal: Clinical Acupuncture and Oriental Medicine
Date: 2002
Title: The Role of Acupuncture Schools and Individual Practitioners in Acupuncture Research
Authors: Lao, L.; Sherman, K.; Bovey
Principal Investigator: Berman, Brian M.
Grant number: P50-AT000084
Pub Med ID: n/a

Journal: Clinical Acupuncture and Oriental Medicine
Date: 2002
Title: The Role of Acupuncture Schools and Individual Practitioners in Acupuncture Research
Authors: Lao, L.; Sherman, K.; Bovey
Principal Investigator: Berman, Brian M.
Grant number: P50-AT000084
Pub Med ID: n/a

Journal: SFN Abstracts
Date: 2002
Title: Electroacupuncture and Brain Protection from Cerebral Ischemia: The Role of Delta-Opioid Receptor.
Authors: Zhao, P.; Guo, J.C.; Xia, Y.; Hong, S.S.
Principal Investigator: Xia, Ying
Grant number: R21-AT001094
Pub Med ID: n/a

Journal: Annals of Internal Medicine
Date: March 5 2002
Title: Acupuncture: Theory, Efficacy, and Practice.
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Date: December 2001
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PERSPECTIVE

Racing Toward The Integration Of Complementary And Alternative Medicine: A Marathon Or A Sprint?

Integrating alternative medicine into the U.S. health care system will be achieved in many small, important steps.

by Richard L. Nahin, Carol H. Pontzer, and Margaret A. Chesney

ABSTRACT: Health care opinion leaders concur that integration of complementary and alternative medicine (CAM) into the U.S. health care system must be based on strong supporting evidence of safety and efficacy. As others have pointed out, integration is under way, despite the lack of reliable, rigorous science supporting the use of most CAM treatments. We contend that optimal integration of CAM is a long-term endeavor—a marathon rather than a sprint. The evidence base does not now support its wholesale assimilation; market forces, although compelling, should not be the primary consideration in integration.

WHAT IS INTEGRATIVE medicine, and why is it growing in acceptance? Mary Ruggie addresses these questions in this volume of *Health Affairs*.[1] She presents evidence that integrative medicine is popular now for several reasons: growing use of complementary and alternative medicine (CAM) by the public, establishment of the National Center for Complementary and Alternative Medicine (NCCAM) at the National Institutes of Health (NIH), and scientific research on CAM's safety and efficacy. These may all contribute to the conditional "integration" of some aspects of CAM by conventional health care providers.

Required evidence. *Integrative medicine* can be defined in many ways. Most definitions include, to some degree, the concept that the best of CAM is combined with the best of conventional medicine, based on evidence.[2] They do not include the type and level of evidence that should be required. Nonetheless, evidence hierarchies place data collected from multiple randomized controlled trials (RCTs) or systematic reviews of multiple RCTs as the highest standard of evidence.[3]

Use versus evidence. An Institute of Medicine (IOM) analysis of all identified systematic reviews relating to CAM (N=496) encompassed such widely used CAM therapies as chiropractic medicine, herbal medicine, and massage therapy, as well as lesser-used therapies such as the Alexander technique, biofeedback, and therapeutic touch.[4] Two striking facts are apparent when this review is compared with data on the prevalence of CAM. First, the attention given to a CAM practice by the scientific community does not correlate with its use by the public. For instance, the

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IOM identified seventy-nine reviews of acupuncture and thirty-eight reviews of homeopathy (placing them third and fourth among all CAM therapies), yet less than 1.5 percent of the U.S. public uses these therapies in a given year.[5] In addition, only one-fourth of the 145 Cochrane Collaboration reviews of CAM examined in the IOM report concluded that a given CAM therapy worked; two-thirds cited insufficient evidence to make a definitive determination. Interestingly, only 11 percent of the reviews supported the use of herbals and other nonvitamin/nonmineral dietary supplements, which are the most prevalent types of CAM used, other than prayer for health reasons.[6] This indicates a disconnect between what people use and where the evidence lies.

The second striking fact is that CAM therapies with relatively infrequent use by the public (such as biofeedback, hypnotherapy, and acupuncture) are those with the highest level of acceptance by physician groups, which typifies the inadequate communication between patients and providers concerning CAM.[7]

Reasons for using CAM. In support of Ruggie's argument, surveys of health maintenance organizations (HMOs) indicate that the most prominent reason such organizations incorporate CAM into their coverage is market demand.[8] This demand might derive partly from the public's desire to take charge of their own health care.[9] Comparisons of national surveys about CAM in 1990–1997 and 2004 suggest that visits to CAM practitioners have remained relatively stable on a percentage basis over time, while the use of dietary supplements has greatly increased.[10] This increase, combined with the large number of people who practice one or more forms of mind-body medicine, suggests that the dominant forms of CAM are those used by the individual as part of self-care. In fact, half of those who used CAM said that they did so because they thought it would be interesting to try, not because of cost or efficacy.[11]

The public's interest in CAM also derives from a belief that CAM approaches are more natural and safer than conventional medicine.[12] On the contrary, some widely used herbal medicines can interact with certain pharmaceuticals and have life-threatening consequences. A well-documented example of this is the effect of a widely used herbal supplement, St. John's wort, on the clearance of many prescription drugs by the liver.[13] Ideally, everyone interested in using any form of CAM would seek the advice of a learned practitioner, but this is unrealistic given the way herbal supplements are advertised and sold in the United States. In fact, the IOM argues that U.S. regulation of dietary supplements needs substantial revision to increase public safety.

Clinical data versus RCTs. Given that integration of CAM is under way, one approach would be to gather epidemiological data on safety and outcomes using practice-based networks, rather than to wait for controlled trials. Recent medical literature, however, is marked with cases, such as hormone replacement therapy (HRT), where conclusions based on extensive epidemiological data from practices in widespread use were overturned by clinical trials. An added complication is the wide variation in the clinical application of many types of CAM, especially those using physical interventions. For instance, it has been found that there is little agreement in the choice of acupuncture points that various acupuncturists might use to treat the same patient with chronic back pain.[14] Similarly, there is considerable variability in how licensed naturopathic physicians would treat a person with multiple sclerosis or breast cancer.[15] Although individualized treatments might eventually prove advantageous when addressing patient heterogeneity, outcomes research on CAM needs to account for this variability. This leaves us with the following question: How can we integrate CAM when so many research questions remain unanswered?

Dissemination and translation. Through the support of rigorous science, the NCCAM and other NIH institutes are committed to answering these and other questions concerning CAM's safety and efficacy. Results of this research, disseminated through the literature and the NCCAM's fact sheets, e-bulletins, and Web site, will help identify CAM

therapies that are ready for integration.

Even when evidence of efficacy is available, issues associated with translation into practice will remain. An Agency for Healthcare Research and Quality (AHRQ) report, *Closing the Quality Gap,* has detailed the difficulties of incorporating evidence-based recommendations into conventional clinical practice.[16] These are likely to be magnified in the case of CAM, which has to overcome the skepticism of conventional providers and concerns regarding safety and efficacy. Conventional providers, unfamiliar with CAM, might require education as well as information dissemination. Optimal integration of effective CAM therapies would also require patient education, since self-care appears to be a current driver of usage. Increased communication between patients, CAM practitioners, and conventional providers is vital to protect patient safety. This is likely to necessitate some organizational change in the practice of both CAM and conventional medicine and in the current system of third-party reimbursement for health care costs.

Just as a marathon is made up of many small steps, so too would be the integration of CAM into the U.S. health care system. With each new piece of information, the scientific base on CAM will increase. It is critical that conventional health care providers learn about CAM and begin conversations with their patients about its potential risks and benefits. Through continued awareness of the CAM scientific literature and support for their patients, providers will help us win the race for maximizing health care quality.

The authors are indebted to many members of the NCCAM for their advice on earlier versions of this manuscript.

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Prevention—Investing in the Health of Minnesota

Mark W. Banks, M.D.
CEO, Blue Cross and Blue Shield of Minnesota

"What if Minnesotans were healthier?"

We don't ask that question often enough, probably because we think of ourselves as the healthiest state in the nation. And there certainly are no shortages of news stories and political speeches to reinforce Minnesota's status as a health leader. But have you ever read the headline to a news story ... then read the entire story and wondered how editors decided on THAT headline?

Buried in a news story I read last month were these facts:

- Minnesota ranks 24th in the country in the rate of smoking.
- The prevalence of obesity places Minnesota 21st among the states.
- And in deaths from cancer . . . we rank 15th.

And in each of these rankings, we've actually lost ground over the past 15 years. Yet the headline on that news story was that Minnesota is the healthiest state in the nation.

The fact is, in many areas of health we have done well. We rank first in the country in access to health insurance, with an uninsured rate of less than 7 percent. Compare that to Texas, where 25 percent of the population is uninsured. We are fifth in high school graduation rates. And we are sixth in per-capita public health spending.

Over my three decades in health care I've witnessed many accomplishments.

- In 1975, the Minnesota legislature passed the Minnesota Clean Indoor Air Act, leading the nation in protections against secondhand smoke.

- As I was beginning my career at Blue Cross, public policy reforms made health insurance more accessible and affordable for small businesses and individuals. Again, Minnesota was an innovator with the creation of MinnesotaCare.

- And, finally, one accomplishment I am especially proud of is the landmark 1994 lawsuit filed by Blue Cross and the State of Minnesota against the tobacco industry.

Minnesota should celebrate these and other achievements that have contributed to our healthy status. But my 30 years in health care have taught me that it's important to keep probing to ask that next question. And some of the questions we need to ask aren't comfortable or easy:

For example - Why is the prevalence of obesity greater in Minnesota than it is in 40 percent of the states? Part of the answer is in the Centers for Disease Control data that show that about half of all Minnesotans don't achieve recommended levels of physical activity. And more than three-quarters of Minnesota adults do not meet important nutritional standards.

And why do 23 states have a lower rate of smoking than Minnesota? According to the Minnesota Adult Tobacco Survey, the rate of smoking among young adults . . . those between 18 and 24 years old . . . is twice that of older adults.

And why does Minnesota have such great disparities in the health of our citizens? According to a 2003 report from the Minnesota Department of Health "populations of color and American Indians in Minnesota experience shorter life spans, higher rates of infant mortality and poorer general health."

And why is it . . . despite all our accomplishments and our headline rating as the healthiest state . . . why is it that business and health leaders . . . probably many of you in this room . . . would rank health care as the most urgent crisis facing Minnesota?

Well, the common answer to all of those questions is this . . . We will never manage health costs or improve our health status unless we tackle the underlying risk factors that are at the root of so many preventable diseases . . . If we want to reform health care, our commitment must be to become more fit, to smoke less and to eat healthier.

Smoking, physical inactivity, and unhealthy eating . . . these are the factors that underlie the leading causes of preventable death and disease in Minnesota. So even though Minnesota is ranked as the healthiest state in the nation, when you dig deeper . . . when you ask more questions . . . it's far more complex and far more challenging.

It's also far more personal . . . behind all these numbers are people. Karen McFadzen is one of those people . . . and a heart attack victim at age 36. When her doctor told her that she had an inherited form of heart disease, her initial reaction was to throw in the towel and take it easy.

It was a natural response for Karen . . . a person who by her own admission hated exercise. But, the combination of a very effective public awareness campaign, and the support of family, friends, and her employer Medtronic . . . all worked to change Karen's mind.

Today, Karen is a walker . . . she walks with co-workers . . . with friends . . . with family. For her, walking isn't exercise . . . it's fun. But it's fun with a benefit. Walking is making her a healthier person.

We need to reach out to more people like Karen McFadzen. We can't afford not to . . . The cost of not tackling the issues of tobacco, physical inactivity and poor nutrition are just too great, both in dollars and in the impact on real people.

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The exciting news is that today Blue Cross announces a bold commitment to make prevention a meaningful part of Minnesota's health care agenda. It's not that prevention is new. After all, Minnesota has an excellent public health system and a network of dedicated non-profits working in prevention. The news is that a private health plan is dedicating unprecedented resources and launching an ambitious campaign for prevention.

In 1994, Blue Cross had the courage to take on the tobacco industry, and filed the now landmark lawsuit with the promise that the proceeds recovered would be invested in a healthier Minnesota.

Today, it is my honor to follow through on the promise we made when we filed that lawsuit. Today, I am proud to announce to you exactly how Blue Cross will fulfill our obligation to all Minnesotans.

Prevention Minnesota is our long-term, $241 million commitment to make Minnesota a healthier state in which to live and work. Our focus will be tobacco use, physical inactivity and unhealthy eating. These are the root causes of preventable heart disease and many cancers.

Our goals are bold:

- Reduce smoking by 50 percent, from today's rate of 18 to less than 10 percent.
- Reduce exposure to secondhand smoke by 90 percent. If we succeed, less than 5 percent of non-smoking Minnesotans will be exposed to secondhand smoke indoors.
- Increase physical activity by 50 percent.
- Increase healthy eating by 100 percent.

Or, in simpler terms, our goals are to make Minnesota's smoking rate the lowest in the nation . . . to make it possible for every person to breathe healthy air at work, at home and in their community . . . and to become the fittest state in the nation.

Although this is the formal announcement of Prevention Minnesota, some of our work is already underway. We've been planning, building partnerships and launching programs to help Minnesotans stop smoking, to exercise and to eat better. Maybe the most exciting of these efforts is the "do" campaign, the program that is making exercise fun for Karen McFadzen and others like her. This community-based initiative encourages people to see opportunities for activity in their everyday lives. It is a common-sense approach to get more exercise . . . 10 minutes of activity, three times a day. Build a

snowman. Take the stairs. Park in the back row of the parking lot and walk. It all adds up to make a tremendous difference in your fitness . . . and your health.

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We know some people will say we should spend these funds in a different way . . . for other purposes . . . or with other priorities.

Some of the money we recovered from the tobacco lawsuit already has been invested in reducing health costs in a variety of ways . . . By sharing a portion of the proceeds with individuals and small businesses . . . By providing grants to the community clinics that often are the only providers of health care to many of our state's most vulnerable populations . . . and by reducing the deficit of the Minnesota Comprehensive Health Association, a financial burden that otherwise falls on many small businesses.

But, we will probably never again have an opportunity like this to address the root problems that affect the health of Minnesotans today. To be successful, we need to have a strategic and defined approach that benefits everyone.

Later this week, we'll release our first community funding initiatives, asking qualified organizations to submit proposals to reduce tobacco use and promote physical activity. We expect these initiatives to not only prompt innovation, but also to be catalysts for community engagement . . . to be part of making prevention an essential part of our day-to-day lives.

We will also work to expand our partnerships with others on the front lines of making Minnesota healthier. Everyone has a role to play, not just the public health departments and health plans. We need more care givers to be prevention advocates with their patients . . . we need more employers to make workplaces healthier . . . and we need policy makers to commit to programs that make our communities healthier places in which to live.

Through Prevention Minnesota, we at Blue Cross will work toward these ambitious goals by developing programs based in science and designed to benefit all Minnesotans.

Some efforts will be obvious. For example . . . community design. It makes sense that when communities are designed with safe, lighted and accessible sidewalks and trails, walking and biking become more frequent activities.

And some actions may be controversial. For example, promoting policies to help all Minnesotans breathe healthy air. We saw recently in Hennepin County that secondhand smoke ordinances make for contentious politics. But we know from the action in St. Paul earlier this month that Minnesotans want clean indoor air and are demanding protection.

Our programs will be aggressive and innovative, and our goals are ambitious. But the stakes are too high to consider anything less. Because when we succeed, the benefits will be enormous. Many of the 5,600 Minnesotans who die annually from tobacco-related diseases will live longer and healthier lives. We expect to see 30 percent fewer cases of heart disease, stroke, colon cancer and osteoporosis...18 percent fewer cases of Type 2 diabetes and high blood pressure . . . and 5 percent fewer cases of breast cancer in those Minnesotans who are physically active.

The fact is, in all these cases . . . and in everything Prevention Minnesota undertakes . . . science tells us that these approaches work . . . they will improve health and manage costs.

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And rising health care costs are a top concern for all of us.

Last year, Blue Cross commissioned an economic impact study of smoking. What we found was shocking. In 2002, smoking was responsible for $1.98 billion annually in excess medical care expenditures. That's nearly 9 percent of the $23 billion spent on providing health care to Minnesotans. Or, put another way, one out of every 11 health care dollars spent in Minnesota is going to treat smoking-related diseases.

As policy makers debate the balance between taxes and spending . . . as Minnesota employers cite affordable health care as their number one issue . . . as all of us worry about the future of our heath system . . . consider the return we get on every dollar invested in prevention:

- Cutting the smoking rates in half would save Minnesota more than a billion dollars each year. That could go a long way to funding access for those Minnesotans without health care coverage. And as important, more than 3,000 people might still be alive.

- And consider the link between physical inactivity, poor nutrition and the epidemic of Type 2 diabetes. This was chronicled recently by the *New York Times* and locally by the *Star Tribune*. If all Minnesotans were physically active, we would save nearly $500 million a year and spare many from the ravages of diabetes and other diseases.

These are the very real stakes when it comes to prevention and to the investments we make. What we do or don't do has very real, bottom line consequences.

To cite one current example, we know that higher cigarette prices reduce smoking. In the first two weeks after Minnesota's tobacco price increase went into effect last August, enrollment in our BluePrint for Health stop-smoking program, increased 65 percent. And we weren't alone. The Minnesota Partnership for Action Against Tobacco also saw requests for stop-smoking services more than double compared to the previous year.

For many people, higher cigarette prices were the incentive they needed to quit smoking.

The need for effective prevention programs is clear, the return on investment is compelling and the improvement in people's lives is dramatic. So why hasn't prevention become an more important part of health reform? Let me suggest three reasons:

- First, the tobacco industry continues to be a powerful interest aligned against effective prevention efforts. Even today, the tobacco industry spends $290 million each year marketing smoking to Minnesotans.

- The second reason is how we live. Many of us feel as if we just don't have enough time to be healthy. When we aren't working, it seems we are stuck in traffic. For many of us, aging parents take up time that is left over from our kids' busy days. Convenience food is an antidote to inconvenient schedules. Television is our tonic for stress. Simply put, time . . . and our perception of time . . . can be the worst enemy of prevention.

- Third, prevention takes public commitment and political will. Too often, we look for easy solutions and quick fixes. Prevention takes time . . . it takes commitment . . . and it takes courage. It takes courage to focus on the largely invisible, but critically important role of prevention.

If we do not rise above these and other challenges, if we do not make a commitment to prevention, we will never achieve the goals of a more affordable, more accessible health care system.

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As we move forward, we will be accountable for all that we do. Our work will be transparent and our programs will focus on benefiting all Minnesotans. We will seek advice from diverse audiences. We will rigorously evaluate and share our progress and outcomes. And, we will seek partnerships with those who share a prevention agenda.

In the long run, success will come down to one thing . . . the willingness of all Minnesotans to make prevention an individual commitment and a community priority.

So, to answer . . . "what if," let me leave you with one short story.

Six years ago, Mr. Dennis Karp, a Blue Cross member, quit smoking after 30 years. He had tried to quit many times before, and he finally succeeded . . . an enormous accomplishment.

So . . . what if someone had been there 10 . . . 15 . . . 20 years ago to help him stop smoking then? What if higher cigarette prices had prevented him from starting to smoke in the first place? What if his favorite restaurant or bar had been smoke-free?

Mr. Karp died one year ago last week, at age 57, from cancer. Maybe if the environment had been different, the policies more supportive, the programs more accessible, he might have enjoyed more good years.

So while we'll measure our success against the hard numbers, we'll be driven by the sweet success of people like Karen McFazdin and the bittersweet triumphs of people like Dennis Karp. We'll invest in prevention and we'll invest in Minnesota.

Thank you for attending. I want you to know, we are asking you to be a partner in this journey, one I hope will continually improve the health of Minnesota. And then . . . perhaps . . . we won't have to ask "what if?" . . . instead, we can ask . . . "what next?" Thank you.

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Chiropractic Care: Is It Substitution Care or Add-on Care in Corporate Medical Plans?

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An analysis of claims data from a managed care health plan was performed to evaluate whether patients use chiropractic care as a substitution for medical care or in addition to medical care. Rates of neuromusculoskeletal complaints in 9e diagnostic categories were compared between groups with and without chiropractic coverage. For the 4-year study period, there were 3,129,752 insured member years in the groups with chiropractic coverage and 5,197,686 insured member years in the groups without chiropractic coverage. Expressed in terms of unique patients with neuromusculoskeletal complaints, the cohort with chiropractic coverage experienced a rate of 162.0 complaints per 1000 member years compared with 171.3 complaints in the cohort without chiropractic coverage. These results indicate that patients use chiropractic care as a direct substitution for medical care. (J Occup Environ Med. *2004;46:847–855*)

After a period of relative stability during the 1990s, the rate of increase in healthcare spending has once again accelerated.[1,2] Annual increases have been between 10% and 15% for the last 3 years (2001–2003). The cost of medical insurance premiums has matched these increases. During the period from 2002 through 2003, the annual rate of increase in insurance premiums averaged 13.9%, and these rates of increase are only expected to increase in the foreseeable future.[3] In response to these increased costs, the employers who fund most private health insurance and the insurance industry are seeking mechanisms to reduce the financial burden of medical care insurance. For the past several decades, the principal mechanism for limiting this financial burden has been the various utilization management tools associated with managed care.

Most agree that although these tools have been relatively effective in controlling costs in the past, there are very few additional savings to be had from utilization management of existing healthcare benefits. This leaves managing the benefit itself, controlling what services are actually covered, and transferring greater financial responsibility to the employees as mechanisms for controlling costs. In this environment, the prospect of providing additional benefits has very little appeal. As health policymakers, employee benefits managers, and insurance company managers decide to what extent chiropractic care should or should not be included in any healthcare benefit package, those decision-makers will be exam-

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ining the net effect of a chiropractic benefit on total premium and medical costs.[4–6] To the extent that the addition of a chiropractic benefit is perceived to add to healthcare costs, there is much less likelihood of adding such a benefit. Similarly, existing chiropractic benefits will come under pressure if it is believed those benefits add costs to the total premium or health plan medical expenses.

In calculating the net cost of a chiropractic benefit, a number of factors must be taken into account. First, the relative unit cost of chiropractic care must be compared with unit cost of medical care. That is, given a comparable patient and severity of condition, what is the cost per episode of chiropractic care versus an episode of medical care? A number of studies have addressed this question but do not arrive at a uniform answer.[7–13,42,43] A study by Carey found that the cost per episode of care under chiropractic care was greater than for primary care medical providers but less than for care by orthopedists.[13] Cherkin found the cost of chiropractic care and that by physical therapists to be nearly identical.[42]

The second factor that will determine the net cost of chiropractic care is the extent to which patients are *substituting* chiropractic care for medical care versus whether patients are using chiropractic care *in addition* to medical care.[16,17] Although chiropractors and physicians undoubtedly treat a similar patient population, their modes of treatment are dissimilar. Because the nature of a chiropractic and medical treatment encounter are different, it might be expected that some patients would use medical care under a certain set of circumstances and chiropractic care under a different set of circumstances.

Finally, to fully measure the economic impact of chiropractic care, it is necessary to evaluate whether chiropractic patient management of back pain, neck pain, and related conditions differs in any way from medical management of these same conditions that affects costs. Specifically, the question arises whether a patient under chiropractic care is more or less likely in the future to seek care for the same or similar health problem than patients treated under medical care. Once again, even if a single episode of care is less costly under chiropractic care, if chiropractors manage patients in a fashion that induces future episodes of care, a chiropractic benefit could increase costs.

This study does not compare the costs of chiropractic versus medical episodes of care. Rather, it analyzes the effect of a chiropractic benefit on the rates of patient complaints for back pain, neck pain, and related conditions and on the number of episodes of care created by chiropractic and medical providers. The investigation takes advantage of a natural experiment in which a set of employers has independently chosen to include or not include a chiropractic benefit in their companies' medical plans. By comparing the rates of patient complaints for a common group of neuromusculoskeletal (NMS) pain diagnoses among those employer groups with and without a chiropractic benefit, it is possible to evaluate the degree to which a chiropractic benefit does or does not create additional demand for medical care services and whether patients are substituting chiropractic care for medical care. The study also measures and compares the frequency of actual episodes of care under chiropractic versus medical care.

Methods

Study Design

Study Population. This 4-year descriptive study (April 1997 to March 2001) used administrative claims data from a large regional managed care network in California. These data included inpatient and outpatient claims data for members of the managed care network who were continuously enrolled during the study period. The dataset included demographic and enrollment information in addition to diagnosis and procedure codes as classified under the *International Classification of Diseases*, 9th Revision (ICD-9) and the *Current Procedural Terminology*, 4th Edition (CPT).

Within this managed care network, individual employers had the option of selecting the health plan with or without a benefit for chiropractic care. This chiropractic benefit was separately administered by American Specialty Health Plans, a health plan that provides benefits riders for services such as chiropractic, acupuncture, and massage therapy. For those employers who selected the chiropractic benefit, the administrative claims data from the 2 networks were merged into 1 unique administrative file, therefore creating 2 main comparative cohorts from the same large health plan: one with access to chiropractic care and the other without. The former group had benefits covering direct access to a chiropractor without the need for a physician referral. Under this benefit plan, the patient copay for a chiropractic office visit was the same as it would be in a medical clinic. The benefit allowed for a maximum of 40 office visits to a chiropractor per year. For the purposes of this study, the following 4 cohorts were evaluated:

1. Cohort A: Patients in health plans that cover chiropractic care who received any treatment (chiropractor or physician) for NMS conditions.
2. Cohort B: Patients in health plans that do not cover chiropractic care who received treatment for NMS conditions (by definition, medical care).
3. Cohort C: Patients in health plans that cover chiropractic care who received chiropractic treatment for NMS conditions.
4. Cohort D: Patients in health plans that cover chiropractic care who received medical treatment for NMS conditions.

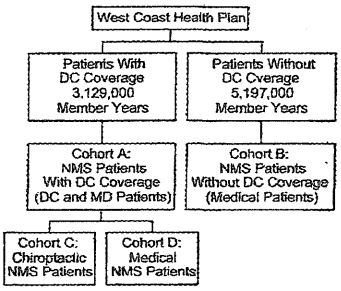

Fig. 1. Overview of study design.

Figure 1 provides an overview of the study design.

There are 2 aspects of this design that need to be emphasized with respect to the study question. First, individual patients do not decide whether they will have chiropractic coverage. That decision is made by benefits managers or others within the particular employer group. Second, the medical physician, hospitals, and clinics that are represented in cohorts B and D are the same group of physicians and institutions. These physicians have patients who both have and do not have chiropractic coverage, and they are unlikely to be systematically aware of this condition. As a result of these 2 design elements, any differences seen between cohorts B and D are most probably the result of the difference in chiropractic coverage and not a confounding factor.

Study Period. The study period covers April 1, 1997, through March 31, 2001.

Identification and Definition of Neuromusculoskeletal Episodes of Care. Identification of NMS pain episodes of care was made by the use of ICD-9 codes that are a part of all administrative claims data. A total of 657 ICD-9 codes were identified as representing this set of conditions. These codes were classified into 8 different diagnostic categories: 1) low back pain, 2) low back pain (complicated), 3) neck pain, 4) neck pain (complicated), 5) thoracic spin pain, 6) headache, 7) myalgias and arthralgias, and 8) other/miscellaneous. The "complicated" designation in the low back and neck pain categories identify those diagnoses suggestive of discopathy and/or radiculopathy. This set of 657 diagnoses represents 96.7% of all chiropractic claims in the health plan. The remaining 3.3% were claims for extremity complaints. Extremity complaints represent a much higher proportion of medical claims. As a result, chiropractic extremity care represented only a very small proportion of total extremity complaints and negligible effects on the total utilization rates. Therefore, these complaints were excluded from the analysis. An expert panel of chiropractors and medical physicians evaluated this diagnostic classification for appropriateness and completeness.

Aggregation of claims into discrete episodes of care was made on the basis of both a "clean period" of 45 days with no claims as well as the diagnostic category that defines the type of episode. The clean period of 45 days is consistent with previous studies using administrative data.[8,9] Each episode is initiated by 1 of the NMS pain codes in the diagnostic list. All services using 1 of these codes and with a maximum gap of 45 days between claims were aggregated into 1 episode of care. Thus, a new episode was created if a new diagnostic category is used or encounters are separated by more than 45 days. A claim-free 45-day window was applied to the start and end points of the 4-year study period to identify and include members with nontruncated episodes. For any episode that begins during this period but extends beyond March 31, 2001, all services related to that episode, within the 45-day limit, were treated as if they fell within the 4-year period. Similarly, any episode that begins within 45 days before April 1, 1997, but extends into the 4-year period was considered to have occurred totally outside of the study period and was not be used in the analysis.

Data Preparation and Merging. Data preparation included transfer of all relevant claims data from the 2 different data sources (see subsequently), loading of the data onto a common server, and filtering by health member continuous enrollment to ready the data for analysis. Data relevant to patient enrollment (ie, insurance coverage information) and health service encounters (ie, dates of service, diagnoses, procedures, and so on) were loaded onto the server. Analysis was conducted using SAS version 6.12. Before the analysis, the data were validated as follows:

- Verification of the names, number of files, and number of records contained in each file with each respective data source.
- Validation of the format of the data (character, numeric, and length).
- Identification of key variables in the datasets (age, diagnosis codes, and so on), production of frequency reports of the data, and validation of the variables' contents, again working with each respective data source.
- Running of algorithms (computer programs designed to detect implausible data) to ensure the integrity of key variables (eg, ICD-9 and CPT-4 codes).

For patients with chiropractic coverage, there is an entirely separate and distinct management and storage of claims data for their chiropractic care than for their medical care. For this study, a patient's chiropractic claims were merged with their medical claims producing a single claims file for each covered patient. Merging of the datasets was accomplished using 1 of the following methods: 1) Each health plan member is assigned a unique identification number that is used for both the medical and chiropractic claims. This number was used to link a patient's chiropractic claims with their medical claims; or

TABLE 1
Demographic and Comorbid Conditions of Patients With Neuromusculoskel etal Claims, Both With and Without Chiropractic Benefits (01/2000 to 12/2000)

	Patients With Chiropractic Coverage	Patients Without Chiropractic Coverage
Demograp hics		
N	707,690	1,001,995
% Female*	51.6%	52.1%
Mean age†	32.9 (SD ⊓ 20.9)	35.5 (SD ⊓ 21.6)
Age groups		
0–17	31.9%	26.2%
18–21*	5.1%	4.3%
22–35*	14.6%	18.4%
36–55*	33.7%	33.2%
56–65	8.2%	8.2%
⊓65*	6.5%	9.6%
Comorbid conditions		
Conges tive heart failure*	0.6%	0.9%
Cardiac arrhythmia*	1.6%	2.0%
Hypertension*	6.6%	7.3%
Diabetes‡	2.8%	3.0%
Hypothyroidism*	1.5%	1.5%
Nutritional/metabolic disorder*	1.6%	1.7%
Psychosis*	1.1%	0.9%
Depression*	1.9%	1.6%

* *P* value ⊓ 0.001.
† *P* value ⊓ 0.0001 .
‡ *P* value ⊓ 0.05.

2) In the event there was no common, unique member identifier (because of data entry errors), the data were linked using both member social security number and date of birth. Once the data were linked, a unique identifier was created and name, address, and social security number were purged from the dataset to assure patient confidentiality. Any data not linked by these 2 methods were eliminated from the study.

Data Analysis. The primary study question, "Is chiropractic care substitution care or add-on care?" was evaluated by comparing the rates of patient complaints in the 9e diagnostic categories of NMS pain described previously. If patients are substituting chiropractic care for medical care, a reduction in the rates of episodes of NMS pain should be seen in cohort D (medical patients in groups with chiropractic coverage) versus cohort B (medical patients in groups without chiropractic coverage). Conversely, if little or no substitution is taking place, the rates in these 2 cohorts should be roughly equivalent.

We also compared the total rates of complaints between cohort A (chiropractic and medical patients with NMS complaints in the groups with coverage) and cohort B (medical patients with NMS complaints in groups without chiropractic coverage). If substitution is occurring, there should be little difference in these rates. If little substitution is occurring, the combined rates of chiropractic and medical patients in cohort A will be higher than the rates in cohort B. Because many patients have multiple episodes of care, rates will be expressed both in terms of total number of episodes per thousand health plan members and total number of unique NMS patients per thousand health plan members. The data reported are population parameters and as such are not subject to tests of statistical significance.

There were some employer groups (and thus, some patients) who, during the study period, either picked up or dropped chiropractic coverage. As these changes took place, the patients and their associated healthcare episodes were shifted into the appropriate study cohort. Thus, in calculating the rates of diagnoses in the various cohorts, the total number of patients in each cohort (the denominator in the rate calculation) was expressed in terms of "insured member years."

Results

Data Preparation

Of the chiropractic claims data files from April 1, 1987, through March 31, 2001, 98.3% were successfully merged with the MCO claims files. For the 4-year study period, there were 3,129,752 insured member years in the groups with chiropractic coverage and 5,197, 686 insured member years in the groups without chiropractic coverage.

Study Population Characteristics

An analysis was conducted on a subset of patients who did not change their chiropractic coverage status during calendar year 2000. (The 4-year data contains a slightly greater number of total patients because it also includes those who did change their chiropractic coverage status at some point during the study.) There were small differences in demographic characteristics and rates of comorbid conditions in the study populations. The group with coverage was slightly younger and had fewer comorbid conditions in most of the categories studied. A summary of the study populations is shown in Table 1.

Comparison of Study Cohorts

A total of 1,394,070 unique patients were identified with NMS complaints during the observation period. Of these, 174,209 were chiropractic patients, 332,548 were medical patients with chiropractic coverage, and 887,313 were medical patients without chiropractic coverage. A breakdown of these patients

TABLE 2
Total Number of Unique Patients With NMS Pain Complaints in Study Cohorts

Diagnostic Category	Cohort A Patients With Chiropractic Coverage (Total of C ∩ D)	Cohort B Patients Without Chiropractic Coverage	Cohort C Chiropractic Patients	Cohort D Medical Patients
Low back pain (uncomplicated)	112,420	198,197	42,095	70,325
Low back pain (complicated)	12,307	22,752	4,612	7,695
Low back pain (total)	124,727	220,949	46,707	78,020
Neck pain (uncomplicated)	80,276	117,703	40,144	40,132
Neck pain (complicated)	1,557	3,346	195	1,362
Neck pain (total)	81,833	121,049	40,339	41,494
Thoracic spine/rib pain	37,429	42,372	25,049	12,380
Headache	56,459	122,496	9,313	47,146
Nonspecific myalgias, arthralgias	68,155	124,920	22,264	45,891
Other (misc. undifferentiated pain diagnoses)	138,154	255,527	30,537	107,617
Total	506,757	887,313	174,209	332,548

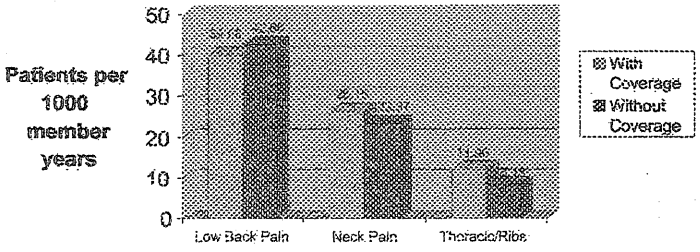

Fig. 2. Rates of patient complaints in groups with and without chiropractic coverage for low back pain, neck pain, and thoracic spine and rib pain.

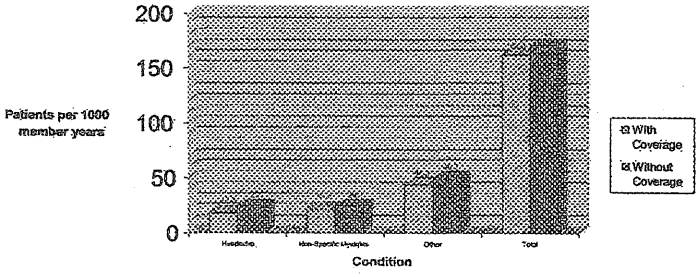

Fig. 3. Rates of patient complaints in groups with and without chiropractic coverage for headache, nonspecific myalgias, and other complaints. Also shown is the total rate of all conditions in the 2 study groups.

by cohort and diagnostic category is shown in Table 2.

Converting these raw counts to rates per 1000 member years allows a direct comparison of the utilization of care in the cohorts with and without chiropractic coverage. In 2 of the diagnostic categories, thoracic spine pain and neck pain, rates were slightly higher in the groups with coverage. In the other 4 categories, low back pain, headache, nonspecific myalgias, and other rates were higher in the groups without coverage. In total, the groups with chiropractic coverage experienced a rate of 162.0 NMS complaints per 1000 member years compared with 171.3 NMS complaints in the groups without coverage. Figures 2 and 3 compare the rates of patient complaints per 1000 member years. The group with coverage includes both chiropractic and medical patients.

Treatment of these patients resulted in 1,997,356 episodes of care for NMS complaints. Of these, chiropractic care resulted in 357,697 episodes; medical care to patients with a chiropractic benefit resulted in 450,221 episodes; and medical care to patients without a chiropractic benefit resulted in 1,189,438 episodes. Table 3 shows a breakdown of these episodes by cohort and diagnostic category.

Expressing the care in terms of episodes per 1000 member years produces a different finding than expressing it in terms of patients per 1000 member years. In 5 of the 6 diagnostic categories, with the exception being headache, rates were higher in the group with chiropractic coverage. They were markedly higher in the spine categories and only slightly higher in the nonspecific and other categories. Including all diagnostic categories, the group with coverage experienced 258.2 episodes per 1000 member years versus 229.6 episodes in the group without coverage. Figures 4 and 5 compare the rates of episodes in per 1000 member years. As stated previously, the group with coverage includes both chiropractic and medical patients.

TABLE 3
Total Number of Episodes of Care for NMS Complaints in Study Cohorts

Diagnostic Category	Cohort A Patients With Chiropractic Coverage (Total of C∩D)	Cohort B Patients Without Chiropractic Coverage	Cohort C Chiropractic Patients	Cohort D Medical Patients
Low back pain (uncomplicated)	183,356	154,960	87,958	95,398
Low back pain (complicated)	18,223	4,041	7,350	10,873
Low back pain (total)	201,579	159,001	95,308	106,271
Neck pain (uncomplicated)	137,989	268,143	86,574	51,415
Neck pain (complicated)	1,884	31,391	281	1,603
Neck pain (total)	139,873	299,534	86,855	53,018
Thoracic spine/rib pain	62,044	52,061	47,973	14,071
Headache	82,953	163,410	17,669	65,284
Nonspecific myalgias, arthralgias	114,982	180,193	47,923	67,059
Other (misc. undifferentiated pain diagnoses)	206,307	335,239	61,789	144,518
Total	807,738	1,189,438	357,517	450,221

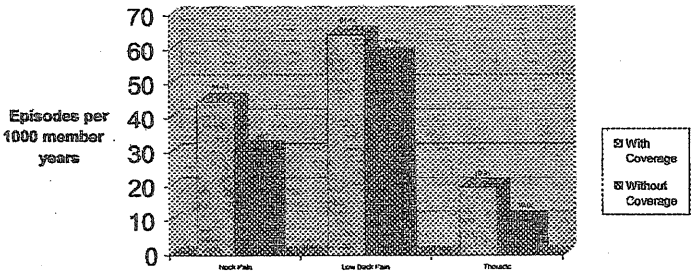

Fig. 4. Rates of episodes of care in groups with and without chiropractic coverage for neck pain, low back pain, and thoracic spine and rib pain.

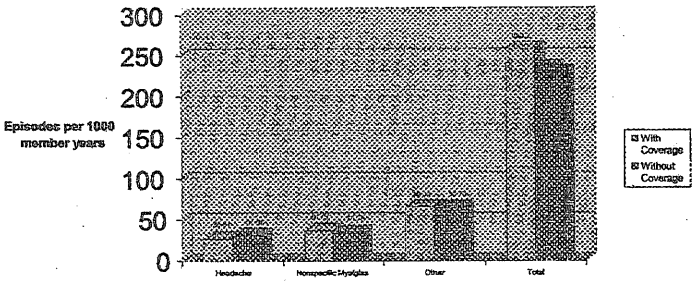

Fig. 5. Rates of episodes of care in groups with and without chiropractic coverage for headache, nonspecific myalgias, and other complaints. Also shown is the total rate of episodes of care for all conditions in the 2 study groups.

Discussion

Table 1 shows that there are statistically significant differences in demographic and comorbid characteristics between the 2 main study groups. However, it should be emphasized that the statistical significance is largely the result of the extremely large sample size and not of large group differences. Overall, the study populations are quite comparable and the small population differences are unlikely to have affected the study results.

Two distinct patterns emerge from this study. First, the presence of a chiropractic benefit does not appear to increase the number of patients who seek care for NMS pain complaints. With some relatively minor exceptions, for instance, thoracic spine pain, patients who seek chiropractic care for NMS conditions appear to substitute that care for medical care on a one-to-one basis for the particular region of complaint. In all of the diagnostic categories, the rates of NMS patient complaints in the cohort with chiropractic coverage (both medical and chiropractic patients) was very similar to the rates in the cohort without coverage. The overall rate of all NMS complaints in the 2 cohorts was within 5% of each other, with the lower rate being in the group with chiropractic coverage.

From the point of view of an insurer or an employer who is considering the impact of adding a chiropractic benefit, these results suggest that a chiropractic benefit is quite different than, for example, a dental benefit. When an employer adds a dental benefit, they are not replacing care from preexisting providers covered by a standard medical benefit. All services provided under a standalone dental benefit represent new costs. A more accurate characterization of the addition of a chiropractic benefit would be that it is the equivalent of expanding the network of available providers for care of NMS conditions. Patients with back pain, neck pain, and related com-

plaints can choose either chiropractic care or medical care, and this expanded choice does not seem to result in more patients seeking care.

The second pattern to emerge is that patients who come under chiropractic care experience more episodes of care than patients under medical care. In most diagnostic categories, chiropractic patients experienced approximately 2 episodes of care, whereas medical patients experienced just over 1 episode. This pattern is most pronounced in the 3 back pain categories. The overall rate of episodes per patient in the chiropractic cohort was 2.05 versus 1.35 among medical patients in the group with coverage.

There are 2 possible interpretations of this second finding. It could be that the treatment effects of chiropractic are not as longlasting as medical care and that chiropractic patients are returning for care as their symptoms return. However, this supposition is not supported in the clinical literature. The evidence that does exist suggests that spinal manipulation, which is the primary treatment modality used by chiropractic providers, is at least as robust as medical interventions relative to long-term effects.[18–23]

A more plausible explanation is that chiropractic management styles encourage patients to return for care. It is possible that the attitude toward back pain among chiropractors and medical physicians is quite different. For chiropractors, the set of NMS complaints considered in this study comprises virtually the whole of chiropractic practice.[24–27] Chiropractors' attitudes toward these complaints undoubtedly reflect this fact. By contrast, NMS pain complaints, at least for nonspecialist physicians, represent a small subset of their total patient population. Medical physicians are known to regard back pain as a frustrating complaint to treat and could communicate this attitude to patients, which could discourage future care.[28–30] Additionally, there is ample evidence that patient satisfaction with chiropractic care for back pain is substantially higher than patient satisfaction with medical care for back pain.[31–37] Patients who have had a generally more positive experience with chiropractic care could be more likely to return for subsequent care.

A study by Stano also reported more episodes of care among chiropractic patients.[38] It was hypothesized that this could reflect a tendency of patients with more chronic NMS conditions to migrate to chiropractic management. Most studies have found chiropractic and medical back pain patients to have a similar level of severity, but there are no data on the relative chronicity of these patients with which to evaluate this hypothesis.

The net effect of this higher rate of episodes among chiropractic patients is relatively modest. The overall rate (all diagnostic categories) of episodes of care among the group with chiropractic coverage is only 12% higher than the group without coverage.

This study demonstrates that in evaluating the relative cost of chiropractic care, it is necessary to evaluate costs at both the episode level and at the patient level. Existing studies that have compared an *episode* of chiropractic care with an *episode* of medical care could have underestimat ed the chiropractic costs.

Most of the data that describe the utilization of chiropractic care is derived from surveys rather than from claims data or from other sources that directly measure care.[39–41] In this study, the rate of utilization of chiropractic care by NMS patients with a chiropractic benefit was quite high. Overall, patients with NMS complaints with chiropractic coverage used chiropractic care 34.4% of the time. It is of particular interest to note that among the patients in the 3 back pain categories, chiropractors saw 45.9% of all patients in the group with chiropractic coverage. This figure is considerably higher than is usually reported. These findings suggest that when patients are offered the choice of chiropractic care, through a chiropractic benefit, versus medical care for back pain, nearly half the patients will choose chiropractic care.

Limitations

There are no data available from the national health plan to determine any potential differences in the types of employers with and without chiropractic coverage. It is not known if the 2 sets of employers, those with and without a chiropractic benefit, examined in this study varied significantly in the industry and job type represented by those employers. Thus, it might be possible that these results are skewed by differences in the makeup of employers in the comparative groups. However, our analysis of the demographic and comorbid status of the 2 groups demonstrated only very minor differences among the employee populations. It is very unlikely that the overall effects seen in this study are systematic artifacts of different patient populations.

It might be argued that the finding of more episodes of care under chiropractic management is simply an artifact of the arbitrary definition of episodes of care and is mostly a reflection of the different styles of chiropractic and medical practice. In this regard, the average duration of an episode of care for uncomplicated low back pain under chiropractic management was 35 days, compared with 10 days under medical care. Results from this study and others indicate that it is clearly a characteristic of chiropractors to provide more services per episode for back pain than medical physicians. If the definition of episode of care were changed to lengthen the "clean period," the rates of chiropractic and medical episodes would be much more similar. In any case, it remains true that the most valid comparison of the cost of chiropractic versus medical management is on a per-

patient basis, thereby aggregating all episodes into 1.

Results of this study might not be generalizable to other medical care settings and financing arrangements. If a different set of economic incentives and management procedures were in place, these could result in different rates of utilization of healthcare services. In this study, the medical providers were reimbursed under a capitated arrangement, which did not provide economic incentives to increase care. Under a more traditional fee-for-service financial arrangement, it might be possible that the medical providers would adjust their behavior to attract and retain more NMS pain patients and thus create provider-induced demand. It should be noted, however, that the chiropractic providers in this study were operating in a fee-for-service environment and their actions did not seem to result in a net effect of increased demand.

In calculating the cost of chiropractic care, it must be observed that chiropractors often manage patients outside of the context of treating a discrete episode of pain. Chiropractors could dispense a variety of nutritional or herbal supplements. Chiropractors could also administer so-called "maintenance care" to asymptomatic patients. These practices were not considered within the parameters of the covered chiropractic benefit that was analyzed in this study, but such practices could well be the norm in other circumstances.

Conclusion

Within a managed care setting, the inclusion of a chiropractic benefit does not increase the overall rates of patient complaints for low back pain, neck pain, and related NMS pain disorders. Patients appear to be directly substituting chiropractic care for medical care. At the same time, those patients who use chiropractic care experience more subsequent episodes of care than patients who use medical care. Thus, the economic effects of a chiropractic benefit in this setting are best evaluated on the basis of a per-patient comparison rather than on a per-episode comparison.

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Reviewer's Comments: The editor and editorial advisors are well known authorities in the field of Traditional Chinese Medicine. One of the Editorial advisors, Giovanni Maciocia, has written perhaps the most widely used textbook of Chinese Medicine in the West. The journal definitely taps into the rich roots of Traditional Chinese Medicine without over-emphasizing herbal remedies. A recent edition, which I recently reviewed, is, in my opinion, representative of the value of this journal and the tradition from which it comes. Some very accomplished practitioners wrote articles in memory of Dr. John Shen, who passed away in 2001. Dr. Shen was a very influential teacher of Traditional Chinese Medicine and the depth of praise expressed by the authors represent the keen appreciation for the oral tradition and mentorship programs associated with Traditional Chinese Medicine. In the West, amongst

the elite, if one was to learn pulse diagnosis, Dr. Shen's name inevitably came up. Many of the articles from the twenty-odd years of the journal reflect a high quality written mentorship for western practitioners of Traditional Chinese Medicine. The articles also read well because of the excellent editorial support. The style is not of a standard Western medical journal, but how could it be if the articles are to help integrate and respect the tradition being shared?

Website: It is well presented with quite a bit of both useful information and links. I've especially enjoyed being able to read some of the free representative articles from past editions. The journal is also most likely the best source for excellent reviews of books regarding Traditional Chinese Medicine.

Audience: The journal is clearly oriented toward clinicians. Although I only integrate certain elements of Traditional Chinese Medicine in my practice of medical acupuncture, I find the journal worthwhile. Each edition often contains several articles that catch my attention. Clinicians who approach their patients only from a neuro-anatomical view or a "five-element" approach are less likely to appreciate this journal.

Keywords: Oriental/anatomy physiology pathology; Traditional Chinese Medicine

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Is Disease Management The New Face Of Managed Care?

By Thomas Spencer, Corinne Abdou, RN, Kathy King, RN, David Spencer, MD

Disease management programs are gaining traction with many of the nation's employers as employers struggle to control rising health care costs. In the current health care system medical providers are compensated for treating acute illnesses in the short term. Disease management programs focus on chronically ill patients in an attempt to both improve the quality of care enrollees receive and to control the growth of health care costs. Disease management incorporates a combination of tools including enhanced screening, patient education, symptoms monitoring, provider coordination and evidence based medical treatment guidelines.(9) Disease management program theory, however, runs counter to the current economics of health care delivery: in other words U.S. medical providers are not paid for preventing disease.

When managed care arrived on the scene in the early 80's as a replacement to the fee-for-service "sickness care" system, it was advertised by the insurance industry as a new wellness and prevention model for health care. (1) With hindsight it can be demonstrated that at least two, popular managed care myths have heavily influenced the development of disease management model assumptions.

Myth #1: Managed Care Delivers Wellness And Prevention

Although the health insurance industry has touted wellness and prevention as its main goal for decades, its main accomplishment has been in area of employer marketing with 69% of all United States employers offering this benefit by 2000. (2)(3) This has resulted in an employer-sponsored health insurance system so rich in benefits that nearly every predictable human condition from the common cold to sore muscles is covered by the employer paid premium. Since nearly all routine and predictable conditions are lumped together with major diseases for coverage under an employer contract, modern health care insurance is no longer insurance against the unforeseen catastrophic disease but rather pre-paid medical care.

Employer-sponsored health insurance works against disease management model theory in two important ways. First, pre-paid health care makes medical services so accessible to employees that there is no immediate incentive for the employee to participate in preventing his own illness.

Second, physicians and other health care providers are contracted with insurance companies to provide medical treatments or the "processes of care". Health care processes, as captured by codes like (CPT) current procedural technology and (DRG) diagnostic related group, are rewarded because they are the easiest to measure and, in theory, to control. Disease management tools like enhanced screenings and patient education, which may result in positive health and economic outcomes, are not rewarded because they are harder to measure and their impact in terms of better health and lower costs may not be known for many years.

The economic bias toward health care processes in the U.S. system of health care delivery has resulted in a structural misalignment of incentives between the two most critical parties in the health care equation, the doctor and his patient. This misalignment became permanent because of the second popular myth of the managed care era.

Myth #2: Insurance Companies Are More Efficient Case Managers

Case management was described as one of the four essential functions of managed care in a 1994 publication by United HealthCare titled The Tools of Managed Care. Before 2000, case management was directed toward patients with diagnosed, complex medical conditions usually triggered by acute episodes of illness. Disease management, in contrast was specifically concerned with the management of chronic illnesses like diabetes, emphysema and osteoporosis.(3) Increasingly the distinctions between the two approaches have diminished, yet two characteristics of each have remained the same: first, the involvement of an insurance company employed nurse case manager to coordinate the provision of care services; second the emphasis on patient education.

Curiously, a search of the medical literature generates almost no peer reviewed evidence to support the notion that insurance company nurse case managers do better in terms of health outcomes than family physicians who directly supervise the care of their patients. According to a Congressional Budget Office report "there is insufficient evidence to conclude that disease management programs can generally reduce overall health spending."

Although patient education is cited in all disease management models as an essential disease management component, it generates almost no reimbursement for the primary care physician. By contrast, case management at the insurance company level employs about 16,000 nurse case managers according to the Case Management Society of America.(4)(7)

How Does Disease Management Work?

Disease management starts by identifying subpopulations of employees who also have a diagnosed or undiagnosed chronic disease. In the case of diabetes, for example, patients need to monitor and to control their blood sugar levels. They may use diet, exercise, insulin and other medications to help them control blood sugar. Patients are largely responsible for their own care and monitoring especially in the home.

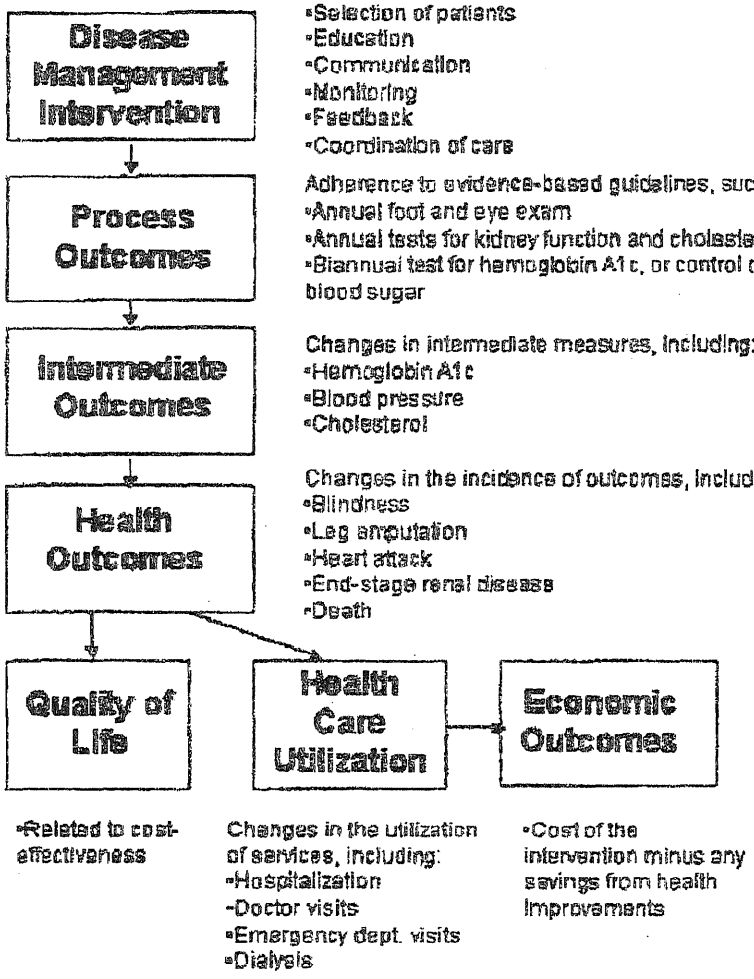
Next, patients are enrolled in a disease management program that offers a standardized set of evidence-based medical processes. In diabetic patients these interactions include blood pressure screenings, annual foot and eye exams, annual lab tests for kidney function and cholesterol and twice yearly checks for hemoglobin.

If the interactions result in the prevention of complications like elevated blood pressure, high cholesterol and low hemoglobin levels they are judged to be successful. The long term benefits of positive diabetes management such as the prevention of blindness,

strokes, renal failure and amputations are not typically captured because they may not be known for years. See Figure 1

Figure 1.

The Path by Which a Disease Management Program for Diabetes Could Lead to Better Health Outcomes and Lower Health Costs



Source: Congressional Budget Office.

Disease management programs are not free to implement. Typically they are offered to employers for an up-front investment. Thereafter they are continued through a per-member-per-month charge to the employer.

Does Disease Management Lower Costs?

In 2004 Blue Cross and Blue Shield of Minnesota began collaborating with American Healthways – a Nashville based HMO – to provide 144,000 participating Blue Cross members with a program that targets 17 chronic health problems. Under the program nurses coordinate care for each of the targeted diseases according to the American Healthways formula. Early results from the program according to Dr. Bill Gold, Blue Cross' Chief Medical Officer and Vice President, show that the insurer saved $4.23 for every $1 invested in the program.(5)

If an employer were to accept the Blue Cross-American Healthways report at face value, then the future success of disease management is not in doubt. According to the Congressional Budget Office, however, there are a number of important methodological issues in assessing the cost effectiveness claims of these companies. These issues stem from the following cost considerations:

- Administrative costs – enrollment, education, intervention etc.
- Disease cost capture – all physician, medication, clinic, emergency room, hospital etc.
- Unintended costs – false positives, invasive testing, new diagnosis etc.
- Selection bias – volunteer costs are lower than the reference group
- Regression to the mean – participants volunteer or are selected on the basis of high cost

Given the economic clout of the health insurance industry, there is a widespread assumption that physicians and providers will embrace disease management program protocols. While there is some evidence in recent studies in the field of rheumatology that suggest that better health and economic outcomes are attainable when physicians implement the formula as designed, important weight was given in these same studies to patient education that led to timely patient access to the rheumatologist. (6)(7)

Peer reviewed studies, however, do not support this assumption. In fact in an October 13, 2004 cover letter introducing the CBO' disease management report Senator Don Nickles' concluded that *"The few studies that report cost savings do so for controlled settings and generally fail to account for all health care costs, including the cost of the intervention itself."* (2)

Is There A Prescription For Disease Management Success?

In a 2004 study conducted by the non-partisan Employee Benefit Research Institute workers rated health insurance as the most important benefit they receive by a margin of 5 to1 (60 percent to 17 percent). The same study concluded that *"employers that do not offer health insurance may have difficulty in attracting and retaining skilled workers."* (7) New health insurance products such as health savings accounts may be used by employers as a foundation from which to build a disease management program. After the employee, the employer has the most to gain from taking an active role in the design of a disease management program.

A cursory review of health care insurance industry pronouncements from 2003 until now would seem to indicate that the future of disease management is now.(5) In important ways its arrival echoes many of the assumptions and the truth claims of the early managed care era 25 years ago. What hasn't changed is that there is little more evidence today than there was in 1980 to prove that sophisticated management of health care processes, or insurance company led case management or patient education as currently practiced will deliver better employee health and lower health care services costs. The lack of contemporary evidence for disease management programs is evidence itself that employers should ask the following questions before embarking on a disease management program:

1) Does the program reward employees for compliance and better health outcomes?

2) Does the program support the physician/patient relationship and plan of care?

3) Are savings in health care resources utilization shared with the employer?

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Mainstreaming Complementary Therapies: New Directions In Health Care

A true collaboration between conventional and alternative medicine promises patients the best of both worlds.

by Mary Ruggie

PROLOGUE: In its decades-long struggle for recognition and respectability, alternative medicine—which covers a range of therapies, including acupuncture, massage, herbal remedies, and chiropractic—has endured many insults and overcome unflattering, and possibly unfair, comparisons to organized medicine in America. As an example, charges that alternative therapies are not safe or effective have always carried with them the implication that, in contrast, Western medicine rested on a firm foundation of evidence supporting its own claims to superiority.

But one need not look beyond recent headlines to find chinks in the armor of Western medicine. For example, the recall of the popular prescription painkillers Vioxx and Bextra over safety concerns has revealed shortcomings in the U.S. drug approval process. On a broader scale, research continues to reveal marked variations in practice patterns by practitioners of conventional medicine, which suggests that there is a lack of consensus on best practices. These observations, among others, have provided fodder for the evidence-based medicine movement, which has itself cast a harsh light on the practice of conventional medicine.

At the same time that conventional medicine has been fighting threats to its credibility, alternative therapies have been enjoying unprecedented popularity, even among groups that have historically been its adversaries. This paper by Mary Ruggie recounts the story of alternative medicine, from its early struggles to its growing acceptance by physicians and other health care professionals as a legitimate and acceptable form of treatment for disease.

Ruggie's interest in this topic is highly personal. She was a breast cancer patient in 1997. At that time, her exposure, in the clinic where she received care, to information on alternative therapies further fueled her incipient interest in the topic. Ruggie (mary_ruggie@harvard.edu) is an adjunct professor of public policy at the John F. Kennedy School of Government, Harvard University. She holds a doctorate in sociology and a master's degree in education, both from the University of California, Berkeley. Her book on alternative medicine, *Marginal to Mainstream: Alternative Medicine in America*, was published by Cambridge University Press in 2004. A Perspective by Richard Nahin, Carol Pontzer, and Margaret Chesney follows.

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ABSTRACT: Within the past decade, complementary and alternative medicine (CAM) has penetrated mainstream U.S. health care. Major medical journals are publishing research on the efficacy of specific CAM therapies, physicians are attending oversubscribed continuing medical education courses on CAM, and hospitals are offering CAM services, sometimes through outpatient integrative medicine clinics. This paper presents factors behind the growth of CAM, analyzes its relationship with conventional medicine, and suggests how the integration of CAM and conventional medicine can be more effectively guided.

ALTERNATIVE MEDICINE IS THE TERM most commonly used in the latter decades of the twentieth century for therapies that ranged from such ancient modalities as acupuncture and herbs to such contemporary innovations as biofeedback and guided imagery. However, during the 1990s both the term and the understanding of the therapies it envelopes underwent major transformation. After the American Medical Association (AMA) disbanded its Committee on Quackery, following a Supreme Court ruling in 1990 that its practices against chiropractors violated antitrust laws, physicians gradually became more open to medical pluralism. The foremost influence on their changing attitudes was surveys showing that increasing numbers of people were using chiropractic, acupuncture, herbs, massage, yoga, and mind-body relaxation techniques, to name a few. It became clear that these therapies were serving less as alternatives than as adjuncts to conventional medicine. Accordingly, the term *complementary* appeared, and a new acronym gained currency: CAM (complementary and alternative medicine). By the end of the decade, major health care institutions were providing CAM services or setting up integrative medicine clinics, primarily for outpatients. These programs combine biomedicine with those CAM therapies for which there is evidence of safety and efficacy.

The changes in name reflect a change in the status and legitimacy of CAM vis-à-vis conventional medicine—from outsider to partner. There are many reasons for the transformation. Four are briefly discussed below: (1) growing use, which led to (2) the establishment of the National Center for Complementary and Alternative Medicine (NCCAM) at the National Institutes of Health (NIH), which led to (3) scientific research on the safety and efficacy of CAM, all of which are (4) stimulating physicians' interest in and acceptance of CAM, albeit conditional. The implications of these developments for the future of health care are far reaching.

The Social Transformation Of CAM

■ **Growing use.** There is a popularized conception in the United States that traces the resurgence of CAM back to the activist (and pacifist) movements of the 1960s and continues to associate CAM with the "New Age." Although partially correct, there is much more to the growth of CAM. By the early 1990s, surveys were identifying a wider population that, despite frustration with conventional medicine, had not turned against it and was using CAM together with standard medical care.[1] A major segment of CAM users were shown to be people in poor health or having

chronic conditions. And because these users had to pay for CAM out of pocket, they tended to have higher incomes and more education. Other isolated characteristics of typical users were white, female, ages 35–55, and living in the West.

The first large-scale survey that included spending on CAM produced startling results.[2] It found that in 1991, one-third of respondents spent about $14 billion—$10.5 billion out of pocket—for these therapies. When the survey was repeated in 1997, all of the numbers were much larger: 42 percent of respondents had spent $21 billion—$12 billion out of pocket. These expenditures exceeded the amount spent on all U.S. hospitalizations. And, as before, Americans were visiting CAM practitioners more frequently than primary care physicians.

■ **Congress and the NIH.** In 1991, before the bulk of surveys on CAM use were published, Iowa's Sen. Tom Harkin, a Democrat who had become interested in alternative medicine, held congressional hearings on what he discerned to be growing use and concern among the medical profession that these therapies were unproven and possibly unsafe. Senator Harkin chaired the Appropriations Subcommittee that determines NIH funding. After the hearings, a bipartisan majority of committee members decided that the NIH should investigate the safety and efficacy of alternative medicine and proposed new funding to set up an Office of Unconventional Medicine, as it was first called, at the NIH.

NIH officials were not pleased with this turn of events.[3] There were years of contention and many changes of directors at the Office of Alternative Medicine (OAM), as it was next called. But with the help of respected medical researchers and practitioners, as well as professional CAM organizations and practitioners, the various directors began to establish programs of scientific research. They stood up to politicians who wanted quick results and ready market access by insisting that scientific proof of safety and efficacy superseded market availability. In response, Congress circumvented the lengthy process of Food and Drug Administration (FDA) approval for botanicals by passing the Dietary Supplement and Health Education Act (DSHEA) in 1994. Led by senators from states with strong dietary supplement industries, it gave herbs the status of food, not drugs.

■ **Scientific research.** The first task of the OAM was to identify and classify the therapies most commonly used in the United States. About 100 therapies were placed into the following categories: mind-body intervention; bioelectromagnetics; alternative systems of medical practice, such as traditional Chinese medicine; manual healing methods; pharmacological and biological treatments; herbal medicine; and diet and nutrition.[4] The next step, setting out a plan for research, took several years. NIH officials felt that it was critical for CAM research to conform to the rigorous standards of scientific medicine, which meant that the therapies had to be investigated in randomized controlled trials (RCTs). At the same time, the medical profession, voicing its opinion in mainstream medical journals, conferences, and seminars, indicated that it would have nothing to do with these therapies unless and until they were proven to be safe and effective. The emphasis on proof implied that

RCTs, the gold standard of scientific medical research, were imperative.

Accordingly, the OAM began to fund research on those more widely used therapies for which there was preliminary evidence of safety and efficacy. Some of the therapies were studied first in laboratories, others in clinical trials. Some readily lent themselves to double-blind, placebo-controlled investigation. For others, researchers had to develop creative modifications of standard RCT methods.[5] Although definitive findings have not yet been established, there is accumulating evidence that a number of CAM therapies are safe and effective for specific medical conditions and that other therapies are questionable, if not unsafe and ineffective. Pleased with the progress, Congress repeatedly increased the budget of the OAM and in 1999 changed its status from an "office" to a "center." The second five-year strategic plan of the National Center for Complementary and Alternative Medicine (NCCAM) expands the scope of its earlier initiatives and, thereby, the reach of CAM in U.S. medicine.

■ **Physicians' growing interest.** The years of litigation between the AMA and the U.S. chiropractic profession undoubtedly soured the attitude of many physicians toward CAM—or certain types of CAM. Nevertheless, one study conducted at the height of the lengthy litigation process found that even though 66 percent of the family physician respondents in Washington State indicated "discomfort with what chiropractors do while acknowledging their effectiveness for some patients," one-quarter viewed chiropractors as an "excellent source of care for some musculoskeletal problems."[6] By the mid-1990s a national survey of family practice physicians and internists found "surprisingly high" support, even encouragement, for patients' use of CAM and referrals to CAM practitioners.[7] The growing number of people using CAM undoubtedly brought these therapies to the attention of physicians. But physicians also might have been motivated to pay more attention to CAM because surveys were finding that many patients were not disclosing their use of CAM to their physicians, and the majority of physicians were not asking.[8] The implications of this finding were threefold. First, it suggested that health care problems could arise from the use of therapies that are unsafe or that have adverse interactions with drugs. Second, if and when patients did talk with their physicians about CAM, it was commonly to ask for advice. Physicians were not, however, sufficiently knowledgeable about CAM to respond. Third, the studies highlighted a more generalized problem in physician-patient communication, one that medical schools have become increasingly aware of and are attempting to correct.[9] In addition to the role of patients, the growing involvement of the NIH in investigating CAM was gradually paving the way for specific therapies' acceptance in conventional clinical settings.

Piecing together surveys conducted throughout the 1990s on physicians' opinions of CAM, one can detect increasingly more favorable attitudes and growing interest in learning about these therapies. A recent survey of faculty at a medical school that emphasizes primary care found that more than 70 percent of respondents rated five therapies (nutrition and diet, counseling and psychotherapy, fit-

ness and exercise, emotional support groups, and biofeedback) as legitimate medical practices, and more than 50 percent rated another six therapies (acupuncture, herbal medicine, massage, chiropractic, hypnotherapy, and meditation) as legitimate.[10] Furthermore, 85 percent of faculty reported that they had training in CAM therapies, and 83 percent had personal experience with CAM, most of it effective. Reflecting demand, a growing number of medical schools are offering courses on CAM, either in the regular curriculum, as electives, or in continuing medical education (CME) programs.[11] Unfortunately, these courses are not yet taught in a uniform manner.

In addition, more physicians are conducting research on CAM. The authors of published articles on CAM, especially involving RCTs, are more likely to be doctors of medicine rather than philosophy. To be sure, skepticism remains, and tolerance or acceptance is likely to be limited to a select few therapies. However, because the tide is turning, we can begin to think about the next stages in the social relations of CAM and conventional medicine.

The Next Stages

For the foreseeable future, research on CAM will likely increase the legitimacy of specific therapies. Research findings as well as expanding the use of CAM are driving demand for a new regulatory framework for certain CAM therapies, particularly botanicals. Some insurers are also expressing interest in CAM's economic implications. If the medical profession responds to these developments by integrating CAM into health care, as we are beginning to see, health care will take a profoundly new direction.

■ **The medical profession and research.** The medical community's acceptance and incorporation of CAM rest in large measure on CAM's scientifically verifiable legitimacy, although it will be exceedingly difficult to sway some of the more hardcore critics.[12] However, staunchly negative attitudes are held by a minority within the medical profession. The research on CAM aims to satisfy the majority of medical professionals who are at least agnostic if not yet fully open-minded.

The medical profession wants CAM researchers to detail their methods of investigation and tests for validity. Researchers are complying, for the most part. For instance, studies of acupuncture now specify the conditions of the experimental treatment (what kind of needle is used, to what depth the needles are inserted and with what force) as well as the nature of the control.[13] Studies that limit the scope of the treatment to specific patient populations with specific medical conditions are also more likely to appeal to the medical community.

Officials at the NCCAM firmly believe that CAM can be studied through scientific methods of investigation. Although there are funding opportunities for various kinds of research methodologies, clinical studies that provide evidence of safety and efficacy in large-scale RCTs are sought whenever possible. However, the agency recognizes that this format cannot be applied to all CAM therapies or

answer all questions about CAM. The NCCAM's new five-year strategic plan elaborates alternative methods and epistemological premises for investigating CAM; it also calls for more systematic study of the placebo effect.[14] Since a growing number of projects (just under half at present) are jointly funded with other NIH institutes and centers, and more collaboration across disciplines is occurring, this diversity will most likely increase our understanding of CAM.

Because research on CAM is still in its early stages, researchers emphasize that the specificity of their investigations limits the generalizability of findings and, as a result, their clinical applicability, which is a problem with all RCT research. In some ways, one can say that there is never enough research, especially given the need for replication and the vast number of therapeutic modalities and applications. However, CAM practitioners may soon ask whether the research base is sufficient to rest the case for safety and efficacy, for certain therapies at least, and to turn to a new endeavor: guiding the next stages of integrating CAM and conventional medicine. Furthermore, insofar as providers are already offering integrative medicine, it appears that the time has come for the scientific and clinical communities to collaborate more effectively.

■ **Regulation of CAM.** Regulation of CAM practitioners varies by state and professional organization.[15] The FDA regulates certain devices that are used in CAM therapies, such as acupuncture needles. However, a more hotly contested domain of regulatory initiative is dietary supplements, including botanicals, which, after chiropractic, are the most widely used type of CAM in the United States. The lax rules (or lax enforcement) surrounding these products pose thorny issues and warrant concerns for both the medical profession and consumers of health care.

Prior to 1994, various pieces of legislation allowed the FDA to regulate dietary supplements as food additives and to require premarket approval of their safety.[16] Under the 1994 DSHEA, dietary supplements reverted to the status of foods, not food additives. The FDA has only postmarketing powers. It is responsible for monitoring the safety and accurate labeling of products on the market (through spot checks of items pulled from store shelves or collected during inspections of manufacturing firms) and for taking any necessary action against violators, such as withdrawing a hazardous product from the market. Manufacturers of dietary supplements are responsible for ensuring that their products are safe before marketing, and they are required to ensure that information on the label is "not false or misleading."[17] Furthermore, manufacturers can claim general health benefits (for example, that products help maintain normal functioning), but they cannot claim that products "diagnose, treat, cure or prevent any disease."[18] Manufacturers must notify the FDA of their claim within thirty days of marketing a product, but they are not required "to disclose to FDA or consumers the information they have about the safety or purported benefits of their dietary supplement products."[19] These regulations and the FDA's reach do not extend to Web sites or the mass media. The Federal Trade Commission (FTC) is responsible for overseeing advertising in

these venues.

The fact that it took the FDA several years to act against manufacturers of ephedra highlights the impotence of this regulatory framework and the power the dietary supplement industry has acquired since passage of DSHEA. The agency began to issue warnings about this product to manufacturers and the public as early as 1997, after the accumulation of consumer complaints. But not until December 2003, after a high-profile death, did it announce, in a joint statement with the U.S. Department of Health and Human Services, plans to prohibit sales of dietary supplements containing ephedra. The rule became effective in April 2004.[20] However, in April 2005 a federal district court in Utah ruled that the DSHEA prohibits the FDA from banning dietary supplements. These must be treated like food, and the FDA must prove substantial or reasonable risk regardless of benefit.

Meanwhile, the FDA has proposed strengthening its enforcement powers through new regulations requiring current Good Manufacturing Practices (cGMPs) that "establish standards to ensure" purity and accurate labeling and that require manufacturers "to evaluate the identity, purity, quality, strength, and composition of their dietary ingredients and dietary supplements."[21] The FDA has completed the stage of receiving comments from the public, but the proposal has not yet been finalized. Although requiring cGMPs is a step in the right direction, the sum of FDA activities is far from meeting the growing demand from consumers and the medical community for better regulation of dietary supplements.[22]

A number of independent agencies help fill the gaps in this regulatory framework through their quality assessment programs. The U.S. Pharmacopeial Convention (USP) has been setting standards for botanicals since 1820. In its Dietary Supplement Verification Program, manufacturers voluntarily submit documentation, including compliance with the FDA's proposed cGMPs, for review in order to bear the USP certification seal. Manufacturers must also agree to audits, including random off-the-shelf testing. A recent article summarizes the certification procedures of four other agencies, which charge for their services: ConsumerLab.com, Good Housekeeping Institute, NSF International, and the National Nutritional Foods Association.[23]

Manufacturers' participation in these programs indicates that they want to prove to the public that their products are safe. A few manufacturers are going one step further. Once sufficient preliminary evidence has accumulated on the efficacy of a botanical for a specific disorder, they are pursuing FDA approval of the botanical as an investigational new drug (IND), which would allow them to make a more focused health claim and study and market the botanical as a drug.[24]

■ **The economics of CAM.** *Cost-effectiveness and savings.* A few studies on the cost-effectiveness and cost-saving potential of CAM are promising. For instance, British researchers found that acupuncture for chronic headache gave patients in the intervention group twenty-two fewer days of headache per year and allowed them to make 25 percent fewer visits to general practitioners (GPs) and to take 15 percent

fewer sick days, compared with the control group.[25] Canadian researchers have found that teaching transcendental meditation (TM) to heart patients greatly reduces health care costs by controlling levels of stress.[26] U.S. research has confirmed the effectiveness of TM in lowering hypertension.[27] If it can be shown that these inexpensive CAM interventions reduce the need for surgery, the savings could be enormous. CAM therapies are also being used before, after, and during surgery to induce relaxation.[28] Studies have shown that providing guided-imagery tapes to heart patients prior to surgery decreases pain and reduces lengths of hospital stay.[29] More investigations are needed on whether CAM can help patients heal faster, use less medication, and leave the hospital sooner.

It appears that many people use CAM for relief from the discomfort of chronic conditions. Even though cost savings may not occur, CAM therapy could still be cost-effective (offer good health value for the money spent) and improve the quality of life. For instance, patients who use one of the three most popular CAM therapies for pain—acupuncture, chiropractic, and massage—might find that they can reduce their consumption of pain medication or be more functional with work or day-to-day activities. These therapies may entail greater out-of-pocket expenses in the short term. However, that people are using them reflects either the adverse side effects of long-term intake of drugs or personal preferences for less interventionist treatment.

Coverage of CAM. Small but growing numbers of insurers and employers are including CAM in their health care packages. The coverage remains low and varies considerably across plans. Both the benefit itself and the specific therapies covered are primarily driven by consumer demand. Insurers have imposed some limits, however, on the number of visits, often to a preferred provider, or on the total amount of coverage. Alternatively, CAM may be included in a defined contribution plan (such as an annual flexible spending account). Some employers believe that offering CAM coverage is "a low-cost benefit with high payoff," in that it improves employee retention and morale, empowers employees with choices, and controls health care costs.[30] However, research has found that insurance coverage increases use of CAM, which may dissuade midsize and small employers from offering it.[31] Once again, scholarly investigation of these issues is required, especially if policymakers are going to encourage insurers to extend coverage for CAM. In its 2001 report, the White House Commission on Complementary and Alternative Medicine Policy urged third-party payers to "evaluate the possibility" of covering CAM.[32] Thus far, only the state of Washington mandates coverage.

■ **Integrative medicine.** The term *integrative medicine* reflects a recent bottom-up development, emerging from educational and clinical pursuits across the country. A number of organizations have evolved to bring together multiple stakeholders from conventional medicine and CAM as well as from philanthropy and business.[33] These organizations engage in dialogue, education, and advocacy. Their Web sites offer links to wide-ranging information on CAM and integrative medicine, to documents

and reports, and to other organizations.[34]

One sign of their success is a recent recommendation by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) that U.S. hospitals make nonpharmacological therapies for pain management available to patients. A monograph describes dozens of possible therapies along with examples of uses; it notes, however, that these "strategies should supplement, but not replace, the use of medications."[35] Another sign is the growing integrative medicine industry. There are no data on the total number of integrative medicine clinics (IMCs) in the United States or on their various forms. But we do know that there are many scattered across the country and that their organizational forms are diverse. Other programs or service delivery models that are not clinic based, such as "service line" or "environment of care" models, also exist, but little is known about them.

Research on IMCs. Current research on IMCs in university hospital settings reveals some interesting commonalities among differences in the meaning and practice of integration.[36] Good relations with hospital physicians are crucial to the success of an IMC.[37] Directors of IMCs, most of whom are medical doctors, are fully aware of the challenges of overcoming physicians' resistance to CAM. They have paved their paths toward acceptance by, for instance, conducting grand rounds to introduce physicians to the science and efficacy of CAM and explaining how particular therapies can be used to facilitate the care of patients with particular illnesses or disorders. Practitioners at IMCs are careful to inform physicians about their treatments and to coordinate, even co-manage, patient care whenever possible. Interesting examples include cancer patients participating in mind-body relaxation techniques before, during, or after chemotherapy and massage therapists, acupuncturists, and oncologists discussing the feasibility of using these therapies on cancer patients.

Obstacles to IMCs. The greatest obstacle now facing IMCs seems to be financial viability. Because CAM work is more labor-intensive and time-consuming, the volume of services is much lower than in conventional medicine. Moreover, insurance reimbursement rarely exists, and when it does, it is too low to cover costs. Accordingly, most IMCs require patients to pay up front in full.

Financial success. The growing popularity of CAM led some academic hospital-based administrators to presume that these "all-cash" services would bring in large sums of money. However, because of hospital regulations and red tape, these expectations have not been met. But many independent IMCs, including those that have separated, legally and financially, from university hospitals, are experiencing greater financial success.

IN JUST A LITTLE OVER A DECADE, CAM has made impressive inroads into U.S. health care. The NCCAM is laying a solid research base for CAM and collaborating with the FDA to build a tighter regulatory framework, all of which is easing physicians' acceptance of CAM. Also relevant for new developments in

health care delivery, a number of clinics are offering integrative medicine. Clinical experience in integrative medicine is building examples of best practices, suggestions for organizational adaptation, guidelines for regulating practitioners, business models, and so on. As a result, models of care based on a true collaboration between conventional medicine and CAM are emerging.

Before full-scale mainstreaming can occur, however, studies must confirm, refute, or modify preliminary findings about the cost-effectiveness of CAM. Sound evidence of cost savings might motivate more coverage and, thereby, wider access. It might also lead to more research on the clinical applications of CAM. All in all, these developments will help us sort the wheat from the chaff in CAM therapies. They also promise patients the best of both worlds.

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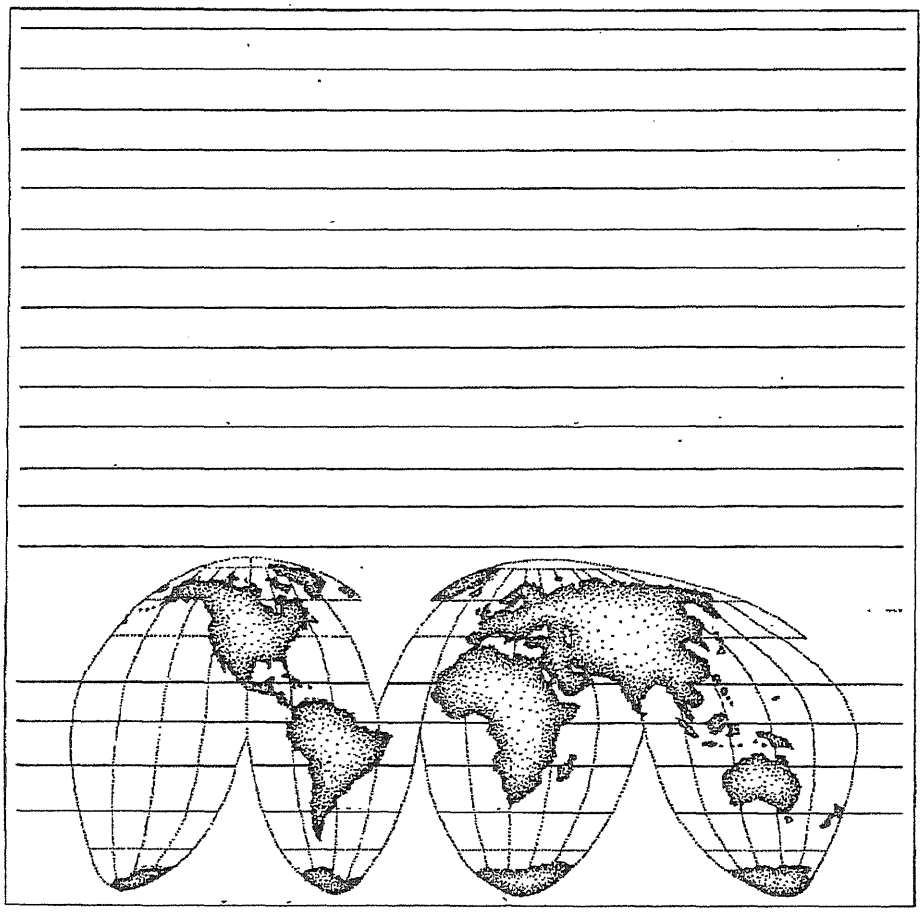
Proceedings of the International Collaborative Effort on Perinatal and Infant Mortality, Volume II

Papers presented at the American Public Health Association, 1985, Washington, D.C., sponsored by the National Center for Health Statistics



U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Centers for Disease Control
National Center for Health Statistics

Hyattsville, Maryland
October 1988

PREFACE

On November 18, 1985, members of the International Collaborative Effort (ICE) on Perinatal and Infant Mortality participated in an American Public Health Association (APHA) session (at the request of the National Center for Health Statistics) for the purpose of presenting papers reflecting the status of their research. Subsequent to the APHA conference, the members convened a seminar to detail their various research perspectives and to discuss their current methodologies.

The ICE is a continuing effort. Through these shared activities of the members, the ICE is providing knowledge and valuable insight into perinatal and infant mortality. Through this dialogue, it is possible to examine international comparisons, to follow trends, and to gain insight into successful interventions, as well as to recognize national gains that have been realized. The goals of this effort are to identify risk factors, to enhance knowledge gained from experiences in intervention programs, and to disseminate data in order to reduce perinatal and infant mortality. In the United States, special attention is directed to the differences in infant mortality rates among various ethnic, racial, and socioeconomic groups in the population.

The ICE Planning Group is comprised of two eminent researchers from each of nine countries: Denmark, England, the Federal Republic of Germany, Israel, Japan, Norway, Scotland, Sweden, and Wales. This group also includes representatives from the National Center for Health Statistics and the Center for Environmental Health and Injury Control of the Centers for Disease Control; the Division of Maternal and Child Health of the Health Resources and Services Administration; the National Institute of Child Health and Human Development of the National Institutes of Health; and the Association for Vital Records and Health Statistics. The participants in this effort represent a diversity of scientific disciplines: physicians, epidemiologists, medical researchers, biostatisticians, and health planners.

The Planning Group's papers and discussions entailed a review of the complex and comprehensive issues in the health field which are critical with respect to perinatal and infant mortality. The presentations are grouped into four general categories:

Risk Factor/Outcome Assessment
Methodology
Comparisons of Trends and Data on Perinatal and Infant Mortality
Comparative Health Care Systems

The presentations published in this volume demonstrate the continuing collaboration which was initiated when this group of individuals first met in August 1984. The material included in this publication may be viewed as a mechanism for concentrating attention on certain methodologies, models, and schemata, which may be of great value in terms of helping the group focus on future areas of interest and in facilitating the process of comparison from one country to another. Eventually, a number of models may evolve from this process, which will then be adopted with appropriate variation by a number of nations in an effort to reduce their perinatal and infant mortality rates.

This volume offers a number of insights and approaches for enhancing perinatal and infant health. The research, the methodologies, the risk assessment, and the prevention efforts suggest certain strategies that, if utilized, may reduce perinatal and infant mortality. A number of the papers in this report offer evidence of successful interventions which certainly hold promise for other nations to emulate.

The Japanese experience with respect to infant mortality is significant. The Japanese attribute their success in this area of health to a concerted national effort of providing both prevention and education programs, as well as maternal and infant health care services. The population appears to have historically embraced the government's goals, and it continues to support these efforts by active participation in and by compliance with the required health practices. The outcome assessment from the Japanese Government indicates that their innovative and far-reaching approach has achieved the goal of reducing maternal and infant mortality.

The methodology undertaken in Sweden appears to have also been successful in achieving a low perinatal and infant mortality rate. As with the Japanese concept, the methodology employed in Sweden is comprehensive and national in nature. Both nations have not only ensured that the population accepts the critical importance of infant and maternal health care but have also succeeded in instilling in the population the conviction that this type of health care is reasonable, necessary, and obligatory. These two nations with their diverse history, customs, and lifestyle have managed to encourage a policy of reasonable and sound maternal and infant health that has become inherent in the culture itself.

Their programs suggest that their accomplishments can be applied to maternal and child health in other countries. In a similar manner, other papers included in this volume offer perspectives that can help guide, foster an awareness, and establish a foundation for implementing various innovations and programs which meet the needs of the population in many different nations.

These papers have been prepared and included in this volume as evidence of the progress of the continuous cooperation of the International Collaborative Effort on Perinatal and Infant Mortality. We look forward to further participation in this project and to the ensuing research rewards of this shared endeavor.

Maternal and Child Health Handbook

Issued on:	
Name of mother:	
Name of child:	(order of birth:)
Name of municipality:	
No.	

Japanese Organization for International Cooperation in Family Planning, Inc. (JOICFP)

Exhibit A: Maternal and Child Health Handbook (English version)

dispute the value of inducing labor in some, perhaps up to 10 percent of women having babies. But in the remainder, the indications are doubtful and can be contested. Attempts to prove a causal relationship between rising induction rates and falling perinatal mortality rates have failed.

All of these obstetrical interventions have been increasing in a number of countries in Europe to an extent that the practices are causing concern. The great variation which has been demonstrated in the use of these interventions also suggests reason for concern. The data from North America suggest that these obstetrical intervention rates are as high or higher than the highest intervention rates presented here for Europe. There is little or no evidence to support the notion that increasing these interventions to such high levels has a significant impact on the overall mortality rates. The European experience in this regard strongly supports the need both in Europe and, especially, in North America to carefully reassess the use of all of these interventions. It is for this reason that a World Health Organization meeting in 1985 made the following recommendations for perinatal services worldwide:

> Countries with some of the lowest perinatal mortality rates in the world have cesarean section rates of less than 10%. There is no justification for any Region to have a rate higher than 10% to 15%.
>
> The induction of labor should be reserved for specific medical indications. No Region should have rates of induced labor higher than 10% (Lancet, 1984).

Midwifery

In 17 of 21 survey countries in the European Region, the midwife is the primary birth attendant for uncomplicated births. The obstetrician is the birth attendant in the great majority of complicated births in the European countries. Five countries indicated, however, that either the midwife or the general practitioner was the attendant for some complicated births. Furthermore, in the great majority of European countries, the midwife is also the principal caregiver for prenatal and postnatal care.

This European pattern of midwives providing the majority of prenatal and postnatal care as well as being the principal birth attendant at uncomplicated births is fundamental to the entire perinatal care system in the European Region. This division of labor is important, since midwives and doctors, in general, have quite different styles of care during pregnancy and birth. The midwife stays with the woman during all stages of labor and birth and sees her role as encouraging and assisting the woman without taking over, while also serving as the woman's advocate when needed. This is a more social as well as noninterventionist clinical approach. The physician does not stay with the woman but rather comes when called by the midwife to diagnose and treat any undesirable deviation. The physician's role is more interventionist and medical in nature. These two styles have nicely complemented each other. In several countries, the midwife's presence, even at complicated births, is an essential reminder to all those present that most of what is going on is still normal.

The implications of midwifery practice in Europe for the situation in North America are profound. The United States and Canada are the only two developed

countries in the world where midwifery is not widely practiced. Every single country in the world with perinatal mortality rates lower than the United States and Canada uses midwives as the principal or only birth attendant for at least 70 percent of all births. This fact alone should dispel any notions that obstetricians are preferable to midwives as birth attendants at uncomplicated births. As mentioned earlier, there is also evidence that a strong independent midwifery profession is an important counterbalance to the obstetrical profession in preventing excessive interventions into the normal birth process. Consequently, it is perhaps not surprising that in the United States and Canada, one finds the highest obstetrical intervention rates as well as serious problems with malpractice suits. The European experience and our data strongly support the urgent need for an introduction of widespread independent midwifery practice in North America as a most important counterbalance to the present situation.

Perinatal Data Systems

The past decade has seen the beginning of cross-national studies of perinatal services and their benefits, hazards, and outcomes. Mention has already been made of the work of the European Regional Office of the World Health Organization in gathering and analyzing such data. The European Perinatal Study Group evaluated the systems for collecting routine perinatal data, and the results are available (Mugford, 1983). The Nordic countries have been involved now for a number of years in comparing their perinatal statistics and perinatal service systems and then actually carrying out various kinds of experimental programs. The Nordic experience in this regard appears to have been quite fruitful (Bergsjø and Bakketeig, 1984). The National Center for Health Statistics in the United States has also recently mounted an international collaborative effort and has begun with an important cross-national evaluation of perinatal data. All of these efforts appear to be important in further understanding the need for improvements in perinatal services. The European experience with perinatal data systems suggests the need for increasing collaboration at the international level if we are all to learn from each other about the best ways to have a baby.

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RECENT RESEARCH

Acupuncture, Other Therapies Should be Presented as Treatment Options to Hypertensives

Non-drug therapies are vital in preventing and treating hypertension. The successive reports of the Joint National Committee on Prevention, Detection, Evaluation and Treatment of Hypertension, WHO scientific report on primary prevention of essential hypertension and national High Blood Pressure Education Program's working groups report on primary prevention of hypertension have stressed on non-drug therapies. Today busy family physicians do not spend enough time explaining to the patient various dietary and lifestyle modifications but straightaway prescribes medication.

Every patient of hypertension from the stage of pre-hypertension to grade 2 hypertension should follow non-drug therapy. If non-drug therapy is strictly adhered, one can prevent cases of pre-hypertension from progressing to hypertension stage and one can reduce or stop the medications in Grade I (mild) hypertension. We have discussed the role of low salt, high potassium diet, role of caffeine intake, calcium and magnesium supplements, fish oil intake, cigarette smoking, alcohol consumption, role of physical exercise, stress reduction and bio-feedback, yoga, meditation and acupuncture. These recommendations regarding diet and lifestyle modifications should be targeted to population at large through public health authorities, non-government organizations and news media.

Sainani, G.S. Non-drug therapy in prevention and control of hypertension. *The Journal of the Association of Physicians of India* 51: 1001-6.

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Acupressure Helps Relieve Bed-Wetting

The authors assessed the efficacy of acupressure for treating nocturnal enuresis compared with oxybutinin. Parents of twelve patients administered acupressure at acupuncture points Gv4, Gv15, Gv20, B23, B28, B32, H7, H9, St36, Sp4, Sp6, Sp12, Ren2, Ren3, Ren6, K3 and K5. Twelve control patients received 0.4 mg/kg oxybutinin. Parents were asked to record incidences of bed-wetting and patients and/or parents completed a questionnaire 15 days and one, three and six months after the start of treatment.

Complete and partial responses after six months of treatment were seen in 83.3% and 16.7%, respectively, of patients treated with acupressure, and in 58.3% and 33.3%, respectively, of children who received oxybutinin.

In conclusion, nocturnal enuresis can be partially treated by oxybutinin but acupressure could be an alternative non-drug therapy. Acupressure has the advantages of being non-invasive, painless and cost-effective.

Yuksek, M.S. et al. Acupressure versus oxybutinin in the treatment of enuresis. *The Journal of International Medical Research* 31(6): 552-6.

Small Study Shows Reduced Stiff Neck Pain

The use of subjective end-points such as VAS pain scales in studies of acupuncture for chronic neck pain have resulted in equivocal results. This study introduces an objective parameter as the primary end-point for the assessment of acupuncture in patients with acute torticollis (stiff neck).

Eighteen patients underwent a single 20-minute treatment session needling two acupuncture points -- Hou Xi (SI-3) and Zuo Zhen (M-UE-24) -- on the side ipsilateral to the predominantly involved side of the neck.

Measuring the angle of lateral head rotation using a simple compass and protractor revealed a mean improvement of 52.9%, more so among those presenting within less than 24 hours as opposed to more than 72 hours.

The author concludes that objective parameters, as seen in acupuncture research of the gastrointestinal and respiratory tracts, should be incorporated into studies of acute and chronic neck pain. The use of sham needle points and placebo needles is problematic since both may elicit physiological responses.

Samuels, N. Acupuncture for acute torticollis: a pilot study. *The American Journal of Chinese Medicine* 31(5): 803-7.

Acupoint Stimulation Can Help Induce Labor

Acupuncture is being increasingly used in Western medical practice. The authors review the various applications of acupuncture during labor in this paper. This ancient therapeutic technique can be employed with a significant percentage of positive results to induce labor in post-term pregnancies, to strengthen uterine contractility and to favor cervical maturation.

The electrostimulating acupoints LI 4 Hegu and SP 6 Sanyinjiao is the most frequently used treatment in labor induction and in increasing the frequency and duration of uterine contractions. Moreover, the authors' experience indicates that the BL 67 Zhiyin can be helpful in accelerating the dilation of the cervix: the treatment is effective in about 75% of patients.

The studies on the use of acupuncture to achieve pain relief and analgesia during labor are more controversial, mainly due to the great heterogeneity of applied treatments and some methodological biases. Nevertheless, the general evidence seems to be positive also for this application.

Allais, G., et al. Acupuncture in labor management. *Minerva ginecologica* 55(6): 503-10.

Western, Oriental medicine may have cooperative benefit for allergic rhinitis

Although a number of methods for treating allergic rhinitis have been tried, many patients have not been satisfied with their treatment. The authors of this study evaluated the effect of a cooperative system of Oriental and Western medicine to develop a new diagnosis protocol for treating allergic rhinitis.

The authors measured improvement rate and acoustic rhinometry after the allergeninduction test and performed a filter paper test as a nonspecific hypersensitivity test with 60 patients who are allergic to dust mites. They divided the patients into two groups, one of which was treated with Western medicine only and the other, which received a combination of Western and Oriental herbal medicines.

According to one of their measurements, the authors observed more symptomatic improvements among the patients who received a combination of Western and Oriental medicines. In the filter paper test there was no significant difference between the two groups.

Jeong, Su-Hyeon, et al. The effect of a cooperative system of Oriental and Western medicine in the treatment of allergic rhinitis. *Korean Journal of Oriental Medicine* 24(4):64-70.

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Acupuncture Found to Lower Elevations in Blood Pressure

Procedure Combined with Electronic Stimulation Can Lower Rates by as Much as 50 Percent, According to UCI Study

Irvine, Calif., March 28, 2005 - Acupuncture treatments using low levels of electrical stimulation can lower elevations in blood pressure by as much as 50 percent, researchers at the Susan Samueli Center for Integrative Medicine at UC Irvine have found.

In tests on rats, the researchers found that electroacupuncture treatments provided temporary relief from the conditions that raise blood pressure during hypertensive states. Such treatments, they believe, potentially can become part of a therapeutic regimen for long-term care of hypertension and other cardiovascular ailments in people.

"This study suggests that acupuncture can be an excellent complement to other medical treatments, especially for those treating the cardiac system," said Dr. John C. Longhurst, director of the Samueli Center and study leader. "The Western world is waiting for a clear scientific basis for using acupuncture, and we hope that this research ultimately will lead to the integration of ancient healing practices into modern medical treatment."

The study appears in the March issue of the Journal of Applied Physiology.

Acupuncture is a 3,000-year-old form of Chinese medicine that involves inserting needles at specific points on the body to help cure disease or relieve pain. In previous studies, Longhurst and his UCI colleagues have identified at the cellular and molecular level how acupuncture excites brain cells to release neurotransmitters that either inhibit or heighten cardiovascular activity.

They have found that when an acupuncture needle is inserted at specific sites on the wrist, inside of the forearm or leg, this triggers the release of opioid chemicals in the brain that reduce excitatory responses in the cardiovascular system. This decreases the heart's activity and its need for oxygen, which in turn can lower blood pressure, and promotes healing for a number of cardiac ailments, such as myocardial ischemia (insufficient blood flow to the heart) and hypertension.

In this study, the Longhurst team applied acupuncture to

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specific points on the forelimb of test rats with artificially elevated blood pressure rates; these same sites on humans are on the inside of the forearm slightly above the wrist. The researchers found that acupuncture alone had no effect on blood pressure.

Next, they added electrical stimulation to the acupuncture treatment by running an electrical current through the needles. High frequencies of stimulation also had no effect, but low frequencies lowered increased blood pressure by as much as 40 to 50 percent. Overall, the researchers found that a 30-minute treatment reduced blood pressure rates in these test rats by 25 mmHg – with the effect lasting almost two hours.

"This type of electroacupuncture is only effective on elevated blood pressure levels, such as those present in hypertension, and the treatment has no impact on standing blood pressure rates," said Longhurst, a cardiologist who is also the Lawrence K. Dodge Professor in Integrative Biology. "Our goal is to help establish a standard of acupuncture treatment that can benefit everyone who has hypertension and other cardiac ailments."

Longhurst and his colleagues currently are testing this electroacupuncture treatment method in an ongoing human study.

Drs. Wei Zhou, Liang-Wu Fu, Stephanie C. Tjen-A-Looi and Peng Li of the UCI Department of Medicine participated in the study, which was funded by the National Heart, Lung and Blood Institute, and the Larry K. Dodge Endowed Chair.

The Susan Samueli Center for Integrative Medicine in the UCI School of Medicine is focused on scientific research and education in the broad field of complementary and alternative medicine. The center, which was established in early 2000 through a gift from Henry and Susan Samueli, is dedicated to public and professional education and scientific research on the use of complementary and integrative approaches in wellness and prevention as well as health care. For more information, see: www.ucihs.uci.edu/com/samueli.

About the University of California, Irvine: The University of California, Irvine is a top-ranked public university dedicated to research, scholarship and community service. Founded in 1965, UCI is among the fastest-growing University of California campuses, with more than 24,000 undergraduate and graduate students and about 1,400 faculty members. The second-largest employer in dynamic Orange County, UCI contributes an annual economic impact of $3 billion.

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Clinical and Cost Outcomes of an Integrative Medicine IPA

Richard L. Sarnat, MD,[a] and James Winterstein, DC[b]

Abstract

Objective: We hypothesized that primary care physicians (PCPs) specializing in a nonpharmaceutical/nonsurgical approach as their primary modality and utilizing a variety of complementary/alternative medicine (CAM) techniques integrated with allopathic medicine would have superior clinical and cost outcomes compared with PCPs utilizing conventional medicine alone.

Design: Incurred claims and stratified randomized patient surveys were analyzed for clinical outcomes, cost offsets, and member satisfaction compared with normative values. Comparative blinded data, using nonrandomized matched comparison groups, was analyzed for age/sex demographics and disease profiles to examine sample bias.

Setting: An integrative medicine independent provider association (IPA) contracted with a National Committee for Quality Assurance (NCQA)-accredited health maintenance organization (HMO) in metropolitan Chicago.

Subjects: All members enrolled with the integrative medicine IPA from January 1, 1999 through December 31, 2002.

Results: Analysis of clinical and cost outcomes on 21,743 member months over a 4-year period demonstrated decreases of 43.0% in hospital admissions per 1000, 58.4% hospital days per 1000, 43.2% outpatient surgeries and procedures per 1000, and 51.8% pharmaceutical cost reductions when compared with normative conventional medicine IPA performance for the same HMO product in the same geography over the same time frame.

Conclusion: In the limited population studied, PCPs utilizing an integrative medical approach emphasizing a variety of CAM therapies had substantially improved clinical outcomes and cost offsets compared with PCPs utilizing conventional medicine alone. While certainly promising, these initial results may not be consistent on a larger and more diverse population. (J Manipulative Physiol Ther 2004;27:336-47)

Key Indexing Terms: *CAM Therapy; Medicine; Outcomes; Primary Care Physician; Managed Care*

Introduction

The escalation of medical expenditures is an urgent problem. Although various types of managed care, once thought by some to be part of the solution to increasing medical expenditures, have been used for decades, little evidence exists that this or any other cost-containment strategy has significantly influenced a 50-year trend of increasing medical expenses on a long-term basis.[1-5] Managed care rates are now posting double-digit annual increases,[6] with pharmaceuticals estimated to account for 50% of the cost increases over the past 3 years.[7]

While the health care system excels in acute care and crisis disease state management, this accounts for only a small percentage of the total medical care in both cost and volume rendered daily.[8] The greater health care burden is the prevention and treatment of the multiple chronic disorders in the general population that now account for the majority of health care expenditures.[9]

Chronic diseases are a major public problem in the United States. Currently, about 40% of the US population (approximately 100 million Americans) suffer from at least 1 chronic disorder.[9] This high level of prevalence within the United States raises concerns about the efficacy and limitations of our conventional health care system.[10] Such concerns appear to contribute to public and professional interest in alternatives to conventional modern medicine.

Studies now suggest that 50% of the deaths[11] and 70% of the diseases[12] in the United States are caused by unhealthy lifestyle habits such as smoking, alcohol abuse, and improper diet. Unlike the preantibiotic era when mortality was

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primarily because of infectious diseases, our nation now faces a behavior-induced epidemic of chronic illness. Managed care and government policy makers are faced with the dilemma of trying to decrease medical costs caused mainly by lifestyle choices while continuing to maintain personal freedom of choice.

Iatrogenic illness (an adverse condition arising from the treatment of a physician) is estimated as the etiology of 15% of our hospital days, and pharmaceuticals are estimated to cause between 100,000 to 250,000 deaths per year,[13,14] as well as nonquantifiable morbidity. Prescription drug addiction, administering the wrong drug, and prescription overdoses are a large percentage[15,16] of reported deaths by medical mistake. The National Conference of State Legislatures, November/December 2000, estimates the cost of lost income, disability, and health care resulting from medical mistakes is as much as $29 billion per year.[17]

Given these facts, it may be time to rethink this country's current medical model with its overall reliance on pharmaceuticals as a first line option. Complementary/alternative medicine is one viable approach that should be considered because it addresses the privacy, quality, and expense considerations facing health care delivery systems.

Unlike conventional medical education and care, which relies heavily on high technology and pharmaceuticals, complementary/alternative medicine exists in a "low-tech arena." "Low-tech" therapeutic modalities such as chiropractic manipulation, homeopathy, stress management, massage, and use of herbal medicines are perceived by the public as more gentle, less morbid, and less costly than conventional modern medicine.[18]

Many previous studies on various complementary/alternative medicine (CAM) modalities have illustrated improved clinical outcomes and substantially decreased costs compared with standard conventional medical practice protocols.[19-44] However, while individual diagnostic categories have been analyzed, a study of the clinical outcomes and cost effectiveness of primary care physicians (PCPs) specializing in CAM, and more particularly chiropractic care, within the context of a classical gatekeeper health maintenance organization (HMO) has never previously been attempted.

Methods

Data reported in this study were drawn from incurred claims data, originating from both the integrative medicine independent provider association (IPA) and the HMO. The IPA data included all inpatient and outpatient encounters for both cost and diagnosis, including the professional fees associated with patient referrals, outpatient diagnostics (encounters and costs), and outpatient laboratories (encounters and costs). The HMO data included the encounters and costs of all pharmaceutical usage, inpatient admissions, and outpatient surgery and procedures. This information was collected prospectively over a 4-year period.

The HMO actuarial department prepared an annual financial projection for the IPA membership as an age/sex risk-adjusted population. On a cost basis, the discrepancies between the projected costs versus the actual costs were analyzed annually.

Standard managed care benchmarks, including hospital days per 1000, hospital admissions per 1000, outpatient surgeries and procedures per 1000, and pharmaceutical utilization were reported annually by the HMO (normative network values) and then compared with the actual utilization of the integrative medicine IPA.

Randomized patient surveys were conducted annually by the HMO to assess member satisfaction, quality of care benchmarks, and member behavior patterns (eg, tobacco usage).

Integrative Medicine IPA-Development and Implementation

In 1996, a large HMO accredited by the National Committee for Quality Assurance (NCQA) servicing the metropolitan Chicago area was initially contacted to test the feasibility of gathering data on a CAM-oriented health care delivery system. This HMO was a classical gatekeeper HMO with over 600,000 members enrolled in the greater Chicago area.

The project's objective was to build an integrated medicine system in the Chicago metropolitan area that would use primary care physicians who specialize in a nonpharmaceutical/nonsurgical approach as their primary modality. These nonpharmaceutically oriented PCPs, notably chiropractic physicians, were organized into a well-defined structure along with their more conventional allopathic counterparts to create a truly integrated health care system encompassing both CAM therapies and conventional modern medicine within a single comprehensive insurance benefit structure. The project was designed for a gatekeeper HMO format because its structure simplified data collection and made mandatory reporting a contractual obligation.

To test this new model, an "alternative medicine" IPA, legally incorporated in 1997 as Alternative Medicine, Inc. (AMI), was formed to function within the classical gatekeeper HMO format under the same rules and regulations as any other contracted conventional allopathic IPA. The data reported herein refer to the contractual relationship between AMI as an integrative medicine IPA and the specific HMO (unless otherwise noted).

The formation of an IPA under contract with the HMO required specific contractual elements to be met according to the National Committee for Quality Assurance. The minimum requirements for PCP network support included:

- Contracted availability of all allopathic specialists
- Contractual relationships with regional hospitals to provide inpatient access

- A minimum roster of both pediatricians and obstetricians/gynecologists exclusive to the IPA
- HMO Peer Review Committee approval of the IPA's utilization management (UM) and utilization review (UR) plan policy and procedures

As reported later in section IV, "Medical Management," each of these prerequisites was successfully addressed prior to PCP impanelment.

All primary care physicians had to pass credentialing by the Credentialing Peer Review Committee of the HMO, which was composed of medical doctors (MDs) exclusively. For a new IPA to be impaneled, every PCP needed to successfully pass the credentialing criteria. A single failure would have prohibited the project from initiation. Initial analysis identified 4 separate and independent but related processes that needed to occur to provide the foundation for successful execution:

1. Physician Recruitment: Targeting that subset of physicians who would be appropriate PCPs to function in a nonpharmaceutical/nonsurgical model. In this study, only chiropractic physicians agreed to participate as PCPs.
2. Credentialing Process: Developing a credentialing process exceeding the existing NCQA requirements for CAM providers, a standardized process to quantify the performance of this subset of prospective primary care physicians according to accepted industry standards.
3. Member Recruitment: Addressing the ability to recruit potential members or patients to test the hypothesis that primary care chiropractic physicians specializing in nonpharmaceutical/nonsurgical approaches as their primary modality and using CAM techniques integrated with allopathic medicine would have superior clinical and cost outcomes compared with PCPs utilizing conventional medicine alone.[4]
4. Medical Management: Formalizing the medical management to provide integrated care between the CAM therapies delivered by the chiropractic physicians and other conventional medical specialists throughout the inpatient/outpatient cycle.

The following sections address the mechanics of how each element was defined and executed to successfully achieve the outcomes reported herein.

Physician recruitment. *Nonpharmaceutical/nonsurgical physicians* were defined to include those physicians who use as their primary diagnostic/treatment modalities such disciplines as chiropractic manipulation, osteopathic manipulation, naturopathy, homeopathy, Traditional Chinese Medicine (TCM), acupuncture, Ayurvedic medicine, herbal medicine preference over pharmaceuticals, massage, and energy healing techniques.

Under the Medical Practice Act and Managed Care Act, the State of Illinois only licenses medical doctors, Doctors of Osteopathy (DO), and Doctors of Chiropractic (DC) as primary care physicians. Therefore, Doctors of Naturopathy (ND) and Doctors of Oriental Medicine (OMD), although licensed in other states, were automatically excluded from the IPA physician network. At the project's inception, personal interviews were conducted with all categories of physicians, including MDs/DOs and DCs whose style of medical practice qualified them as potential CAM-oriented PCPs. For a variety of professional, personal, political, and economic reasons, only the Doctors of Chiropractic were willing to undertake the project.

All CAM-oriented MDs/DOs interviewed rejected participation for reasons including too restrictive a reimbursement model, philosophical or political issues with managed care in general, inability to meet credentialing requirements because of lack of board certification, or independent ("lone ranger") personality, not comfortable with third-party oversight and review.

Credentialing process. Since, to our knowledge, Doctors of Chiropractic had previously never served as PCPs in a classical gatekeeper HMO model, this presented an immediate credentialing challenge. A unique credentialing process was developed to identify that subset of Doctors of Chiropractic who could successfully function as PCPs.

Each prospective PCP underwent a personal interview to review his or her treatment modalities, criterion for referrals, and comfort in dealing with a primary care role. Preference was given for such qualities as broad scope of practice patterns, history of appropriate interactions with other medical specialists, and demonstrated understanding of the pathophysiologic basis of disease as currently understood by evidence-based Western medicine. This process has now been formalized into a standardized test and is currently offered as provisional credentialing to students at the National University of Health Sciences in Lombard, Illinois, as well as endorsed by the American Academy of Chiropractic Physicians (AACP).

The credentialing process also involved an educational component, including seminars given by AMI MD medical directors to review conventional medicine diagnostic and referral decision trees. Registered nurses provided the onsite component where prospective physicians and their office staff received training in Health Employer Data and Information Set (HEDIS) compliance, Occupational Safety & Health Administration (OSHA) compliance, and instruction in proper charting requirements. Time spent in the onsite component varied between 4 hours and 20 hours to achieve successful completion. All primary care chiropractic physicians were held accountable to the same criteria as their MD/DO counterparts under NCQA regulations.

It is important to note the educational training of the chiropractic physician. While similar in many regards to medical training, there is no training in surgical procedures or in the use of drugs in the management of human illness. The standard course of training is in excess of 4800 hours, with approximately one quarter spent in the clinical setting. Course work encompasses programs in standard

diagnosis (ie, cardiovascular diagnosis, neurological diagnosis, gastrointestinal diagnosis, genitourinary diagnosis, etc.), as well as more specifically chiropractic programs (ie, manipulation of the spine and extremities, physiotherapeutic modalities) and other forms of CAM (ie, homeopathy, herbal therapy, botanical medicine, etc.).[45,46]

The HMO Peer Review Committee formally approved all of AMI's primary care chiropractic physicians in the fall of 1998. AMI began patient encounters on January 1, 1999 with 16 fully credentialed primary care chiropractic physicians. As of December 31, 2002, AMI had 30 primary care chiropractic physicians in the HMO model.

Member recruitment. The HMO under contract had an enrollment of over 600,000 members and was available only to companies with a minimum employee base of 100 enrollees. AMI's prospective members originated from open enrollment offered to the total population of the HMO. Most members obtained information about AMI from the HMO's standard primary care and specialist physician directories or their company's human resource (HR) personnel. The HMO used no marketing incentives to attract potential patient enrollees to the alternative medicine IPA. Like all classical HMOs, there was no exclusion of patients having preexisting illnesses.

In the first month of operation, January 1, 1999, AMI's HMO had an enrollment of 37 members. Enrollment as of December 31, 2002 was 649 members. Because marketing had been by "word of mouth," growth in IPA enrollment was steady but slow. IPA enrollment measured in member months (mm) per calendar year grew from 1726 mm (calendar year 1999) to 4987 mm (calendar year 2000), to 6932 mm (calendar year 2001), and to 8098 mm (calendar year 2002). In total, 21,743 mm of data were analyzed. This standard managed care unit is calculated by multiplying each unique member by the number of months enrolled within the IPA during a calendar year.

The HMO calculates the ratio of new member "transfer in" versus "transfer out" for each IPA on a monthly basis. AMI's range for "transfer in" lies between 3.43% and 5.53%, and "transfer out" is between 2.83% and 3.50%. The higher ratio of transfer in versus out correlates with the observed growth in member enrollment.

Medical management. The intention was to provide members with the best treatment that both chiropractic, using a variety of CAM techniques, and conventional modern medicine had to offer. All of the AMI primary care chiropractic physicians focused primarily on the assessment and evaluation of all risk factors whether they were related to diet/nutrition, exercise, postural/structural problems, behavioral/emotional problems, physiological disease, or the need for improved stress management. Similar to the role allopathic PCPs assume in a conventional medical IPA, all examinations, treatments, and procedures that occurred within the offices of the primary care chiropractic physicians were at the discretion of the PCP. The number of recommended visits, the choice of appropriate treatments, and ancillary modalities utilized did not require approval from the IPA MD medical directors. All ancillary testing and treatment outside the personal office of the primary care chiropractic physician was subject to MD medical director approval to benefit from the enhanced experience of allopathic physicians in dealing with more complex and varied disease states.

One inpatient-oriented and 2 outpatient-oriented MD medical directors were available 24 hours a day, 7 days per week to provide consultation and comanagement by phone or facsimile, as required, according to the complexity of the patient's presentation. Over 3000 medical specialists and 18 hospitals (including university based) were under contract by AMI as part of the IPA to provide integrated care as appropriate to medical necessity. Ongoing telephonic and/or facsimile consultation and comanagement between the PCPs and the MD medical directors occurred daily.

In general, primary care chiropractic physicians practiced what they do best: nonpharmaceutical/nonsurgical prevention. When and if acute life threatening disease or advanced disease management required inpatient status or conventional modern medicine, the PCP delegated his/her authority to the attending medical physician consulted. A registered nurse specializing in utilization management and utilization review coordinated continuity of care between the inpatient and outpatient cycle.

By design, AMI's PCPs had a higher number of encounters initially to correct structural dysfunctions and provide re-education in lifestyle choices that left unchanged may have manifested into more serious disease states. It was not atypical for new AMI members to have PCP encounters at an average of twice per month. This is in contrast to conventional medical IPAs, wherein the majority of members have PCP encounters on a "crisis-only" basis.

AMI's "New Member Welcome" letter informed the patient that it was IPA policy to have a mandatory initial visit with their PCP within the first 3 months of enrollment. These frequent education-oriented encounters combined with hands-on healing were believed to forge a strong doctor/patient relationship. The PCP then became the "trusted guide" and assisted the patient with the required lifestyle changes or gave professional advice on the many and varied uses of CAM. Many modalities of CAM remain unregulated and are most safely and effectively utilized when supervised by a licensed physician truly knowledgeable from extended training in CAM.

The chiropractic PCPs also utilized nonphysician (CAM) providers. These providers were licensed and/or credentialed in various CAM therapies, such as massage, acupuncture, cranial sacral therapy, and stress management techniques, including meditation, yoga, and energy balancing, as well as more traditional cognitive therapy. It

Table 1. *Diagnostic profile of AMI's HMO population year 2000*

Diagnoses	Diagnoses by percentage	Diagnoses by members
Wellness	28.5%	149
Orthopedic	23.5%	123
Other medical	11.7%	61
Mental health*	8.1%	43
Gynecological	6.7%	35
Sinus/allergy	6.0%	31
Cardiac/hypertension	4.6%	24
Headaches (all variations)	2.7%	14
Neoplastic	1.5%	8
URI	1.5%	8
Asthma	1.4%	7
Gastrointestinal	1.3%	7
Thyroid disease	1.2%	6
Diabetes	1.2%	6
	100%	522

522 members with diagnoses includes 31 severely ill patients (multiple ICD-9 comorbidities).

AMI, Alternative Medicine, Inc; *HMO,* health maintenance organization; *URI,* upper respiratory infection.

*Mental health defined as those patients requiring a referral to a mental health specialist.

Table 2. *Comparison of "well" members AMI versus comparison groups I and II*

IPA	Members enrolled	Members with no or non-ICD-9 encounters	Percentage of members coded as "wellness"	Percentage of members coded for active disease
AMI	522	149	28.5%	71.5%
Control group I	7549	2618	34.7%	65.3%
Control group II	7723	3206	42.0%	58.0%

AMI, Alternative Medicine, Inc.; *IPA,* independent provider association.

is important to note that the chiropractic physicians included in this study utilized all the modalities noted above and not just the chiropractic adjustment as a sole therapeutic intervention.

It was anticipated that this increased intensity in prevention-oriented encounters and concomitant comanagement with AMI's MD medical directors would reduce the utilization of high-cost, high-technology conventional medicine downstream.

Member Populations: AMI Versus Nonrandomized Matched Comparison Groups

In this section, Tables 1 through 3 compare various aspects of the AMI membership versus 2 nonrandomized matched comparison groups. Both comparison groups represent separate conventional IPA enrollment within the same commercial HMO product, in the same geographic region, and during the same time frame as AMI's data.

AMI patient population demographics versus comparisons. While the comparison groups' demographics have been matched as much as possible to remove any underlying bias, certain dissimilarities exist. "Children," defined as member enrollment under the age of 20, represents a smaller population percentage in the AMI program compared with the comparison groups: 11.9% (AMI) versus 32.8% (comparison group I) and 19.0% (comparison group II). The smaller percentage of children enrolled is not accidental. Chiropractic physicians are unable to legally administer childhood immunizations because of limitations in the scope of practice of their licensure. While AMI does not prohibit enrollment for children under 10, it is not encouraged.

Statistical analysis also reveals a slightly decreased average age of adult members in the AMI population (39.5 years) compared with comparison groups I (41.3 years) and II (40.3 years). While this slight average age discrepancy certainly favors increased cost expenditures in the comparison groups, this may be offset by the fact that AMI has a greater percentage enrollment of female members compared with male members. The actuarial department of the HMO predicts more than a 50% greater utilization within the IPA by female members versus male members. The sex distribution of AMI membership is 61.6% female members and 38.4% male memers. By contrast, comparison group I had 58.9% female members and 41.1% male members; comparison group II had 59.1% female members and 40.9% male members.

The HMO forwarded age/sex distribution data to AMI in the form of monthly eligibility lists. Comparison group data were forwarded to the authors from the conventional IPAs after receiving their individualized data from the HMO.

AMI patient population disease profile. AMI's HMO membership, as reported herein, represented a unique population dissimilar from previously published literature of disease states commonly seen by chiropractors.[47] Chiropractors primarily care for patients with complaints of musculoskeletal origin or headaches. As AMI was the first managed care program to utilize chiropractors in a PCP role, it was not surprising that membership included a wide range of disease states not seen in the typical chiropractic office, as illustrated in Table 1.

When analyzing IPA data, diagnostic classification was assigned to individual patients based on PCP encounter data, specialist encounter data, referral activity, and pharmaceutical usage. When multiple *International Classification of Diseases, Ninth Revision* (ICD-9) codes were listed on encounter data, the diagnosis requiring the higher expenditure for workup or treatment was chosen as the primary classification. If the presence of prominent severe comorbidity such as hypertensive cardiac disease, diabetes

Table 3. *Comparison of ICD-9 diagnostic profile by percentage of member enrollment AMI versus comparison group I*

Diagnosis	AMI %	Comparison group I
Wellness	28.5%	34.7%
Orthopedic	23.5%	8.0%
Other medical	11.7%	17.0%
Mental health	8.1%	1.3%
Gyne (non-OB)	6.7%	9.4%
Sinus/chronic allergy	6.0%	2.8%
Cardiac/hypertension	4.6%	9.4%
Headache (all variants)	2.7%	0.7%
Neoplastic (all)	1.5%	1.1%
URI	1.5%	10.4%
Asthma	1.4%	1.3%
GI	1.3	0.9%
Diabetes	1.2%	3.4%
Thyroid disease (all)	1.2%	1.4%

AMI, Alternative Medicine, Inc.; *GYN*, gynecology; *OB*, obstetrics; *URI*, upper respiratory infection; *GI*, gastrointestinal.

Table 4. *AMI outcomes comparison with HMO network data (1999–2002)**

	AMI percentage utilization vs HMO	AMI percentage reduction vs HMO
Hospital-based data		
Hospital admissions/1000	57.0%	43.0%
Hospital days/1000	41.6%	58.4%
Average length of stay	76.2%	23.8%
Outpatient-based data		
Outpatient surgical cases/1000	56.8%	43.2%
Pharmaceutical usage (cost)	48.2%	51.8%

AMI, Alternative Medicine, Inc.; *HMO*, health maintenance organization.

* Obstetrics admissions excluded from comparison percentages.

mellitus, and bipolar disorder were all prominent in a patient's encounter data, then the patient received 3 separate and distinct classifications. This explains why 491 unique patients in the year 2000 received 522 disease classifications (Table 1).

The diagnostic category "wellness" referenced in Tables 1 through 3 was defined as: (1) members having patient encounters but not receiving ICD-9 codes (these patients may have been symptomatic but received chiropractic codes for subluxation/dysfunction by their PCPs); (2) members having encounters for nonsymptomatic screening test only; or (3) members having no encounters within a given calendar year.

The category "other medical" listed in Table 1 (11.7% of AMI's population) encompassed a wide range of diseases affecting 61 patients. These diseases included (listed in order of frequency) but were not limited to the following: neurologic disorders, abdominal pain, dermatologic disorders, prostate disease, adrenal cortical insufficiency, chronic fatigue syndrome, cystitis, esophageal reflux, multiple sclerosis, tinnitus, temporomandibular joint (TMJ), and human immunodeficiency virus (HIV).

As Doctors of Chiropractic had not previously functioned as PCPs, the congruence of their diagnoses when compared with conventional PCPs when reporting on a Health Care Financing Administration (HCFA) 1500 encounter form was unknown. When PCP diagnostic coding data were cross-correlated with both specialist referral data and pharmaceutical usage, agreement was found between the conventional medical specialist and the chiropractic PCP 93.1 % of the time. When the diagnosis necessitated a treatment that required the use of pharmaceuticals or surgery, then an appropriate referral was made to a conventional medical specialist.

ICD-9 Profile of Nonrandomized Matched Medical Comparison Groups I and II

In this section, Tables 2 and 3 reflect membership breakdown by ICD-9 diagnostic coding percentage comparing AMI's membership with the membership of comparison groups I and II. Both comparison groups represent conventional IPA enrollment for the same commercial HMO product in the same geographic region during the same time frame as AMI's data. A blinded independent contractor with previous employment in the medical records department of a local hospital analyzed ICD-9 coding data, compiling the disease profiles between AMI's membership and comparison group I membership.

Previously published literature indicates that users of CAM modalities are not necessarily the "worried well" and may actually represent an adverse selection of patients who are "medical failures" in the traditional medical system.[48,49] The prevalence of active disease in the AMI population as shown in Tables 2 and 3 is consistent with earlier reports of this phenomena.

The fact that potentially life-threatening disease states, such as cardiac disease, hypertension, and diabetes had higher enrollment in conventional medicine IPAs was not surprising. The similar percentage enrollment of patients with asthma and neoplastic disease between conventional and integrative medicine IPAs was somewhat surprising. The large enrollment disparity among patients with upper respiratory infections (URI), as previously mentioned, reflects the small percentage of AMI's enrollment under 10 years of age.

A comparison of smoker prevalence among the AMI population, the HMO population, and the general state population further demonstrates possible adverse selection in the AMI population. Member satisfaction surveys, randomly distributed by stratified random selection to between 35,000 and 45,000 HMO members, annually elicited a response rate that varied between 25% and 30%. These

Table 5. *Calendar year 2000 hospital days incurred among major Illinois Managed Care Organizations (MCO) versus AMI*

Managed care entity	Total member months	Total hospital days incurred per 1000 member months	AMI percentage utilization	AMI percentage reductions
HMO Illinois	7,537,362	344.85	33.3%	66.7%
Personal Care Insurance Company of Illinois	787,853	320.02	35.9%	64.1%
Prudential Health Care Plan	269,268	285.38	40.3%	59.7%
United Healthcare of the Midwest	361,437	236.75	48.6%	51.4%
CIGNA Healthcare of IL	143,236	201.00	57.2%	42.8%
Aetna US Healthcare of IL	1,664,525	177.64	64.7%	35.3%
Humana Health Plan, Inc.	3,536,085	170.94	67.3%	32.7%
AMI 3-year cumulative	13,645	115.0		

AMI, Alternative Medicine, Inc; *HMO,* health maintenance organization.

surveys revealed a variance in the AMI population when measuring for smoker prevalence rate.

In calendar year 2001, the AMI membership showed its highest rate of smoker prevalence: 34.9% versus the HMO population rate of 18.0% versus the Illinois general population of 22.3%.[50]

In calendar year 2003, by contrast, AMI membership had its lowest smoker prevalence rate of 13.3% versus the HMO population rate of 16.3%. We assume the large variance from year to year was secondary to the relatively low membership response rates elicited by the survey.

Data Analysis

AMI's outcomes data are based on claims incurred. Data were collected in parallel by the HMO and Independent Health Resources (IHR), which functions as AMI's third-party administrator (TPA). The HMO specifically analyzed all inpatient costs, outpatient facility costs, and pharmaceutical usage. AMI, via its TPA, analyzed all inpatient and outpatient professional encounters and utilization, as well as outpatient laboratory. The HMO reported all utilization back to AMI on a 6-month delay to allow for the reporting of all claims during the experience period. This reporting method produced actual claims, removing the potential inaccuracies of claims incurred but not reported (IBNR).

Data Reporting

The HMO prepared quarterly reports to AMI on such managed care benchmarks as:

Hospital admissions per 1000 members
Total hospital days per 1000 members
Outpatient surgical cases and procedures per 1000 members
Average length of stay
Pharmaceutical utilization and cost per member/per month

These statistical benchmarks were reported as a comparison between the performance of AMI as an IPA and the HMO network as a whole. Because of the HMO's proprietary concerns regarding their network's unique data points, AMI's outcomes are reported as percentage comparisons with HMO outcomes.

Results

Outcomes: Clinical

These data points are based on the HMO's corroborated data for the 4 calendar years 1999, 2000, 2001, and 2002. AMI's encounter data represent 21,743 member months over this 4-year period. The traditional managed care benchmarks depicted in Table 4 illustrate AMI's apparent superior clinical outcomes compared with conventional IPA performance over the same time frame.

AMI's outcomes are reported as "percentage utilization" and "percentage reduction" versus the HMO network as a whole. Percentage utilization is based on actual claims data after a 6-month runoff comparing AMI's utilization of key benchmarks versus the HMO network as a whole. Percentage reduction reflects the mathematical complement of AMI's utilization percentages using the HMO network outcomes as the normative value of 100%.

Traditional P values of statistical significance could not be reported. Insurance actuaries do not currently have data points for variance and mean on groups of similar size and demographics. Only aggregate data (the HMO normative network performance) representing groups of all sizes and demographics were available.

Calendar year 2000 data on hospital admission days (Table 5) obtained from the Illinois Department of Insurance similarly reflect improved AMI outcomes compared with all the major HMOs in the Chicago metropolitan area.

The referral pattern of AMI's PCPs compares favorably with historical referral patterns generated by traditional

Table 6. *Analysis of referral patterns on AMI HMO population, calendar year 2000*

1. Average number of members during 2000 (4987 member months/12)	416
2. Total number of referrals	330
3. Total number of unique patients requiring a referral	167
4. Percentage of population requiring referral to allopathic specialist (167/416)	40%
5. Percentage of population managed by chiropractic primary care physicians (PCPs) without allopathic referral (100% $-^{4}$)	60%

AMI, Alternative Medicine, Inc; *HMO,* health maintenance organization.

allopathic IPAs utilizing internists, pediatricians, or OB/GYNs as PCPs. As shown in Table 6, the strategy of comanagement resulted in only 40% of the AMI membership requiring an allopathic specialist referral in the calendar year 2000. In other words, during the year 2000, 60% of \the patients were managed solely by their primary care chiropractic physicians.

Referral data analysis annualized for the year 2001 shows AMI primary care chiropractic physicians generated 1 referral per 33 patient encounters (1:33 ratio). This is in contrast to data generated from comparison group II illustrating that conventional medicine PCPs generate 1 referral per 3 patient encounters (1:3 ratio). This referral pattern was consistent with our prediction that an increase in CAM-oriented PCP encounters initially would result in less utilization of conventional medicine downstream.

In addition to the clinical outcomes referenced in Table 6, measures of Quality Care were benchmarked by randomized patient satisfaction surveys and an annual audit of all UM/UR Committee documents by the HMO nursing administrators. Annually, the HMO independently surveyed by "stratified random selection" over 45,000 patients. Response rates were between 25% and 30% annually. The HMO required a minimum score for patient satisfaction to be between 80% and 90%, depending on the calendar year. AMI member satisfaction scores for the first 4 years were 100%, 89%, 91%, and 90%, respectively. Analysis of HMO member satisfaction surveys demonstrates the AMI members consistently rated their experience with AMI above the HMO network normative average.

Annual audit scores measuring IPA compliance with Utilization Management Adherence/Utilization Review Activity written policy and procedures conducted by HMO onsite nurse auditors also were above the HMO network normative values. AMI's annual audit scores for medical administration and medical management were between 97% and 100% in each category. The HMO minimum required score for IPA performance is 90%.

Outcomes: Cost

AMI also received an annual age/sex adjusted risk pool analysis of its members by the HMO's actuarial department. Derived from this risk pool analysis was a hypothetical budget of predicted expenditures excluding pharmaceuticals for AMI's actual membership defined as the utilization management fund (UM fund). This budget was calculated in "target usage units" that have an assigned dollar equivalency. IPA actual performance was then calculated against IPA-predicted performance. AMI's utilization management fund cost savings (below predicted budget) were 66.7%, 88.1%, 57.1%, and 69.3% for the calendar years 1999, 2000, 2001, and 2002, respectively.

It is believed that the improvement in cost effectiveness between year 1 (1999) and year 2 (2000) occurred primarily due to an innovative mental health initiative. In calendar year 1999 (AMI's first year), 33% of the hospital days were categorized as "mental health." Beginning in calendar year 2000 (AMI's second year), a quality initiative targeting stress management techniques was introduced to impact the high percentage of mental health admissions.

In the subsequent 3 years following this initiative, mental health admissions have accounted for less than 2% of all hospital days utilized. This protocol relied heavily on "mind/body" techniques such as cranial sacral therapy and energy balancing, as well as more traditional cognitive therapy.

Discussion

Certainly, we now appreciate the importance of lifestyle and environmental factors in the optimization of health and subsequent prevention of disease. Reliance on the conventional medical model, in which pharmaceuticals and surgical interventions represent first-line treatment, may not provide the best therapeutic index to our patients. The AMI model seems to demonstrate the potential superiority of an integrated health system in which chiropractic and CAM therapies play a significant primary care role.

Traditional PCPs, be they MDs or DOs, have little formal training in the various evidence-based techniques within the CAM arena. Doctors of Chiropractic, however, receive extensive formal training in the arts of spinal manipulation, herbal medicine, and nutrition, as well as conventional modern physical diagnosis. Most of the AMI PCPs electively received additional postgraduate training in homeopathy, TCM, and other CAM modalities. Students of chiropractic learn to auscultate heart and lungs, draw blood, and read electrocardiograms (EKGs), as well as perform pelvic and rectal exams. However, the educational focus and scope of practice laws vary among chiropractic colleges and states, respectively.

It is incumbent on the primary care physician, of whatever licensure, to look at all evidence-based risk factors and seek to coordinate their reduction. Most of the time this will involve the re-education of patients regarding lifestyle choices such as diet, exercise, nutrition, supplementation, correction of posture, and stress management issues. Lifestyle re-education emphasizing prevention and wellness may be best addressed by PCPs with an unconventional medical orientation, as opposed to conventional medical physicians who have been educated and focus primarily on disease management. The AMI experience seems to indicate that a nonpharmaceutical/nonsurgical orientation can reduce overall health care costs significantly and yet deliver high-quality care. These results have been achieved not by decreasing or denying access to care but, rather, by increasing the frequency of PCP prevention-oriented encounters.

The chiropractic profession is the largest stakeholder in the ongoing evolution of integrating CAM therapies into mainstream conventional medicine. Doctors of Chiropractic are licensed in all states, compared with Doctors of Naturopathy licensed in 11 states and Doctors of Oriental Medicine licensed in only 5 states. Acupuncturists and massage therapists are licensed in 40 and 30 states, respectively. Chiropractic is the most commonly utilized CAM therapy, as published in many previous surveys. Yet, paradoxically, core coverage by insurance benefit design rarely includes unrestricted access to chiropractic. Instead, a myriad of excuses both by the private insurance industry and by the federal government currently reduce one's personal freedom by restricting access to choose unconventional medicine, even when practiced by licensed physicians in good standing. Various authors believe the restrictions on covered benefits for CAM therapies and unconventional physicians are indefensible, given the growing evidence base on these therapies.[51]

"Discount affinity programs" promoted as a "value added" service are currently the most common insurance format by which CAM therapies are available. In reality, these programs are not covered insurance benefits at all. They do not place the mainstream insurance underwriter at financial risk. Rather, they provide the insured with a discount off market fee-for-service rates for severely restricted pseudo benefits.[52] The American Chiropractic Association (ACA), the largest professional association representing the largest stakeholder to the delivery of CAM therapies, has formally rejected discount affinity programs as an insurance sham.[53]

While the availability of discount affinity programs gives the public the illusion that CAM therapies are a covered service on par with conventional medicine, that is not the case. The AMI Wellness Model, by contrast, has been formally recognized by both the ACA and the American Academy of Chiropractic Physicians as a future template of an integrated medical model, which is "front-end loaded" to address prevention and wellness. An increase in initial PCP services is required by the patient to re-educate and emphasize the modification of inappropriate lifestyle choices, thereby re-empowering the patient toward improved self-determination. The good news is that within a 3- to 4-month time period, much of the behavior responsible for the etiology of new or chronic disease has been modified. The initial investment of time, energy, and financial resources for CAM therapies has been successful, apparently much more successful than a quick pharmaceutical prescription and a hasty visit with a conventional PCP (typical of the way managed care is practiced today).

Recently published literature also suggests patient preference and increased satisfaction with integrative therapies for chronic disease states. In the articles by Eisenberg et al[54-56] comparing patients' subjective perceptions as to the relative value of conventional care versus CAM therapies, in only 3 of 10 therapies was conventional medicine perceived as superior to CAM therapies. The 3 disease states scoring higher for conventional medicine were high blood pressure, lung conditions, and digestive conditions. By contrast, back conditions, allergies, fatigue, arthritis, headaches, neck conditions, and strains and sprains were perceived better treated by CAM therapies.[54-56] AMI's higher percentage of members with ICD-9 codes for orthopedics, mental health, chronic sinus, allergy, gastrointestinal problems, and headaches versus the comparison group enrollment is consistent with this pattern.

Limitations

This article's methodology is a nonrandomized longitudinal population study comparing and contrasting both clinical and cost outcomes among similar populations enrolled in the same insurance product for the same time frame and geography.

The strengths of this article's methodology are numerous: (1) study length of approximately 4 years; (2) cost and clinical data reported "at arms length" by the actuarial department of the HMO to the IPA; (3) availability of matched comparison groups for blinded analysis of membership population for ICD-9 comparisons; (4) availability of randomized patient surveys generated by the HMO to analyze both membership satisfaction with ongoing treatment and preexisting risk factors, such as lifestyle behaviors (tobacco usage); (5) availability of corroborating data, such as pharmaceutical usage and specialist consultations, to cross-check the accuracy of membership ICD-9 population profiles; and (6) patient-oriented medical management, whereby a variety of CAM therapies were individualized for each patient in the "real life" setting of a metropolitan-wide IPA doing business as a "clinic without walls."

Of course, this article's methodology also suffers from inherent weaknesses: (1) the relatively limited enrollment

of AMI's membership population versus the matched comparison groups; (2) the inability to determine the exact effect of membership transfer in and transfer out on the cost and clinical outcomes; (3) lack of uniformity in disease-specific treatment protocols utilized among all AMI's physicians; (4) no randomization of comparative IPA memberships; and (5) inability to perform standardized statistical probability analysis due to industry nonavailability of required actuarial data.

So, at the end of the day, where does this leave us? Have we derived valid and credible knowledge that is useful? At the very least, this article, for the first time, has demonstrated that a select group of chiropractic physicians successfully functioned in both a safe and effective manner as PCPs in a classical gatekeeper HMO model. Second, it has demonstrated that these same chiropractic physicians were capable of initiating and coordinating care for patients with a broad spectrum of disease states, representing a wider variety of diagnostic presentations than is commonly seen in most chiropractic offices. Third, the magnitude of improvement in both clinical and cost outcomes compared with normative values is so large that it is difficult to dismiss as purely coincidental to population bias and nothing more.

While admittedly the data are not definitive because of all of the methodological concerns enumerated, this article seems to demonstrate, for the first time, the potential superiority of integrating a nonpharmaceutical/nonsurgical-oriented gatekeeper or entry point with our already existing conventional health care system. Why should this change in PCP orientation make seemingly such a profound impact on outcomes?

Conclusion

AMI's integrative medicine IPA represents a new model in the delivery of managed care. This unique model has demonstrated promising clinical and cost outcomes by the integration of complementary alternative medicine with conventional medicine in a defined program encompassing physician selection, medical management, and scientific accountability. AMI believes this model to be replicable on a much larger scale and is currently implementing different programs, such as preferred provider organization (PPO), point-of-service (POS), and Workers' Compensation to new geographies. AMI's HMO outcomes reported herein were the results of an initial prototype still in evolution. The performance of physicians with other licensures, such as Doctors of Naturopathy and Doctors of Oriental Medicine, as well as MDs and DOs who are nonpharmaceutically oriented needs to be studied in this context as well.

The traditional argument against coverage for prevention-oriented medicine is that it will not reap immediate financial benefits and that employee or insurance turnover is too high to wait for an extended turnaround time. The AMI experience suggests that cost savings may occur in the first calendar year of operations.

The magnitude of improvement in both clinical outcomes and cost savings documented herein may not remain constant when the AMI model is utilized on larger and more diverse populations. However, even a small percentage of the AMI outcomes would still have significant implications, given a $1.3 trillion national health care budget. At such a high price, AMI's initial results should warrant additional funding for a larger and better controlled replication of these findings.

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Comparative Analysis of Individuals With and Without Chiropractic Coverage

Patient Characteristics, Utilization, and Costs

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Background: Back pain accounts for more than $100 billion in annual US health care costs and is the second leading cause of physician visits and hospitalizations. This study ascertains the effect of systematic access to chiropractic care on the overall and neuromusculoskeletal-specific consumption of health care resources within a large managed-care system.

Methods: A 4-year retrospective claims data analysis comparing more than 700 000 health plan members with an additional chiropractic coverage benefit and 1 million members of the same health plan without the chiropractic benefit.

Results: Members with chiropractic insurance coverage, compared with those without coverage, had lower annual total health care expenditures ($1463 vs $1671 per member per year, P□.001). Having chiropractic coverage was associated with a 1.6% decrease (P = .001) in total annual health care costs at the health plan level. Back pain patients with chiropractic coverage, compared with those without coverage, had lower utilization (per 1000 episodes) of plain radiographs (17.5 vs 22.7, P□.001), low back surgery (3.3 vs 4.8, P□ .001), hospitalizations (9.3 vs 15.6, P□.001), and magnetic resonance imaging (43.2 vs 68.9, P□ .001). Patients with chiropractic coverage, compared with those without coverage, also had lower average back pain episode–related costs ($289 vs $399, P□.001).

Conclusions: Access to managed chiropractic care may reduce overall health care expenditures through several effects, including (1) positive risk selection; (2) substitution of chiropractic for traditional medical care, particularly for spine conditions; (3) more conservative, less invasive treatment profiles; and (4) lower health service costs associated with managed chiropractic care. Systematic access to managed chiropractic care not only may prove to be clinically beneficial but also may reduce overall health care costs.

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IN THE UNITED STATES, BACK PAIN is the second leading cause of physician visits and is second only to childbirth for hospitalizations.[1] It is also the most prevalent chronic medical problem, the number one cause of long-term disability, and the second most common cause of restricted activity and use of prescription and nonprescription drugs.[2,3] Ten years ago health expenditures for chronic back pain were estimated to be $50 billion to $100 billion annually,[4] and studies[1,3] suggest expenditures have risen exponentially since that time. Epidemiologic studies also indicate an upward trend for back pain in both men and women,[5] a trend that is likely to continue as the average age of the US population continues to increase.

For editorial comment see page 1953

EFFICACY AND SAFETY OF CHIROPRACTIC CARE FOR BACK PAIN

There is evidence supporting the efficacy of chiropractic care for back pain. A comprehensive review[6] of the literature evaluating the efficacy of chiropractic treatments for low back pain and other conditions reported that randomized control trials "show spinal manipulation to be better, and no trial finds it to be significantly worse, than conventional treatment."[6(p2220)] Despite a number of methodologic limitations in some of the investigations,[6] an overview of the literature, including clinical trials, case-control studies, and meta-analyses, reflects favorably on the efficacy of chiropractic care relative to conventional medical treatment for back pain.[1,3,5,7-14]

Although serious complications from spinal manipulation therapy have been re-

ported in a small proportion of chiropractic patients,[15] for most of the population, chiropractic treatment is associated with a relatively low risk level, on par with conventional medical treatments.[5,16] On the other hand, comprehensive overview of the literature reveals that it is essentially unanimous in reporting that chiropractic care is associated with significantly higher patient satisfaction compared with patients who receive conventional treatments.[17-20]

COST EFFECTIVENESS OF CHIROPRACTIC CARE

Several studies[5] have produced preliminary evidence demonstrating cost-effectiveness of chiropractic compared with medical management. A series of studies by Stano and colleagues[21-24] and one study by Dean and Schmidt[25] report cost benefits of chiropractic care compared with conventional medical treatment for neuromuscular conditions in a review of current literature (mostly workers' compensation studies). For instance, a 1996 cost comparison study,[23] which adjusted for demographic, insurance, and condition variables, revealed higher total (30% to 217% higher) and outpatient (27% to 94% higher) mean payments of medical treatment relative to chiropractic treatment. These later studies support the applicability of findings to managed health care settings by including large sample sizes and examining existing fee-for-service health claims data.

In contrast, a study by Carey et al[26] found significantly higher health care costs for patients with chiropractic or orthopedic care for back pain (secondary to a greater number of visits) than for patients who received their back pain care from a primary care physician at a health maintenance organization. Patients were interviewed over the telephone for up to 24 weeks to assess use of health care services and outcomes of care. Patients who received care from doctors of chiropractic care (DCs) paid more per episode than patients who received care from primary care physicians (69% in urban setting and 3% in rural setting). However, in this study the analyses were limited to outpatient costs rather than total costs; the costs were estimated using average statewide charges for a large insurance carrier; and, although the analyses adjusted for sciatica, baseline functional status, and duration of pain,[20] the study did not specifically adjust for the variables comorbidities, severity, and type of diagnosis.

Another study[6,27] that compared cost of care for episodes of back pain between various kinds of medical practitioners (orthopedists and chiropractors) found differential costs for care compared with care provided by a general medical practitioner. This study, however, based analyses on data collected up to 25 years ago and thus may not be applicable to today's health care market. In addition, these studies were characterized by small sample sizes, increasing the probability of type II errors (failure to find a real difference between groups). Given the discrepant cost-effectiveness findings and significant methodologic differences that limit study comparisons, the issue of the benefit of chiropractic care in today's health care system remains unresolved.

ACCESS TO CHIROPRACTIC CARE

Chiropractors now represent the third largest segment of health care practitioners in the United States,[1] with 50 000 practitioners in 2000 according to the Bureau of Labor Statistics.[28] According to the American Chiropractic Association, an estimated 21 million to 28 million people now receive chiropractic services each year, with approximately 192 million annual visits to DCs: between 1990 and 1997, chiropractic use increased from 10% to 11%.[29] With growing public demand,[30] the profession is also expected to increase 21% to 35% by 2008.[16]

A recent study[31] of employers in large companies shows that chiropractic insurance coverage is now being offered to most American workers who are covered by health insurance and is increasingly being offered in all health plan types. This and other studies[32] note that although health insurance for chiropractic services is expanding, insurers often restrict coverage to manage risk.

Chiropractic coverage is often limited in terms of referral restrictions, conditions covered, number of visits, maximum annual dollar benefit, requirement for physician referral, and amount paid per visit. Some plans do not provide covered benefits but instead offer a network program in the form of discounted services. Health plan designs may impede appropriate access to chiropractic clinical care and may diminish the strength DCs have in treating neuromusculoskeletal (NMS) disorders.

The disconnect between evidence regarding the efficacy and safety of chiropractic care, consumer demand, and the limited research on cost of chiropractic care in applied settings has served to hinder integration of chiropractic coverage in traditional health care services. To help bridge this divide, improve access to appropriate chiropractic services, and promote best practices of chiropractic care, there is a need for community-based research to ascertain the effect and benefits of chiropractic care and the associated utilization of health care resources.

The data analyzed in this study were obtained from a natural experiment setting. A natural experiment is an experiment conducted in real-life setting rather than the controlled environment, where researchers "rely on truly naturally occurring events in which people have different exposures that resemble an actual experiment."[33(p150)] In this case, the data were collected and analyzed from a naturalistic setting rather than a laboratory setting. Although this is not a true experiment, such an approach is common in health services research because of the high external validity and generalizibility of the results obtained from studies that used natural experiment methods.

This study was conducted to identify and describe the demographics, disease, and utilization patterns of individuals with access to chiropractic care compared with individuals without such coverage. Toward this end, this study compared members of the same health plan, both with and without an additional chiropractic benefits rider. This natural experiment offers a particularly rich opportunity to understand the effects of supplemental chiropractic coverage on utilization of medical care because it employs members of the same health plan as a comparison group. Both groups studied were members of the same

large managed-care system with access to the same physician network; with the same or similar covered benefits; with the same rules on referral to specialty care, high-cost diagnostic tests, and hospital and surgery approval guidelines; and with the same exclusions and limitations.

STUDY POPULATION

This 4-year study (April 1, 1997, to March 31, 2001) used administrative claims data from a large regional managed-care network in California. These data included inpatient and outpatient data for more than 1.7 million continuously enrolled members containing demographic and enrollment information in addition to diagnosis and procedure codes as classified under the *International Classification of Diseases, Ninth Revision* (*ICD-9*) and the *Current Procedural Terminology, Fourth Edition*. Administrative claims data from the largest chiropractic health plan in California, American Specialty Health Plans, were used to subsequently identify approximately 700 000 of the 1.7 million patients enrolled in the large managed-care organization who also received additional chiropractic coverage through an American Specialty Health Plans benefits rider. These 700 000 members who were enrolled in both plans and had access to a medical and chiropractic network of practitioners were compared with the 1 million members who were enrolled in the managed care network only. For those members enrolled in both plans, the administrative claims data from the 2 networks were merged into one unique administrative file, thereby creating 2 main comparative cohorts from the same large health plan: one with access to chiropractic care and the other without. The former group had benefits covering direct access to a DC without the need of a physician referral. Under this benefit plan the patient copay for a chiropractic office visit was the same as it would be in a medical clinic. The benefit allowed for a maximum of 40 office visits to a DC per year.

STUDY DESIGN

This study applied a retrospective, longitudinal, quasi-experimental, participant-nonparticipant design. The carve-out feature of the chiropractic insurance coverage offered by the managed-care health plan as an option to its employer groups was used to create retrospective control cohorts at 3 different levels. At the first level, managed care members with chiropractic insurance coverage were compared with the members in the same health plan without chiropractic coverage. At the second level, we compared members with and without chiropractic coverage but only if they had had NMS claims at any time during the study period. At the third level, we compared episodes of care for members with NMS conditions receiving care only from DCs against members with NMS claims receiving care only from medical doctors (MDs).

The effect of adding a chiropractic benefit on the health plan's overall resource consumption was assessed over a typical horizon for employer-sponsored health insurance. To achieve this, the observation period and analyses were annualized to a study period from January 1 to December 31, 2000, when assessing group differences in demographics, comorbidities, and total plan claim expenditures.

However, to comprehensively compare the effects of treatment for NMS conditions between DCs and MDs, a longer observation period was appropriate, because NMS conditions are typically time limited but recurrent and can manifest over multiple episodes spanning a longer period. Therefore, we expanded our analysis period across 4 years from April 1, 1997, to March 31, 2001, to study the costs and utilization patterns associated with NMS episode-specific care.

To enable meaningful comparisons of utilization and costs of medical and chiropractic care for categories of NMS disorders based on anatomic and clinical similarity, a classification system grouping individual *ICD-9* codes for NMS conditions into more aggregative diagnosis groups was developed for this study. The classification also took into account the severity of specific conditions such as neck and lower back diagnoses. A total of 654 *ICD-9* codes, identified by separate panels of DCs and MDs as NMS conditions most commonly treated and eligible for insurance coverage, were sorted into the following categories: neck, lower back, thoracic spine and rib disorders, headache, upper extremity, lower extremity, myalgias or arthralgias, latent effects, and other. Additionally, severity distinctions were made for neck and lower back diagnoses by sorting into complicated and uncomplicated conditions, thus extending the diagnostic groups to 11. The *ICD-9* codes for these diagnostic groups were comprehensively reviewed for possible inclusions, exclusions, and crossover by a panel of DCs and medical NMS experts.

To maximize comparability between medical and chiropractic coding, a subanalysis was performed to examine a small group of codes that would be equally applicable to chiropractic and medical practice. This set of codes was selected for its high frequency of occurrence in both medical and chiropractic cohorts. To level the playing field between chiropractic and medical care for these low back pain–specific analyses, cases that were associated with any claims for back surgery were excluded from the subanalysis, because such cases are likely to have complications for which chiropractic care would not be appropriate.

DEFINING EPISODES OF CARE

In addition to encounter-specific comparisons, entire episodes of care were of interest in the study. For each member with at least 1 NMS claim or a sequence of NMS claims, an episode of NMS care was determined by the diagnosis group of the sequence of claims and an allowable gap between any 2 consecutive claims of less than 45 days. Claims separated by 45 days or more were considered separate episodes. The 45-day interval was derived from a previous study[20-22] that used the 9 most common *ICD-9* codes for low back pain to evaluate the percentage of treatment encounters that were captured using different intervals to terminate an episode. The study found that for the most common *ICD-9* code (724.2) an interval of 6 weeks (42 days) captured 86% of all encounters, and the remaining 8 diagnoses yielded values ranging from 42 to 49 days. A sensitivity analysis of these values demonstrated that there was little change in the overall study results if these values were moved upward or downward. Based on these results and on the clinical consensus of an expert panel of both DCs and MDs, a value of 45 days was judged to be appropriate. For neck- and back-related episodes, which were stratified into complicated and noncomplicated diagnosis groupings, any switch in diagnosis between uncomplicated and complicated neck-related conditions during the 4-year sample period triggered the entire sequence of claims to be identified within the complicated neck diagnosis grouping.

OVERALL EXPENDITURES AND UTILIZATION

The primary health care expenditures considered for this study were total health care claim expenditures, individual components of total health care claim costs such as those associated with inpatient and outpatient services, and cost associated with NMS care at the episode level. Utilization metrics included the following: outpatient services, plain radiographs, magnetic resonance (MR) images, lumbar spine surgical procedures, and in-

patient stays. Health risk characteristics, based on demographics and comorbidity rates, were used to compare the risk profiles for different groups. The health plan expenditures from inpatient, outpatient, and chiropractic outpatient paid amounts were used in the calculation of health care costs and reflect the dollar value of the payers' resource consumption in providing access to medical and chiropractic care to its members. Prescription claims and physical therapy claims were not included during this phase of the ongoing study, and therefore pharmacy and physical therapy costs were not included in health care costs.

STATISTICAL ANALYSIS

Descriptive statistics, including mean values, standard deviations, and column percentages, were computed and average differences between groups were evaluated. We used ^{2} tests to evaluate differences between categorical variables. This included variables with proportional values, such as sex, proportion of patients in the comorbidity and diagnosis groups, and proportion of complicated episodes. To test the difference in mean values for continuous variables, such as age and costs, and to account for the skewed distribution of variables, we applied nonparametric analysis of variance instead of conventional parametric tests such as *t* tests. We applied the Wilcoxon test when comparing 2 cohorts and the Kruskal-Wallis test when comparing 3 cohorts.

A semilogarithmic regression model was also used to estimate the effect of chiropractic insurance coverage on total annual health care expenditures. The total health care costs of plan members with positive utilization during calendar year 2000 were regressed on their chiropractic coverage status, after adjusting for their demographic, NMS, and comorbid characteristics using the following specification:

$$\text{Log}[(\text{Total Health Care Costs})_i/(\text{Total Health Care Costs})_i|\ 0] = \ |\ +|_1(\text{Chiropractic Coverage})_i + |_2(\text{Female})_i + |_3(\text{Age})_i + |_4(\text{Comorbidity Score})_i + |_5(\text{Neuro musculoskeletal})_i + \cdot\cdot_i.$$

The logarithmic transform of the total health care costs was used as the dependent variable to correct for nonnormality and heteroscedasticity in the cost distribution. The comorbidity score, computed as the number of comorbid conditions that a member was identified with during the annual period, was used as a risk adjuster in addition to age, sex, and presence of a NMS condition. The primary independent variable of interest was the dummy variable, which was equal to 1 if the member had chiropractic coverage during the period and equal to 0 if otherwise. The antilog of the estimated regression coefficient, after accounting for its variance, was used to estimate the effect of chiropractic coverage on the annual total health care costs of the health plan as follows[34]:

$$\hat{g} = \exp\_\hat{}_1 \ \frac{1}{2}\text{Var}(\hat{}) \boxed{1.}$$

where Var($\hat{}$) is the squared standard error of the estimated regression coefficient $_1$.

COMPARISON OF MEMBER COHORTS

Year 2000 claims for 707690 health plan members with chiropractic coverage and 1001995 members without chiropractic coverage were compared. Demographic characteristics and comorbid conditions for members with and without chiropractic insurance coverage are displayed in the **Table**.

Members with chiropractic coverage were younger (mean age, 33 years) than members without chiropractic coverage (mean age, 36; *P*□.001). The cohort without chiropractic coverage contained a slightly higher percentage of female members (52.1% female) than the cohort with chiropractic coverage (51.6% female, *P*□.001).

Members with chiropractic coverage also were less likely than members without chiropractic coverage to have comorbid medical conditions. The proportions of members who had specific comorbid conditions, including hypertension, diabetes, cardiac arrhythmias, heart failure, and nutritional disorders, ranged from 0.6% to 6.5% in the population with chiropractic coverage and 0.9% to 7.3% in the population without coverage (*P*=.001 for each comparison). In particular, heart failure (0.6% vs 0.9%), cardiac arrhythmias (1.6% vs 2.0%), and hypertension (6.5% vs 7.3%) were lower in relative occurrence in the member population with chiropractic coverage. Annual total health care claim costs of the member populations with and without chiropractic coverage for year 2000 are presented in **Figure 1**. The per-member-per-year (PMPY) cost of members with chiropractic coverage was $1463, which was $208 lower (*P*□.001) than the PMPY cost of members without the coverage ($1671). This translates to a 12% reduction in annual costs incurred by the managed care organization on members with chiropractic coverage.

COMPARISON OF NMS PATIENT COHORTS

The 141616 patients with NMS conditions who had chiropractic coverage were also compared to 189923 NMS patients without chiropractic coverage. As with members with and without chiropractic coverage, NMS patients with chiropractic coverage were younger (mean age, 41 years) than NMS patients without chiropractic coverage (mean age, 44 years; *P*□.001). Similarly to members with and without chiropractic coverage, NMS patients with chiropractic coverage were less likely than NMS patients without chiropractic coverage to have comorbid medical conditions (*P*□.001 for each of the comorbid conditions previously mentioned).

The overall medical expenditures of the patients with NMS conditions during the year 2000, including the major components of the expenditures, are presented in **Figure 2**. The PMPY cost of NMS patients with chiropractic coverage was $2345, which was $361 lower (*P*□.001) than the PMPY cost of NMS patients without the coverage ($2706). This translates to a 13% reduction in annual costs incurred by the health plan on NMS patients with chiropractic coverage.

Annual per capita hospital cost for NMS patients with chiropractic coverage ($1224) was $210 lower or 15% (*P*□.001) than that for NMS patients without chiropractic coverage. The annual per capita ambulatory cost for NMS patients with chiropractic coverage ($1121) was 12% lower (*P*=.01) than the corresponding cost for NMS patients without chiropractic coverage ($1272). The annual per capita cost of providing chiropractic care was

Table. Baseline Demographics.*

Demographics	Members With ASHP Coverage, %	Members Without ASHP Coverage, %	P Value
Age group, yr			
0-17	32	26	.001
18-21	5	4	.001
22-35	15	19	.001
35-55	34	33	.001
56-64	8	8	1.05
≥65	6	10	.001
Comorbid condition			
Congest iveheart failure†	0.55	0.86	.001
Cardiac arrhythmias†	1.58	1.97	.001
Valvular disease†	0.59	0.69	.001
Pulmonary circulation disorders†	0.05	0.09	.001
Peripheral vascular disorders†	0.40	0.55	.001
Hypertension †	6.46	7.26	.001
Paralysis†	0.15	0.17	.001
Other neurologic disorders†	0.49	0.56	.001
Chronic pulmonary disease†	3.55	3.78	.001
Diabetes†	2.77	3.01	.001
Hypothyroid ism	1.54	1.51	.07
Renal failure†	0.21	0.28	.001
Liver disease	0.29	0.31	.03
Peptic ulcer disease excluding bleeding†	0.16	0.19	.001
AIDS†	0.05	0.16	.001
Lymphoma or leukemia†	0.12	0.14	.001
Cancer or tumor†	1.76	2.10	.001
Rheumatoid arthritis or collagen vascular diseases	0.63	0.65	.04
Coagulopathy	0.17	0.19	.01
Nutritional or metabolic disorders (obesity or weight loss)†	1.58	1.65	.001
Anemia†	1.29	1.44	.001
Alcohol and other drug abuse	0.22	0.23	.14
Psychoses†	1.09	0.91	.001
Depression†	1.83	1.64	.001
Tobacco	0.44	0.43	.32

Abbreviation: ASHP, American Specialty Health Plans.
* Members with chiropractic coverage were younger, overall and in the 65-year and older group, and had lower comorbidities for 20 of the 25 conditions.
† Statistically significant at $P<.001$.

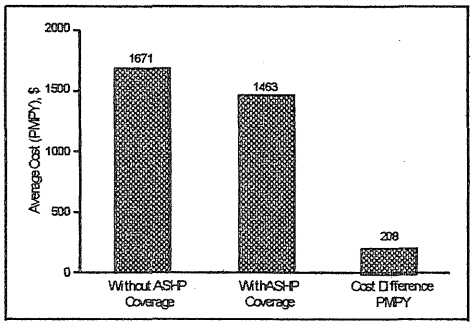

Figure 1. Annual total cost reduction. Members with chiropractic coverage were associated with $208 lower per-member-per-y ear (PMPY) total health care expenditures for the year 2000 ($P<.001$). ASHP indicates American Specialty Health Plans.

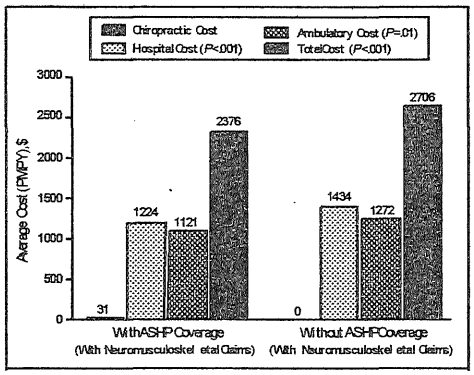

Figure 2. Overall medical expenditures. Patients with neuromusculoskel etal conditions who had chiropractic coverage were associated with $330 lower per-member- per-year (PMPY) total health care expenditures for the year 2000. The lower cost is derived from both lower hospital cost by $210 and lower ambulatory cost by $151. P values were determined using the Wilcoxon test. Further regression analysis will be conducted. Hospital costs include outpatient hospital services, emergency department visits, and inpatient services. Total costs include hospital costs and ambulatory costs. ASHP indicates American Specialty Health Plans.

$31, which amounted to only 1% of the total dollar value of resources consumed ($2376) by NMS patients between the 2 cohorts.

To adjust for age, sex, presence of an NMS condition, and comorbidity differences between cohorts, a semi-

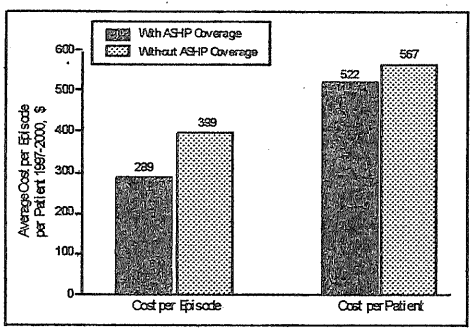

Figure 3. Episode of care utilization analysis for back pain patients. Presence of chiropractic coverage was associated with a $110 reduction in cost per episode and a $45 reduction in cost per patient for all expenditures related to neuromusculoskeletal care during the 4-year period (April 1, 1997, to March 31, 2001) (*P*<.001). ASHP indicates American Specialty Health Plans.

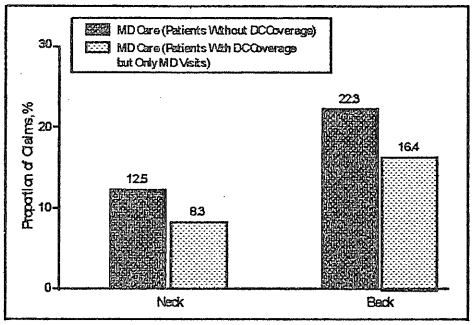

Figure 5. Medical care substitution. Presence of chiropractic coverage was associated with a shift in the case distribution away from medical doctors (MDs) to doctors of chiropractic care (DCs) for neck and back problems, indicating a substitution of chiropractic for physician care. All proportional differences are statistically significant at the *P*<.001 level.

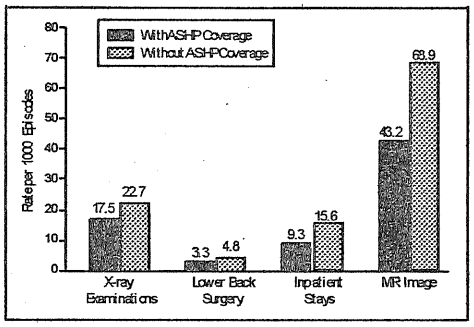

Figure 4. Breakdown by high-cost items. Access to chiropractic care was associated with lower rates of high resource-utilizing components of neuromusculoskeletal care (*P*<.001). ASHP indicates American Specialty Health Plans; MR, magnetic resonance.

log regression analysis was also used to estimate the impact of chiropractic care as a covered benefit on total health care costs of the health plan for year 2000. The estimated coefficient for chiropractic coverage indicator (β_1) was 0.0162. The regression results indicate that the presence of chiropractic insurance coverage was systematically associated with an approximately 1.6% lower (*P*=.001) average total health care cost of members, after controlling for differences in age, sex, and the number of comorbidities. The 1.6% reduction in total health care costs per member is equivalent to approximately 13% of the $208 PMPY observed cost difference reported in Figure 1. This translates to an approximately $27 PMPY potential cost saving that can be attributed to the presence of chiropractic insurance coverage in the plan, after accounting for differences in demographic and comorbidity risks of the members.

BACK PAIN–SPECIFIC TREATMENT

Figure 3 presents data related to the cost of providing care for back pain, at an episode level, for the 4-year period (April 1, 1997, to March 31, 2001). The average cost per back pain episode for patients with chiropractic coverage was $289, which was $110 or 28% lower (*P*<.001) than for back pain patients without chiropractic coverage. Aggregating episodes for each patient during the 4-year period, the average cost of back pain treatment for patients with chiropractic coverage was $522, which was $45 or 8% lower than the corresponding back pain treatment cost for patients without chiropractic coverage.

Furthermore, the proportion of complicated back pain episodes was only marginally higher (10% vs 8%, *P*<.001) for patients who received care only from MDs compared with the patients who received care only from DCs.

Utilization rates for back pain episodes presented in Figure 4 indicate significantly lower utilization of resources across all major high-cost areas for NMS patients with chiropractic insurance coverage compared with those without. Back pain patients with chiropractic coverage had fewer inpatient stays than did those without chiropractic coverage (9.3 vs 15.6 stays per 1000 patients, *P*<.001). The MR image rate was also lower for back pain patients with chiropractic coverage compared with those without chiropractic coverage (43.2 vs 68.9 MR images per 1000 patients, *P*<.001). The rate of lower back surgery among patients with chiropractic coverage was lower as well (3.3 vs 4.8 surgical procedures per 1000 patients, *P*<.001). Back pain patients with chiropractic coverage also received fewer radiographs (17.5 vs 22.7 per 1000 patients, *P*<.001) than did back pain patients without chiropractic coverage.

SUBSTITUTION EFFECTS

Figure 5 presents the distribution of NMS claims reported for neck and back pain episodes during the 4-year period. This table compares 2 groups of patients, both who sought care for NMS complaints from MDs only. However, members of one of the groups were limited by the absence of access to chiropractors within the plan due to lack of chiropractic insurance coverage. The proportion of neck complaints seen by MDs for patients with chiropractic coverage was 8.3%, 4 percentage points lower (*P*<.001) than for the corresponding proportion for patients without chi-

ropractic coverage. Similarly for back pain, the proportion of complaints seen by MDs for patients with chiropractic coverage was 16.4%, 6 percentage points lower (P < .001) compared with patients without coverage. Correspondingly, a very high rate (approximately 60%) was also observed for the proportion of neck and back complaints seen by the network DCs during the same period. This suggests a substitution of DC care for MD care for neck and back complaints.

COMMENT

The high prevalence and recurrent incidence of back pain, as well as the heavy economic and disability burden that it imposes on society as documented in the literature, point to a major area of public health concern. Simultaneously, there is growing evidence for the low risks associated with chiropractic spinal manipulation in most cases and favorable evidence for its effectiveness in treating low back pain. In addition, patients treated for back pain by DCs tend to be more satisfied than patients treated by MDs. However, despite this evidence for safety, effectiveness, and growing public demand, health insurance coverage for chiropractic care continues to remain restricted, relative to other health services, particularly in the managed care sector.

This restriction of access to health insurance for chiropractic care is not due to a lack of DCs, however. Rather, chiropractic care is becoming increasingly prevalent in the American health care system. The increasing acceptance of chiropractic care as a source of comprehensive complementary care for NMS problems is reflected in that the chiropractic field is the fastest growing among all doctoral-level health professions.[17]

To date, there has been little research linking chiropractic and medical utilization data at a patient level. Thus, a powerful opportunity to compare the effects of chiropractic and medical management of costly NMS conditions, such as back pain, in a real-world managed care setting has been underused. This study integrated and analyzed comprehensive administrative data from a large managed medical care organization and the chiropractic care plan that provided an additional chiropractic benefit to more than 40% of its members. By comparing members within the same medical managed care plan both with and without direct access to chiropractic care, this study provides additional information on the effect of chiropractic insurance benefits on the resource utilization within a managed care network.

For the managed care plan studied, the presence of a supplementary chiropractic insurance option was associated with favorable member selection by the plan. This is evident in that members with covered chiropractic benefits were significantly younger and had less comorbidity burden. This favorable selection could have been an artifact of 2 factors that reflect employer and employee preferences. The larger companies in particular, in the interest of maintaining a large productive workforce, may have been likely to offer additional benefits, such as supplementary insurance, to attract younger and healthier individuals. At the same time, potential employees, particularly those who maintain a healthier lifestyle may have been more likely to seek employment in companies that offer benefits covering complementary care (eg, chiropractic or acupuncture) that can be perceived as less aggressive treatment modalities.

This study found that members with chiropractic coverage had a 12% lower annual medical care cost, not adjusting for member risk characteristics. After controlling for the cost-saving effects associated with favorable demographic and medical risk factors, the regression analysis found a statistically significant 1.6% reduction in total medical care costs that can be isolated to the presence of chiropractic coverage. Most of this 1.6% reduction in the plan's total medical costs is likely derived from the 13% reduction in the total medical costs observed for the subset of members with NMS conditions who also had chiropractic coverage. In our study population of 0.7 million members who had chiropractic coverage in the medical plan, we estimated an annual reduction of approximately $16 million as a result of lower utilization of high-cost items. This is a conservative estimate of the cost savings for the plan that can be associated with members in the medical plan using their supplementary benefits to seek chiropractic treatment of their NMS problems. The estimated cost saving appears to more than offset the amount spent to cover the associated costs of the chiropractic benefit.

The analyses related to NMS episodes elucidate sources of these cost savings relating to chiropractic treatment of common NMS complaints, such as neck and back pain. Focusing on low back pain diagnoses that were selected specifically for comparability between medical and chiropractic practice, our analysis found that patients with chiropractic coverage had significantly lower rates of use of resource-intensive technologies, such as x-ray examinations, MR image, and surgery, and lower use of more expensive patient care settings, such as inpatient care. This is reflected in the significantly lower cost, at both the episode level and the patient level, of providing care for back pain. The difference in episode-specific and patient-level resource utilization did not seem to be due solely to a difference in severity of cases seen by DCs and physicians, since the estimated 2% difference in severity between chiropractic and medical patients of back pain did not constitute a clinically meaningful difference. In addition, the substitution of chiropractic for physician care evident from the shift in the case distribution between physicians and DCs when chiropractic coverage was present also contributed to the conservation of health care resources.

Although the results from the study may carry policy implications in the managed care industry, the limitations of this study are worth noting, especially since they also open up avenues for future research. This study only analyzes effects of chiropractic coverage in a large but specific managed care population. Future research covering geographically diverse populations across several plans is needed to ascertain and validate the effect of a chiropractic benefit on utilization patterns and cost effects, after controlling for differences arising from factors, including location, plan-specific benefit design, industry type, and other undetected biases, such as patient burden of disease. Comorbidity score and demographic characteristics such as age were controlled for in the regression model. However, the significantly more favorable profile of the plan mem-

bers who selected chiropractic coverage poses some concern regarding the generalizability of the results to a sicker, older population. Especially as the average age of the American population continues to increase in the next decade, the safety and appropriateness of chiropractic care for elderly patients will need to be more thoroughly evaluated. Further research is also necessary to quantify utilization and costs associated with DC vs MD care for other NMS conditions, and to ascertain clinical outcomes for specific NMS conditions.

The substitution of chiropractic utilization for medical care is central to the issue of providing cost-effective care for NMS conditions in a managed care environment, since the provision of chiropractic benefits as supplementary insurance raises the possibility of induced demand for medically unnecessary care. This study found evidence that a substantial portion of the chiropractic care sought by the members with insurance coverage was more often substituted for medical care rather than add-on care. Further research is needed to quantify this substitution effect. The effects of substitution of chiropractic care utilization for medical care could be further pursued by analyzing data on patients with episodes of NMS care comanaged by DCs and MDs, which was beyond the scope of this study. Although most back pain patients have nonspecific syndromes, a few back pain cases are caused by severe underlying conditions. Accurate diagnosis and appropriate referral are essential for this subset of low back pain cases and demand an integrative approach. This point is especially important in light of the substitution between DCs and internists found by this study. Finally, questions continue to remain regarding the effectiveness of chiropractic care relative to the cost of care and quality of the health care received. Future research using patient surveys (quality-of-life and patient satisfaction measures) in conjunction with medical record review are warranted to further evaluate the cost-effectiveness of chiropractic care in managed care settings.

This study provides additional information regarding the economic benefits and utilization patterns associated with systematic access to chiropractic care. Furthermore, it offers an integrated baseline (combining chiropractic and medical utilization claims data for a common cohort of members) for future research evaluating the effect of alternative clinical management approaches to medical conditions (ie, back pain specifically) with high direct and indirect consumption of medical resources and a high derivative societal cost given the absenteeism and burden of disease associated with them.

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Chiropractic Care: Is It Substitution Care or Add-on Care in Corporate Medical Plans?

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An analysis of claims data from a managed care health plan was performed to evaluate whether patients use chiropractic care as a substitution for medical care or in addition to medical care. Rates of neuromusculoskeletal complaints in 9e diagnostic categories were compared between groups with and without chiropractic coverage. For the 4-year study period, there were 3,129,752 insured member years in the groups with chiropractic coverage and 5,197,686 insured member years in the groups without chiropractic coverage. Expressed in terms of unique patients with neuromusculoskeletal complaints, the cohort with chiropractic coverage experienced a rate of 162.0 complaints per 1000 member years compared with 171.3 complaints in the cohort without chiropractic coverage. These results indicate that patients use chiropractic care as a direct substitution for medical care. (J Occup Environ Med. *2004;46:847–855*)

After a period of relative stability during the 1990s, the rate of increase in healthcare spending has once again accelerated[1,2] Annual increases have been between 10% and 15% for the last 3 years (2001–2003). The cost of medical insurance premiums has matched these increases. During the period from 2002 through 2003, the annual rate of increase in insurance premiums averaged 13.9%, and these rates of increase are only expected to increase in the foreseeable future.[3] In response to these increased costs, the employers who fund most private health insurance and the insurance industry are seeking mechanisms to reduce the financial burden of medical care insurance. For the past several decades, the principal mechanism for limiting this financial burden has been the various utilization management tools associated with managed care.

Most agree that although these tools have been relatively effective in controlling costs in the past, there are very few additional savings to be had from utilization management of existing healthcare benefits. This leaves managing the benefit itself, controlling what services are actually covered, and transferring greater financial responsibility to the employees as mechanisms for controlling costs. In this environment, the prospect of providing additional benefits has very little appeal. As health policymakers, employee benefits managers, and insurance company managers decide to what extent chiropractic care should or should not be included in any healthcare benefit package, those decision-makers will be exam-

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ining the net effect of a chiropractic benefit on total premium and medical costs.[4–6] To the extent that the addition of a chiropractic benefit is perceived to add to healthcare costs, there is much less likelihood of adding such a benefit. Similarly, existing chiropractic benefits will come under pressure if it is believed those benefits add costs to the total premium or health plan medical expenses.

In calculating the net cost of a chiropractic benefit, a number of factors must be taken into account. First, the relative unit cost of chiropractic care must be compared with unit cost of medical care. That is, given a comparable patient and severity of condition, what is the cost per episode of chiropractic care versus an episode of medical care? A number of studies have addressed this question but do not arrive at a uniform answer.[7–13,42,43] A study by Carey found that the cost per episode of care under chiropractic care was greater than for primary care medical providers but less than for care by orthopedists.[13] Cherkin found the cost of chiropractic care and that by physical therapists to be nearly identical.[42]

The second factor that will determine the net cost of chiropractic care is the extent to which patients are *substituting* chiropractic care for medical care versus whether patients are using chiropractic care *in addition* to medical care.[16,17] Although chiropractors and physicians undoubtedly treat a similar patient population, their modes of treatment are dissimilar. Because the nature of a chiropractic and medical treatment encounter are different, it might be expected that some patients would use medical care under a certain set of circumstances and chiropractic care under a different set of circumstances.

Finally, to fully measure the economic impact of chiropractic care, it is necessary to evaluate whether chiropractic patient management of back pain, neck pain, and related conditions differs in any way from medical management of these same conditions that affects costs. Specifically, the question arises whether a patient under chiropractic care is more or less likely in the future to seek care for the same or similar health problem than patients treated under medical care. Once again, even if a single episode of care is less costly under chiropractic care, if chiropractors manage patients in a fashion that induces future episodes of care, a chiropractic benefit could increase costs.

This study does not compare the costs of chiropractic versus medical episodes of care. Rather, it analyzes the effect of a chiropractic benefit on the rates of patient complaints for back pain, neck pain, and related conditions and on the number of episodes of care created by chiropractic and medical providers. The investigation takes advantage of a natural experiment in which a set of employers has independently chosen to include or not include a chiropractic benefit in their companies' medical plans. By comparing the rates of patient complaints for a common group of neuromusculoskeletal (NMS) pain diagnoses among those employer groups with and without a chiropractic benefit, it is possible to evaluate the degree to which a chiropractic benefit does or does not create additional demand for medical care services and whether patients are substituting chiropractic care for medical care. The study also measures and compares the frequency of actual episodes of care under chiropractic versus medical care.

Methods

Study Design

Study Population. This 4-year descriptive study (April 1997 to March 2001) used administrative claims data from a large regional managed care network in California. These data included inpatient and outpatient claims data for members of the managed care network who were continuously enrolled during the study period. The dataset included demographic and enrollment information in addition to diagnosis and procedure codes as classified under the *International Classification of Diseases*, 9th Revision (ICD-9) and the *Current Procedural Terminology*, 4th Edition (CPT).

Within this managed care network, individual employers had the option of selecting the health plan with or without a benefit for chiropractic care. This chiropractic benefit was separately administered by American Specialty Health Plans, a health plan that provides benefits riders for services such as chiropractic, acupuncture, and massage therapy. For those employers who selected the chiropractic benefit, the administrative claims data from the 2 networks were merged into 1 unique administrative file, therefore creating 2 main comparative cohorts from the same large health plan: one with access to chiropractic care and the other without. The former group had benefits covering direct access to a chiropractor without the need for a physician referral. Under this benefit plan, the patient copay for a chiropractic office visit was the same as it would be in a medical clinic. The benefit allowed for a maximum of 40 office visits to a chiropractor per year. For the purposes of this study, the following 4 cohorts were evaluated:

1. Cohort A: Patients in health plans that cover chiropractic care who received any treatment (chiropractor or physician) for NMS conditions.
2. Cohort B: Patients in health plans that do not cover chiropractic care who received treatment for NMS conditions (by definition, medical care).
3. Cohort C: Patients in health plans that cover chiropractic care who received chiropractic treatment for NMS conditions.
4. Cohort D: Patients in health plans that cover chiropractic care who received medical treatment for NMS conditions.

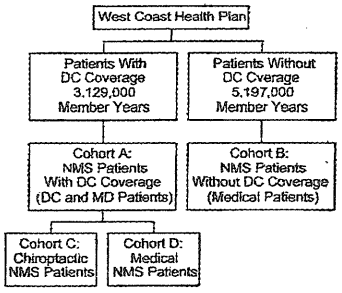

Fig. 1. Overview of study design.

Figure 1 provides an overview of the study design.

There are 2 aspects of this design that need to be emphasized with respect to the study question. First, individual patients do not decide whether they will have chiropractic coverage. That decision is made by benefits managers or others within the particular employer group. Second, the medical physician, hospitals, and clinics that are represented in cohorts B and D are the same group of physicians and institutions. These physicians have patients who both have and do not have chiropractic coverage, and they are unlikely to be systematically aware of this condition. As a result of these 2 design elements, any differences seen between cohorts B and D are most probably the result of the difference in chiropractic coverage and not a confounding factor.

Study Period. The study period covers April 1, 1997, through March 31, 2001.

Identificaton and Definition of Neuromusculoskeletal Episodes of Care. Identification of NMS pain episodes of care was made by the use of ICD-9 codes that are a part of all administrative claims data. A total of 657 ICD-9 codes were identified as representing this set of conditions. These codes were classified into 8 different diagnostic categories: 1) low back pain, 2) low back pain (complicated), 3) neck pain, 4) neck pain (complicated), 5) thoracic spin pain, 6) headache, 7) myalgias and arthralgias, and 8) other/miscellaneous. The "complicated" designation in the low back and neck pain categories identify those diagnoses suggestive of discopathy and/or radiculopathy. This set of 657 diagnoses represents 96.7% of all chiropractic claims in the health plan. The remaining 3.3% were claims for extremity complaints. Extremity complaints represent a much higher proportion of medical claims. As a result, chiropractic extremity care represented only a very small proportion of total extremity complaints and negligible effects on the total utilization rates. Therefore, these complaints were excluded from the analysis. An expert panel of chiropractors and medical physicians evaluated this diagnostic classification for appropriateness and completeness.

Aggregation of claims into discrete episodes of care was made on the basis of both a "clean period" of 45 days with no claims as well as the diagnostic category that defines the type of episode. The clean period of 45 days is consistent with previous studies using administrative data.[8,9] Each episode is initiated by 1 of the NMS pain codes in the diagnostic list. All services using 1 of these codes and with a maximum gap of 45 days between claims were aggregated into 1 episode of care. Thus, a new episode was created if a new diagnostic category is used or encounters are separated by more than 45 days. A claim-free 45-day window was applied to the start and end points of the 4-year study period to identify and include members with nontruncated episodes. For any episode that begins during this period but extends beyond March 31, 2001, all services related to that episode, within the 45-day limit, were treated as if they fell within the 4-year period. Similarly, any episode that begins within 45 days before April 1, 1997, but extends into the 4-year period was considered to have occurred totally outside of the study period and was not be used in the analysis.

Data Preparation and Merging. Data preparation included transfer of all relevant claims data from the 2 different data sources (see subsequently), loading of the data onto a common server, and filtering by health member continuous enrollment to ready the data for analysis. Data relevant to patient enrollment (ie, insurance coverage information) and health service encounters (ie, dates of service, diagnoses, procedures, and so on) were loaded onto the server. Analysis was conducted using SAS version 6.12. Before the analysis, the data were validated as follows:

- Verification of the names, number of files, and number of records contained in each file with each respective data source.
- Validation of the format of the data (character, numeric, and length).
- Identification of key variables in the datasets (age, diagnosis codes, and so on), production of frequency reports of the data, and validation of the variables' contents, again working with each respective data source.
- Running of algorithms (computer programs designed to detect implausible data) to ensure the integrity of key variables (eg, ICD-9 and CPT-4 codes).

For patients with chiropractic coverage, there is an entirely separate and distinct management and storage of claims data for their chiropractic care than for their medical care. For this study, a patient's chiropractic claims were merged with their medical claims producing a single claims file for each covered patient. Merging of the datasets was accomplished using 1 of the following methods: 1) Each health plan member is assigned a unique identification number that is used for both the medical and chiropractic claims. This number was used to link a patient's chiropractic claims with their medical claims; or

TABLE 1
Demographic and Comorbid Conditions of Patients With Neuromusculoskel etal Claims, Both With and Without Chiropractic Benefits (01/2000 to 12/2000)

	Patients With Chiropractic Coverage	Patients Without Chiropractic Coverage
Demograp hics		
N	707,690	1,001,995
% Female*	51.6%	52.1%
Mean age†	32.9 (SD ⊓ 20.9)	35.5 (SD ⊓ 21.6)
Age groups		
0–17	31.9%	26.2%
18–21*	5.1%	4.3%
22–35*	14.6%	18.4%
36–55*	33.7%	33.2%
56–65	8.2%	8.2%
⊓65*	6.5%	9.6%
Comorbid conditions		
Conges tive heart failure*	0.6%	0.9%
Cardiac arrhythmia*	1.6%	2.0%
Hypertension *	6.6%	7.3%
Diabetes‡	2.8%	3.0%
Hypothyroidism*	1.5%	1.5%
Nutritional/ metabolic disorder*	1.6%	1.7%
Psychosis*	1.1%	0.9%
Depression*	1.9%	1.6%

* *P* value ⊓ 0.001.
† *P* value ⊓ 0.0001 .
‡ *P* value ⊓ 0.05.

2) In the event there was no common, unique member identifier (because of data entry errors), the data were linked using both member social security number and date of birth. Once the data were linked, a unique identifier was created and name, address, and social security number were purged from the dataset to assure patient confidentiality. Any data not linked by these 2 methods were eliminated from the study.

Data Analysis. The primary study question, "Is chiropractic care substitution care or add-on care?" was evaluated by comparing the rates of patient complaints in the 9e diagnostic categories of NMS pain described previously. If patients are substituting chiropractic care for medical care, a reduction in the rates of episodes of NMS pain should be seen in cohort D (medical patients in groups with chiropractic coverage) versus cohort B (medical patients in groups without chiropractic coverage). Conversely, if little or no substitution is taking place, the rates in these 2 cohorts should be roughly equivalent.

We also compared the total rates of complaints between cohort A (chiropractic and medical patients with NMS complaints in the groups with coverage) and cohort B (medical patients with NMS complaints in groups without chiropractic coverage). If substitution is occurring, there should be little difference in these rates. If little substitution is occurring, the combined rates of chiropractic and medical patients in cohort A will be higher than the rates in cohort B. Because many patients have multiple episodes of care, rates will be expressed both in terms of total number of episodes per thousand health plan members and total number of unique NMS patients per thousand health plan members. The data reported are population parameters and as such are not subject to tests of statistical significance.

There were some employer groups (and thus, some patients) who, during the study period, either picked up or dropped chiropractic coverage. As these changes took place, the patients and their associated healthcare episodes were shifted into the appropriate study cohort. Thus, in calculating the rates of diagnoses in the various cohorts, the total number of patients in each cohort (the denominator in the rate calculation) was expressed in terms of "insured member years."

Results

Data Preparation

Of the chiropractic claims data files from April 1, 1987, through March 31, 2001, 98.3% were successfully merged with the MCO claims files. For the 4-year study period, there were 3,129,752 insured member years in the groups with chiropractic coverage and 5,197, 686 insured member years in the groups without chiropractic coverage.

Study Population Characteristics

An analysis was conducted on a subset of patients who did not change their chiropractic coverage status during calendar year 2000. (The 4-year data contains a slightly greater number of total patients because it also includes those who did change their chiropractic coverage status at some point during the study.) There were small differences in demographic characteristics and rates of comorbid conditions in the study populations. The group with coverage was slightly younger and had fewer comorbid conditions in most of the categories studied. A summary of the study populations is shown in Table 1.

Comparison of Study Cohorts

A total of 1,394,070 unique patients were identified with NMS complaints during the observation period. Of these, 174,209 were chiropractic patients, 332,548 were medical patients with chiropractic coverage, and 887,313 were medical patients without chiropractic coverage. A breakdown of these patients

TABLE 2
Total Number of Unique Patients With NMS Pain Complaints in Study Cohorts

Diagnostic Category	Cohort A Patients With Chiropractic Coverage (Total of C∩D)	Cohort B Patients Without Chiropractic Coverage	Cohort C Chiropractic Patients	Cohort D Medical Patients
Low back pain (uncomplicated)	112,420	198,197	42,095	70,325
Low back pain (complicated)	12,307	22,752	4,612	7,695
Low back pain (total)	124,727	220,949	46,707	78,020
Neck pain (uncomplicated)	80,276	117,703	40,144	40,132
Neck pain (complicated)	1,557	3,346	195	1,362
Neck pain (total)	81,833	121,049	40,339	41,494
Thoracic spine/rib pain	37,429	42,372	25,049	12,380
Headache	56,459	122,496	9,313	47,146
Nonspecific myalgias, arthralgias	68,155	124,920	22,264	45,891
Other (misc. undifferentiated pain diagnoses)	138,154	255,527	30,537	107,617
Total	506,757	887,313	174,209	332,548

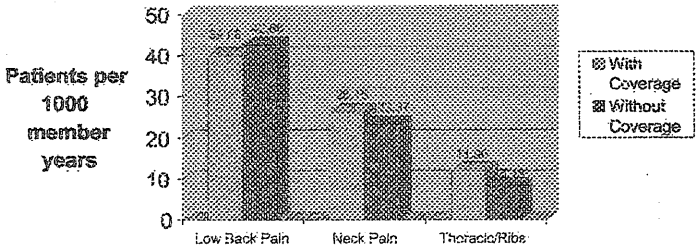

Fig. 2. Rates of patient complaints in groups with and without chiropractic coverage for low back pain, neck pain, and thoracic spine and rib pain.

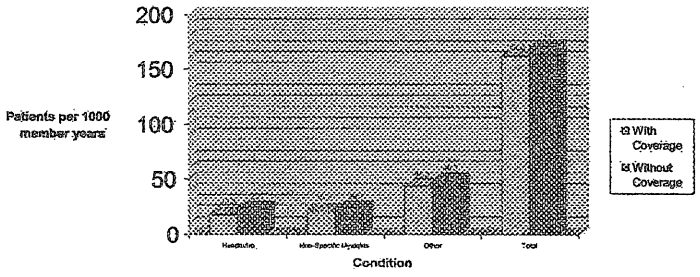

Fig. 3. Rates of patient complaints in groups with and without chiropractic coverage for headache, nonspecific myalgias, and other complaints. Also shown is the total rate of all conditions in the 2 study groups.

by cohort and diagnostic category is shown in Table 2.

Converting these raw counts to rates per 1000 member years allows a direct comparison of the utilization of care in the cohorts with and without chiropractic coverage. In 2 of the diagnostic categories, thoracic spine pain and neck pain, rates were slightly higher in the groups with coverage. In the other 4 categories, low back pain, headache, nonspecific myalgias, and other rates were higher in the groups without coverage. In total, the groups with chiropractic coverage experienced a rate of 162.0 NMS complaints per 1000 member years compared with 171.3 NMS complaints in the groups without coverage. Figures 2 and 3 compare the rates of patient complaints per 1000 member years. The group with coverage includes both chiropractic and medical patients.

Treatment of these patients resulted in 1,997,356 episodes of care for NMS complaints. Of these, chiropractic care resulted in 357,697 episodes; medical care to patients with a chiropractic benefit resulted in 450,221 episodes; and medical care to patients without a chiropractic benefit resulted in 1,189,438 episodes. Table 3 shows a breakdown of these episodes by cohort and diagnostic category.

Expressing the care in terms of episodes per 1000 member years produces a different finding than expressing it in terms of patients per 1000 member years. In 5 of the 6 diagnostic categories, with the exception being headache, rates were higher in the group with chiropractic coverage. They were markedly higher in the spine categories and only slightly higher in the nonspecific and other categories. Including all diagnostic categories, the group with coverage experienced 258.2 episodes per 1000 member years versus 229.6 episodes in the group without coverage. Figures 4 and 5 compare the rates of episodes in per 1000 member years. As stated previously, the group with coverage includes both chiropractic and medical patients.

TABLE 3
Total Number of Episodes of Care for NMS Complaints in Study Cohorts

Diagnostic Category	Cohort A Patients With Chiropractic Coverage (Total of C∩D)	Cohort B Patients Without Chiropractic Coverage	Cohort C Chiropractic Patients	Cohort D Medical Patients
Low back pain (uncomplicated)	183,356	154,960	87,958	95,398
Low back pain (complicated)	18,223	4,041	7,350	10,873
Low back pain (total)	201,579	159,001	95,308	106,271
Neck pain (uncomplicated)	137,989	268,143	86,574	51,415
Neck pain (complicated)	1,884	31,391	281	1,603
Neck pain (total)	139,873	299,534	86,855	53,018
Thoracic spine/rib pain	62,044	52,061	47,973	14,071
Headache	82,953	163,410	17,669	65,284
Nonspecific myalgias, arthralgias	114,982	180,193	47,923	67,059
Other (misc. undifferentiated pain diagnoses)	206,307	335,239	61,789	144,518
Total	807,738	1,189,438	357,517	450,221

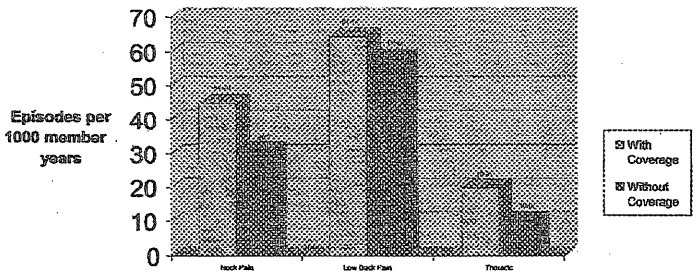

Fig. 4. Rates of episodes of care in groups with and without chiropractic coverage for neck pain, low back pain, and thoracic spine and rib pain.

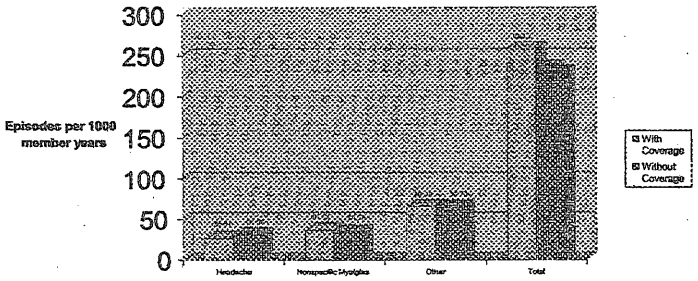

Fig. 5. Rates of episodes of care in groups with and without chiropractic coverage for headache, nonspecific myalgias, and other complaints. Also shown is the total rate of episodes of care for all conditions in the 2 study groups.

Discussion

Table 1 shows that there are statistically significant differences in demographic and comorbid characteristics between the 2 main study groups. However, it should be emphasized that the statistical significance is largely the result of the extremely large sample size and not of large group differences. Overall, the study populations are quite comparable and the small population differences are unlikely to have affected the study results.

Two distinct patterns emerge from this study. First, the presence of a chiropractic benefit does not appear to increase the number of patients who seek care for NMS pain complaints. With some relatively minor exceptions, for instance, thoracic spine pain, patients who seek chiropractic care for NMS conditions appear to substitute that care for medical care on a one-to-one basis for the particular region of complaint. In all of the diagnostic categories, the rates of NMS patient complaints in the cohort with chiropractic coverage (both medical and chiropractic patients) was very similar to the rates in the cohort without coverage. The overall rate of all NMS complaints in the 2 cohorts was within 5% of each other, with the lower rate being in the group with chiropractic coverage.

From the point of view of an insurer or an employer who is considering the impact of adding a chiropractic benefit, these results suggest that a chiropractic benefit is quite different than, for example, a dental benefit. When an employer adds a dental benefit, they are not replacing care from preexisting providers covered by a standard medical benefit. All services provided under a standalone dental benefit represent new costs. A more accurate characterization of the addition of a chiropractic benefit would be that it is the equivalent of expanding the network of available providers for care of NMS conditions. Patients with back pain, neck pain, and related com-

plaints can choose either chiropractic care or medical care, and this expanded choice does not seem to result in more patients seeking care.

The second pattern to emerge is that patients who come under chiropractic care experience more episodes of care than patients under medical care. In most diagnostic categories, chiropractic patients experienced approximately 2 episodes of care, whereas medical patients experienced just over 1 episode. This pattern is most pronounced in the 3 back pain categories. The overall rate of episodes per patient in the chiropractic cohort was 2.05 versus 1.35 among medical patients in the group with coverage.

There are 2 possible interpretations of this second finding. It could be that the treatment effects of chiropractic are not as longlasting as medical care and that chiropractic patients are returning for care as their symptoms return. However, this supposition is not supported in the clinical literature. The evidence that does exist suggests that spinal manipulation, which is the primary treatment modality used by chiropractic providers, is at least as robust as medical interventions relative to long-term effects.[18–23]

A more plausible explanation is that chiropractic management styles encourage patients to return for care. It is possible that the attitude toward back pain among chiropractors and medical physicians is quite different. For chiropractors, the set of NMS complaints considered in this study comprises virtually the whole of chiropractic practice.[24–27] Chiropractors' attitudes toward these complaints undoubtedly reflect this fact. By contrast, NMS pain complaints, at least for nonspecialist physicians, represent a small subset of their total patient population. Medical physicians are known to regard back pain as a frustrating complaint to treat and could communicate this attitude to patients, which could discourage future care.[28–30] Additionally, there is ample evidence that patient satisfaction with chiropractic care for back pain is substantially higher than patient satisfaction with medical care for back pain.[31–37] Patients who have had a generally more positive experience with chiropractic care could be more likely to return for subsequent care.

A study by Stano also reported more episodes of care among chiropractic patients.[38] It was hypothesized that this could reflect a tendency of patients with more chronic NMS conditions to migrate to chiropractic management. Most studies have found chiropractic and medical back pain patients to have a similar level of severity, but there are no data on the relative chronicity of these patients with which to evaluate this hypothesis.

The net effect of this higher rate of episodes among chiropractic patients is relatively modest. The overall rate (all diagnostic categories) of episodes of care among the group with chiropractic coverage is only 12% higher than the group without coverage.

This study demonstrates that in evaluating the relative cost of chiropractic care, it is necessary to evaluate costs at both the episode level and at the patient level. Existing studies that have compared an *episode* of chiropractic care with an *episode* of medical care could have underestimat ed the chiropractic costs.

Most of the data that describe the utilization of chiropractic care is derived from surveys rather than from claims data or from other sources that directly measure care.[39–41] In this study, the rate of utilization of chiropractic care by NMS patients with a chiropractic benefit was quite high. Overall, patients with NMS complaints with chiropractic coverage used chiropractic care 34.4% of the time. It is of particular interest to note that among the patients in the 3 back pain categories, chiropractors saw 45.9% of all patients in the group with chiropractic coverage. This figure is considerably higher than is usually reported. These findings suggest that when patients are offered the choice of chiropractic care, through a chiropractic benefit, versus medical care for back pain, nearly half the patients will choose chiropractic care.

Limitations

There are no data available from the national health plan to determine any potential differences in the types of employers with and without chiropractic coverage. It is not known if the 2 sets of employers, those with and without a chiropractic benefit, examined in this study varied significantly in the industry and job type represented by those employers. Thus, it might be possible that these results are skewed by differences in the makeup of employers in the comparative groups. However, our analysis of the demographic and comorbid status of the 2 groups demonstrated only very minor differences among the employee populations. It is very unlikely that the overall effects seen in this study are systematic artifacts of different patient populations.

It might be argued that the finding of more episodes of care under chiropractic management is simply an artifact of the arbitrary definition of episodes of care and is mostly a reflection of the different styles of chiropractic and medical practice. In this regard, the average duration of an episode of care for uncomplicated low back pain under chiropractic management was 35 days, compared with 10 days under medical care. Results from this study and others indicate that it is clearly a characteristic of chiropractors to provide more services per episode for back pain than medical physicians. If the definition of episode of care were changed to lengthen the "clean period," the rates of chiropractic and medical episodes would be much more similar. In any case, it remains true that the most valid comparison of the cost of chiropractic versus medical management is on a per-

patient basis, thereby aggregating all episodes into 1.

Results of this study might not be generalizable to other medical care settings and financing arrangements. If a different set of economic incentives and management procedures were in place, these could result in different rates of utilization of healthcare services. In this study, the medical providers were reimbursed under a capitated arrangement, which did not provide economic incentives to increase care. Under a more traditional fee-for-service financial arrangement, it might be possible that the medical providers would adjust their behavior to attract and retain more NMS pain patients and thus create provider-induced demand. It should be noted, however, that the chiropractic providers in this study were operating in a fee-for-service environment and their actions did not seem to result in a net effect of increased demand.

In calculating the cost of chiropractic care, it must be observed that chiropractors often manage patients outside of the context of treating a discrete episode of pain. Chiropractors could dispense a variety of nutritional or herbal supplements. Chiropractors could also administer so-called "maintenance care" to asymptomatic patients. These practices were not considered within the parameters of the covered chiropractic benefit that was analyzed in this study, but such practices could well be the norm in other circumstances.

Conclusion

Within a managed care setting, the inclusion of a chiropractic benefit does not increase the overall rates of patient complaints for low back pain, neck pain, and related NMS pain disorders. Patients appear to be directly substituting chiropractic care for medical care. At the same time, those patients who use chiropractic care experience more subsequent episodes of care than patients who use medical care. Thus, the economic effects of a chiropractic benefit in this setting are best evaluated on the basis of a per-patient comparison rather than on a per-episode comparison.

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Clinical Observation on the Treatment of Hypertension by Combination of Western Medicine and TCM

Objective: To observe the clinical effect in the treatment of hypertension by integrate TCM with western medicine on basis of differentiation, classification and individuation.

Method: 492 cases were from inpatients, outpatients and coordinate area. They were randomly divided into two groups, control group and observation group. The patients in the observation group were classified into six types by way of combining TCM with western medicine on the vases of differentiation, classification and individuation.

The administrated the series of Jiangyabao No. 00 to No.04 respectively. (the series of Jiangyabao consists of 5 kinds of products: Jiangyabao No. 00 for administering laxatives and resolving phlegm, invigoration the spleen and dispelling dampness; Jiangyabao No. 01 for replenishing qi and nourishing Yin, regulating and tonifying the liver and kidney; Jiangyabao No. 02 for tonifying Yin and checking exuberance of Yang, subduing Yang and endogenous wind; Jiangyabao No. 03 for subduing the liver and removing the fire, dispelling the heart and removing dysphasia; Jiangyabao No. 04 for replenishing qi and invigorating blood circulation, dispelling wind and administeringf the vessels. The drugs mentioned above are manufactured by the drug-manufacture center of the academy according to the relevant coordinate prescriptions to 0.5g capsule. The patient control group administrated nimodipine or compound Jiangya tablets. The criteria for diagnosis and evaluation of curative effect rate were based on *Criteria Established by the Symposium on Epidemiology, Prevention and Treatment of Cardiovascular Disease.*

Result: the overall effective rate and remarkable effective rate for the observation group were 98.3% and 88.3% respectively, 86.7% and 50.0% for the control group ($P<0.05$ and P,0.01) respectively. One to five years follow-up for the observation group showed the control rate of diastolic pressure lower than 90mmHg (12pa) was 87% and the series drugs of Jiangyabao, didn't induced the disturbance of metabolism of potassium, lipoid and sugars.

Conclusion: The curative rate of the observation group was better than that of the control group and the control rate was improved. Moreover, there was no reverse effect on the metabolism of organism.

(By Deng Qihua & Fu Wenzeng, from Henan Academy of TCM, Zhengzhou, Hennan, China)

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Is complementary and alternative medicine (CAM) cost-effective? a systematic review

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Abstract

Background: Out-of-pocket expenditures of over $34 billion per year in the US are an apparent testament to a widely held belief that complementary and alternative medicine (CAM) therapies have benefits that outweigh their costs. However, regardless of public opinion, there is often little more than anecdotal evidence on the health and economic implications of CAM therapies. The objectives of this study are to present an overview of economic evaluation and to expand upon a previous review to examine the current scope and quality of CAM economic evaluations.

Methods: The data sources used were Medline, AMED, Alt-HealthWatch, and the Complementary and Alternative Medicine Citation Index; January 1999 to October 2004. Papers that reported original data on specific CAM therapies from any form of standard economic analysis were included. Full economic evaluations were subjected to two types of quality review. The first was a 35-item checklist for reporting quality, and the second was a set of four criteria for study quality (randomization, prospective collection of economic data, comparison to usual care, and no blinding).

Results: A total of 56 economic evaluations (39 full evaluations) of CAM were found covering a range of therapies applied to a variety of conditions. The reporting quality of the full evaluations was poor for certain items, but was comparable to the quality found by systematic reviews of economic evaluations in conventional medicine. Regarding study quality, 14 (36%) studies were found to meet all four criteria. These exemplary studies indicate CAM therapies that may be considered cost-effective compared to usual care for various conditions: acupuncture for migraine, manual therapy for neck pain, spa therapy for Parkinson's, self-administered stress management for cancer patients undergoing chemotherapy, pre- and post-operative oral nutritional supplementation for lower gastrointestinal tract surgery, biofeedback for patients with "functional" disorders (eg, irritable bowel syndrome), and guided imagery, relaxation therapy, and potassium-rich diet for cardiac patients.

Conclusion: Whereas the number and quality of economic evaluations of CAM have increased in recent years and more CAM therapies have been shown to be of good value, the majority of CAM therapies still remain to be evaluated.

Background

Complementary and alternative medicine (CAM) has a reputation for good value among health conscious consumers [1]. In the United States consumers spend over $34 billion per year on CAM therapies [2], dollars spent outside the conventional health care financing system. Such evidence on out-of-pocket expenditures is a testament to the widely held belief that CAM therapies have benefits that outweigh their costs. Regardless of public opinion, there is often little more than anecdotal evidence on the health and economic implications of CAM therapies.

The paucity of outcomes research in CAM has likely depressed access to CAM therapies by impeding their integration into financial mechanisms commonly found in conventional health care. Most US consumers who have health insurance coverage, either through public or private institutions, bear the entire cost of CAM therapies out-of-pocket [3]. Theoretically, CAM therapies seem effective and a good candidate for cost savings because they avoid high technology, offer inexpensive remedies, and harness the power of *vis medicatrix naturae* (the body's natural ability to heal itself). As such, a thorough and external review of economic and health outcomes of CAM is necessary for evidence-based consideration of CAM therapies as a covered expense. That being said, it is also known that affirmative evidence on economic and health outcomes is a necessary, but not sufficient step toward CAM coverage, and not the decision itself. Other factors such as historical demand, political expediency, consumer demand, and practitioner enthusiasm may also be considered in the decision to incorporate CAM into a health insurance policy [1,4,5].

The need for economic evaluations is also growing in conventional healthcare. An increasing number of health plans and hospitals have moved from a simple budgetary focus in formulary decisions to requiring detailed evidence on the economic value of considered therapies relative to alternatives [6,7]. Beyond their use in decisions concerning health insurance coverage, economic outcomes of both CAM and conventional therapies also influence health policy, justify licensure of practitioners, inform industry investment decisions, provide general evidence to consumers about potential economic benefits, and can guide future research efforts through identifying decision-critical parameters for additional research [8,9].

In their systematic review of CAM economic evaluations, White and Ernst [4] identified 34 economic evaluations of CAM conducted between 1987 and 1999; only eleven of which were full economic evaluations (ie, compared both economic and health outcomes between two or more alternatives) [10]. Quality was evaluated by noting whether cost data were collected prospectively and whether comparison groups were comparable – ie, assigned randomly. Unfortunately, their search strategy included the term "alternative medicine" but not "complementary medicine." Therefore, all single therapy studies in their review are of CAM therapies that are usually used as substitutes (alternatives) to conventional care (eg, acupuncture, homeopathy, and spinal manipulation). No studies of complementary therapies (those used in conjunction with conventional care) were included, despite the use of the term "complementary" in their conclusion that spinal manipulative therapy may have benefits for back pain, but "there was a paucity of rigorous studies that could provide conclusive evidence of differences in costs and outcomes between other complementary therapies and orthodox medicine [4]."

The objectives of this paper are: 1) to introduce concepts commonly applied in economic evaluations of health technologies (often called technology assessment) so that practitioners and CAM users can translate and benefit from published evidence; and 2) present a systematic review of the current scope and quality of economic evaluations of CAM. We begin with an overview of economic evaluation, including didactic examples from the CAM economic literature to help clarify the concepts presented. Readers familiar with this type of analysis can skip this section and proceed directly to the methods section.

In our systematic review we expand upon and update the initial review by White and Ernst. We evaluate study quality in more detail, using both additional study design criteria and quality of reporting criteria, and present a summary of the results from exemplary studies. While their review was the first of its kind, economic evaluations in the CAM literature have improved greatly in the last five years. We end the paper with a description of the attributes of CAM that make economic evaluation challenging and how these issues may be addressed. We hope that practitioners' interest in economic evaluation will continue to grow, leading to greater incorporation of this research into CAM trials.

What is an economic evaluation?

An economic evaluation is a comparison of outcomes among alternative ways of achieving common objectives. These analyses are conducted according to explicit, systematic, and consistent criteria, and take into account both the positive and negative consequences of each alternative. Consequences may include economic, clinical, and humanistic outcomes, known as the ECHO model [11]. Economic outcomes represent the consumption and production of resources and their monetary value from the perspective of a decision maker. Clinical outcomes are

Table 1: Three forms of full economic evaluations

	Cost-benefit Analysis (CBA)	Cost-effectiveness Analysis (CEA)	Cost-utility Analysis (CUA)
Number of Health Outcomes	Multiple outcomes	One outcome	Multiple outcomes
Unit of Health Outcomes	Summary measure in monetary units (eg, US dollars)	Natural units (eg, reduction in number of hot flashes)	Summary measure in quality of life units (eg, quality-adjusted life-years, QALY)
Results	Net benefits $(B_1 + B_2 - C_1 - C_2)$	Cost-effectiveness ratio* $(C_1 - C_2) / (E_1 - E_2)$	Cost-utility ratio* $(C_1 - C_2) / (QALY_1 - QALY_2)$

* Results are calculated when both the costs and the effects (health outcomes) of one therapy are higher than those of another. When the costs are lower and the effects are higher for one therapy, it is said to dominate the alternative (and the alternative is said to be dominated) and no ratio is presented. C_1 = total costs of alternative 1; C_2 = total costs of alternative 2; B_1 = monetary value of health outcomes of alternative 1; B_2 = monetary value of health outcomes of alternative 2; E_1 = health effects of alternative 1; E_2 = health effects of alternative 2; $QALY_1$ = quality-adjusted life-years of alternative 1; $QALY_2$ = quality-adjusted life-years of alternative 2.

medical events that are professionally meaningful. Humanistic outcomes are a broad category of intangible personal attributes, typically collected through self-report. Humanistic outcomes include quality of life characteristics such as sense of safety, physical comfort, enjoyment, meaningful activity, relationships, functional competence, dignity, privacy, individuality, autonomy, and spiritual well-being. Conventionally, clinical and humanistic outcomes are considered health outcomes, and we follow this convention for the remainder of the article.

There are several forms of economic evaluations that can be performed (cost-effectiveness analysis being only one of these) and each differs based on the selection and measurement of health outcomes. The perspective (or point of view) taken for the analysis also influences the selection and measurement of consequences, because not all outcomes are important to all decision makers. Generally, there are three perspectives for economic analysis: individual (eg, patient), institutional (eg, health maintenance organization), or societal. The societal perspective accumulates all outcomes, while individual and institutional analyses are more selective. Regardless of perspective, the objective of an economic evaluation is to provide information on consequences relating to alternatives faced by a decision maker.

The most basic form of economic evaluation is a table that lists the individual economic and health outcomes of alternative interventions. This table is known as a cost-consequence study. Cost-identification studies and cost-minimization analyses only address economic outcomes and are discussed below in that section. The remaining forms of economic evaluations summarize economic and health outcomes into a single result (Table 1).

The advantages of performing cost-benefit and cost-utility analyses are that multiple outcomes are summarized into a single unit, either monetary units such as dollars (CBA) or QALYs (CUA) and that therapies with different sets of health outcomes can be compared based on the differences in the summary measures. Cost-benefit analysis has the additional benefit of directly indicating whether the therapy pays for itself.

The disadvantages of CBA and CUA come from the techniques required to produce a summary measure. Cost-benefit analysis requires putting a monetary value on all health outcomes (and ultimately on life), and cost-utility analysis assigns value to health outcomes based on their contribution to quality of life under the presumption of population-based preferences. An extensive literature addresses the methodological and theoretical issues involved in the construction of these summary measures. The process usually occurs in two steps. In the first step, health outcomes of the intervention are measured, and in the second the outcomes are valued in summary units and aggregated. Cost-benefit analyses often assess the monetary value of health outcomes based on willingness-to-pay using a technique called conjoint analysis [12-14]. Willingness-to-pay inherently places a lower values of life on individuals with low income, because they can not pay what they do not have. Cost-utility analyses have multiple methods to place quality of life values on health outcomes, also known as social tariffs. Summary measures of quality of life may not be sensitive enough to pick up short-term changes such as for acute conditions and will not pick up specific clinical outcomes like blood pressure control [15]. Examples of instruments used to capture these general health states include the EuroQoL (EQ-5D) [16] and the Health Utilities Index [17].

Cost-effectiveness analysis (CEA) is the current standard in the literature, and has the most straight forward interpretation. Under CEA, therapies useful for a specific disease or condition can be directly compared using a metric of effectiveness relevant to that condition, such as blood pressure control. Although these types of analyses do not

Table 2: Economic outcomes to include in economic evaluation

Type of Cost	Examples	Perspectives in Which This Cost is Included
Direct costs: Medical	Intervention costs: Practitioner fees Diagnostic costs Therapy costs Service costs: Facilities and equipment, including hospitalization or clinic/office costs Ancillary staff	Portion paid by health plan included in institutional perspective Portion paid by patient included in individual perspective All included in societal perspective
Direct costs: Non-medical	Transportation costs Time off work for appointments/hospitalization	Usually all paid by the patient, so often included in individual perspective All included in societal perspective
Indirect costs	Lost work productivity during recuperation Lost leisure time Child care costs Costs to care givers	Usually all paid by the patient, so often included in individual perspective All included in societal perspective
Intangible costs	Pain Suffering Grief	Not usually included as costs; instead, may be included in humanistic outcomes in cost-utility analysis

Summarized from similar tables in other references [1, 20, 22].

allow a summary of multiple outcomes they tend to respond well to the most urgent questions, such as how much would it cost to reduce the number of gestational diabetes cases by 10%? Clearly, a reduction in gestational diabetes cases has measurable implications in quality of life and economic units, but the creation of a summary measure is not necessary to address the decision maker's question.

No matter the approach taken, it is recommended that the estimated outcomes (economic, clinical and humanistic) of health care alternatives used in economic evaluation are best estimated in pragmatic clinical trials that directly and realistically compare the therapies of interest [10]. Rarely are the results of placebo-controlled trials appropriate [1,4,18-20]. Also, since many CAM therapies target chronic disease, it is important that the study period be long enough to capture the full benefits and costs of each therapy, and that future costs and benefits be discounted to the present for comparison. Finally, all economic evaluations should include some type of sensitivity analysis to test the robustness of results to the various assumptions made [1,20,21].

What are economic outcomes?

Economic outcomes are the net bundle of resources forgone due to an intervention valued at the opportunity cost of those resources (the value of their next best use or "opportunity"). Since the cost of a therapy differs depending on whether you are a patient, a health plan, or a health care provider, the economic outcomes (ie, costs) of each therapy depend on the perspective of the study. Studies that only measure the economic outcomes of interventions are known as cost-identification studies. A study that describes the economic and health outcomes of a single therapy can also be called a cost-identification study. These studies inform full economic evaluations. That is, they provide the data needed to better design future studies that consider both the economic and health outcomes of two or more alternative therapies. A cost-minimization analysis (CMA) explicitly assumes equivalence in health outcome among alternative therapies, and examines only economic outcomes. In practice, it appears the same as a cost-identification study, but under the assumption of equivalence, a CMA is a full economic evaluation.

Table 2 has been summarized from other references [1,20,22] and gives a list of the types of economic outcomes and the perspective of analysis where each is considered. Note that these types of economic outcomes should be inclusive of both the full costs of the therapy and of any treatment for adverse effects, which can be expensive. In economic evaluations, the safety of a therapy is addressed through accounting for the cost of treating these adverse events as well as through their impact on clinical and quality of life outcomes.

It is recommended that economic outcome data are best collected prospectively as part of a pragmatic clinical trial [1,4,19,20]. Inclusion and exclusion criteria for cost data should be established in the protocol, as for clinical outcome measurements, but provision must be made to add extra categories of costs which only become apparent after the trial has commenced [1,20]. Many studies try to collect cost data retrospectively, often after a therapy has shown clinical effectiveness. However, retrospective data

collection is seldom fertile, adapted, or exhaustive, and it is subject to bias [18,20].

Examples of the different forms of economic evaluations of CAM

Our systematic review of the CAM economic evaluation literature (presented below) revealed no cost-consequence studies and no cost-benefit analyses. However, we did find examples of a cost-identification study, cost-minimization analysis, cost-effectiveness analysis, and cost-utility analysis. These examples are presented below.

Cost-identification study

Frenkel and Hermoni, 2002 [23], performed a retrospective comparison of medication consumption costs from computerized medication charts three months before and three months after a homeopathic intervention for atopic and allergic disorders. The review was performed on 48 consecutive self-referred patients in one clinic over one year with a diagnosis of an atopic condition who agreed to a classical homeopathic treatment in addition to usual conventional care. Of the 31 medication users (prescription and non-prescription allergy-related medications) before the intervention, 27 reduced their use, two increased their use, and two had their medication level unchanged after the intervention. Of the 17 who had not used medication before the intervention, 4 began medication after the intervention. There was an average drop in 3-month medication costs after homeopathy of $14 (1998 US$) or 54% per person.

Cost-minimization analysis

Herron and Hillis, 2000 [24], retrospectively compared government payments to physicians for 1418 Quebec health insurance enrollees who practiced the Transcendental Meditation (TM) to payments for 1418 randomly selected and matched enrollees who did not. Long term health outcomes were assumed to be equal for both groups. Before starting meditation, the groups were similar in the yearly rate of increase in payments. After starting TM, annual physician payments for the meditation group declined 1 to 2% per year, while those for the non-TM group increased annually over the six year period. The difference in the annual change in payments was statistically significant at a rate between 5 and 13% per year.

Cost-effectiveness analysis

Franzosi et al, 2001 [25], prospectively gathered health and economic outcomes during the 3.5 year follow-up period of a large randomized open-label study (n = 5664) of omega-3 polyunsaturated fatty acids (n-3 PUFA) as secondary prevention for patients with recent myocardial infarction. The perspective was that of a third-party payer; accordingly only direct health care costs (hospital admissions, laboratory and diagnostic tests, and medications) were considered. The incremental number of life-years saved by n-3 PUFA treatment over the 3.5 years (discounted at 5%) was 0.0332 per patient. The incremental cost discounted over the same period was 817€ per patient. Therefore, the incremental cost-effectiveness ratio is 24,603€ (approximately $25, 415 in 1999 US$ [26]) per life-year saved.

Cost-utility analysis

Korthals-de Bos et al, 2003 [27], performed an economic evaluation alongside a randomized controlled trial to compare manual therapy, physiotherapy, and care by a general practitioner for neck pain. The study used the societal perspective and collected direct and indirect costs (including hours of help from family and friends, and hours of absenteeism from work or other activities) through the use of cost diaries kept by patients over one year. Data on each patient's overall health state were gathered at baseline and at one year using a survey instrument called the EuroQoL [16]. The utility of these health states were then calculated by using "society's" preferences for each of those health states. Society's preferences were estimated from a sample of the general population by the developers of the EuroQoL instrument. Using the comparison of manual therapy to general practitioner care, manual therapy had a lower one-year cost ($402, US$) than general practitioner care ($1241). The QALYs were 0.82 for manual therapy and 0.77 for general practitioner care. Since the costs were lower and the QALYs higher for manual therapy as compared to usual care, manual therapy is said to dominate general practitioner care and no cost-utility ratio is calculated.

Methods

The National Center for Complementary and Alternative Medicine (NCCAM) defines CAM as "a group of diverse medical and health care systems, practices, and products that are not presently considered to be part of conventional medicine [28]." We further defined CAM as including only those therapies that could be prescribed (or recommended) and/or performed by a CAM practitioner who does not also have a conventional medical license (eg, doctor of medicine – MD, or doctor of osteopathy – DO). Therefore, we did not include therapies such as chemotherapy regimens nor therapies requiring surgical implantation (such as neuroreflexotherapy [29]) as CAM therapies even though these therapies do appear in searches using the keywords complementary and/or alternative medicine. We also did not include well-accepted vitamin and mineral supplementation therapies such as calcium and vitamin D for osteoporosis, niacin for dyslipidemia, and vitamin B12 and folic acid for homocysteine reduction.

Search strategy

We searched the following electronic databases from January 1999 to October 2004: Medline, AMED, Alt-HealthWatch, and the Complementary and Alternative Medicine Citation Index via NCCAM and the National Library of Medicine (NLM). Searching was restricted to English language journals and human studies with the keywords: complementary medicine or alternative medicine, and costs or cost analysis or cost-benefit or cost-effective or economic analysis or economic evaluation.

We removed duplicates from the search results and selected papers that reported original data on specific CAM therapies from any form of standard economic analysis, analysis of costs, or economic modeling. Studies were then excluded if they were cited in the White and Ernst review [4], or if they were case studies or case series of five or fewer subjects.

Data analysis

The following data were extracted from each of the included studies: full citation information (author(s), date, title, journal, etc), form of economic evaluation (stated or inferred), the therapies being compared and whether the CAM therapies were being used in addition to usual care (complementary) or instead of usual care (alternative), the perspective of analysis (stated or inferred), the study design, the sample size, and summary results.

The studies were categorized as either full economic evaluations (defined as a comparison between two or more alternatives and considering both costs and consequences [10]) or partial economic evaluations (those studies that did not contain a comparison, or only addressed costs). Studies that estimated resource utilization were included as full economic evaluations even if resources were not valued.

We captured data on quality of the full economic evaluations using two approaches. The first approach was to gather from each study the data needed to assess quality according to a 35-item checklist developed by the *BMJ* Economic Evaluation Working Party [30]. This checklist was developed to improve the quality of published economic evaluations, and was chosen because it is thorough, and entails an objective assessment of whether essential components of an economic evaluation are reported in the article. Therefore, the checklist is mainly a measure of reporting quality and not necessarily of study quality. We also report available results from several other general reviews of economic evaluations of conventional therapies that use this checklist for comparison.

As the purpose of economic evaluations is to inform clinical practice and health policy decisions, the best evaluations are timely and use the best data available at the time [10]. On the other hand, an evaluation is only as good as the data upon which it is based. It has been suggested that the ideal situation for data collection is to collect economic data along side health outcomes in a randomized pragmatic trial [10]. Pragmatic trials offer a compromise between the goals of internal and external validity. To assess study quality, we went beyond White and Ernst's [4] criteria of randomization (to reduce bias by creating comparable groups) and prospective collection of economic outcome data (to ensure all costs are captured) to include two additional indicators of whether a pragmatic (effectiveness or "real world") rather than efficacy trial was conducted. The first is that the comparison group was usual care, and the second was that the study was not blinded and not mandatory – ie, that physicians and patients could react realistically to the therapy [10]. These criteria relate to the external validity or generalizability of the study. Other indicators of a study's generalizability, such as the determination of whether study participants could be assumed to represent a normal case load, were not used as they required detailed knowledge as to the appropriateness of the inclusion and exclusion criteria for each condition studied – a level of expertise not held by the study's authors.

Based on the study quality criteria, we report summarized results of the exemplary studies – ie, those meeting all four study quality criteria. If the health outcomes for one therapy are better than that of its alternative and the economic outcomes are better or equal (lower or equal costs), that therapy is said to dominate (be clearly better than) its alternative. This is also the case if both therapies have equal health outcomes and one has lower costs. In all other cases, the decision maker must elect whether the increase (loss) in health benefits is worth the increase (savings) in cost.

Results

The database search rendered 1765 potential studies to screen. Application of inclusion and exclusion criteria reduced the list to 56 economic evaluations [23-25,27,31-82]. The therapies compared, study design employed, sample size used, and a summary of study results are provided for each study in an appendix [see Additional file 1]. The list contains 39 full evaluations and 17 partial evaluations. The evaluations cover a range of CAM therapies applied to a variety of conditions (Table 3). Some therapies, such as acupuncture, homeopathy, and manual therapy, were studied mainly as alternative therapies (ie, as substitutes or alternatives for conventional care). Other therapies, such as guided imagery, were studied as com-

Table 3: Types of complementary and alternative medicine (CAM) therapies studied for various conditions (full/partial economic evaluations)

	Acupuncture	Homeopathy	Manual therapy	Spa therapy	Mind-body therapy	Hypnosis	Botanical medicine	Nutritional supplements	Diet	Biofeedback	Hyperbaric oxygen therapy	Miscellaneous*	TOTALS†
Populations with mixed conditions‡		3/2			2/1			0/1				0/1	10
Back, neck, and/or leg pain	1/0		5/0				1/0					1/0	8
Surgery						2/1		2/0					5
Cardiac patients					2/0			1/0	1/0				4
Rheumatic disorders		0/1		1/0						1/0			3
Epilepsy									0/3				3
General costs	0/1		0/2										3
Allergy		0/1										1/0	2
Cancer chemotherapy					2/0								2
Diabetic ulcers											2/0		2
Dyspepsia	1/0	1/0											2
EENT in children		1/1											2
Headache/migraine	2/0												2
Midwifery/obstetrics										1/0		0/1	2
Miscellaneous§		1/0		2/0	1/0		1/0	1/2	2/0				10
TOTALS†	5	11	7	3	8	3	2	7	6	2	2	4	60

EENT = Eye, ear, nose, and throat conditions

* Miscellaneous CAM therapies include: multivitamins, shoe orthoses, electrodermal screening, and aromatherapy.

† Some studies compared more than one CAM therapy. Therefore, totals exceed the number of studies found.

‡ Populations with mixed conditions include: patients with chronic disease, patients at one general practice (4 studies), long-term care workers, persons in Quebec health system, inner city children, and older adults (2 studies).

§Miscellaneous conditions include: anxiety, Parkinson's, psoriasis, uterine fibroids, urinary tract infection, macular degeneration, severe burn, AIDS, obesity, and hypertension.

plementary therapies (ie, used in addition to conventional care).

Reporting quality checklist

Table 4 shows the results of the application of the *BMJ* 35-item quality checklist [30] to the 39 full economic evaluations. For comparison, Table 4 also contains comparable results from systematic reviews in conventional medicine [6,83,84].

Study design

These checklist items indicate whether essential components of the study design were reported. About half the studies stated the form of the economic evaluation, however, several were stated incorrectly and only one justified the form chosen. The bulk of the studies presented cost-effectiveness analyses (36 or 92%), five presented cost-utility analyses, and one was a cost-minimization study [24]. Only one-third of studies stated the perspective of the analysis, however, it could be determined from the costs included for all studies. Ten used a societal perspective, and the majority (33 or 85%) used some sort of institutional perspective (eg, health insurance company or hospital). Note that the totals by form and perspective add to more than 39. This is because individual studies can include analyses using more than one form of economic evaluation and can report costs from more than one perspective.

Data collection

These checklist items relate to the presence of information essential to the generalizability of study results. All studies that included health outcomes (ie, all except the one cost minimization study [24]) reported the source of their effectiveness estimates. In 36 of the 38 cases the source was a single study, often the economic evaluation itself. The two other studies were modeling studies [49,78] where reviews were used as the source of effectiveness estimates. Items 12 and 13 are appropriate for cost-utility analyses (where health states are valued in terms of utility) and there were four such studies [27,35,51,78], only one of which gave details on the subjects from whom the valuations were obtained [35]. Productivity changes (items 14 and 15) are appropriate for studies using the societal perspective. Eight studies included the costs of changes in productivity from improvement in back or leg pain [47,82], neck pain [27], migraine [32], anxiety [44], ankylosing spondilitis [51], psoriasis [49], and children's rhinopharyngitis [41]. All but one [49] reported these amounts separate from total costs. However, few discussed the relevance to the study of productivity changes.

Table 4: Reporting quality of complementary and alternative medicine (CAM) economic evaluations and comparable results of similar reviews in conventional medicine

Items from the *BMJ* Checklist [30] (Indented items apply only to a subset of studies)	Review of CAM Studies N (%)	Reviews of Conventional Medicine Studies N (%)
Study design		
(1) The research question is stated	39 (74)	43 (16)*
(2) The economic importance of the research question is stated	39 (51)	
(3) The perspective of the analysis is stated	39 (33)	228 (52)†
(4) The rationale for choosing the alternatives is stated	39 (69)	
(5) The alternatives being compared are clearly described	39 (74)	228 (83)†
(6) The form of economic evaluation used is stated	39 (49)	
(7) The choice of form of economic evaluation is justified	39 (3)	43 (7)*
Data collection		
(8) The source(s) of effectiveness estimates are stated	38 (100)	
(9) Details of the effectiveness study are given	36 (94)	
or (10) Details of the review or meta-analysis are given	2 (50)	
(11) Primary outcome measures are clearly stated	39 (95)	
(12) Methods to value health states are stated	4 (100)	228 (75)† 43 (79)‡
(13) Details of the subjects from which values were obtained are given	4 (25)	228 (76)† 43 (46)‡
(14) Productivity changes are reported separately	8 (88)	
(15) The relevance of productivity changes is discussed	8 (25)	
(16) Quantities of resources are reported separately from unit costs	39 (67)	43 (19)‡
(17) Methods for the estimation of quantities and unit costs are described	39 (67)	
(18) Currency and year are recorded	39 (41)	228 (68)†
(19) Details of adjustments for inflation or currency conversion are given	39 (21)	43 (21)*
(20) Details of any model used are given	3 (100)	
(21) The choice of the model and its key parameters are justified	3 (100)	
Analysis and interpretation of results		
(22) Time horizon of costs and benefits is stated	39 (100)	
(23) The discount rate is stated	4 (50)	228 (65)†
(24) The choice of discount rate is justified	4 (25)	43 (16)* 34 (21)‡
(25) An explanation is given if costs and benefits not discounted	4 (50)	8 (12)‡
(26) Details of statistical tests and confidence intervals are given for stochastic data	38 (87)	
(27) The approach to sensitivity analysis is given	5 (100)	43 (2)*
(28) The choice of variables for sensitivity analysis is justified	5 (40)	39 (79)‡
(29) The ranges over which variables are varied are stated	5 (100)	228 (57)† 38 (66)‡
(30) Relevant alternatives are compared	39 (36)	228 (57)†
(31) Incremental analysis is reported	13 (54)	228 (46)†
(32) Major outcomes are presented disaggregated and aggregated	39 (85)	
(33) The answer to the study question is given	39 (69)	
(34) Conclusions follow from the data reported	39 (100)	
(35) Conclusions are accompanied by the appropriate caveats	39 (67)	228 (84)†

* Comparable estimates available from Jefferson et al, 1998 [83].
† Comparable estimates available from Neumann, 2004 [6], a systematic review of cost-utility analyses.
‡ Comparable estimates available from Gerard et al, 2000 [84], a systematic review of cost-utility analyses.

About two-thirds of studies reported resource use quantities separate from unit costs, or described the methods used to estimate both quantities and unit costs. Whereas, almost all reported the currency used, only a minority (16 or 41%) reported the currency year. A smaller number reported the details of adjustments for inflation or currency conversion, but this was not often required in studies collecting and reporting data in the same year and currency. Models (one decision tree model [78] and two multiplicative-type or impact [49,57] models) were used in three studies and in all cases the details of the model were given and justified.

Analysis and interpretation of results

All studies stated the time horizon for costs and benefits and most (35 or 90%) reported a time horizon of one year or less. Items 23 through 25 apply only to the four remaining studies with time horizons longer than one year. The discount rate is reported in two of these studies (one with a time horizon of 42 months [25] and the other that included a 12-year projection [78]), but only one justified the choice of discount rate [78]. Two studies gave an explanation for why they did not discount costs and benefits, however, neither needed to – one had a one-year time horizon [35] and the other stated its time horizon as one course of chemotherapy [55]. Five studies performed sensitivity analyses [25,27,35,51,78]. In all cases the approach and the range of variables tested were stated, but the choice of variables to test was only justified in two cases [35,51].

In about one-third of studies there was some comparison of study results to that of other studies. In most cases this was done as a simple statement noting that the results were either similar, or that they were dissimilar and that this might be because of differences in study design. Incremental cost-effectiveness or cost-utility ratios are usually only required when one therapy offers clearly better health outcomes than the other, but at a higher cost. In the 13 studies where this was the case over one-half reported incremental analyses. In most cases the major outcomes of the studies were shown disaggregated, and the study question was answered. We did require that a proper research question be stated (see the answers to item 1) for it to be answered. In all cases, we felt that the conclusions followed the data, but in about one-third of cases the conclusions were not presented with the appropriate caveats. For example, if a study did not explicitly discuss its limitations, it was not included as meeting the last item.

Measures of study quality

Twenty-seven studies (69%) gathered cost data prospectively and 21 (54%) used randomly assigned comparison groups. In 32 studies (82%) the physicians and patients were not blinded to the treatment received and participation was not mandatory (a worksite intervention [57]), and therapies were compared to usual care in 34 (87%) of studies. Fourteen studies [25,27,32,34,35,50,51,53-55,68,74,76,82] met all study quality criteria, and a summary of their results is shown in Table 5.

Discussion

The number of economic evaluations of CAM has increased in recent years, even if we only count full evaluations of alternative therapies. Study quality has also increased, and although reporting quality can use improvement, it is on the whole similar to that seen in economic evaluations of conventional medicine. Nevertheless, there are still too few good quality evaluations to draw many conclusions about the cost-effectiveness of specific CAM therapies for particular conditions.

Potential reasons for paucity

A possible explanation for the paucity of studies is that there may be less of an incentive to perform economic evaluations of CAM. Consumers are already spending a large amount of their disposable income on CAM without formal proof of effectiveness or cost effectiveness. Economic evaluations are typically required for the incorporation of therapies under traditional financing mechanisms and for adjustment of coverage under these mechanisms. Therefore, the market for economic evaluation in CAM may be small due to reduced involvement of third-party payers in CAM financing.

Some CAM practitioners do not see the need for economic evaluations. An interesting study by Kelner et al [85] asked chiropractors, homeopaths, and Reiki practitioners about the need to demonstrate the effectiveness, safety and cost effectiveness of their therapies. The chiropractors agreed that high quality economic evaluations are essential to their practice, but Reiki practitioners could see no reason for this research, and the homeopaths were divided on these issues. There may be good reason why some practitioners resist economic evaluation. If studies are performed that show economic benefit of CAM therapies, third party reimbursement may follow which could reduce practitioner autonomy. Coverage may also be restricted to the standardized forms of botanical medicines, nutritional supplements, or protocols used in the studies [86]. This could dramatically change how CAM is practiced by decreasing the use of multidimensional multicomponent interventions, by institutionalizing care into conventional health care systems, and by limiting the individualization of care.

Relative quality of evaluations

The reporting quality was poor for certain items, but was comparable to the quality found by systematic reviews of economic evaluations in conventional medicine [6,83,84]. Although the *BMJ* checklist was mostly objective (ie, required the least amount of judgment compared to the other checklists available), a fair amount of interpretation was still required for many items. For example, in our review we interpreted Item 1 as whether the study stated either a specific research question or study objectives in terms of economic and health outcomes. Three-quarters of the full economic evaluations of CAM met this criterion. However, in Jefferson et al, 1998 [83], only 16% of the 43 economic evaluations of conventional medicine reviewed where identified as fulfilling Item 1. It is likely

Table 5: Summary of the results of complementary and alternative medicine (CAM) economic evaluations with exemplary study quality

	CAM Therapy Compared to Usual Care*	Patient Population	Form of Economic Evaluation	Health Effects of CAM Compared to Usual Care†	Cost of CAM Compared to Usual Care†
Liguori et al, 2000 [32]	Acupuncture	Patients with migraine	CEA	**Better**	**Lower‡**
Wonderling et al, 2004 [35]	Acupuncture	Patients with chronic headache	CUA	Better	Higher‡
Paterson et al, 2003 [34]	Acupuncture	Patients with dyspepsia	CEA	Similar	Similar
	Homeopathy		CEA	Similar	Similar
Korthals-de Bos et al, 2003 [27]	Manual therapy	Patients with neck pain	CEA CUA	**Better** **Similar**	**Lower¶**
Brefel-Courbon et al, 2003 [50]	Spa therapy	Patients with Parkinson's disease	CEA	**Similar**	**Lower**
Van Tubergen et al, 2002 [51]	Combined spa-exercise therapy	Patients with ankylosing spondylitis	CEA CUA	Better Better	Higher¶
Tusek et al, 1999 [53]	Complementary guided imagery	Cardiac surgery patients	CEA	**Better**	**Lower**
van Dixhoorn and Duivenvoorden, 1999 [54]	Complementary relaxation therapy	Patients with previous myocardial infarction	CEA	**Better**	**Lower**
Jacobsen et al, 2002 [55]	Complementary professionally-administered stress management training	Cancer patients undergoing chemotherapy	CEA	Similar	Higher‡
	Complementary self-administered stress management training		CEA	**Better**	**Lower‡**
Franzosi et al, 2001 [25]	Complementary omega-3 polyunsaturated fatty acids	Patients with recent myocardial infarction	CEA	Better	Higher
Smedley et al, 2004 [68]	Complementary preoperative and post operative oral nutritional supplementation	Patients undergoing lower gastrointestinal tract surgery	CEA	**Better**	**Similar**
Norris et al, 2004 [56]	Potassium-rich diet	Postoperative cardiac patients	CEA	**Similar**	**Lower**
Ryan and Gevirtz, 2004 [76]	Biofeedback-based psychophysiological treatment	Patients with "functional" disorders (e.g., irritable bowel syndrome)	CEA	**Better**	**Lower**
Larsen et al, 2002 [82]	Complementary custom-made biomechanical shoe orthoses	Recent military conscripts	CEA	Better	Higher

Bold entries indicate that the CAM therapy was shown to be clearly superior to (dominate) usual care.
CEA = cost-effectiveness analysis; CUA = cost-utility analysis
* The use of the term "complementary" in this column indicates CAM therapies used in addition to usual care.
† If tests of statistical significance were performed, costs must be significantly higher or lower (and health effects significantly better or worse), or they were considered "similar."
‡ This study used both a societal and an institutional perspective, and the results were in the same direction.
¶This study used a societal perspective only. All other studies used an institutional perspective only.

that Jefferson et al took a more restrictive interpretation of this quality criterion.

Several studies have shown that at least some aspects of quality in economic evaluations improve over time [6,87]. Our findings suggest a trend of quality improvement in these studies in CAM. We found that 69% (27 of 39) of the cohort of full economic evaluations collected cost data prospectively as compared to 45% (5 of 11) in White and Ernst's review. Similarly, we found that 54% (21 of 39) of our studies used randomization to create the comparison groups as compared to 45% (5 of 11) in White and Ernst's review.

We found that 14 (36%) of full economic evaluations met all four study quality criteria and were identified as exemplars. However, the evidence from these criteria must be interpreted cautiously; meeting all study quality criteria does not guarantee an adequate study design. Some aspects of what makes a good pragmatic trial could not be judged by what was reported. For example, pragmatic trials enroll patients typical of normal caseload in typical

settings with average physicians following them under routine conditions [10]. Judgments as to whether these criteria were met were not possible because of vague reporting. It is also not generally agreed across all health economists that a pragmatic trial, even a well-designed one, can fully represent the real world of health care. These economists advocate for the collection of cost data using an observational study design.

A study may also be of "poor" quality because it applied the CAM therapy inappropriately. This can happen when a study is designed by researchers not familiar with a therapy. In response to this problem researchers and practitioners of several CAM therapies have begun development of standards for research and reporting. Reporting standards do not guarantee that the therapy was used appropriately, but they at least allow determination of what was done. One such set of reporting standards are the STRICTA recommendations for acupuncture [88]. Of the four full evaluations of acupuncture, two (one of which was included in Table 5[32]) met STRICTA reporting standards. As these types of guidelines are not yet available for all CAM therapies, we did not assess whether CAM therapies were applied appropriately in the studies reviewed.

Cost-effectiveness of CAM

The exemplary studies summarized in Table 5 indicate that a number of CAM therapies may be considered cost-effective compared to usual care for a number of conditions: acupuncture for migraine, manual therapy for neck pain, spa therapy for Parkinson's, complementary guided imagery for cardiac surgery patients, complementary relaxation therapy for patients with previous myocardial infarction, complementary self-administered stress management for cancer patients undergoing chemotherapy, complementary pre- and post-operative oral nutritional supplementation for lower gastrointestinal tract surgery, potassium-rich diet (rather than potassium supplements) for postoperative cardiac patients, and biofeedback for patients with "functional" disorders such as irritable bowel syndrome. Acupuncture and homeopathy were both found to be equivalent in terms of effects and costs to usual care for dyspepsia. The attractiveness of the other CAM therapies shown in Table 5 depends on whether the increased health benefits are worth the additional cost, or whether other aspects of the therapy make them attractive, such as patient preference. Only one of the studies summarized in Table 5 reported results of a CAM therapy being dominated by (clearly inferior to) usual care. The use of professionally-administered stress management for cancer patients undergoing chemotherapy was shown to have higher costs, but no additional health benefits over usual care. It is important for CAM that this contradictory evidence is also known for best clinical practice and the efficient use of CAM resources.

On the surface one might expect that therapies that substitute for usual care (alternative medicine) would be much more likely to be cost effective. In this sample of exemplar studies, of the nine study comparisons where CAM therapies were shown to be superior to usual care (better effects and lower costs, similar effects and lower costs, or better effects and similar costs), four were studies of complementary therapies. Therefore, there is evidence that even though complementary therapies are given in addition to usual care, they can improve clinical outcomes without increasing costs.

Issues specific to the economic evaluation of CAM

In many ways the economic evaluation of CAM therapies is similar to that of conventional medicine. However, there are a number of issues specific to CAM that must be considered. These issues can roughly be divided into three groups: those involved with the impact of economic evaluation on CAM in general, those involving the estimation of health outcomes (ie, issues involved with estimating the efficacy or effectiveness of CAM), and those specific to CAM's economic and humanistic outcomes. The first group of issues has already been addressed above under the potential reasons for paucity.

The methodological challenges involved in determining the clinical effectiveness of CAM have been discussed at length in a number of papers. These include the appropriateness of population-based studies when individualized treatments are used and individualized outcomes are expected [89-91], reductionist focus on one therapy for one outcome when that therapy comes from a holistic healing system [92-94], the difficulties with blinding when no appropriate placebo is available [94,95], and the requirement for randomization when most CAM users have strong preferences for their therapy of choice and will often either refuse to be randomized, or will bypass the randomization if it is not to their liking [94]. These challenges are relevant to economic evaluations since they are dependent on effectiveness studies for health outcomes. Also since humanistic and economic outcomes are ideally measured alongside health outcomes in the same trials [1,4,19,20], the challenges above are also relevant to their measurement.

However, there are several additional issues specific to CAM humanistic and economic outcome measurement which must be considered. First, although CAM therapies can be used to treat acute conditions, they are more commonly used to treat chronic disease, to prevent future disease (risk reduction), and to optimize health and well-being. Using CAM for those indications requires that long

term studies be performed [96]. However, there are a number of challenges inherent in long term studies in addition to the increase in cost (eg, increased loss to follow-up through patient attrition) [97]. In our systematic review we found only two clinical trials that followed patients prospectively longer than one year: a five-year study of relaxation therapy for patients with a previous myocardial infarction [54], and a 3.5-year study of n-3 PUFA as secondary prevention for patients with previous myocardial infarction [25].

Economic evaluations in CAM must recognize that the process of healthcare itself can be effective for patients. Attributes of the process of using CAM that may have value include patient empowerment, the operationalization of patient preference for a particular type of intervention, the length and process of the consultation, and still having treatment options open when other medical approaches have failed [4,98]. Therefore, economic evaluation of CAM needs to measure and include this value where appropriate.

Optimizing health, maximizing wellness, and enhancing well-being are patient-centered outcomes – ones that by definition require subjective measurement [99]. Economic evaluation of CAM must include appropriate measurement of these humanistic outcomes to account for the full value of CAM therapies. Our systematic review found five studies where humanistic outcomes were captured. The more well-known instruments used to measure health status in these studies included the SF-6D [35] and the EuroQoL (EQ-5D), and health status was translated into quality of life units using population-based preferences [27,51]. Sensitivity of these instruments to the changes in quality of life is an important concern for the evaluation of CAM therapies. Although the use of the EuroQoL for manual therapy for neck pain [27] resulted in a statistically insignificant change in quality of life, two other studies demonstrated small, but statistically significant differences in quality of life using the SF-6D for acupuncture for chronic headache [35], and using the EuroQoL for spa therapy for ankylosing spondylitis [51]. Therefore, it is possible to measure a change in humanistic outcomes for CAM therapies with these instruments.

The collection of economic outcome data is complicated by that fact that in the United States and other countries many CAM therapies are available over the counter and/or are often paid for out-of-pocket. The lack of administrative claims data on CAM therapies in countries where these costs are not covered or reimbursed means that cost studies require primary data collection (eg, patient self-report instruments) [100]. In their study on manual therapy for neck pain, Korthals-de Bos and colleagues used weekly cost diaries to obtain economic outcomes [27]. The second, related challenge is that many over-the-counter products, such as certain botanical medicines and nutritional supplements, are not standardized and of inconsistent quality. Standardization and quality will affect both the costs of the therapy and its outcomes. Finally, since there is often no provider "gatekeeper" controlling access to CAM therapies, monitoring of patient use can be complicated and labor intensive.

Recommendations for future research

Despite the challenges described for economic evaluations of CAM therapies, these studies ought to be done. Every planned trial of CAM therapies should at least consider the feasibility of including an evaluation of economic impacts. Observational studies should also include these data, and as information accumulates regarding economic impacts, these costs and cost savings can be estimated more accurately. Although in the ideal every cost category shown in Table 2 should be measured and outcomes should include a measure of quality-adjusted life-years, the estimation of direct medical costs and savings associated with the therapy (eg, practitioner fees, lab fees, and the cost of herbs or other supplements prescribed) will be fairly straightforward for most studies, and the planned primary outcome of the study can serve as the measure of effects to determine cost effectiveness. Even if the clinical outcomes of a CAM therapy are similar or slightly less beneficial than those of usual care, a lower cost of care can still make these therapies attractive to decision makers. However, if no cost data are available, even highly effective therapies can be easily overlooked.

Limitations

The limitations of this study are similar to those of the other reviews. First, the reader was not blinded to journals and article authors, which may have influenced results. Second, our measures of study quality depend on the information reported in an article, and no attempt was made to judge the merits of clinical or modeling assumptions made in the analyses. Third, only one reader read all the papers and extracted all the data. This may have lead to inaccurate reporting of results, and/or a biased interpretation of study quality. To maximize accuracy, data extraction was performed at least twice for each paper with several months break between extractions. Also, the approach and assumptions used to determine study quality were discussed at length with the other authors. These discussions led to a homogeneous approach being taken to both the application of the reporting quality criteria and the definition as to what constitutes an economic evaluation.

Conclusion

As health care costs continue to rise, decision makers must allocate their increasingly scarce resources toward thera-

pies which offer the most benefit per unit of cost. Economic evaluations inform evidence-based clinical practice and health policy. To be considered by these decision makers, CAM therapies and their outcomes must be known and compared to conventional approaches. However, CAM practitioners must themselves decide whether the cost of performing these studies is worth the potential impacts to their profession of being considered in managed care. Nevertheless, these evaluations will be done and they will be better done with practitioner involvement. Whereas the number and quality of these studies has increased in recent years and more CAM therapies have been shown to be good value, there are still not enough studies to measure the cost effectiveness of the majority of CAM. If CAM providers wish to increase the provision of therapies to improve population health, they must report the potential outcomes of CAM therapies widely and well.

Competing interests

The author(s) declare that they have no competing interests.

Authors' contributions

PH had the main responsibility for the manuscript and for bringing together the concepts of CAM and economics. PH also read and evaluated the quality of all papers included in the review. BC ensured that the health economic concepts were presented appropriately. PH and OC conceived the idea for the paper. OC contributed clinical and methodological insights. All authors read and approved the final manuscript.

Additional material

Additional File 1

Descriptions of included studies ordered by complementary and alternative medicine (CAM) modality, form of economic evaluation, and publication date. The appendix contains a table summarizing each of the 56 economic evaluations found in the systematic review. For each evaluation the following are reported: therapies compared, study population, study design and sample size, whether it was a full or partial economic evaluation, form of the evaluation, perspective, and summary results.

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