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rt from the Minnesota Department of Health

# Immunization Law Study

# A Report and Recommendations on Immunization Policy in Minnesota

January 15, 1997 Minnesota Department of Health Acute Disease Prevention Services Section



RA 638 .146 1997



## Minnesota Department of Health

121 East Seventh Place P.O. Box 64975 St. Paul, MN 55164-0975

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February 21, 1997

Scott Giebink, M.D. Professor and Vice-Chair, Department of Pediatrics University of Minnesota School of Medicine 420 Delaware Street SE, 850 Mayo Building Minneapolis, Minnesota 55455

Dear Dr. Giebink:

Thank you for your thorough and thoughtful report on the immunization policy in Minnesota. I appreciate the crucial involvement of the task force on Immunization Practices in this report, and value the input and perspectives of the many partners represented on the task force.

As you know, the timing of this report means that the report's recommendations could not be part of the Governor's budget for 1997. However, they will help to shape future immunization activities and policies of the Department, and hopefully of other organizations as well. It also provides valuable context for the two immunization-related bills in the Legislature this session.

Again, I extend my thanks to you and all the task force members for your considerable work and for sharing your expertise with the Department of Health.

I ask for your continued support as we work together to promote immunizations across the lifespan for all Minnesotans.

Sincerely,

Anne M. Barry

Commissioner



717 Delaware Street Southeast Minneapolis, MN 55440-9441

February 14, 1997

Ms. Anne Barry, Commissioner Minnesota Department of Health 717 South East Delaware Street Minneapolis, Minnesota 55440

Dear Commissioner Barry:

I am pleased to forward for your approval the recommendations contained in the enclosed Immunization Law Study. This report and the accompanying recommendations were developed by the Commissioner's Task Force on Immunization Practices in response to a request from the 1996 Minnesota Legislature. The task force gratefully acknowledges the considerable Department staff support provided in developing this report.

The task force took this opportunity to thoroughly discuss and examine the many and increasingly complex issues surrounding immunizations across the lifespan. The resulting report and recommendations represent the balanced perspectives of clinical practitioners, school nurses, public health agencies, payors, and others.

The final recommendations to the Commissioner include:

- changes to Minnesota's school immunization law;  $\succ$
- ➤ legislative funding to support:
  - schools in administering and enforcing the school immunization law; ►
  - school-linked immunization clinics for adolescent immunizations;
  - matching grants to regions establishing community-based immunization registries;
  - grants to Community Health Boards to sustain local immunization initiatives; and
- > future professional and consumer education activities for the Department.

The funding recommendations are based upon critical activities that occur in the public sector, or where the State is an important partner but not currently contributing State funds. Please note that State funding is currently less than 1% of the total immunization program funding in Minnesota.

I hope and anticipate that these recommendations will merit your full approval and support.

Sincerely,

Scott Giebink, M.D.

Chair, Immunization Practices Task Force and Professor and Vice-Chair, Department of Pediatrics University of Minnesota School of Medicine

# **Immunization Law Study**

# January 15, 1997

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# **Acknowledgments**

We would like to thank the members of the Commissioner's Task Force on Immunization Practices for their time and effort to review the issues and make recommendations for this report. We also acknowledge the support of MDH staff who have helped write, review and offer suggestions on this document.

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# **1996 Immunization Law Study**

Minnesota Department of Health

# **Executive Summary**

### **Purpose of the Study**

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By January 15, 1997, the commissioner of health shall report recommendations to the legislature and governor relating to Minnesota immunization law and policy regarding vaccine-preventable diseases for which immunization is not currently required by law, including but not limited to hepatitis A, hepatitis B, varicella, and other vaccine-preventable diseases identified by the commissioner.

Minnesota Laws 1996, Chapter 451, art. 4, sec. 62

### Introduction

In 1996, the Commissioner of Health asked the Task Force on Immunization Practices to assist the Department of Health in conducting a study of Minnesota immunization law and policy, and in developing recommendations for future initiatives. Members of the task force are listed on the acknowledgment page.

The final report and recommendations are based on a review of state and national data, including current and historic data on the occurrence of vaccine-preventable diseases, prevention activities and immunization rates statewide, and information derived from the clinical and professional experience of task force members.

## Background

Immunization is among the most cost-effective disease prevention strategies available to public health and preventive medicine. In terms of its impact on human health, immunization is comparable to such basic measures as safeguarding the quality of our drinking water. The widespread use of vaccines as part of routine preventive health care has led to dramatic reductions in morbidity and mortality from vaccine-preventable diseases such as Measles, Mumps, Rubella, Diphtheria, Tetanus, Pertussis, Hemophilus Influenza, Hepatitis B, and Polio.

Immunization laws provide an important mechanism for preventing disease outbreaks in settings where children, adolescents, or adults congregate and can spread disease—including schools and child care facilities. State laws requiring immunization of school children are in effect in all 50 states. Minnesota's immunization law currently covers licensed child care facilities, kindergartens, elementary and secondary schools, and post-secondary schools.

## **Immunization Law and Policy Issues**

Approximately 67,000 births occur each year in Minnesota. These children are currently recommended to receive 17 separate doses of vaccine between birth and age six, often requiring six or more clinic visits. The vaccines are delivered by approximately 800 private and public clinics across the state. The Minnesota Department of Health (MDH) estimates that 85 percent of childhood immunizations are delivered by providers in the private sector, six percent by the public sector, and the remaining nine

1996 Immunization Law Study

Executive Summary – Page ii

percent by a combination of public and private providers. There are also recommended immunizations for adolescents, and for adults throughout the lifespan. Additional immunizations may be needed for some occupational groups, and for international travel.

Parents, private health care providers, health plans, schools and local and state public health are all important parts of the immunization delivery system in Minnesota. This system has achieved dramatic reductions in vaccine-preventable disease rates in our state. However, although we are making progress toward the Year 2000 goal of achieving 90 percent immunization levels, the system is struggling to cope with the introduction of new vaccines, the growing complexity of the immunization schedule, and the very complex task of managing immunization data. In a 1995-96 statewide retrospective study of 1085 kindergarten enterers, only 71 percent were up-to-date for the primary series of immunizations (4 DTP, 3 Polio and 1 MMR) by the age of two.

Historically, 99 percent of the funds used to support statewide public health immunization programs, and to purchase vaccines for those who lack insurance coverage, have come from the federal government. A decrease in federal funding has been announced for 1998. Unless alternative funding is obtained from the state or other sources, it may be necessary to eliminate a number of community programs, and to forego new initiatives designed to sustain current immunization levels.

Without action on the recommendations in this document, it is unlikely that the year 2000 goal will be met statewide. This report addresses recommended changes in the school and day care immunization laws, and related policy and delivery system issues, which are essential to maintaining this critical disease prevention system.

#### **Recommendations of the Task Force to the Commissioner of Health**

Based upon its study, the task force offers the recommendations beginning on the following page to the Commissioner of Health:

Beginning During the 1997 Session								
Issue	Legislative Action	Appropriation Needed	Rationale					
Tetanus–Diphtheria	Amend M.S. 123.70 to include clarifying language on how to manage students who received Td at <11 years of age.	None	Current law does not allow for deferring Td booster even though it may be medically not indicated.					
Vaccines	Establish a state fund to purchase vaccines for under-insured children if federally-supplied vaccines are not adequate or in emergencies.	\$350,000 one time appropriation	Current federally-purchased vaccines are sufficient to cover all under-insured Minnesota children, for 1997, increased cost of vaccines and uncertain levels of future federal support will lead to shortfalls.					
	Funding for vaccines for jr. high students in school-linked immunization clinics.	\$700,000 annually	School-linked immunization clinics are the most efficient means to provide required adolescent immunizations but no means currently exists to supply vaccines to all students.					
Schools	Provide funds for assuring compliance with school immuni- zation laws	\$ 1,772,000 annually	Schools are devoting increasing effort to enforcement of the immunization law.					
•	Funds for administering school-linked immunization clinics.	\$ 978,000 annually	School-linked immunization clinics are the most efficient way to provide required adolescent immunizations but no reimbursement mechanism exists for staff time in administering the vaccines and for record keeping.					
Community Immunization Programs	Replace reduced federal funding for local immunization programs.	\$1,500,000 annually	Support is needed for community coalitions so they can continue assessing and addressing local barriers to age- appropriate immunizations.					

1996 Immunization Law Study

Minnesota Department of Health

Beginning During the 1997 Session (cont.)								
Issue	Legislative Action	Appropriation Needed	Rationale					
Community-based Immunization Registries	Provide matching funds to support start-up and operations of community-based immunization registries.	\$ 5,000,000 annually	Start-up and operation costs are a significant barrier to establishment of community- based immunization registries.					
	Provide funds for training, consultation, education, planning, technical design and implementation of a state hub to electronically link community-based immunization registries.	\$1,500,000 annually	A state hub is required to link regional community-based data and to conduct statewide population-based assessments.					

For Action During the 1998 Session							
Issue	Legislative Action	Appropriation Needed	Rationale				
Hepatitis B	Add to school law for children entering kindergarten, effective 1999-2000.	None	Hepatitis B vaccine is part of national and state recommendations for routine childhood immunizations. Less costly to immunize pre- schoolers than adolescents.				
Varicella (Chickenpox)	Re-examine the possibility of including in school law for children entering kindergarten.	None	Varicella vaccine is included in national and state recommendations for routine childhood immunizations. Most children have natural chickenpox disease prior to kindergarten.				
Universal perinatal screening for hepatitis B	Add to any future comprehensive pre-natal screening legislation.	None	Screening for maternal hepatitis B infection is part of recommended pre-natal screening.				

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#### Conclusion

Existing immunization delivery systems and current immunization laws have been very effective at reducing the occurrence of vaccine-preventable diseases in Minnesota. However, we need to launch new initiatives in the area of immunizations—backed by appropriate legislation—if we are to maintain these past achievements. We need to take action if we are to assure the future health and safety of Minnesota's people, and protect them from costly, potentially fatal, and highly preventable diseases. Increasingly complex vaccine schedules, a changing health care system, decreasing federal dollars, and expanded international travel have all served to place our citizens at greater risk for vaccine-preventable disease. This increase in risk applies to adolescents and adults, as well as children. If we are to sustain our past achievements—and continue to provide protection to the public through an effective program of immunization— we need to enlist the help of the entire community. We need to forge a broad public partnership that includes parents private health care providers, health plans, schools, and the public health community.

# I. Background on Immunization in Minnesota

#### A. Introduction

In 1796, Edward Jenner inoculated the first person against smallpox. Within 185 years, this deadly and feared disease was eradicated from the globe. Fifty years ago, a vaccine to prevent poliomyelitis was developed, and the world is now within reach of eradicating its second disease.

Immunization is among the most cost-effective disease prevention strategies available to public health and preventive medicine. In terms of its impact on human health, immunization is comparable to such basic measures as safeguarding the quality of our drinking water. The widespread use of vaccines as part of routine preventive health care has led to dramatic reductions in morbidity and mortality from vaccine-preventable diseases (see Table 1 below).

Table 1. Comparison of Maximum and Current Reported Morbidity ofVaccine-Preventable Disease in Minnesota, 1995									
Disease Maximum Cases (year) 1995 Percent Chang									
Diphtheria	5,012 (1910)	0	-100.0						
Measles	29,759 (1935)	9	-99.9						
Mumps	2,080 (1955)	11	-99.5						
Pertussis	5,272 (1933)	237	-95.5						
Polio	3,926 (1952)	0	-100.0						
Rubella	3,232 (1964)	0	-100.0						
Tetanus	Tetanus 40 (1923) 3 -92.5								

In 1944, the Minnesota State Board of Health created a Division of Preventable Diseases, charged with the following duties:

- "(1) To record, tabulate, and study official reports of communicable diseases with the State, to check the completeness of official returns, and to investigate unofficial reports.
- (2) To make investigations of the existence, prevalence, sources, and modes of spread of all these diseases within the State.
- (3) To supervise the adequacy of local administrative measures in dealing with the control of preventable disease.
- (4) To make special investigations of problems whose solutions may prove of value in conserving public health or in the advancement of science.
- (5) To produce and furnish or administer biological preparations for therapeutic and prophylactic use:
  - (a) for the treatment of diphtheria; pneumonia; epidemic, pneumococcic and H. influenza (type b) meningitis; and whooping cough in children under 18 months;
  - (b) for the passive immunization of persons exposed to diphtheria and children under age 18 months exposed to measles;
  - (c) or active immunization against smallpox, diphtheria, tetanus, typhoid fever, and whooping cough; and
  - (d) for the determination of immunity against or susceptibility to diphtheria."

# How do immunizations prevent disease?

Immunizations provide protection at two levels.

Individual protection from vaccine-preventable diseases occurs when a vaccine stimulates a person's immune system to produce anti-bodies to an infectious agent.

Group protection occurs when routine, universallyadministered immunizations provide sufficient "herd immunity" in a population that infectious agents cannot find enough susceptible hosts to replicate in and create outbreaks of disease. Creating this new Division was in part driven by Minnesota's success in lowering disease by distributing increasing numbers of free vaccines and serums between the 1920's and the 1940's. In 1924-1925, Minnesota experienced an epidemic of smallpox that took a heavy toll of lives, especially in Minneapolis where 365 persons died in an 18 month period. At the time, Minnesota did not have a compulsory law for smallpox vaccinations, as did many other states. By 1943, through the distribution of free vaccines, Minnesota had its first 12 month period free of any smallpox.

Smallpox is now officially eradicated in the entire world—the first disease to be completely conquered. Global efforts are intensifying to eradicate polio by the year 2000, and measles eradication campaigns are also underway around the world. These historic and massive efforts are possible because of safe and effective vaccines, laws requiring immunizations in susceptible populations, and organized community efforts to distribute and administer vaccines to those who need them.

Unfortunately, the very success of immunizations has become perhaps its greatest current challenge—maintaining provider, parental and community commitment to high immunization coverage levels in the face of little or no apparent disease. Maintaining this commitment was considerably easier when vaccine-preventable diseases were feared in communities across the country, and to be immunized was seen as part of an individual's civic duty. Today's parents are more likely to be concerned with vaccine safety than with any risk of natural disease.

New vaccines and combination vaccines are being developed at an unprecedented rate. More vaccines were introduced in 1996 than the entire decades of the 1970's and 1980's (see Table 2 on the next page). Providers and parents alike are becoming increasingly confused as the simplicity and clarity of earlier vaccine schedules is being replaced with a complex table of vaccines and extensive footnotes. And there is increasing debate about the cost, risk, and benefits of adding new vaccines to the routine schedule and to state immunization laws.

The recommendations for routine immunizations are issued nationally by three expert groups—the U.S. Public Health Service Advisory Committee on Immunization Practices (ACIP) for the public sector, and the Committee on Infectious Diseases of the American Academy of Pediatrics (AAP) and the American Academy of Family Physicians for the private sector. The Minnesota Department of Health (MDH), through its Commissioner's Task Force on Immunization Practices, reviews these recommendations and, where necessary, makes modifications before releasing them for use by Minnesota providers (see Attachment A for the 1996 Minnesota Immunization Schedule).

Table 2. Changes in Recommended Vaccines Over Time						
Year	Year New vaccines/New Doses					
1970–1979	None	0				
1980–1989	Hib vaccine for toddlers 2nd dose of MMR	1 1				
1990–1995	Infant Hib Hepatitis B DTaP Combination DTP–Hib	3-4 3 2* 3				
1996	Infant Varicella Adolescent & adult varicella Hepatitis A DTaP Combination HBV–Hib	1 2 2 3 <sup>§</sup> 3				

\* Substitute for doses 4 and 5 of whole cell DTP vaccine

§ Substitute for doses 1 through 3 of whole cell DTP vaccine

#### **B.** Current Immunization Coverage Levels in Minnesota

"By the year 2000, create a system that ensures that all geographic areas, racial and ethnic groups, and socio-economic strata receive age-appropriate immunization against diphtheria, tetanus, pertussis, poliomyelitis, measles, mumps, rubella, Haemophilus influenza type b, and hepatitis B such that 90% of the children are up-to-date when measured within two months of the date(s) on which they were to be vaccinated." Minnesota's Immunization Goal for the Year 2000

The most recent immunization coverage level data for Minnesota comes from a national random digit dialing telephone survey conducted by the Centers For Disease Control and Prevention (CDC). For the period July, 1994 through June, 1995, CDC reported estimates for Minnesota immunization levels among children aged 19–35 months as:

- 79 ± 5.2% for 4 DTP, 3 polio, and 1 MMR (4:3:1)
- 78 ± 5.2% for 4 DTP, 3 polio, 1 MMR, and 3 Hib (4:3:1:3)
- 93 ± 3.3% for 3 Hib
- 93 ± 3.2% for MMR
- $31 \pm 5.5\%$  for 3+ HBV (among the nation's lowest HBV rates)

The levels have been steadily increasing in Minnesota, as in the rest of the country. The nationwide measles outbreak in 1989-1991 contributed to improved immunization coverage. This outbreak involved >55,000 cases and >130 measles-related deaths, and shook the nation's complacency about vaccine-preventable diseases. After that frightening reminder, childhood immunizations became a popular political issue in Washington, in state government throughout around the country, and among vocal child advocacy groups calling for dramatic action to increase immunization levels.

Minnesota, which had 462 cases and three deaths from measles in the outbreak, conducted a statewide study in 1992-1993 to look at immunization levels of all children entering kindergarten. The study involved the Minnesota Department of Health, local health departments, and schools. Its unique feature was to examine immunization data, not just by completion of the required vaccines by 24 months of age, but by specific vaccines, month of age (0–48 months of age), kindergarten schools, and in inner city Minneapolis and St. Paul, by zip codes.

The study revealed a number of important findings:

- Most children received their first doses within two months of the recommended age but tended to fall behind on subsequent doses. Eventually, by the fourth year of life, almost all children were up-to-date *due to child care and school immunization laws*.
- While the overall immunization coverage level at 24 months of age was disappointingly low (61%), most children had received enough early doses to prevent or minimize transmission of many of the vaccine-preventable diseases during their most vulnerable period of life.
- Every community had pockets of under-immunized children. Even though the 1989-1991 measles outbreak had been a largely urban experience, even rural communities had the potential for an outbreak of vaccine-preventable disease.
- Disturbingly, every community also had children that did not start their immunization series until late in their first year. Many of these children may have also not been receiving timely well-child care and developmental screening.

This statewide study of kindergarten immunization levels is being repeated during the 1996-1997 school year.

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# II. History of Immunization Laws, Requirements and Recommendations in Minnesota

#### A. Laws as a Disease Control Strategy

The use of laws to prevent communicable disease outbreaks is one of the most powerful tools available to public health. The ability to use laws and regulations for public health purposes derive from a combination of government's police powers and its responsibility "to protect the health and welfare of the people."

Immunization laws provide an important mechanism for preventing disease outbreaks in settings where children, adolescents and adults congregate and can spread disease—including schools and child care facilities. State laws requiring immunization of school children are in effect in all 50 states, the District of Columbia, and Puerto Rico. These statutes have been upheld as constitutional, despite objections that they interfere with parental rights of privacy in child-raising<sup>1</sup>.

#### B. Child Care Immunization Law—Purpose, Monitoring, and Implementation Issues

#### Purpose

Nearly 80,000 children were enrolled in the state's 1,400+ licensed child care centers throughout Minnesota in 1995-96, and another unknown number may be enrolled in one of the state's 14,000+ licensed day care homes. Assurance of age-appropriate immunization is especially important for children in child care settings because preschool-aged children are at higher risk for complications from most vaccine-preventable diseases. Because of their enrollment in day care, these children have additional opportunities outside the home environment to come in contact with infectious agents to which they may be susceptible.

History of immunization requirements for child care centers:

- 1973: measles and rubella required
- 1978: polio, DTP, and mumps added
- 1988: annual reporting of summary data to DHS/MDH added
- 1992: Hib added

#### Monitoring

Current law requires annual reporting from each of the state's 1,400+ child care centers. These reports reflect summary data only and enable the MDH to tabulate the overall immunization levels for all enrollees except infants. Centers that do not respond to the reporting requirement receive individual follow-up from the DHS licensing consultants. The charts on the next page show the results of the surveys.

Compulsory Immunization Statutes, JAMA, May 20, 1974, Vol.228, No.8, pages 1059-1060.



The data are also compiled in county-specific reports and sent to the respective county public health agency. Local public health personnel are invited to review the findings and provide consultation where needed.

#### Implementation Issues

- Documentation: Some child care centers do not regularly communicate with parents about the need to provide updated information to the center as their child receives additional shots; consequently, the center's records do not adequately reflect the child's immunization status.
- Enforcement: The primary enforcer of these requirements is either the center director or day care home provider. Day care homes are licensed by the county under Rule 2; child care centers are licensed by the state under Rule 3.

# C. Elementary and Secondary School Immunization Law—Purpose, Monitoring, and Implementation Issues

#### Purpose

As with child care facilities, the mingling of large numbers of children in schools presents a communicable disease risk. The School Immunization Law requirements reduce that risk by requiring all children entering kindergarten and secondary school to be fully immunized against select and usually highly contagious diseases.

The origins of the School Immunization Law date back to 1967 when the law required proof of immunization against measles prior to initial enrollment. Further amendments to the law were as follows:

- 1967: measles required
- 1973: rubella (German measles) added
- 1978: polio series, DTP series, and mumps requirements added
- 1980: requirements expanded to K-12 enrollees
- 1992: second dose of MMR required for secondary students, to be phased in over the subsequent five years
- 1996: booster doses of Td for adolescents required for secondary students, to be phased in over the subsequent five years

#### Monitoring

All elementary and secondary schools are required to submit summary data to the Department of Children, Families and Learning (%MDH) that reflect the number of students enrolled, the number of students who are not immunized according to the law's requirements, and the number who have a legal exemption. MDH staff compile the individual school data into reports that includes both statewide and school district results which are sent to all school superintendents. Separate reports with county-wide data, comprised of school district data from within each county, are sent to local public health agencies.

MDH and local public health agency staff audit immunization records on a random sample of schools to validate the data originally submitted. The audits over the years consistently show excellent compliance with the law.

#### Implementation Issues

- Schools currently spend considerable time each year assembling student immunization records, locating lost records, and referring and following-up on non-compliant students. While achieving immunization high levels is a public health goal, much of the implementation and enforcement of the immunization law falls to schools—and more specifically, school nurses—without any corresponding funding to support implementation. In many schools, the majority of the school nurses time is spent in immunization follow-up. If funding were provided for this activity, school districts could hire additional school nurses to implement and enforce the immunization law requirements, while preserving the role of school nurses in other important areas.
- Many large school districts have reduced staff significantly over the years such that some school nurses cover multiple building sites. Smaller school districts may not employ any school nurses but rather rely on para-professional staff to handle health-related duties. The current immunization schedule and recommendations are too complex for non-nursing staff.
- In the school setting, only Registered Nurses should be responsible for:
  - assessment of a student's specific need for immunizations;
  - reviewing potential contraindications to any immunization;
  - providing education to students and/or parents as needed to assure compliance with recommendations; and
  - referral to health care providers or other appropriate staff for immunizations.

These activities are within the scope of Minnesota's licensure requirements for Registered Nurses.

- International students frequently arrive without immunization records, with records that use non-English terms and are not understood by the school staff, or without having all of the required immunizations. (Note: The MDH has developed and distributed an Immunization Record for International Students. MDH also provides translation services for foreign records.)
- Schools are frequently placed in the position of being the enforcer of a medical practice issue. If a particular practice is not widely accepted in the community but is required by state law (e.g., Td boosters for students at 11-12 years of age), the school may receive notices from parents that their physician refused to administer the required vaccine.
- Some schools find that a phased-in approach (e.g., MMR#2 and Td booster requirements over a 5year period) is more problematic than having all affected grades covered at one point in time.

# D. Post-Secondary School Immunization Law—Purpose, Monitoring, and Implementation Issues

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#### Purpose

The occurrence of vaccine-preventable diseases on American campuses was a major health issue during the 1980s. In general, the outbreaks of disease among college students resulted in a significant amount of morbidity (e.g., nearly 10% of vaccine-preventable disease cases in 1988 involved college students), potential mortality, significant expenditures of time and resources, and disruption of usual campus activities. College students tend to be more at risk of disease because of: their close contact in dormitories, classrooms, and campus activities; their frequent travel between campuses; and domestic and international travel.

In May 1983, the American College Health Association (ACHA) adopted a Pre-admission Immunization Policy (PIR) recommending that, by September 1985, colleges and universities require all students to present documentation of immunity to measles, rubella, and other vaccine-preventable diseases as a prerequisite to matriculation or registration<sup>2</sup>. That PIR has been amended several times since and, since 1993, has been expanded to include second doses of measles-containing vaccine, a complete 3-dose series of Td plus a booster within 10 years, polio vaccine for students younger than 18 years, hepatitis B vaccine for health care students (and strongly encouraged for all students), and tuberculosis skin testing for all students living in high incidence areas in the U.S. (large cities or who have occupational exposure).

The Minnesota College Immunization Law became effective on July 1, 1990. The law applied to all students taking more than one class (or housed on campus) and who were born in 1957 or later. Basic requirements of the law included:

- Documentation of MMR vaccination given  $\ge 12$  months of age
- Documentation of a dose of tetanus-diphtheria toxoid (Td) given within 10 years of initial enrollment

In 1996, the law was amended to exempt students who had graduated from a Minnesota high school in 1997 or later (because they would presumably have met the law's requirements as secondary students).

#### Monitoring

Unlike the state's law that governs child care facilities and K-12 schools, there is no reporting requirement within the College Immunization Law. To monitor enforcement, yearly audits are conducted by Minnesota Department of Health staff. Over the five year period 1990-91 through 1994-95, all institutions were audited at least once. Compliance with the Td requirement ranged from 85.0% to 96.1% (see Table 3) and those in compliance with the MMR requirement ranged from 87.4% to 98.4% (see Table 4).

<sup>&</sup>lt;sup>2</sup> American College Health Association. Position statement on immunization policy. J Am Coll Health 1983;32:7-8

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Table 3. Tetanus-Diphtheria (Td) Immunization Status Based on           Selected Post-Secondary Student Records, Minnesota, 1990-91 through 1994-95										
	1990-	-91	1991	1991-92		1992-93		1993-94		-95
Status of Record	#	%	#	%	#	%	#	%	#	%
Date of Td within ten years	1,125	92.0	1,151	95.0	1,014	91.0	994	84.7	957	82.3
Exemption indicated: - medical - conscientious - unknown	28 (4) (1) (23)	2.3	14 (2) (6) (6)	1.1	23 (0) (6) (17)	2.1	4 (1) (3) (0)	0.3	50 (7) (3) (40)	4.3
Total records in compliance	1,153	94.3	1,165	96.1	1,037	93.1	998	85.0	1007	86.6
Date of Td > ten years	69		47		77		92		20	
No Td date given	1		0		0		84		135	
Total records not in compliance	70	5.7	47	3.9	77	6.9	176	15.0	155	13.3
Total records audited	1,223	100	1,212	100	1,114	100	1,174	100	1,162	100

Table 4. Measles, Mumps, and Rubella (MMR) Immunization StatusBased on Selected Post-Secondary Student Records, Minnesota, 1990-91 through 1994-95										
	1990-91		1991	1991-92		1992-93		1993-94		-95
Status of Record	#	%	#	%	#	%	#	%	#	%
Date of MMR >1 yr of age			1,142	94.2	1,057	94.9	1,009	85.9	986	84.9
Exemption indicated			50	4.1	39	3.5	17	1.5	60	5.2
Total records in compliance	1,082	88.5	1,192	98.3	1,096	98.4	1,026	87.4	1,046	90.0
Total records not in compliance	141	11.5	20	1.7	18	1.6	148	12.6	116	10
Total records audited	1,223	100	1,212	100	1,114	100	1,174	100	1,162	100

#### Implementation Issues

- College students, especially those enrolled in public institutions, are likely to change enrollment more frequently than students in K-12 settings or those in private colleges.
- Many colleges have established one-character fields in their automated student record to indicate compliance with the law's requirements (e.g., 1=immunization information submitted, 2=exempt, etc.) but did not automate the actual dates of immunization. Consequently, they also maintain paper files for auditing purpose.

#### **E.** Requirements of Other States

The U.S. Centers for Disease Control and Prevention compiles annual reports of state immunization requirements. In its 1994-95 report, the following highlights are included:

- All 50 states, the District of Columbia, and Puerto Rico have requirements for children in day care and/or Head Start programs.
- Eight states have added hepatitis B requirements (Idaho, Illinois, Massachusetts, New York, North Carolina, Pennsylvania, South Carolina, Virginia, )
- All 50 states, the District of Columbia, and Puerto Rico have requirements for students in elementary and/or secondary schools.
- All but nine states have requirements for second doses of MMR.
- Eight states have hepatitis B requirements for day care, Head Start, and/or school entrance.
- Thirty states, the District of Columbia, and Puerto Rico have requirements for students in colleges and/or universities (see attached map).
- Six states have requirements for premarital rubella susceptibility testing.
- Three states and the District of Columbia have requirements for prenatal rubella susceptibility testing.
- The CDC currently encourages all states and territories to have laws requiring screening for HBsAg in pregnant women. As of 1996, only eleven states and Puerto Rico have such laws.
- Twenty-eight states and Puerto Rico require reporting of HBsAg-positive women to the state health department.

# III. Vaccine-Preventable Disease Epidemiology and Prevention

The following section discusses only those vaccine-preventable diseases for which new laws or other recommendations may apply. It does not include a discussion of measles, mumps, rubella, polio, pertussis, or any of the international travel vaccines.

## A. Varicella (Chickenpox)

#### **Epidemiology**

Varicella—commonly known as chickenpox—is caused by the varicella zoster virus (VZV). Varicella is spread from person to person by direct contact or aerosols. Varicella is usually mild, starting with an itchy vesicular rash, and mild fever. Although usually not life threatening to otherwise healthy children, varicella may be severe in infants, adolescents, adults, and persons with impaired immune systems. After a chickenpox infection, persons generally have life long immunity to chickenpox and do not have a second episode of disease. However, the virus can reactivate later in life as a different problem—zoster or shingles. This is particularly likely to happen if a person has a problem with their immune system such as can occur with older age, disease, or drugs.

Varicella is endemic in the U.S. and most persons acquire varicella by adulthood. As a result, the annual number of cases should approximate the birth cohort. The majority of cases, approximately 90%, occur in children less than 15 years of age. The highest age specific-attack rates are in children 5 to 9 years of age (44% of cases).

#### Vaccine

- Varicella zoster vaccine is a live attenuated viral vaccine derived from the OKA strain of VZV.
- Varicella vaccine was licensed for general use in the U.S. in March 1995. It has been in general use in Japan and Korea since 1988.
- After one dose of vaccine, 97% of children developed detectable antibody titer.
- In Japanese studies, an estimated 97% of children had antibody when tested 7 to 10 years after vaccination. Clinical efficacy is estimated to be 95% after 7 years.

#### Target populations

#### One dose:

All susceptible children at age 12 - 18 months All unvaccinated children 18 months - 12 years without disease history

#### Two doses:

Individuals >13 years and adults without a reliable disease history and who are:

- susceptible family contacts of immuno-compromised persons;
- susceptible health care workers;
- persons with high risk of exposure (i.e. teachers of young children, daycare workers, residents/staff in institutional settings including college students, inmates/staff of correctional institutions, and the military);
- non-pregnant women of childbearing years;
- international travelers.

Vaccination of other susceptible adolescents and adults is desirable and may be offered at the time of routine health care visits.

#### Vaccine Products and Costs

Only one varicella vaccine is currently licensed, with a price range of 32.70 to 40.00. Varivax<sup>TM</sup> (Merck):

- 1996 Federal contract price \$32.70
- Private purchase price \$41.41

#### **Delivery and Implementation Issues**

#### Recommended Schedule

- Routine immunization of all susceptible children at 12 18 months of age.
- Unvaccinated children >18 months of age without a reliable disease history
- Susceptible adolescents >13 years and susceptible adults in the targeted populations described above should receive two doses 4-8 weeks apart

#### Handling and storage issues

- Extremely temperature sensitive; must be maintained at 5°F (-15°C) or colder (although can be stored on "wet" ice if used within 72 hours).
- Must be used with 30 minutes after reconstitution.
- Difficulties in maintaining proper temperature when transporting vaccine to off-site clinics
- Potential for non-viable vaccine being administered because of improper storage and/or handling

#### *Product interchangeability*

• Only one product is currently licensed for use in the U.S.

#### Other issues that could affect implementation

- Provider and parental ambivalence over whether varicella vaccination is preferable for infants and young children than natural disease.
- Storage and handing requirements may force clinics to upgrade vaccine freezers and temperature monitoring equipment.
- May shift morbidity to older ages when the disease is more serious.
- No surveillance system currently exists to monitor reductions in morbidity and possible shifts in age of cases.
- No data currently exists to indicate if a booster dose will be needed in the future. This seems to decrease consumer confidence in the vaccine.
- Adds one more "shot" to childhood immunization schedule
- Unlike other vaccine-preventable diseases, parental history of disease is considered reliable.
- May require schools to ascertain history of varicella disease or immunization history

#### Cost-benefit data

Indirect + direct medical savings = \$5.4 per dollar invested (indirect savings includes work loss, death, and disability)

(Source: National Immunization Program, 6/96)

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# **B.** Hepatitis B

#### Epidemiology

Hepatitis B virus (HBV) infection is an established cause of acute and chronic hepatitis, cirrhosis, and primary hepatocellular carcinoma. Approximately 300,000 persons in the United States become infected with HBV each year; 100,000 develop symptoms of hepatitis B. Approximately 10% of all acute HBV infections progress to chronic infection, with the risk of chronic HBV infection decreasing with age. As many as 90% of infants who acquire HBV infection from their mothers at birth become chronically infected. Of children who become infected with HBV between 1 and 5 years of age, 30-50% develop chronic infection. By adulthood, the risk of developing chronic infection is 6 to 10%.

HBV infection is transmitted through blood or body fluids such as wound exudates, semen, cervical secretions, and saliva. Blood and serum contain the highest quantities of virus; saliva contains the lowest titer.

Between 1990–1995, 591 acute cases of hepatitis B were reported in Minnesota, of which two persons died. The age range of these cases was:

- 0 17 years 5%
- 18 29 years 47%
- 30+ years 48%

The MDH has recently begun surveillance of hepatitis B carriers, who do not have acute infections but can transmit the hepatitis B virus to others who subsequently may develop acute infections.

Perinatal transmission of hepatitis B (that is, the administration of hepatitis B immune globulin at birth and subsequent immunizations failed to protect the child) involved another 17 newborns since 1990.

#### Vaccine

- A plasma-derived vaccine was licensed in the United Sates in 1981. The vaccine was safe and effective, but not well accepted. It was removed from the U.S. market in 1992.
- Recombinant hepatitis B vaccine was licensed in the U.S. in July 1986. It was the first vaccine licensed in the U.S. using recombinant DNA technology. A second recombinant vaccine was licensed in 1989.
- After three intramuscular doses of hepatitis B vaccine, over 90% of healthy adults and over 95% of infants, children, and adolescents develop adequate antibody response.
- The vaccine is 80-100% effective in preventing infection or clinical hepatitis in those who receive the complete course of vaccination.

#### Target populations

- Universal vaccination of infants (infants born to HBsAg positive mothers should receive the first dose at birth, along with HBIG; infants born to HBsAg negative mothers should receive the first dose at age 1-2 months)
- Adolescents
- Selected high risk groups :
  - Persons with occupational risk (health care workers, law enforcement personnel, lab technicians, ambulance staff, and others at risk of exposure to blood products)
  - · Clients and staff of institutions for the developmentally disabled
  - Hemodialysis patients

- Recipients of certain blood products
- Household contacts and sex partners of HBV carriers
- Adoptees from countries where HBV infection is endemic
- International travelers
- Injecting drug users
- Sexually active homosexual and bisexual men
- Inmates of long-term correctional facilities

#### Vaccine Products and Costs

Hepatitis B vaccine formulations vary depending upon age and risk status. The price ranges for these formulations are:

Pediatric: \$7.27 - \$18.00 Adolescent: \$7.75 - \$18.00 Adult: \$25.42 - \$47.97

#### **Delivery and Implementation Issues**

CDC's estimate for immunization coverage levels for hepatitis B in Minnesota is only 26% at 24 months, compared to 42% nationally.

#### Schedule/spacing/fit with current recommended schedule

- 3 dose series for everyone. Dosage varies by age of recipient and product administered
- Current schedule recommendations for infants coincide fairly well with recommendations for other vaccines (e.g. DTP, Hib, OPV). For infants of HBSAG + mothers, the coordination with the rest of the childhood schedule is not as consistent since the first dose of HBV should be given at birth and the second 1 month later and the third 6 months after the first.
- Vaccination of adolescents should begin at age 11 12 years which coincides with the recommendation for other adolescent immunizations (MMR #2, Td). The subsequent 2 doses of the 3 dose series must follow one of the following regimes: 0,1,6 months; 0,1,4 months; or 0,2,4 months.
- Vaccination of adults in selected high risk groups

#### Handling and storage issues

• All current hepatitis B vaccine products must be refrigerated and cannot be frozen.

#### Product interchangeability

- Merck & Smith-Kline-Beecham products are interchangeable
- Complicated dosing differences between products and formulations of products could lead to improper doses and insufficient antibody response.

#### Other issues that could affect implementation

- Provider ambivalence about universal vaccination of infants and adolescents.
- Parental ambivalence about the need for the vaccine, particularly since the principal risk factors are sexual activity and IV drug use.
- The need for future booster doses has not been determined.

- Flexible dosage schedules are required to effectively integrate Hepatitis B vaccine into current and future immunization programs.
- Product inter-changeability is necessary for patients who do not receive all 3 doses from the same provider
- Future combination vaccines that include HBV may increase immunization levels for hepatitis B.
- Hepatitis B vaccine is not universally available at family planning / STD clinics unless the patient is eligible for MnVFC
- State law allows minors to consent to hepatitis B immunization without parental consent.

# C. Hepatitis A

#### Epidemiology

Hepatitis A is a liver infection caused by the hepatitis A virus (HAV). In 1993, 24,238 cases of hepatitis A were reported in the United States. Correcting for under reporting, it is estimated that approximately 75,000 cases of hepatitis A occurred in that year. Direct and indirect costs of hepatitis A are estimated to reach \$150-200 million each year.

Between 1990 and 1994, 2,450 cases of hepatitis A were reported to the Minnesota Department of Health. This represents nearly 6 times the number of hepatitis B cases reported during the same time frame (433). In Minnesota, hepatitis A is most common in children and young adults; nearly 83% of the cases occurred in persons 39 years of age or younger, with up to 40% of cases in persons  $\leq 19$  years of age.

Hepatitis A virus infection is usually transmitted by the fecal-oral route and most often from close personto-person contact, especially from child to adult. Risk factors for transmission identified for Minnesota cases during this five-year period were as follows: food borne outbreaks (72 cases (3%)), day care outbreaks (82 cases (3%)), having contact with a case (915 cases (39%)), travel history (144 (6%)) and shellfish consumption (30 cases (2%)). Nearly half of the reported cases (1207 (49%)) had no known risk factor for transmission.

#### Target populations

#### Routine vaccination

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Routine hepatitis A vaccination is recommended for persons at increased risk:

- Travelers to intermediate or high risk HAV-endemic countries
- tourists
- missionaries
- others working or studying abroad
- Homosexual and bisexual men
- Drug users in communities where outbreaks have occurred in these groups
- Persons with clotting factor disorders
- Persons with chronic liver disease (increased risk of severe consequences of hepatitis A)
- Children living in high rate communities as defined by the Centers For Disease Control and Prevention

#### Selective use

• Some intermediate-rate communities during outbreaks

Everyone is potentially at risk for hepatitis A but funding does not currently support universal vaccination.

#### Vaccine Products and Costs

Both pediatric and adult formulations of hepatitis A vaccine are currently licensed in the U.S. The price range is:

Pediatric — \$11.15 Adult — \$32.59

#### **Delivery and Implementation Issues**

Schedule/spacing/fit with current recommended schedule

- Current hepatitis A vaccines are only licensed for children 2 years of age and older
- Does not fit with current infant immunization schedule.
- Two or three doses are required, depending upon the product.

#### Handling and storage issues

• Must be refrigerated, cannot be frozen

#### *Product interchangeability*

- Two products are currently licensed in the U.S. Both can be administered to children and adults.
- The two products are *not* interchangeable.
- The two products have different schedules and doses.

#### Other issues that could affect implementation

- Low levels of public awareness of disease could adversely affect acceptance of any future universal immunizations recommendation.
- Current vaccines only have FDA approval for persons > 2 years of age.
- The pediatric immunization schedule for hepatitis A does not fit with the schedule for well-child exams in two-year children.
- Various combination vaccines that include hepatitis A are being tested.
- ACIP currently recommends only for targeted populations; no funding available to expand publicly-funded immunizations to other populations.
- No serology data available to assist Minnesota in targeting vaccine to high-risk populations.

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### **D.** Pneumococcal

#### Epidemiology

Pneumococcal disease, caused by the bacterium *Streptococcus pneumoniae*, results in wide-spread illness and death throughout the U.S. each year. Pneumococcal disease kills more people in the U.S. every year—40,000 or more—than all other vaccine-preventable diseases combined. Over 500,000 cases of invasive pneumococcal disease are believed to occur annually in the U.S.. Persons of all age groups may be affected. However, disease is most commonly reported in children < 2 years of age, and adults > 40 years of age.

The major clinical syndromes of pneumococcal disease include pneumonia, bacteremia, and meningitis, with pneumonia being the more common clinical presentation. An estimated 150,000-570,000 cases of pneumococcal pneumonia occur annually in the U. S.. This accounts for 36% of adult community-acquired pneumonia and 50% of hospital-acquired pneumonia. The case-fatality rate for pneumonia is 5-7% and may be much higher in elderly persons.

Transmission of *Streptococcus pneumoniae* occurs as the result of direct person-to-person contact via droplets. Pneumococcal infections are more common during the winter and early spring when respiratory diseases are more prevalent.

#### Vaccine

- The first polysaccharide pneumococcal vaccine was licensed in the United States in 1977. It contained purified capsular polysaccharide antigen from 14 different types of pneumococcal bacteria.
- In 1983, a 23-valent polysaccharide vaccine was licensed and replaced the 14-valent vaccine, which is no longer produced. This pneumococcal vaccine contains polysaccharide antigen from the 23 types of pneumococcal bacteria that cause 88% of bacteremic pneumococcal disease.
- Pneumococcal vaccine efficacy studies have suggested that the vaccine is 60-70% effective in preventing invasive disease.

#### **Target Populations**

- Pneumococcal polysaccharide vaccine should be administered routinely to all adults 65 years and older.
- The vaccine is also indicated for adults with normal immune systems who have chronic illnesses.
- Immunocompromised adults who are at increased risk of pneumococcal disease or its complications should also be vaccinated.
- Children 2 years old and older with long-term illnesses that are associated with a high risk of getting serious pneumococcal infection or its complications should be vaccinated. In addition, children with immunosuppression should be vaccinated.
- Persons living in special environments or social settings with an identified increased risk of pneumococcal disease, such as certain Native American populations, should receive vaccine.

#### Vaccine Products and Costs

Pneumovax - Merck: \$8.17 - \$8.48 MN Multistate Contract price - \$8.17 (no federal contract) Private purchase price - \$8.48

#### **Delivery and Implementation Issues**

Schedule/spacing/fit with current recommended schedule:

#### Pediatric schedule:

- One dose recommended for children at risk of acquiring pneumococcal disease
- Re-vaccination recommended for children 10 years of age and older who were vaccinated more than 6 years ago
- Vaccine efficacious only for children > 2 years of age

#### Adult schedule:

- One dose recommended for adults > 65 years of age
- One dose recommended for adults < 65 years of age at. risk for pneumococcal disease

#### Handling and storage issues

• Must be refrigerated, cannot be frozen

#### *Product interchangeability*

• Only one product is currently available

#### Other issues that could affect implementation

- No dedicated funding currently exists to enhance the delivery of pneumococcal vaccine
- Re-vaccination (boosters) is only for special populations at this time.
- Current vaccination levels very low, especially among adults >65 years
- Vaccine very safe
- While current vaccine is effective in preventing some strains of this disease, improvement is needed to improve the vaccine's protective abilities

## E. Influenza

#### **Epidemiology**

Influenza is a highly infectious viral illness. "Classic" influenza disease is characterized by the abrupt onset of fever (101-102°F), myalgia, sore throat, and nonproductive cough. Symptoms usually last 2-3 days, rarely more than 5 days. Influenza is transmitted via aerosolized or droplet transmission from the respiratory tract of of infected persons. Disease occurs most commonly from December to March in temperate climates.

A clear association exists between influenza and excess mortality. Ten thousand or more excess deaths have been documented in each of 19 different epidemics during the years of 1957-1986; more than 40,000 excess deaths occurred in each of several recent epidemics. There is a documented association between influenza and increased morbidity in "high-risk" adults. Hospitalization for adults with high-risk medical conditions increases 2-fold to 5-fold during major epidemics.

#### Vaccine

- The influenza vaccines available in the U.S. are composed of inactivated (killed) influenza virus.
- Each year the influenza vaccine is modified to include the strains anticipated to cause disease during the upcoming influenza season.

• Vaccines are effective in protecting up to 90% of healthy adult vaccinees from illness when the vaccine strain is similar to the circulating strain. However, the vaccine is only 30-40% effective in preventing illness among frail elderly persons. Although, the vaccine is not highly effective in the prevention of clinical illness in this group, it *is* effective in preventing complications and death. Among elderly persons, the vaccine is 50-60% effective in preventing hospitalizations and 80% effective at preventing death.

#### Target Populations

- Influenza vaccine is recommended for all persons 65 year of age or older, regardless of the presence of chronic illness.
- Residents of long-term care facilities, and persons 6 months of age to 18 years of age receiving chronic aspirin therapy should also receive vaccine.
- Persons 6 months of age or older with chronic illness should be vaccinated.
- In addition, groups with contact with high-risk persons should be vaccinated. These groups include health care workers, employees of long-term care facilities, and household members of high risk persons.
- Persons infected with HIV should be vaccinated. Persons who provide essential community services and students or others in institutional settings may be considered for vaccination. Foreign travelers may want to be vaccinated.

#### Vaccine Products and Costs

Connaught: 1995 Federal Contract price - \$1.72 Wyeth-Ayerst: MN Multistate Contract price - \$1.57 to \$2.96 Private purchase price - variable

#### Delivery and Implementation Issues

Schedule/spacing/fit with current recommended schedule

Vaccine should be administered prior to each flu season according to the following recommendations:

#### Pediatric schedule:

- One dose administered annually to children 6 months of age or older who have specific risk factors
- Children 12 years and younger should receive split virus vaccine in age-appropriate dose
- Children less than 9 years of age receiving flu vaccine for the first time should receive 2 doses at least 1 month apart

#### Adult schedule:

- Adults >65 years should receive one dose annually
- Adults <65 years who have risk factors OR are in contact with others who have risk factors (e.g. health care workers) should receive one dose annually
- Adults wishing to protect themselves against influenza should get one dose annually

#### Handling and storage issues

• Must be refrigerated; cannot be frozen.

#### Other issues that could affect implementation

- Vaccine is safe and highly effective against the strains of flu contained in the vaccine
- Immunization is less effective in preventing disease in the elderly than in younger persons, but is still effective in decreasing the severity of disease

- Vaccine is relatively inexpensive
- Vaccine is relatively well accepted as an important prevention measure
- Vaccine historically has been targeted only to persons with risk factors or those > 65 years of age. Recent published evidence suggests that workers and employers alike benefit from less absenteeism
- People still believe that they can get the flu from flu vaccine
- Flu vaccine is easily administered at community-based sites

#### Cost-benefit data

Economic benefits of vaccination were analyzed by examining both the direct and indirect costs associated with immunization and upper respiratory infection. Direct savings per vaccinated person per year equal \$117.00 (NEJM,10/5/95).

## F. Tetanus and Diphtheria

#### Tetanus

#### Epidemiology

Tetanus is an acute often fatal disease caused by an exotoxin produced by *Clostridium tetani*. It is characterized by increased rigidity and convulsive spasms of skeletal muscles. The muscle stiffness usually involves the jaw (lockjaw) and neck first and later becomes generalized. Tetanus spores are normal inhabitants of human and animal intestines, and are present in the soil. The portal of entry is almost always the site of minor or major puncture wounds. Tetanus is not contagious from human to human. It is the only vaccine-preventable disease that is infectious, but not contagious.

Tetanus cases occur almost exclusively in persons who are unvaccinated or inadequately vaccinated. A recent serologic study of immunity to tetanus found that although 80 % of persons 6 to 39 years of age had adequate levels of tetanus immunity, the prevalence of immunity dropped sharply with increasing age, until in persons 70 or older, only 28% had immunity to tetanus. Tetanus incidence in Minnesota reflects a similar pattern. Between 1985-1995 there were 18 cases of tetanus, two (11%) of which were fatal, reported to the Minnesota Department of Health. Fourteen (78%) of these cases occurred in persons aged 40 or older.

#### Vaccine

- Tetanus toxoid has been safe and useful since its first production in 1924. There are two types of toxoid available—adsorbed toxoid and fluid toxoid. The adsorbed toxoid is preferred because the antitoxin response reaches higher titer and is longer lasting than with the fluid toxoid.
- Three doses constitute a primary series of Td. The first two doses are separated by a minimum of 4 weeks, with the third given 6-12 months after the second. A booster dose of Td should be given every ten years. There is no reason tetanus toxoid should be given as a single antigen preparation. It should be given in combination with diphtheria toxoid, since periodic boosting is needed against both diseases.
- Following a properly administered primary series, virtually all persons develop protective level of antitoxin. Antitoxin levels fall over time. While some persons may be protected for life, most persons have antitoxin levels that approach minimal protective level by 10 years after the last dose. As a result, boosters are recommended every ten years.

#### **Target Populations**

- Primary tetanus immunization, usually with combined DTP vaccine, is recommended for all persons at least 6 weeks old, but less than 7 years of age without contraindications to vaccinations.
- Routine tetanus immunization, usually combined with diphtheria toxoid, is recommended for *all* persons 7 years and older, with boosters every 10 years.

#### Diphtheria

#### **Epidemiology**

Diphtheria is an acute, toxin-mediated disease caused by *Corynebacterium diphtheriae*. The organism produces a toxin which causes local tissue destruction and membrane formation. The toxin produced at the site of the membrane is absorbed into the bloodstream and distributed to other tissues in the body. Disease can involve almost any mucus membrane. The most common sites of infection are the tonsils and the pharynx. The most frequent complications of diphtheria are: myocarditis, neuritis, and death. The overall case-fatality rate for diphtheria is 5-10%, with higher death rates (up to 20%) in persons < 5 and > 40 years of age. The case-fatality rate for diphtheria has changed little during the last 50 years.

From 1980 through 1993, only 40 cases of diphtheria were reported in the United States, an average of 3 cases per year. The current rarity of diphtheria in the U.S. is due primarily to the high levels of adequate immunization of children and an apparent reduction in the circulation of toxigenic strains of *C. diphtheria*. The last case of diphtheria in Minnesota occurred in 1990 in an Asian immigrant who was incompletely immunized. This was the first case reported in the state in 20 years. An outbreak began in the Russian Federation in the late 1980s which has continued into the early 1990s, with more than 15,000 cases reported in 1993. The outbreak has spread to several other countries of the former Soviet Union, especially the Ukraine. Many cases have been reported in young adults. Low vaccination coverage is thought to be an important factor in the resurgence of diphtheria in Russia.

#### Vaccine

- The diphtheria vaccine is a formalin-inactivated diphtheria toxin.
- Toxoid was developed around 1921, but was not widely used until the early 1930s. It was incorporated with tetanus toxoid and pertussis vaccine and became routinely used in the 1940s.
- The usual schedule is a primary series of three or four doses with a booster dose. Because of waning immunity, additional booster doses are required every ten years to maintain antitoxin levels.

#### Target Populations

- Vaccine is recommended for all children 6 weeks through 6 years of age. The usual schedule is a primary series of three or four doses with a booster dose. DTaP is the vaccine of choice for all five doses. DT should be used when the pertussis component is contraindicated.
- Td is the vaccine of choice for children 7 years old and older and adults. A primary series is three doses. Boosters are given every ten years in conjunction with tetanus (Td).

#### **Td Vaccine Products and Costs**

Connaught: \$0.19 - \$1.24 1995-1996 Federal contract price - \$0.19 Private purchase price - \$1.06

#### **Delivery and Implementation Issues**

#### Schedule/spacing/fit with current recommended schedule

- Adolescents: Booster recommended at 11–12 years of age if at least 5 years have elapsed since the previous dose of DTP, DTaP, or DT.
- Adults: Booster dose recommended every ten years throughout the adult lifespan. (If the adult had not received a primary series as a child, they would require a three-dose series given at (minimum) intervals of 0,1, and 6–12 months.)

#### Handling and storage issues

• All current products must be refrigerated and cannot be frozen.

#### Product interchangeability

• All current products are interchangeable

#### Other issues that could affect implementation

- Record keeping essential to assure intervals between adults boosters is not less 5 years and not greater than 10 years.
- Not all providers support adolescent booster at age 11–12 years of age (prefer the 15–16 year old recommended age which existed previously).
- Adult Td boosters can be provided at influenza/pneumococcal clinics.

# **IV. Immunization Delivery System Problems and Issues**

Approximately 67,000 births occur each year in Minnesota. These children are currently recommended to receive 17 separate doses of vaccine between birth and age six, often requiring six or more clinic visits. The vaccines are delivered by approximately 800 private and public clinics across the state. The Minnesota Department of Health (MDH) estimates that 85 percent of childhood immunizations are delivered by providers in the private sector, six percent by the public sector, and the remaining nine percent by a combination of public and private providers. There are also recommended immunizations for adolescents, and for adults throughout the lifespan. Additional immunizations may be needed for some occupational groups, and for international travel.

Parents, private health care providers, health plans, schools and local and state public health are all important parts of the immunization delivery system in Minnesota. This system has achieved dramatic reductions in vaccine-preventable disease rates in our state. However, although we are making progress toward the Year 2000 goal of achieving 90 percent immunization levels, the system is struggling to cope with the introduction of new vaccines, the growing complexity of the immunization schedule, and the very complex task of managing immunization data. The enrollment turnover or "churning" of families in some metropolitan health plans can be 20–25% annually. In a 1995-96 statewide retrospective study of 1085 kindergarten enterers, only 71 percent were up-to-date by the age of two.

#### MDH Immunization Program Funding

The MDH has received Federal funding annually since 1972 from the Centers for Disease Control and Prevention (CDC) to implement a statewide immunization program. The vast majority (99%) of all funding for immunization activities to MDH comes from the Federal government (see Table 5). Additional reductions are expected for 1998, while expectations for increased coordination, technical support, and education increase. Over \$4.5 million dollars in initiatives to support delivery of immunizations requested in the 1997 grant application to CDC were not funded for 1997. Many of these unfunded initiatives included grants to local communities.

Table 5. Federal Funding to MDH for Immunization Programs, 1994 – 1997 (1) (Excluding vaccines )						
Year of Funding Federal Allocation to Minnesota <sup>(2)</sup>						
1994	\$2,456,000					
1995	\$4,340,000					
1996	\$2,949,000					
1997	\$2,758,000 <sup>(3)</sup>					

(1) 99% of MDH funding for immunizations is federal funding authorized by Section 317 of the Public Health Services Act

(2) Federal funds currently support statewide programs for provider and consumer education including printing and distribution of over 750,000 materials, technical consultation, statewide immunization hotline, consultation on immunization registries, perinatal hepatitis B control, grants to all local public health agencies, statewide immunization surveys, disease surveillance, and outbreak control.

(3) Included in the 1997 funding request to CDC but not funded was \$4,500,000 in the following areas: grants to all local public health agencies for 1998, international travel health information service, Hepatitis B and Hepatitis A programs for persons attending STD clinics, consumer and medical education initiatives, grants to communities for immunization registries, statewide computer hub for immunization registries, adult health education materials, adult immunization services, enhanced pertussis disease surveillance, and a statewide conference on immunizations.

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# A. Vaccine Funding for Children and Adolescents

#### Enhanced Vaccines for Children Program

The federal Vaccines for Children Program (VFC) supports the costs of vaccine given to children (0-18 years) who are on the state's Medicaid program, uninsured, or are American Indian/Alaskan Native. The state's enhanced VFC program, known as MnVFC, utilizes federal immunization grant dollars to support the costs of vaccine given to children whose health insurance does not fully support the costs of vaccine; i.e., lacks any coverage for immunizations or is subject to a deductible or co-pay. It is estimated that approximately 20% of children and adolescents fall into this category.

During the second year of the MnVFC program (10/95-9/96), approximately \$1.55 million of federal grant dollars were spent on vaccines given to under-insured children. This funding, as authorized by Section 317 of the Public Health Services Act, was used to purchase vaccines from Federal contracts. The total costs of vaccinating a pre-school aged child with these lower cost vaccines has increased from \$6.69 in 1982 to \$126.86 in 1994 to \$180.37 in early 1997. It may be noted that, during this same time period, the costs of vaccines purchased through private sources increased from \$23.29 to \$302.77.

A total of fifteen states (30%) currently provide vaccines to all health care providers to vaccinate all children seen in their clinics. These states are known as "universal" vaccine distribution states because of their public policy that entitles all children to "free" (that is, public-supported) vaccine, regardless of their ability to pay or health insurance status.

A first step to becoming a universal vaccine distribution state in Minnesota would be to provide vaccine for all children who are under-insured. With 20% of the estimated 65,000 children in the birth cohort under-insured, the costs of providing vaccine to these 13,000 children at \$180 per child would be \$2,340,000. Another 14,380 adolescents would be under-insured (20% of 71,900) and will need the adolescent series of vaccines at a cost of \$42.60 for an additional \$612,588. The total cost of the vaccines for this program, purchased through the lower cost Federal contracts, would be \$2,952,588. The 1997 federal grant to MDH will provide \$3,567,756 purchase vaccines for persons not eligible for the Federal VFC program; therefore, current levels of funding from the CDC appear to be adequate for 1997 and (projected) for 1998. There is concern, however, that additional factors may jeopardize future support for vaccine purchase, including the increasing costs of vaccine (e.g., new combinations, improved products, etc.), increasing numbers of vaccines included in routine immunization of children (e.g., rotavirus vaccine, respiratory syncytial virus vaccine, pneumococcal conjugate vaccine against otitis media), increasing numbers of employers becoming self-insured and, consequently, more families that would be under-insured, and continued Federal support for vaccine purchase for non-VFC eligible children. A state fund of \$350,000 should be established to provide coverage for future shortfalls and emergencies.

#### School-linked Immunization Clinics

In November of 1996, recommendations for adolescent immunization were issued as a joint statement of the Advisory Committee on Immunization Practices to the U.S. Centers for Disease Control and Prevention, the American Academy of Pediatrics, the American Academy of Family Physicians, and the American Medical Association.<sup>3</sup> This statement presented a new strategy to improve the delivery of immunization services to adolescents, including the delivery of vaccines in school-linked immunization clinics. All fifty states and territories have established laws that require immunization of school children and many have found that the school is an ideal setting to provide these vaccination services. School-linked immunization clinics for administering hepatitis B vaccine to adolescents have shown completion

<sup>3</sup> 

CDC. Immunization of Adolescents; MMWR 1996;45 (No.RR-13).

rates of over 70%, an achievement that is difficult in traditional clinic settings for this vaccine which requires three visits to complete the full series.<sup>4</sup>

The Minnesota School Immunization Law currently requires that all students entering grade seven have documentation of an additional vaccination for measles, mumps, and rubella (MMR) and a booster dose for tetanus and diphtheria (Td). Many communities have also shown an interest in offering the hepatitis B vaccine series to their adolescent students, even though the current law does not require it. The following table gives an estimate of the costs of a comprehensive adolescent program:

Table 6. Estimate of the Number and Costs of Vaccines Needed to Support a         School-linked Immunization Initiative for Adolescents, Minnesota, 1997									
Vaccine	No. of Students in Grade 7	% to be Imm in School <sup>(1)</sup>	No. to be Imm.	No. of Doses	Vaccine Costs	Total Cost	State Share of Total Costs <sup>(2)</sup>		
MMR (1 dose)	71,900	50	35,950	35,950	\$16.31	\$586,345	\$410,442		
Td (1 dose)	71,900	50	35,950	35,950	\$0.194	6,974	4,882		
Hepatitis B (3 doses)	71,900	20	14,380	43,140	\$26.10	375,318	262,723		
Total				115,040	\$42.60	\$968,637	\$678,047		

(1) The percent of students projected to be vaccinated in school-based clinics for MMR is based on MnVFC vaccine usage reporting;. It is projected that the number of students receiving Td would match the MMR data; however, students receiving hepatitis B vaccine would be less than half as much because it is not required by the School Immunization Law.

(2) The "State Share of Total Costs" is the total costs of vaccines less that covered by VFC.

Approximately 30% of these vaccines would be administered to adolescents eligible for the Federal VFC program, another 20% of the vaccines would be given to students who are under-insured, and the remainder (50%) would be given to students who are fully insured. Full statewide coverage of vaccines for this adolescent cohort would require nearly \$1,000,000 annually, of which approximately 70% or \$700,000 would not be covered by the Federal VFC program.

# **B.** Support for School Health Immunization Activities

There are two broad areas of responsibility that involve school personnel—the enforcement of immunization law requirements for students and the provision of needed vaccines through school-linked immunization clinics. Neither of these time-intensive areas of responsibility currently receive dedicated funding.

Current state law requires that all students who are enrolled in a public or private elementary or secondary school have documentation of immunization against seven vaccine-preventable diseases. The law applies to students at all grade levels (i.e., K-12), including transfer students and students in home schools. In

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CDC. Hepatitis B Vaccination of Adolescents — California, Louisiana, and Oregon, 1992-1994. MMWR 1994;43:605-9.

order to meet this requirement, school staff expend considerable resources communicating the law's requirements to parents, maintaining comprehensive record systems, updating student records as additional immunizations become due, referring and following-up with non-compliant students, locating missing or out-of-state immunization records, and compiling annual reports that are required by the law.

The administration of this law has become more complex over the years as increases have occurred in the numbers of students, the number of vaccines needed, the number of students not having immunization records, and the number in need of individualized follow-up. During the 1995-1996 school year, immunization records for 885,891 students were obtained and reviewed to measure compliance with the state's School Immunization Law. At an estimated cost of \$2.00 per record reviewed, the total cost of this activity would be \$1,771,782.

The second major area of need for schools is in acquiring adequate support for administering vaccines in school-linked immunization clinics. The proposal contained in section IV.A. above addresses the costs of vaccines for these clinics. In addition to these vaccine costs, MDH estimates vaccine administration costs of \$977,840 annually, based on the current cap on reimbursement for vaccines administered to Minnesota Health Care Program enrollees of \$8.50 per vaccine and the 115,040 total vaccine doses that would be given to pre-seventh grade students in school-linked immunization clinics.

### C. Decreased Federal Funding for Community-wide Immunization Activities

Effectively delivering 17 doses of vaccine for every Minnesota child requires the coordinated efforts of physicians, nurses, clinics, state and local public health agencies, health plans, health systems, parents, and child health-related programs. Coordinating these many partners to assure age-appropriate immunizations in Minnesota is the responsibility of state and local public health.

Since 1993, the Minnesota Department of Health has received federal funding to support state and local collaborative planning as a means to strengthen the immunization delivery system. These local coalitions now exist for every county in the state, identifying community barriers and community solutions. The federal funds were allocated by MDH to Community Health Boards on a formula basis using factors most associated with under-immunization (number of live births and poverty).

A key lesson from these initiatives is that the barriers to age-appropriate immunizations are complex in nature, challenging to solve, and ongoing. Addressing the barriers to immunizations also addresses barriers to health care access because both involve the complex interplay of consumer knowledge and attitudes, provider knowledge and attitudes, financing, systems issues, access (linguistic, cultural, geographic, financial), and other factors.

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Unfortunately, the local gains made in addressing these barriers may not be sustainable. Federal funds to support these initiatives are dwindling, while discretionary local public health funding is limited and subject to many competing needs. State funds to provide ongoing support for these collaborative initiatives is critical to sustain improvements in immunization levels and low disease incidence. At a minimum, \$1.5 million annually is required to ensure that each county's allocation is sufficient to support staffing and the coalition activities.

Table 7. MDH Immunization Grants to Community Health Boards, 1993–1998.					
Year	Total Grant Allocation (Basis For Grant Award)				
1993–94	\$930,000	(competitive)			
1995	\$1,500,000	(formula)			
1996	\$1,500,000	(formula)			
1997	\$1,300,000	(formula)			
1998	\$0 (Currently unfunded)				

## D. Development of Immunization Registries Statewide

Immunization registries are becoming a critical part of a health system designed to assure that all children are age-appropriately immunized and to maintain low incidence of vaccine preventable diseases in Minnesota.

#### Problems with the Current Systems

Currently, Minnesota falls short of our Year 2000 Immunization Goal, particularly among children from poor families and those who lack adequate health insurance or access to health care. And the increasingly complex immunization schedule and recommendations are confusing for providers and parents alike. By documenting immunizations in a way that can be easily accessible to all public and private providers, computerized registries can serve as an invaluable tool to efficiently identify children who have never been immunized or who fall behind on their immunizations. These registries provide assessment data to monitor the immunization status of an individual, a practice, or a community, and save staff time by providing easy access to reports for school, day care, and other requirements.

It would be difficult to over-estimate the amount of time spent searching for and clarifying children's immunization records, and the negative impact this may have on childhood immunization. Every year, children's records are checked by schools, day care programs, camps, hospitals, and clinics - an estimated 2.2 million record checks in a system that must deliver and track about 1.6 million doses of vaccine to Minnesota children aged 0 to 18 annually. Registries can improve both the efficiency and effectiveness of the current manual and labor intensive process. One study suggests that it costs up to \$25 dollars every time a manual immunization record needs to be checked by a health care provider. If this cost is reflective of other clinics, the inefficient paper system used for immunization record checks could be costing Minnesota's health care system an estimated \$50 million dollars each year.

#### Registries—A Vital Part of the Solution

Immunization registries can improve the health of all Minnesota children and provide benefits to communities, parents, and health care providers.

Children will benefit:

- Children will be protected from vaccine-preventable diseases.
- Under-immunized groups of children will be identified to receive more services, outreach, and education.
- Children will be less likely to receive unneeded immunizations because of lost or missing records.

Parents will benefit:

- Accurate shot records will always be available for each child.
- Immunization reminders and follow-up notices will help them keep children on schedule.
- The link<sup>\*</sup>to schools will make it easier to comply with school requirements.



Health care providers and health plans will benefit:

- Staff time spent searching for immunization records will be reduced.
- The cost and risks of giving unnecessary immunizations will be reduced.
- The quality of care will improve because of more accurate patient assessments.
- Quality measures for health plans, such as HEDIS (Health Employers Data Information Set), can be easily generated.
- School nurses will spend less time policing immunizations and have more time to devote to other health needs of school children.

Communities will benefit:

- Data to evaluate and monitor the effectiveness of immunization services, outreach, and education will be available.
- Accurate information to assess the immunization status of communities will be easily obtained.
- A system that will save dollars, protect the community, and improve family health and safety will be established.
- Pockets of need are easily identified and targeted for services, outreach, and education.

Immunization registries are a powerful tool that can produce benefits for all the people of Minnesota. They are also complex systems that require months of careful planning with the committed involvement of numerous community partners.

Pioneering projects, such as Communities Caring for Children (10 public health agencies in 13 counties of northwestern Minnesota), Saint Paul Public Health, Hennepin County Community Health Department, Olmsted County, and Countryside Public Health Service, as well as studies from cities across the country have demonstrated the effectiveness of community-based immunization registries.

The proposed Minnesota immunization registry system is designed to support three distinct but integrated activities.

- 1. Improve the quality of established provider-based record systems and prepare them for sharing with community registries. These are mostly manual record systems serving public and private clinics. They contain information on clients served by individual providers.
- 2. Establish community-based registries which link clinics, hospitals, health plans, public health departments, and schools in a particular region. These community registries share immunization records, ensuring complete individual immunization records exist to avoid under- or over-immunization of individuals. They can also conduct immunization reminder and recall, and conduct immunization assessments (see figure below).
- 3. Create a statewide populationbased registry hub to connect community-based registries. This statewide hub would also support immunization assessment and public health research.

Registries are complex and require the collaborative effort of many community partners to appropriately manage and safeguard the data. Partners whose responsibilities include inputting data, maintaining data quality and security, and supporting the systems are:

- Providers of immunizations, including clinics, public health agencies, hospitals, and schools;
- Payors;
- Community-based registries, which may be city, county, or regionally organized; and
- The Minnesota Department of Health.

In addition to partners with responsibilities for adding to and maintaining data in registries, there are partners who are primarily users of the system, such as schools. Although they can be a provider of immunizations through school-linked immunization clinics, their most important connection to registries is through their need to access records to verify students' compliance with immunization laws. In addition, schools are an important way to help identify new children moving into the community.

#### Comprehensive, registry-specific legislation to address the operation of immunization registries

Minnesota Statutes 144.3351 provides the ability for health care providers to share immunization records



for the purpose of providing service to the client without the permission of the parent. How this statute applies to community registries is open to interpretation. The article, "Childhood Immunization Registries: A National Review of Public Health Information Systems and the Protection of Privacy," (JAMA, December 13, 1995, volume 274), includes experiences from other states, and encourages states to adopt specific legislation to address the operation of immunization registries.

A Registry Work Group of the Commissioner's Task Force on Immunization Practices has proposed draft registry legislation and recommends that it be moved through the legislative process as quickly as possible.

#### Funding

Registries often require an investment in new resources to get started but over time can both substantially reduce staff time to locate records and improve the quality of patient care. Ongoing costs are expected to be supported by all partners joining in the registry. Each partner in the registry should be involved in sharing for the operation of community registries. Limited cost studies and experience of some pioneers in Minnesota to date has estimated that community-based immunization registries require an investment of about \$5.00 – \$8.00 per record per year to operate. Based on those estimates, costs for maintaining a system of registries statewide for persons age 0 to age 18 in Minnesota would require an investment of approximately \$5 million to \$10 million dollars per year. An annual appropriation of \$5 million is needed to use as matching grants to regions establishing and operating community-based immunization registries. An annual appropriation of \$1.5 million is needed for MDH to provide training and consultation for community registries, and for the planning, design, implementation, and operation of a statewide hub for connecting community-based immunization registries.

Additional details on registries can be found in the Task Force recommendations on registries, available upon request from the MDH Acute Disease Prevention Services Section.

# V. Recommendations of the Task Force

The following are recommendations of the Commissioner's Task Force on Immunization Practices (see membership on acknowledgments page) to the Commissioner of Health. The recommendations are divided into three parts: Legislation Action With Funding, Legislative Action Without Funding, and No Legislative Action Required. A summary of the two parts that include legislative action is included below.

Tal	Table 8. Summary of Recommendations Requiring Legislative Action						
Legislative Session	Issue	<b>Recommendations for Legislation</b>					
Beginning During	Tetanus–Diphtheria	<ul> <li>Introduce clarifying language on how to manage students who received a Td booster at &lt;11 years of age.</li> </ul>					
1997	Delivery System	<ul> <li>Vaccines: Establish a state fund for vaccines: \$350,000</li> <li>Vaccines: Purchase vaccines for school-immunization linked clinics: \$700,000 annually</li> <li>Schools: Provide funds for assuring compliance with laws: \$1,772,000 annually</li> <li>Schools: Provide funds for administering vaccines in school-linked immunization clinics: \$978,000 annually</li> <li>Pubic Health Agencies: Replace reduced federal funding for local immunization programs: \$1,500,000 annually</li> <li>Registries: Provide matching funds for community-based immunization registries: \$5,000,000 annually</li> <li>Registries: Provide funding for MDH to provide training, consultation, and planning, design, implementation and operation of a statewide hub: \$1,500,000 annually</li> </ul>					
1998	Hepatitis B	• Add to school law for kindergarten entrance effective 1999-2000.					
	Varicella	• Re-examine possible inclusion into school law for kindergarten entrance in the 1998 legislative session.					
	Universal perinatal screening for hepatitis B	• Add to any future comprehensive pre-natal screening legislation.					

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# **Part A: Recommendations for Legislative Action With Funding**

#### A-1. Vaccine Funding for Children and Adolescents

#### Legislative Action Recommended

- Establish a fund to purchase vaccines if federally-supplied vaccine are not adequate to cover all under-insured Minnesota children or in emergencies: \$350,000 one time appropriation
- Funds for purchase of vaccines for school-linked immunization clinics: \$700,000 annually

#### **Implementation Considerations for Legislation**

- No state funds currently go towards purchase of vaccines, which are among the most cost-effective measures in public health and preventive medicine.
- Schools are an efficient and effective location for administering vaccines but lack dedicated funding for this purpose.

#### A-2. Support for School-linked Immunization Activities

#### Legislative Action Recommended

- Funds for schools to manage compliance with immunization laws: \$1,772,000 annually
- Funds for administering vaccines in school-linked immunization clinics: \$978,000 annually

#### **Implementation Considerations for Legislation**

- Implementing and enforcing the school immunization law is increasingly complex and timeconsuming because of the increasing numbers of students, increasing complexity of the immunizations required, and the mobility of families.
- The administration costs are estimated based on the \$8.50 per dose reimbursement allowed for Minnesota Health Care Program enrollees.

### A-3. Funding to Replace Decreased Federal Funding for Community-wide Immunization Activities

#### Legislative Action Recommended

• Funding to Community Health Boards to coordinate local immunization coalitions: \$1,500,000, annually.

#### **Implementation Considerations for Legislation**

• Local public health agencies are in the best position to coordinate local coalition-building and assessment of immunization delivery problems.

# A-4. Support for public and private partnership in the development of Immunization Registries Statewide

#### Legislative Action Recommended

- Funds to use as matching grants to regions to establish and operate community-based immunization registries: \$5,000,000 annual appropriation
- Funds to MDH to provide training, consultation, support to community-based registries and providers and to plan, design, implement and operate a statewide hub with comments to the community -based registries: \$1,500,000 annually

#### **Implementation Considerations for Legislation**

- Start-up costs for community-based immunization registries could be a barrier to full provider participation.
- Ongoing costs need to be shared by participants once registries are operational because the cost savings will accrue to participants who use registries to replace costly manual record systems.

# Part B: Recommendations for Legislative Action Without Funding

#### **B-1.** Varicella

#### Legislative Action Recommended

- Perhaps add to law in 1998 to be effective in 1999 or 2000
- Continue to recommend universally
- Rely on education versus law for now

#### **Implementation Considerations for Legislation**

• Parental history of natural disease could be accepted as evidence of immunity.

#### **Related activities/recommendations**

- Ensure that sufficient number of clinics are offering the vaccine before making a requirement.
- Establish surveillance systems to document baseline morbidity.
- Ensure that providers support universal varicella immunization of children.
- Provide professional and consumer education on value of vaccine versus natural disease and on the issue of possible boosters in the future.
- Provide professional education to ensure correct vaccine handling
- Compare ratio of varicella to MMR usage in MnVFC providers to assess current use of varicella vaccine.

# **B–2.** Hepatitis B

#### Legislative Action Recommended

- Add to school law for kindergarten entrance in 1998, effective 1999-2000 to allow for extensive promotion (and the aging of currently immunized infants).
- Continue to recommend universally for 7th graders.

#### Implementation Considerations for Legislation

- To enroll or remain enrolled in kindergarten, all students would be required to have documentation of HBV vaccine series.
- Inclusion into a law may alleviate provider and parental ambivalence about the need for HBV.

#### **Related activities/recommendations**

- Provide professional and consumer education on HBV
- Work with health plans and others on pilot projects for school-linked adolescent immunization clinics to address current delivery and financing issues.
- Assess current HBV coverage levels in Minnesota preschoolers.

# **B-3.** Hepatitis B—Universal Perinatal Screening

#### Legislative Action Recommended

Add requirement that all pregnant women be screened for hepatitis B surface antigen (HBSAG) to any future comprehensive pre-natal screening legislation

#### **Implementation Considerations for Legislation**

• CDC is requesting that each state adopt legislation requiring universal perinatal screening for hepatitis B by 1998.

#### **Related activities/recommendations** (not directly related to legislation)

- Promote HBsAg screening as the standard of care for pre-natal screening.
- Expand education and follow-up efforts to non-metro areas
- Assess current screening levels statewide
- Work with the Maternal and Child Health and the HIV Task Forces on any legislative proposal/language

#### **B–4.** Tetanus–Diphtheria

#### Legislative Action Recommended

• Introduce clarifying language this session on how to manage students who received Td at <11 years of age.

#### **Implementation Considerations for Legislation**

• Current law does not allow for deferring Td booster even though it may be medically contraindicated.

#### **Related activities/recommendations**

- Expand education regarding adult immunization.
- Explore creative avenues to reach these populations (e.g. drivers license renewal)
- Increase assessment of adult immunization levels.
- Conduct serosurveys for tetanus and diphtheria immunity in adults.

### **B–5.** Population-based Immunization Registries

#### Legislative Action Recommended

• Support enabling legislation for population-based immunization registries as proposed through the Task Force.

#### **Implementation Considerations for Legislation**

- Community-based registries, which are emerging across the state, are in a legal grey area for sharing immunization records.
- Start-up costs could be major barrier for population-based immunization registries (see recommendation A–4).
- Ongoing operational costs will need to shared by the participants who benefit from immunization registries, including the State (see recommendation A–4).

#### **Related activities/recommendations**

- Complete and distribute registry guidelines to providers.
- Provide consultation to communities interested in establishing community-based immunization registries.

# Part C: Recommendations With No Required Legislative Action

### C-1. Hepatitis A

#### **Action Recommended**

• Once HAV is incorporated into the routine childhood schedule, legislation should be re-considered for school and/or child care laws.

#### **Related activities/recommendations**

- Need to ensure that sufficient number of clinics are offering the vaccine and support universal vaccination before making a requirement
- Continue to include HAV as a vaccine to be considered for certain high risk groups until it becomes part of universal recommendations.
- Continue HAV education and targeting groups at risk for hepatitis A (e.g., migrant workers, travelers, and food handlers.)
- Obtain CDC morbidity data on HAV for Task Force review in 1997.

## C-2. Influenza

#### **Action Recommended**

- Require that all nursing home residents be offered influenza vaccine annually.
- Ensure that a resident can conscientiously object to vaccination.

#### **Related activities/recommendations**

- Could be added to MDH's annual nursing home inspection checklist.
- Check with Facility and Compliance Division at MDH to assess feasibility and how compliance would be evaluated.
- Provide expanded adult immunization education and other initiatives to meet statewide goals.
- Expand education regarding adult immunization.
- Increase assessment of adult immunization levels.

#### C-3. Pneumococcal

#### Action Recommended

- Require that all nursing home residents over age 65 or otherwise at risk be screened for and offered pneumococcal vaccine if indicated
- Ensure that a resident can conscientiously object to vaccination.

#### **Related activities/recommendations**

- Could possibly be added to MDH's annual nursing home inspection checklist.
- Check with MDH Facility and Compliance Division to assess feasibility and how compliance would be evaluated.
- Nursing home management and staff need to know immunization recommendations for all health care workers and residents.
- Provide expanded adult immunization education and other initiatives to meet statewide goals.
- Increase assessment of adult immunization levels.

## C-4. Measles, Mumps, Rubella

#### **Action Recommended**

• Conduct serosurveys for measles immunity in the adult (20-39 yr.) population.

#### **Related activities/recommendations**

• MDH to continue provider and consumer education, especially about second dose recommendations.

## C-5. Minimum Vaccine Handling Standards for Clinics

#### **Action Recommended**

• Distribute and promote vaccine handling standards to all clinics which provide immunizations.

#### **Related activities/recommendations**

- Need to ensure that sufficient number of clinics are able to properly store and handle all vaccines before universal recommendations can be made.
- Need to assure that all statutorily-required vaccines are available to clinics.
- Work with the Academies and others to develop and implement a vaccine management and immunization practices QA visit for MnVFC providers and others as time allows.

#### C-6. Health Care Worker Recommendations

#### **Action Recommended**

• Develop materials/strategies for health care workers.

#### **Related activities/recommendations**

• ACIP has recommendations for HBV, rubella, measles, mumps, polio, pneumococcal and influenza for health care workers, as well as HBV for lab workers and rabies for veterinarians

# C-7. Immunizations for International Travel

#### **Action Recommended**

• Support providers and public health agencies by developing new or distributing existing international travel recommendations.

#### **Related activities/recommendations**

- Requests for international travel information increasing for providers, local public health agencies and MDH
- Distribute international travel immunization information through travel agents, airlines, etc., seeking funding and partners as necessary.

This concludes the main body of the 1996 Immunization Law Study Report

# Attachments

Attachment A — 1996 Minnesota Immunization Schedule

- Attachment B Summary of Immunization Rates
- Attachment C Summary of Counties with Immunization Registries
- Attachment D Immunization Laws in Other States

Attachment E — Summary of Draft Bill Authorizing the Creation of Community-Based and Statewide Immunization Registries

# Attachment A

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# 1996 Minnesota Immunization Schedule

# Recommended Childhood Immunization Schedule Minnesota, 1996

Bars indicate range of acceptable ages; shaded bars indicate catch-up vaccination. Vaccines below dotted line are for selected populations.

Vaccine ▼ Age ►	Birth	1 mo	2 mos	4 mos	6 mos	12 mos	15 mos	18 mos	2 yrs	4-6 yrs	11-12 yrs	14-18 yrs
Hepatitis B <sup>1,2</sup>		HBV-1									HBV <sup>2</sup>	
			HBV-2			HB	V-3				(1-3)	
Diphtheria, Tetanus, Pertussis³			DTP	DTP	DTP	(DTa	DTP <sup>3</sup> P at 15+m	los.)		DTaP or DTP	T(	3]
<i>Haemophilus influenzae</i> type b⁴			Hib	Hib	Hib⁴	<u> </u>	b⁴					
Polio⁵			OPV <sup>5</sup>	OPV		0	PV			OPV		
Measles, Mumps, Rubella <sup>6</sup>						M	AR			MN	IR <sup>6</sup>	
Varicella <sup>7</sup>							Varicella			Varie	cella <sup>7</sup>	di cirente
— — — — — — — — — — — Hepatitis A <sup>®</sup>										н/	 \V <sup>8</sup> 	
Influenza <sup>9</sup>						L		Inf	luenza			
Pneumococcal <sup>10</sup>										Pneum	ococcal	

#### Footnotes

- Hepatitis B (Infants): Infants born to HBsAg-negative mothers should receive 2.5 μg of Merck vaccine (Recombivax HB) or 10 μg of SmithKline Beecham (SB) vaccine (Engerix-B). Administer a 2nd dose ≥1 month after the 1st dose and a 3rd dose at 6-18 months of age. Infants born to HBsAgpositive mothers should receive 0.5 mL Hepatitis B Immune Globulin (HBIG) within 12 hours of birth, and either 5 μg of Recombivax HB or 10 μg of Engerix-B at a separate site. The 2nd dose is recommended at 1-2 months of age and the 3rd dose at 6 months of age. Infants born to mothers whose HBsAg status is unknown should receive either 5 μg of Recombivax HB or 10 μg of Engerix-B within 12 hours of birth. The 2nd dose of vaccine is recommended at 1 month of age and the 3rd dose at 6 months of age.
- Hepatitis B (Adolescents): Adolescents who have not previously received 3 doses of hepatitis B vaccine should initiate or complete the series at about 11-12 years of age. The vaccine may be administered at 0, 1, 6 months; 0, 1, 4 months; or 0, 2, 4 months.
- 3. Diphtheria, Tetanus, Pertussis: DTP-4 may be administered as early as 12 months of age, provided at least 6 months have elapsed since DTP-3. DTaP (diphtheria and tetanus toxoids and acellular pertussis vaccine) is licensed for use for the 4th and/or 5th dose of DTP vaccine in children 15 months of age or older and is preferred to reduce the chance of local reactions and fever that often follow whole-cell DTP, particularly in older-aged children. Children who have a true contraindication to whole-cell pertussis vaccine should receive DT (which is for pediatric use) and not DTP or DTaP. Td (tetanus and diphtheria toxoids, adsorbed, for adult use) is recommended at 11-12 years of age if at least 5 years have elapsed since the last dose of DTP, DTaP, or DT.
- 4. Haemophilus influenzae type b: Three Hib conjugate vaccines are licensed for infant use. Note that if PRP-OMP (PedvaxHIB® from Merck) is administered at 2 and 4 months of age, a dose at 6 months is not required. After completing the primary series, any Hib conjugate vaccine may be used as a booster.
- Polio: Oral poliovirus vaccine (OPV) is recommended for routine infant vaccination; inactivated poliovirus vaccine (IPV) is an acceptable alternative. IPV is recommended for persons with a congenital or acquired immune

deficiency disease or an altered immune status as a result of disease or immunosuppressive therapy and for children who have household or close contacts with these conditions. A 4-dose series of IPV should be given with a minimum interval of 4 weeks between the 1st and 2nd doses and 6 months between the 2nd and 3rd doses followed by a booster dose before entering school.

- 6. **Measles, Mumps, Rubella:** While it is preferable to provide MMR-2 to children at about 11-12 years of age, the 2nd dose may be given any time after the child reaches 4 years of age.
- Varicella: Varicella vaccine should routinely be administered to susceptible children at 12-18 months of age. Unvaccinated children ≥18 months who lack a reliable history of chickenpox should also be vaccinated. Children ≤12 years should receive one dose; those ≥13 years should receive 2 doses 4-8 weeks apart.
- Hepatitis A: Hepatitis A vaccine should be administered to children and adolescents at increased risk of infection and may be considered for all other persons over 2 years of age wishing to obtain immunity. Children should receive 1-2 doses, depending on the product given, and a booster dose ≥ 6 months after the initial dose. Consult package insert for specific scheduling and dosing information.
- 9. Influenza: Influenza vaccine should be administered annually to children 6 months of age and older who have specific risk factors. Children 12 years and younger should receive split virus vaccine in a dosage appropriate for their age (0.25 mL if 6-35 months or 0.5 mL if 3 years or older). Children less than 9 years of age who are receiving influenza vaccine for the first time should receive 2 doses, separated by at least 1 month.
- 10. **Pneumococcal:** Pneumococcal vaccine should be administered to children 2 years of age and older who have increased risk of acquiring systemic pneumococcal infections or increased risk of serious disease if they become infected. Children ≤10 years of age who previously received the 23-valent vaccine should be considered for revaccination after 3-5 years if they are at high risk of severe pneumococcal infection; children >10 years with these conditions should also be revaccinated if it has been ≥6 years since their first vaccination.

Based on recommendations of the Advisory Committee on Immunization Practices, the American Academy of Pediatrics, the American Academy of Family Physicians, and the Immunization Practices Task Force of the Minnesota Department of Health (MDH)

Questions? Call the MDH, (612)623-5237 or toll-free, (800) 657-3970.

Minnesota Department of Health, May 1996

# **Special Notes on Immunization**

- □ True Contraindications: Only true contraindications to vaccination should be followed. For example, children who present with a mild acute illness, with or without fever, should not be deferred for vaccination. (See MDH Guide to Contraindications.)
- Avoiding missed opportunities: Use all clinical encounters to screen for and provide needed vaccines.
- Simultaneous vaccination: There are no contraindications to simultaneous administration of vaccines recommended for routine use in children. Multiple vaccines may be administered in one or two visits for children 12-15 months of age and are strongly encouraged in one visit for children who have fallen behind.
- Reporting adverse reactions: Report adverse reactions to vaccines through the federal Vaccine Adverse Event Reporting System (VAERS). For information on reporting reactions following vaccines administered by private physicians, call the 24 hour national toll-free information line (1-800-822-7967). Report reactions to vaccine administered in public clinics to the Minnesota Department of Health, (612) 623-5414 or toll-free 1-800-657-3723.
- Disease Reporting: Report suspect cases of vaccinepreventable diseases to the local health department or to the Minnesota Department of Health, 717 Delaware Street S.E., Minneapolis, Minnesota 55440, (612) 623-5414 or toll-free 1-800-657-3723.

# For children who start late or have fallen behind

If a child has delayed immunizations, it is not necessary to start over. Refer to the tables below for recommended schedule and minimum intervals between vaccines. Determine the number of previous doses of each vaccine received, find that number in the first column, and read across to the appropriate column for the next dose and minimum interval.

#### Table 1. Catch-up schedule for children 4 months through 6 years (DTP/DTaP, OPV, HBV, and Hib)

Number of	Doses to be given and minimum intervals									
of each vaccine	First dose	Second dose	Third dose	Fourth dose	Fifth dose					
None	DTP OPV HBV Hib <sup>1</sup>	DTP: 4 weeks after 1st dose OPV: 6 weeks after 1st dose HBV: 4 weeks after 1st dose Hib <sup>1</sup> : If current age <12 months, 4 weeks after 1st dose. If	DTP: 4 weeks after 2nd dose OPV: 6 weeks after 2nd dose HBV: 2 months after 2nd dose <sup>2</sup> Hib: If current age <12 months, 4 weeks after 2nd dose	DTaP/DTP: 6 months after 3rd dose (Give DTP if 12-15 months of age or DTaP if ≥ 15 months.) OPV: 6 weeks after 3rd dose <sup>3</sup> Hib <sup>3</sup> : Only necessary for	DTaP/DTP <sup>4</sup> : 6 months after 4th dose					
		weeks after 1st dose (final dose).	current age 12-59 months, 8 weeks after 2nd dose (final dose).	who received 3 doses <12 months.						
One										
Тwo										
Three				-						
Four					-					

#### Table 2. Catch-up schedule for children age 7 and older (Td, OPV<sup>4</sup>, and HBV<sup>2</sup>)

Number of	Doses to be given and minimum intervals							
of each vaccine	First dose	Second dose	Third dose	Booster dose				
None	Td	Td: 4 weeks after 1st dose	Td: 6 months after 2nd dose	Td: every 10 years				
	OPV	OPV: 6 weeks after 1st dose	OPV: 6 months after 2nd dose	OPV: none				
	нву	HBV: 4 weeks after 1st dose	HBV: 2 months after 2nd dose <sup>2</sup>	HBV: none				
One								
Тwo								
Three								

1. Hib: Unvaccinated children 15-59 months should receive a single dose of vaccine. Vaccine is not generally recommended for children ≥60 months.

2. HBV: The minimum interval between HBV-2 and HBV-3 is 2 months; however, an interval of 4-12 months will result in higher final titers of anti-HBs.

3. Hib: If PRP-OMP was given for the first 2 doses, no more than 3 doses are needed with the final dose given at 12-15 months and at least 2 months from the previous dose. If a 3rd dose of HbOC or PRP-T is given ≥ 12 months of age, a 4th dose is not needed.

4. Polio, DTP/DTaP: Neither the 4th OPV or 5th DTaP/DTP is necessary if the previous dose was administered after the 4th birthday.

#### Provide MMR and varicella vaccine at $\geq$ 12 months.

A 2nd dose of MMR should be administered between 4 and 12 years, preferably at age 11-12 years.

# **Recommended Adult Immunization Schedule**

This schedule supplements the schedule of routine childhood immunizations.

Vaccine ▼ Age ►	19-64 years	65+ years			
Diphtheria & Tetanus <sup>1</sup>	Booster every ten years				
Hepatitis A <sup>2</sup>	2 doses if at increased risk of HAV infection & of	thers wishing to obtain immunity			
Hepatitis B <sup>3</sup>	3 doses for those with risk factors				
Influenza <sup>4</sup>	nnually, if risk factors exist, and others wishing immunity	annually			
Measles, Mumps, Rubella <sup>5</sup>	1-2 doses if born after 1956				
Pneumococcal <sup>6</sup>	1-2 doses for those with risk factors	1 dose			
Varicella <sup>7</sup>	2-dose series for selected groups				

#### FOOTNOTES

- Diphtheria and Tetanus (Td): All adults should complete a 3-dose primary series of diphtheria and tetanus toxoids with the first 2 doses given at least 4 weeks apart and the 3rd dose given 6-12 months after the 2nd. All adults for whom 10 years have elapsed since completion of their primary series or since their last booster dose should receive a Td booster. Booster doses of Td are thereafter needed every 10 years.
- 2. Hepatitis A: Hepatitis A vaccine should be given to persons who are at increased risk of hepatitis A infection (HAV), food handlers, and others wishing to obtain immunity. Populations at increased risk include: persons traveling to or working in countries with high rates of HAV; men who have sex with men; persons who use street drugs; persons with chronic liver disease; persons who work with HAV-infected primates or with HAV in a research setting; and persons with clotting factor disorders. Adults should receive a single 1 mL dose, followed by a booster dose ≥6 months later.
- 3. Hepatitis B: Adults at risk of HBV infection include: persons who are exposed to blood or blood products in their work; clients and staff of institutions for the developmentally disabled; hemodialysis patients; recipients of factor VIII or IX concentrates; household or sexual contacts of persons identified as HBsAg-positive; persons who plan to, or live in, parts of the world where HBV infections are common; injecting drug users; sexually active homosexual or bisexual males; sexually active heterosexual persons with multiple partners or recent episode of an STD; inmates of long-term correctional facilities; and persons of Pacific Islander ethnicity or first generation immigrants/refugees from countries where HBV infection is of high/intermediate endemicity. Pre-exposure dosage for adults is 10 µg of Merck vaccine (Recombivax HB) or 20 µg SmithKline Beecham (Engerix-B).
- Influenza: Influenza vaccine should be administered annually to all adults ≥65 years of age; residents of nursing homes and other long-term care facilities; younger adults with chronic cardiopulmonary disorders, chronic metabolic diseases (including diabetes), renal dysfunction, hemoglobinopathies, or immunosuppression; as well as household members and care-givers, including health care workers and household workers, to the above. Other adults who wish to reduce their likelihood of becoming ill with influenza may also be vaccinated.
- 5. Measles, Mumps, Rubella: Adults born before 1957 are considered naturally immune. Adults born in 1957 or later should receive one dose of MMR vaccine. Some adults may need two doses, such as college students, those working in health-care facilities, and international travelers.

- 6. Pneumococcal: Pneumococcal vaccine should be given to adults under the age of 65 years with cardiovascular disease, pulmonary disease, diabetes mellitus, alcoholism, cirrhosis or cerebrospinal fluid leaks; splenic dysfunction, asplenia, Hodgkin's disease, lymphoma, multiple myeloma, renal failure, nephrotic syndrome; or asymptomatic or symptomatic HIV infection. In addition, all previously unvaccinated adults ≥ 65 years of age should be vaccinated. Generally, revaccination is not indicated except for patients at highest risk of fatal pneumococcal infection (e.g., asplenic patients) who received the 14-valent vaccine or the 23-valent vaccine ≥6 years ago and persons who received the 23-valent vaccine ≥6 years ago who have nephrotic syndrome, renal failure, or are transplant recipients.
- 7. Varicella: Varicella vaccine should be administered to susceptible persons who will have close contact with persons at high risk for serious complications (e.g., health care workers and family contacts of immunocompromised persons) and considered for susceptible persons who are at high risk of exposure, such as those with occupational risk (i.e., teachers of young children, day care workers and residents and staff in institutional settings); college students; inmates and staff of correctional institutions; military personnel; non-pregnant women of childbearing age; and international travelers.

#### SPECIAL NOTES

- Assessing adult vaccination status: All adults should be assessed at age 50 years to determine current vaccination status, receive Td toxoid as indicated, and be evaluated for risk factors for other vaccinepreventable diseases (e.g., influenza and pneumococcal disease).
- Reporting adverse reactions: Report vaccine reactions through the federal Vaccine Adverse Event Reporting System. For information on reporting reactions following vaccines administered by private physicians, call the 24 hour toll-free information line 1-800-822-7967. Report reactions to vaccine administered in public clinics to the MDH, (612) 623-5414 or toll-free 1-800-657-3723.
- **Disease reporting:** Report suspect cases of vaccine-preventable diseases to the local public health department or to the MDH, 717 Delaware Street S.E., Minneapolis, Minnesota 55440, (612) 623-5414 or toll-free 1-800-657-3723.

Based on recommendations of the Advisory Committee on Immunization Practices, the American College of Physicians and the Immunization Practices Task Force of the Minnesota Department of Health (MDH)

Questions? Call the MDH (612) 623-5237 or toll-free 1-800-657-3970.

Minnesota Department of Health, June 1996 IC#141-0316

# Attachment B

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# Summary of Immunization Rates

# Attachment B—Summary of Immunization Rates

Immunization rates for infants and young children appear to be on the rise in Minnesota, although many of the state's preschoolers still aren't getting all of their shots on time. In a comprehensive survey of over 69,000 children who started kindergarten during the Fall of 1992, MDH found that only 61% had completed the required doses of the primary series on time —meaning they had not received all the recommended doses of vaccine for measles, mumps, rubella, polio, diphtheria, tetanus and pertussis by age two (Table 1). Similar retrospective surveys have been completed every Fall since 1992 by identifying a random sample of Kindergartners and collecting their school immunization records. These subsequent surveys indicate that pediatric immunization levels are improving, as shown below with the results of 1995-96 retrospective survey.

Table 1						
Survey Type	% UTD for	% UTD	% UTD			
	DTP, Polio, &	for MMR1	for HepB3			
	MMR by Age 2	by Age 2	by Age 2			
1992-93 Retrospective Kindergarten Survey (Comprehensive, n=69,115)	61%	83%	Not Available			
1995-96 Retrospective Kindergarten Survey	71%	89%	Not Available			
(Random Sample, n=1085)	(±3%)	(±3%)				
1995 National Immunization Survey	79%	94%	26%			
(Random Digit Dialing, n=318)	(±5.2%)	(±2.9%)	(±5.7%)			

The most recent immunization coverage level data for Minnesota comes from the National Immunization Survey (NIS), completed by the Centers for Disease Control and Prevention (CDC). The state-specific rate for the primary series was 79% (±5.2%) for children aged 19 to 35 months as measured during the period from July of 1994 through June of 1995 (Table 1). Minnesota tied with five other states for the 15th rank.

Although rates are rising, Minnesota's preschool immunization levels continue to vary widely with age, vaccine type, and geographic area. Therefore MDH is currently conducting a second comprehensive retrospective Kindergarten survey during the 1996-97 school year. The advantage to repeating the comprehensive survey is the ability to identify typical ages when children tend to be behind, as well as geographic and racial/ethnic pockets of need. In addition, MDH will be able to judge progress made in improving immunization rates in our state.

Summary of Minnesota's Immunization Levels—December 27, 1996—Minnesota Department of Health—Acute Disease Prevention Services

# Attachment C

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Counties With Immunization Registries



Minnesota Department of Health, based on survey completed in October, 1996.

The numbers shown in each county represent the number of live births in 1994.

# Attachment D

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# Immunization Laws in Other States

# Summary of State Immunization Requirements Applicable to Any or All Grades K-12, 1994-95 School Year

Required For All Grades K-12

State	Diphtheria	Tetanus	Pertussis*	Measles	Mumps	Rubella	Polio
Alabama					Net De suise si		
aska					Not Required		
izona					Not Deguired		
Arkansas					Not Required		
California							
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\* Pertussis vaccine is required only through age 6 years

# Attachment E

# Summary of Draft Bill Authorizing the Creation of Community-Based and Statewide Immunization Registries

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# Community Immunization Registries

# Description

Protecting children and the community from vaccine-preventable diseases and supporting the immunization efforts of families, health care providers, and schools are the goals of the Community Immunization Registries for Children Initiative. Immunization registries are computerized systems that make records more easily available to parents, and health care providers, and assist public health agencies in assessing immunization rates in the community.

Incomplete immunization records and an increasingly complex immunization schedule make it difficult for parents to know what shots their children need by when. Parents also need complete and accurate shot records for day care, sports, camp, and school, but find this difficult–especially when previous immunizations have been received at different clinics.

Immunization registries can send reminder notices to parents and health care providers telling them what shots are due next and when. They make it possible to more quickly assess immunization rates in the community and statewide to better target limited resources.

# **Specifics**

This funding would accomplish four goals. First, it would make available \$1 million annually in community grants for the planning and implementation of community-based immunization registries. This funding is critical to support the start-up costs associated with a new community system, so that it can more quickly achieve its cost-savings potential.

Second, the funding would support technical assistance and consultation to communities, regardless of whether or not they were awarded grant funding.

Third, it would support a broadly representative immunization registry task force to advise the Commissioner of Health on data protection and access standards, quality assurance standards, and recommended policies and procedures. The task force would also advise the Commissioner on the community grant goals and award criteria.

And, lastly, it would support the technical design and feasibility testing of a possible statewide immunization registry "hub" to connect and support community-based registries.

# Historical Background

Current laws provide for sharing of what is now largely manual records, but this process is time consuming and inefficient. Automating these records is critical and this law will assure that standards are in place for safe and secure operation.

Parents often have to contact many providers to get complete immunization histories for their children. Computerized registries will help parents and providers protect children by:

saving parents time by providing quick and easy access to immunization reports on all their children;

#### 2 Legislation on Immunization Registries

- making immunization records easily accessible to all public and private immunization providers so children receive the right immunizations on time;
- identifying children who have never been immunized or who fall behind on their immunizations and triggering reminders to parents and providers; and
- making it possible to quickly and easily assess the immunization rates of individual clinics and entire communities to better target resources.

It would be difficult to over-estimate the amount of time spent searching for and clarifying children's immunization records—and the negative impact this may have on childhood immunization. Every year, children's records are checked by schools, child care programs, camps, hospitals, and clinics – an estimated 2.2 million record checks in a system that must deliver and track about 1.6 million doses of vaccine to Minnesota children annually. Registries will improve both the efficiency and effectiveness of this process. Further, they will improve the health of children and provide benefits to communities, parents, and health care providers.

Community registries in Minnesota are growing. Some 33 Minnesota counties have communitybased registries in operation or under development. This is an increase from under five just three years ago.

Immunization registries will not change Minnesota's immunization requirements for child care and schools, nor limit a person's ability to conscientiously object to immunizations.

# Supporters

Private and public providers of immunizations, clinics, health plans, and professional associations are very supportive of having access to complete and accurate immunization records, and of ensuring tracking and follow-up of families who are delayed in receiving preventive health services.

# Opposition

Some providers and professional associations may oppose community registries if they believe that new immunization requirements or computer systems are being forced on them, even though that is not the case. And any attempt to enhance immunization data sharing may be opposed by data privacy advocates or groups who oppose immunizations, even though immunization information sharing is already authorized.

> 3/5/97 Minnesota Department of Health DP&C - ADPS 612/623-5237

