Minnesota Birth Defects *Information System*

REPORT TO THE MINNESOTA LEGISLATURE

By the
Minnesota Department of Health
Disease Prevention & Control

March 1997

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

March 17, 1997

Dear Members of the Minnesota Legislature:

This report, Minnesota Birth Defects Information System, discusses the public health burden of birth defects and presents the recommendations of the Technical Advisory Work Group regarding the development of a birth defects information system for the state of Minnesota. This report was prepared in response to the following legislation:

> *The Commissioner of Health shall develop a statewide birth defects registry system to provide for the collection, analysis, and dissemination of birth defects information. The commissioner shall consult with representatives and experts in epidemiology, medicine, insurance, health maintenance organizations, genetics, consumers, and voluntary organizations in developing the system and may phase in the implementation of the system. [§144.2215] The commissioner shall submit to the Legislature a report by January 31, 1997, on the development of the birth defects registry system, including recommendations for additional statutory authority necessary to implement the system.*

The Minnesota Department of Health (MDH) would like to thank the many people on the Work Group who contributed their time and expertise to the development of a birth defects information system for the state of Minnesota over the past six months. They put substantial thought into the recommendations that MDH will carefully consider if the system moves towards full implementation.

If there are questions in reference to this report, please contact Dr. Marian Marbury or Dr. Debora Boyle of my staff at (612) 623-5216

Thank you for your time and attention to this important public health matter.

Sincerely,

Anne M Barry

Anne M. Barry
Commissioner

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Minnesota Birth Defects Information System

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EXECUTIVE SUMMARY

Birth defects are the single biggest cause of death in children under one year of age. They also cause a large number of stillbirths and miscarriages. In Minnesota it is likely that over 3,000 children are born each year with a birth defect and these children account for 25 to 30 percent of all hospitalizations in childhood. Birth defects are also very costly; a recent study reported that total direct medical costs for birth defects exceeds 1.4 billion dollars nationally every year. These estimates do not include the emotional impact on families who have children with birth defects.

Despite the magnitude of the problem, little is known about the actual causes of birth defects. About 25 percent are due to genetic defects. Maternal infections, diseases, and use of drugs and alcohol account for another 3 to 5 percent, and it is likely that occupational and environmental exposures may account for 2 to 3 percent. This means that the causes of about two-thirds of all birth defects are unknown. In Minnesota, the rates of various defects and, whether they are increasing or decreasing is unknown. For example, the finding of deformed frogs in some counties of Minnesota has recently generated public attention and concern. The Minnesota Department of Health (MDH) cannot provide any information about "deformed" frogs, but it has received questions about the rates of cancer and birth defects in these counties. Currently there is information about the occurence of cancer in Minnesota through the Minnesota Cancer Surveillance System, but there is no complete and accurate information about the occurence of birth defects. Data gathered through a statewide Birth Defects Information System would assist the MDH in responding to these concerns by providing information about the rate and number of birth defects in a county compared to the entire state of Minnesota. This information is often quite valuable in helping to put concerns into perspective.

Recognizing the seriousness of the problem and the state's lack of information on birth defects, the 1996 Minnesota State Legislature directed the Commissioner of Health to develop a Birth Defects Information System (BDIS) within the Minnesota Department of Health. The MDH was given a one year, one time appropriation to prepare a report to the Legislature on the development of the system, with guidance from a Technical Advisory Work Group. The Work Group was defined in statute to include representatives and experts in epidemiology, medicine, insurance, health maintenance organizations, genetics, consumers, and voluntary organizations. The Work Group met monthly for six months to discuss the principles, goals, and objectives of the system, what data should be collected and on whom, how the data should be collected and used, and who should have access to it. This report presents the Work Group recommendations. Implementation of these recommendations would require additional on-going funds.

The overall purpose of a BDIS is to prevent birth defects. Prevention efforts may include preventing a defect from ever occurring or helping to ease the long-term disabling consequences of having a birth defect. To achieve prevention, the BDIS has three principle goals: (1) research and monitoring, (2) education, and (3) helping link children with birth defects to services. Research and monitoring includes describing the occurrence of defects and evaluating trends over time; responding to concerns of citizens; directly supporting needed studies aimed at finding causes of defects; and evaluating our efforts to prevent birth defects through public health education. The BDIS should also be a primary source of information and education for both health providers and citizens about the occurrence of and risks for defects. Information from a BDIS can also assist in making sure that children with birth defects have access to the services they need.

Conducting surveillance for birth defects is not an easy task, however. Although the state has reporting systems for cancer and infectious diseases, it quickly became clear that these methods are not applicable to birth defects. In looking at other states' efforts at birth defects surveillance, the Work Group found a wide variety of methods and approaches. Some systems that were more service-oriented were very incomplete in their case-finding, so that their data could not be used to calculate rates, monitor trends, or assist in research. Other states had very complete case-finding methods, but their data took so long to collect that the opportunity to connect children to services at an early stage was lost. The Work Group believes that Minnesota citizens need a system that can do both, and is efficiently designed and adequately funded. As a basis for designing such a system, the Work Group agreed on basic principles that should be the foundation of the BDIS. These principles, discussed more fully in the report, state that the system should be comprehensive, scientifically valid, flexible, efficient, and protective of the privacy of individuals. In addition, the costs of collecting the data should not be borne by the institutions and healthcare practitioners who provide it.

With a clear vision of what the BDIS could and should accomplish, the Work Group started discussing the various components of the system. The first decision concerned how a birth defect should be defined. Including any abnormality present at birth, including all genetic diseases and developmental disabilities, would be overwhelming. The Work Group decided that, at least initially, the BDIS should focus on collecting information on children born with major and some selected minor structural defects. This definition is similar to that used by some of the best systems currently operating, such as California and Metropolitan Atlanta. In addition, the defects should be either diagnosed within the first year of life or have signs and symptoms within the first year and diagnosed by six years of age. Since birth defects need not be defined in statute, there can be the option to expand the definition in rules to include developmental disabilities or other conditions at a later date.

The Work Group concluded that the exact methods to be used in collecting birth defect data need to be evaluated in the first two years of implementation. For the system to have widespread acceptance, data collection methods must be designed to have a minimal impact on data providers. The two major methods of data collection that meet this criterion are linkage of existing datasets (e.g., hospital discharge data, vital statistics, medical assistance data) and active case-finding, in which abstracters employed by the state visit hospitals and genetic clinics to gather data. It is well known that passive reporting, where institutions or healthcare providers are required to fill out report forms on each child, would be burdensome and that reporting would likely be incomplete.

The Work Group agreed that using the information to facilitate linking children and their families to services was an important and valuable function. At a minimum, counts of cases and rates should be used to assist with needs assessment and service planning. The Work Group also agreed that whether the system should help assure that individuals are aware of available services needed to be evaluated in the first two years. More information is needed to determine to what extent this already occurs and more discussion with parents and with service providers is critical.

The Work Group believes that protecting the privacy of the data is essential and that only the MDH and the citizens in the database should have access to their data. Access of researchers to data should be controlled by a review process and identifying information should not be released without the permission of the individuals.

The Work Group advised that the system should start up in stages. During the first two years, methods should be evaluated in three regions: Olmsted County, the northwest area of the state, and the Metropolitan area. Statewide surveillance would start some time in 2000.

Budget estimates for the first year of implementation is $670,000. Each additional year of support for data collection, analysis and report development is estimated to be $1,000,000.

SUMMARY

This report was prepared in response to Minnesota Statutes Section 144.2215 (1996), "the Commissioner of Health shall develop a statewide birth defects registry system to provide for the collection, analysis, and dissemination of birth defects information." This bill provided funding for one year to start designing a system. During the first year, the MDH was required to form an advisory group and submit a legislative report on the development of the birth defects registry system.

Public health burden of birth defects

- Three to six percent of all babies are born with a birth defect, and many children have multiple defects. This means that approximately 1,800 to 3,600 babies are born in Minnesota each year with a serious structural defect.
- Birth defects are the leading cause of infant mortality in Minnesota, causing 597 of the 2,331 infant deaths (26 %) that occurred from 1991 to 1995.
- Based on 18 common defects, which represent less than one-third of babies born with defects each year, we estimated that these defects will cost Minnesota close to 90 million dollars each year.

Causes of birth defects

The causes of birth defects are unknown in about 60 to 70 percent of cases. Inherited abnormalities are thought to cause about 25 percent and prenatal factors account for another 5 to 15 percent.

Known non-genetic causes of birth defects include maternal nutrition, maternal diseases, maternal infections, maternal use of drugs, alcohol and tobacco, and paternal or maternal occupational and environmental exposures. The magnitude of the contribution of occupational and environmental exposures is unknown.

Benefits of a Birth Defects Information System

- Calculate incidence rates and monitor trends in order to provide accurate information about the occurence of birth defects in Minnesota.
- Respond to citizen concerns about clusters of birth defects.
- Conduct research into causes with the potential to identify preventive measures.
- Evaluate intervention/prevention efforts.
- Educate the public and inform health professionals.
- Help facilitate the connection of children with birth defects to services.

The Birth Defects Information System should be guided by the following principles

- The Birth Defects Information System should be population-based. That is, complete ascertainment of defined birth defect diagnoses must be obtained from a population of known size and demographic characteristics. The methods for finding cases must ensure a high level of case identification.

- The system should be based primarily upon diagnoses for which medical criteria are well defined.

- The system should provide for prompt identification of defined birth defects once they have been diagnosed and rapid computer processing of incoming information.

- The core data of the system should meet three criteria: usefulness, scientific validity, and economic feasibility. Data should be collected in an efficient and cost effective manner and data that can only be acquired through patient contact should not be part of the core information system.

- The system should be designed for close collaboration with research, treatment, and service programs. It is through this collaboration that effective new knowledge for the prevention of birth defects and education and support for families can be developed.

- The design of the system should be flexible enough to facilitate modifications and extensions that take advantage of new technologies (including new methods of case identification), or that address newly identified needs of health professionals, families affected by birth defects, and researchers.

- The system must provide strict confidentiality for families affected by birth defects. To protect data privacy, the system should maintain records that could be used to identify individual patients in a separate database from medical information.
- Information in existing databases should be used whenever possible to maximize the efficiency of operation of the system.
- Data collection methods should be designed to have a minimal impact on data providers.

Recommendations of the Technical Advisory Work Group

1. Case Definition. The case definition should include children with selected major and minor structural congenital defects whose mothers are Minnesota residents. Children must have signs or symptoms related to a birth defect prior to one year of age, but may be diagnosed by a health care provider at any time before their sixth birthday. The case definition should also include children who are diagnosed with infantile spasms. Following establishment of the BDIS, a work group should be formed in approximately five years to determine whether the system should also conduct surveillance for developmental disabilities.

2. Data to be collected. The system should collect available information on the infant/child, mother, and father. This information can be used to: (1) make sure that each individual only appears once in the database, (2) determine the most accurate diagnostic code for the birth defect, and (3) provide necessary information for education, service planning, and research.

3. Data collection methodology. The data collection methodology should consist of either active case-finding methods (state employees review selected hospital and clinic records to identify children with birth defects and fill out standardized forms on each case) or linkage of databases. The cost and completeness of each method should be evaluated in the first two years of the implementation of the system.

4. Uses of data. The data should be used for research and epidemiology, education, and services, as described in the goals and objectives. The exact form in which the data can be used for services needs further evaluation. At a minimum, it should be provided to service planners on an aggregate basis, with no personal identifiers.

5. Data privacy issues. The data must be legally protected, and access to the data must be strictly controlled. The data should be classified as private, non-public, meaning only the MDH and the citizens in the database can have access to their data.

6. Staged implementation. Implementation of the system should take place in two stages. During the first two years (1997-1999), the BDIS should collect data and evaluate methods for three areas of the state. Statewide implementation could take place starting in the year 2000.

7. Enabling legislation. The Work Group agreed on a number of general principles for a statute regarding a Minnesota Birth Defects Information System.

HISTORY OF BIRTH DEFECTS IN MINNESOTA

In 1981, the Minnesota State Legislature passed a bill requiring the Commissioner of Health to conduct birth defects surveillance in Minnesota. In response, the Minnesota Department of Health (MDH) analyzed birth defect information on birth certificates, and produced a report in January 1984 entitled "An Overview of Birth Defects in Minnesota: 1950 - 1980." This report documented the inadequacy of relying on birth certificates for information on birth defects and described the need for additional funding to establish a surveillance system.

No further birth defects surveillance activities took place until 1994, when the national office of the March of Dimes made the establishment of state surveillance systems one of their top priorities. In August 1994, the local chapter of the March of Dimes convened a day-long meeting on birth defect surveillance in Minnesota. At this meeting, they decided that the goal of a birth defects information system should be to improve birth outcomes and the health of children. Purposes of the system included: (1) monitoring trends and incidence; (2) improving child health services; (3) addressing environmental concerns; (4) identifying risks; (5) expanding primary prevention; and (6) evaluating the effectiveness of prevention programs. As part of this process, a broad-based group worked toward passage of legislation with funding in the 1995 legislature. Bills were introduced in the House and Senate, but there were no hearings.

In 1996, the bills were reintroduced, passed, and signed into law. Representative Ann Rest was the chief author of the Birth Defects Information System (BDIS) bill for the House and Senator Linda Berglin was the chief author of the bill for the Senate. According to Minnesota Statutes Section 144.2215 (1996), "the Commissioner of Health shall develop a statewide birth defects registry system to provide for the collection, analysis, and dissemination of birth defects information." This bill provided $195,000 for one year to start designing a BDIS. During the first year, the Commissioner was required to "consult with representatives and experts ... in developing the system" and submit a legislative report by January 31, 1997. A copy of the existing statutes is included in Appendix A.

In response to this bill, the MDH formed a Technical Advisory Work Group (hereafter referred to as the Work Group) representing a broad variety of disciplines, institutions, and the public that would either benefit from or provide data for a BDIS. (See Appendix B for the membership.) This group met monthly for six months and discussed a broad range of issues pertaining to the development and implementation of a BDIS. Many issues were raised and most were resolved. In those instances where a resolution could not be achieved without more information, a plan was devised for moving towards a resolution. This report represents a substantial commitment of time and energy from Work Group members. That commitment reflects the belief that a BDIS, adequately designed and implemented, can contribute to the health of Minnesota's citizens, and particularly to those who are born with birth defects.

OVERVIEW OF BIRTH DEFECTS

The March of Dimes Birth Defects Foundation defines a birth defect as:

> *an abnormality of structure, function, or metabolism, whether genetically determined or the result of environmental influence during embryonic or fetal life. A congenital defect may cause disease from the time of conception through birth or later in life.*

This definition provides an excellent starting point for understanding the problem and indicates the wide range of conditions that can be considered as birth defects.

For case-finding purposes, however, it is too broad; it combines conditions that vary in severity from quite minor, such as pigmented skin lesions, to conditions that are very severe and may be life-threatening, such as heart abnormalities. In addition, it includes any disease with a genetic origin, including some types of cancer and some diseases that don't appear until middle age, such as Huntington's chorea. It also implies that birth defects are caused by either genetic or environmental influences. Increasing scientific evidence points to this dichotomy as being false in many cases. Many defects are probably the result of a genetic susceptibility and an environmental influence, neither of which alone would result in a defect. And in some cases defects are probably the result of genetic mutations or chromosomal abnormalities in the germ cells (sperm or ova) that happened before conception.

Surveillance for birth defects is a complex undertaking, much more difficult than for diseases such as cancer. Almost all cancers are diagnosed by pathology and most hospitals that treat cancer patients already have tumor registries. In contrast, birth defects are a much more diverse group of disorders, and depending on the specific type of defect, children with birth defects are seen by a wide array of health care practitioners. This difficulty mandates that surveillance start with conditions that can be precisely defined. For this reason, the Work Group defined a birth defect as a major structural malformation that is serious enough to require medical attention within the first year of life.

This report first describes the impact of birth defects on public health; the associated economic costs; known risk factors for birth defects; and the contribution of a BDIS to the prevention of birth defects. With this as background, the report presents the recommendations of the Technical Advisory Work Group that has been meeting monthly to provide the Commissioner of Health with advice regarding the development of a BDIS.

Appendix C describes data on birth defects that are currently available in Minnesota, and service programs for children with birth defects.

Birth defects are a major public health problem

- Three to six percent of all babies are born with a birth defect, and many children have multiple defects. This means that approximately 1,800 to 3,600 babies are born in Minnesota each year with a structural defect.
- Birth defects are the leading cause of infant mortality in Minnesota, causing 597 of the 2331 infant deaths (26 %) that occurred from 1991 to 1995. Birth defects are also the leading cause nationwide, causing 20 percent of all deaths (about 8,000) under one year of age.
- Birth defects are responsible for 12 percent of the deaths that occur in children between one and four years of age in Minnesota.
- Birth defects account for 25 to 30 percent of all pediatric admissions to hospitals.
- Birth defects are the fifth leading cause of years of potential life lost.
- Based on 18 common defects, which represent less than one-third of babies born with defects each year, we estimated that these defects will cost Minnesota close to 90 million dollars each year.
- All these statistics actually underestimate the problem as the vast majority of babies with birth defects are miscarried early in pregnancy or are stillborn.
- These statistics also fail to reflect the emotional and financial burden of families who have children with birth defects.
- Despite their importance, Minnesota does not have good data on the rates of birth defects in the state or a systematic means of addressing birth defect-related issues.

Birth defects have a substantial economic impact.

While Minnesota lacks specific data on rates of birth defects and their economic costs, a recent study in California demonstrates the immense economic burden suffered as a consequence of birth defects (Waitzman 1994). In this study, the researchers calculated the lifetime costs per case for 18 common birth defects. These costs reflect both direct costs, such as the costs of medical treatment, developmental services, and special education; and indirect costs, such as lost productivity, including wages, due to early death or occupational limitations. The estimates incorporate costs at each stage of life, reflecting the usual treatment, survival, and disability rate for each condition.

- "Correctable" conditions. With early care and successful surgery for correctable conditions, survivors will likely have normal lifespan and functioning. Medical expenses are high during the first year of life but subsequent costs are low. Examples of potentially correctable defects include intestinal atresia and urinary tract obstruction.

- Disabling conditions. These birth defects often have below normal survival beyond infancy and/or result in lifelong disability. Affected individuals need repeated surgeries or continued medical care (e.g., heart defects, cleft palate). Medical treatment and nonmedical costs extend beyond one year of age. In addition, many have physical defects or require special education or other developmental services (e.g., spina bifida, Down syndrome).

People with birth defects often have related problems (additional defects, low birth weight, developmental disability), and the researchers included estimates of the extra costs for treating associated problems in affected persons.

Nonetheless, as dramatic as these cost estimates are, they actually underestimate the total economic burden. The calculations did not include the lost wages of family members taking time from work to care for those with birth defects; the psychosocial costs, such as the pain and suffering of affected individuals or their families; or the private, out-of-pocket spending for special vehicles, transportation to treatment, home modifications, and appliances.

Based on these cost and rate estimates, birth defects will cost Minnesota over 90 million dollars per year (Table 1). The selected defects account for less than one-third of the total number of children that are born with defects each year. Clearly, prevention or early treatment of even a fraction of these defects would save Minnesota citizens millions of dollars a year. For example, each case of spina bifida costs about $250,000. If the BDIS assisted in preventing four cases of spina bifida each year, the BDIS would pay for itself.

Table 1.

Estimated Number and Lifetime Costs of 18 Common Birth Defects for One Year in Minnesota

DEFECT	ESTIMATED NUMBER OF CHILDREN	TOTAL ECONOMIC COSTS*
Heart Defects		
Single ventricle	8	$2,432,000
Truncus arteriosus	7	3,059,000
Tetralogy of Fallot	21	4,767,000
Transposition great vessels	29	6,873,000
Gastro-Intestinal Defects		
Small intestine atresia	23	1,472,000
Tracheal-esophageal fistula	17	2,176,000
Colorectal/anal atresia	28	3,108,000
Cleft lip/palate	106	9,752,000
Genito-Urinary Defects		
Urinary tract obstruction	62	4,774,000
Renal agenesis/dysgenesis	26	5,980,000
Musculoskeletal Defects		
Gastroschisis	16	1,504,000
Omphalocele	11	1,749,000
Lower limb reduction defect	13	2,366,000
Upper limb reduction defect	26	2,366,000
Diaphragmatic hernia	22	4,944,000
Central Nervous System		
Spina bifida	25	6,450,000
Down syndrome	63	25,830,000
TOTAL	**503**	**$89,602,000**

*Total economic costs include direct costs (medical treatment, developmental services, and special education) and indirect costs (lost productivity due to disability and early death).

Known Causes of Birth Defects

The causes of birth defects are unknown in about 60 to 70 percent of cases. Inherited abnormalities are thought to cause about 25 percent and prenatal factors account for another 5 to 15 percent. Thus for most parents of children with birth defects, their two most critical questions - What caused my child's defect? Will it happen again? - must go unanswered. As a first step in answering these questions, researchers have used birth defects information systems as a source of cases to study the causes of birth defects. Once the causes have been identified, further research may identify ways to prevent these birth defects from occurring.

Inherited abnormalities. Many birth defects, especially those that occur as part of syndromes, have a known genetic link. These genetic defects can be inherited through damaged genes that are passed down through generations from the father, the mother or from both parents. Other genetic damage that is passed to the child may be caused by environmental or occupational exposures to the parent, or simply occur by chance random mutation.

Defects may also be caused by abnormalities of the chromosomes (the "packages" that contain the genes). For example, one of the best known conditions involving an excess of chromosomal material is Down syndrome. Children with Down syndrome have short stature, mental retardation which ranges from mild to profound, and characteristic facial features. Research has shown that about 1 out of 700 children are born with Down syndrome, and that it is most common in children born to teenagers and women over the age of 35 years. In fact women over 40 years of age are 30 times more likely to have a baby with Down syndrome than women in their 20s or 30s. Although we know age is a strong risk factor, we don't know why this is true (i.e., why age is linked to a failure of chromosomes to separate). The extra chromosomal material is also contributed by the father in 10 to 20 percent of cases.

Advances in molecular biology have led to new understanding about what causes certain defects, and it is likely that as our understanding increases, we will find more and more cases where birth defects are the result of a gene/environment interaction. For example, studies have shown that women of Hispanic origin are more likely to have babies with spina bifida than other women (Shaw 1994). At first it was thought to be due to a lower dietary intake of folic acid. However, a more recent study has shown that this is not the explanation (Shaw 1995). Current thinking is that the higher incidence may be due to the increased frequency of certain genes that interfere with folic acid metabolism and that are found more frequently in people of Hispanic descent. This hypothesis is now being investigated in epidemiologic studies.

Prenatal factors. Prenatal factors are those factors that are not inherited and that affect the cells of the developing baby during pregnancy. Known prenatal risk factors include maternal nutrition, diseases and infections; maternal use of drugs, alcohol, and tobacco; and various environmental and occupational exposures. In the latter category, it is possible that some birth defects may be caused by damage to sperm or ova from exposures that occur before conception. However, current scientific understanding of this area is quite limited.

Maternal nutrition. In general, we know that adequate protein and calorie consumption during pregnancy is necessary for proper development of the brain. Folic acid is important in the prevention of neural tube defects, and recent studies have suggested that it may also reduce the rates of heart and limb defects.

Maternal diseases. Certain diseases of the mother have been shown to cause birth defects. For example, mothers with diabetes are much more likely to have babies with birth defects, as well as babies who die early. Maternal heart and kidney disease are also associated with abnormalities of their babies' vital organs.

Maternal use of drugs, alcohol, and tobacco. Alcohol and over-the-counter, prescription and illegal drugs have been shown to cause birth defects. Alcohol use by pregnant women can cause Fetal Alcohol Syndrome (FAS). FAS is the leading known cause of mental retardation, ranking well ahead of Down syndrome. In international studies FAS has been found to occur in 1.9 cases per 1,000 live births. However, in families where one case has occurred, the risk of a re-occurrence is much higher, about 700 in 1,000. In Minnesota an estimated 200 - 800 children a year are born with FAS, a completely preventable condition.

Fetal Alcohol Effects (FAE) is a less severe condition that occurs about 10 times as frequently as FAS among children born to women who abuse alcohol. Although the birth defects and retardation are less severe than in FAS, most of these children will require special education.

Illegal drugs are also known to cause birth defects. For example, babies whose mothers use cocaine are at higher risk for mental retardation, limb deformations, and defects in the gastrointestinal, genital, and urinary tracts. This type of problem is often difficult to study, since most people do not want to admit to illegal drug use. It is likely that illegal drug use results in more defects than we currently know about.

Many prescription drugs have also been implicated as causes of birth defects, which is why most medications carry warnings that they should not be used by pregnant women. Thalidomide is the best known example of a prescription drug taken during pregnancy that resulted in heart and renal defects and deformities of the limbs of babies in the 1960s. Accutane, a prescription drug used to treat acne, is known to carry a 25 percent risk of causing a deformed baby when taken during pregnancy. Certain anticonvulsant drugs, anticancer treatments, and anticoagulant drugs have also been shown to cause birth defects and/or central nervous system abnormalities, resulting in behavior or learning problems.

While maternal smoking has been demonstrated to cause low birth weight in babies and more respiratory infections in their children, its association with birth defects is less clear. However, a few studies have suggested that this is the case.

Environmental and occupational exposures. Prior to conception, exposure of either parent to certain environmental or occupational factors may affect the eggs or sperm, resulting in a child with birth defects. For example, one study suggested that male farmworkers exposed to pesticides and painters exposed to solvents may have a slightly increased risk of fathering a baby with anencephaly (no brain) (Brender 1988). Another study found an association between upper limb defects in children with paternal occupations of painter, truck driver and electrician, and between cleft lip and/or palate and occupations that work with chemicals or cleaning solvents (Olshan 1988). It must be stressed that these were very preliminary studies without good measures of exposure, and mostly serve to illustrate the kinds of studies that need to be done.

Just as environmental factors may cause changes in the genes and chromosomes of the parents prior to conception, exposures to environmental factors during the pregnancy may also be linked to birth defects. Various chemicals, radiation, and other factors are believed to harm the fetus. As we conduct more research, we may find that some defects of unknown cause are linked to environmental contaminants.

BENEFITS OF A BIRTH DEFECTS INFORMATION SYSTEM

A birth defects information system cannot, by itself, solve the problem of birth defects. However, establishment of such a system is an essential step in learning more about what causes birth defects, understanding their impact, and ultimately learning how to prevent them. The lack of a BDIS has been a major impediment towards making progress in this arena, at both a state and national level. The potential benefits of having a BDIS in Minnesota are described below. At the present time, the MDH lacks the capacity to address these issues.

Calculate incidence rates and monitor trends. Currently the only data available for birth defects in Minnesota are based on birth certificate information. Studies have shown the inadequacy of this data source. In a recent study in Georgia, only 14 percent of defects that were found by the Metropolitan Atlanta Congenital Defects Program were reported on the birth certificate (Watkins 1996). When the researchers considered only those defects that should be obvious at birth, still only 28 percent were reported.

A comprehensive, population-based BDIS in the state of Minnesota can help MDH to accurately calculate rates for each type of defect. This will allow the comparison of these rates to those in other states to see if Minnesota's rates are lower, higher, or about the same. Because of the relatively small numbers of each specific defect, it will be several years before there would be enough data for accurate comparisons, and there is likely to be some fluctuation in the rates. Nonetheless, comparisons with other states will help MDH evaluate if Minnesota has specific problems that need further investigation.

A BDIS will also enable MDH to evaluate trends in Minnesota rates over time. For example, a few years ago scientists noticed that the rate of ventricular septal defects (a type of heart defect where there is a hole between the two large chambers of the heart) was increasing. A follow-up study showed that the increase was due to better and more complete diagnosis, made possible by advances in medical technology. However, this increase would never have been detected without a BDIS.

Respond to citizen concerns. Currently the MDH lacks the ability to respond to citizen concerns about birth defects. For example, the MDH occasionally receives calls from citizens who believe that an excess of birth defects may be occurring in their neighborhood. In the absence of a BDIS, the MDH's only options for response are to either conduct an investigation that will be expensive and time consuming, and usually not provide clear answers, or to send general information about birth defects. The same was true for the MDH's response to perceived cancer clusters until the Minnesota Cancer Surveillance System was established in 1988. This inability to mount a comprehensive timely response is frustrating to both public health officials and to citizens.

Environmental concerns may also raise additional questions about birth defects. For example, the finding of deformed frogs in some counties of Minnesota has recently generated public attention and concern. The MDH cannot provide any information about "deformed" frogs, but it has received questions about the rates of cancer and birth defects in these counties. Currently there is information about the occurence of cancer in Minnesota through the Minnesota Cancer Surveillance System, but there is no complete and accurate information about the occurence of birth defects. Data gathered through a statewide Birth Defects Information System would assist the MDH in responding to these concerns by providing information about the rate and number of birth defects in a county compared to the entire state of Minnesota. This information is often quite valuable in helping to put concerns into perspective.

Conduct research into the causes of birth defects. One of the largest impediments to conducting research into causes of birth defects, either epidemiologic or clinical research, is identifying individual cases for studies. In the absence of a BDIS, one of two approaches is generally used: use of a single source of cases, such as a regional referral center; or use of an incomplete source, such as birth certificates. Both of these approaches suffer from problems with the data, however.

The first approach suffers from a weakness because the cases are not drawn from a known population. There may be factors related to their referral that could be confused with factors related to the causes of the defects. For example, let's assume that a study is being done in a certain referral center. Dr. X, a physician in a town with a paint factory who sees all the employees of that factory and their families, refers all of his patients with that defect to that center. Dr. Y, another physician in the same town, sends his patients with birth defects to another referral center. Any study of patients from the first center might well conclude that parental employment in the paint factory is a major cause of the defect. Any case series that is not population-based (i.e., drawn from a known population) is subject to this kind of problem.

The second approach is subject to a related problem. As stated earlier, birth certificates are known to be a very incomplete source of information on birth defects (Watkins 1996). A recent study in Minnesota demonstrated that the rates of certain birth defects are higher in the northwestern part of the state than in other areas, a finding which the investigator suggested might be due to pesticide exposure (Garry 1996). With the data systems currently available, there is no way to either confirm or disprove this hypothesis. It is possible that the finding is simply due to better completion of the birth certificate in that part of the state, either because mothers stay in hospitals longer in rural areas or because of some difference in the medical culture. The only thing we know for sure is that birth certificates are not a good way to study the causes of birth defects.

Another way in which a BDIS facilitates research into causes of birth defects is through the potential for combining data with other states. Most individual defects are relatively rare. Thus, if scientists wanted to study the causes of truncus arteriosus (a type of heart defect) for example, they would need either to collect cases over a long period of time, or combine Minnesota cases with cases from other states to have sufficient numbers. Comprehensive case identification is the single most expensive aspect of doing good studies into causes of birth defects. A BDIS substantially decreases those costs.

Although the issue of data privacy will be discussed in more detail later in this report, it is important to note here that the above discussion should not be misconstrued as suggesting that sensitive data on individuals would be distributed without their knowledge and approval. Aside from ethical considerations, the acceptance of a BDIS by Minnesota citizens will depend on the MDH being able to assure them that these data are carefully protected.

Evaluate intervention/prevention efforts. Recently, several studies (reviewed in Butterworth 1996) have shown that consumption of folic acid early in pregnancy can prevent up to 50 percent of all cases of neural tube defects (e.g., anencephaly, spina bifida). As a result, the Centers for Disease Control and Prevention and the March of Dimes have embarked on an effort to encourage all women of childbearing potential, particularly those who are planning a pregnancy, to take folic acid supplements. It is likely that as research continues, more preventable causes of birth defects will be discovered. However, knowledge alone is not enough; unless that knowledge is translated into effective public health education campaigns, which are successful in changing behavior, the opportunity for prevention is lost. But an essential component of education depends on the ability to measure whether efforts are effective. One way, of course, is to conduct annual surveys of folic acid consumption, but these surveys are expensive and often overestimate the behavior. A more direct method is to monitor trends in the outcome targeted for prevention. If folic acid education campaigns are successful, this should result in a decline in the prevalence of neural tube defects at birth.

Education. A BDIS can serve as the focus for both health professional and public education about the prevalence, cost, and opportunities for prevention of birth defects. This can take several forms. At a minimum, most BDIS publish annual reports on the prevalence and trends in birth defects. These reports, when designed and distributed appropriately, facilitate an understanding of the magnitude of the problem. Staff of a BDIS become local experts on the topic and their interactions with the institutions and individuals that contribute data to the system serve as educational opportunities. California, for example, has developed a series of very impressive fact sheets that are distributed nationwide, as well as to citizens who call with specific concerns and questions. Currently there are a number of different state and local programs in Minnesota that serve children who have birth defects, but there is no program whose sole focus is birth defects and whose primary goal is to generate and disseminate the information necessary for the prevention of birth defects.

Help facilitate the connection of children with birth defects to services. While there are a variety of services for children with birth defects, it is unlikely that all children who could benefit from services will receive them. A BDIS can facilitate this linking of children to services at both a population and individual level. At the population level, the information generated by a BDIS can be used for needs assessment and the planning of services. For example, is genetic counselling available to all families that could benefit from it? Are pediatric surgery facilities available where the needs are greatest? Every four years the Community Health Service Agencies plan their activities. These plans are increasingly based on an analysis of the data available to them. Without any data on birth defects, they have no way of considering this issue in their planning.

Many states also use their data to link children directly to available services. This takes many forms, from sending pamphlets with information and resources to the parents of affected children, to providing the names of children to local public health agencies after obtaining consent from parents. As will be discussed in detail later, the Work Group did not reach a final decision about whether or how these data should be used to link children to services, concluding that the magnitude and the nature of the gap needed evaluation during the first phase of implementation. However, there was a general consensus that this could be a worthwhile activity if the evaluation indicated that there was a need that the BDIS could fill.

WHAT OTHER STATE BIRTH DEFECTS INFORMATION SYSTEMS ARE DOING

As part of the data gathering phase, the Work Group invited Larry Edmonds, Senior Health Officer from the Centers for Disease Control and Prevention to talk about surveillance for birth defects. He started with a description of the Metropolitan Atlanta Congenital Defects Program, which is run by the CDC and is the oldest system in the United States. He also described what other states are doing. Occasionally the Work Group asked for additional information about how other states were approaching a problem. We have summarized that information which is most relevant to the Work Group recommendations in this section.

Currently, 31 states have some type of birth defects information system in place and 15 others are either interested in or actively planning for a system. Although a large number of systems are in place, there is no one "gold standard approach" that everyone uses. There are some common elements between the systems, however, and some states are more similar in their approach than others. The three primary areas where state birth defect information systems may differ include their (1) goals and objectives, (2) definition of a birth defect, and (3) the manner in which data is collected.

Goals and objectives: States primarily use the data they collect on birth defects for (1) epidemiology and research, (2) education, and (3) services. All of the systems use the data to describe the numbers and rates of specific birth defects within their state. These numbers may vary, however, depending on their definition of an eligible birth defect and on the type of data collection system they have in place. These systems also provide the backbone of accurate, current information on birth defects to parents, volunteer/support groups, health professionals, health/service programs, as well as state, county, and local government agencies. Educational outreach may be conducted by the information system or by other interested groups and may include elements such as brochures, journal articles, newsletters, electronic media, or personal presentations.

The greatest variability among states in the goals and objectives of the systems is the degree to which they use their data to connect families of children with birth defects to services. At a minimum, all states generally provide aggregate/summary information (e.g., no individuals could be identified) for planning of services. This information is usually provided in the form of a report looking at the distribution of birth defects across their state. Service providers could use this information to decide where to set up a new cardiac clinic in their state or to assist counties with strategic planning.

Some states, particularly those with newer surveillance systems, also use their data to connect families to available services. This connection has been accomplished in a number of ways: (1) in Texas, the system provides names of children with birth defects directly to case managers who are also located within the health department; (2) in Illinois, the system provides names to local service providers; or (3) in Colorado, the system, which collects data on children with birth defects and developmental disabilities, provides names of children to local public health agencies, who act as case managers, after sending a letter to the parents to receive permission. Considerations in deciding on the appropriate referral process depend on the identified needs of the families, the infrastructure of the health care system within the state, and the statutes which address data confidentiality.

Definition of a birth defect. The definition of a birth defect varies among states, both in terms of the actual case definition and the age limit for each case. The Metropolitan Atlanta Congenital Defects Program stipulates that a child must have signs/symptoms relating to a birth defect by one year of age, but they do not have to have a specific eligible diagnosis until age six. They also collect information on prenatal diagnoses of birth defects. Other states have more conservative or liberal age definitions: Illinois restricts its cases to newborns, while Arkansas has no upper age limit. A conservative age restriction may lead to missed cases and under-reporting for rates of birth defects. This is particularly true for states that only include defects diagnosed at birth. On the other hand, a more liberal age definition results in a larger caseload and increased expense for the system.

States also vary in their definition of a birth defect. Some states, such as Maryland and Utah, collect information for a very restricted set of conditions such as trisomies or cleft lip and/or palate. The managers of the system in both of these states believe that this approach is inadequate, and are actively working to enlarge their case definition. The majority of the states collect information on all structural congenital abnormalities, with some minor variations in definition. For example, some states include all children with specific International Classification of Disease (ICD) codes, while others include any child with an ICD code from 740 to 759.

A few of the states received specific funding from CDC to pilot test the collection of information on children with developmental disabilities. The disabilities most often included are cerebral palsy, mental retardation, and hearing and vision loss. These systems have found that a number of difficulties arise with the addition of developmental disabilities to a surveillance system. First, these disabilities may be difficult to identify, particularly mental retardation, and these children often do not receive a definitive diagnosis until the child is in school. Often the diagnosis depends on the "judgement" of a physician or other health care provider rather than a laboratory test or physical abnormality. Second, identification of these children requires using very different sources of information than those with congenital abnormalities. Third, addition of these conditions to a system greatly increases its' caseload and their need for additional funding. The manager of the Arkansas system reported that the addition of disabilities doubled their costs and more than doubled their caseload. In Atlanta, the CDC set up an entirely separate system for this activity because of the difficult problems encountered. The states that collect information on developmental disabilities recommended that disabilities should only be added after a system is already functioning. They thought that it would overwhelm a new system to begin collecting information on children with developmental disabilities in addition to congenital abnormalities.

Data collection methods. The methods of data collection differ among states, but in general they can be categorized as passive, active, or linkage of available datasets. Some states employ a combination of methods. Passive systems require institutions or health care providers to report all cases of children with birth defects to them. In New York, hospitals submit their discharge databases to the system. This discharge information also provides identifying information which is used by the system to delete duplicate reports. New Jersey requires each hospital to pull the charts and complete an abstract form for each child they identify with a birth defect. They then compare the data they receive with each hospital's discharge database in order to identify institutions where the reporting is low. Wisconsin initially required individual health care providers to submit abstract forms for each child they saw with a birth defect, but the compliance with this mandate was extremely poor. It improved somewhat when the reporting requirement changed to the institution rather than the individual provider, although under-reporting was still a major problem. These systems are less expensive for the state, but require more time and effort from the reporting institutions and relies on these institutions to provide reliable, accurate information. In addition, because the reporting institutions often assemble these data for purposes unrelated to birth defects surveillance, the data may or may not be reliable, accurate, or current.

Three states (Colorado, North Carolina, and Missouri) gather data by linking already available datasets, such as hospital discharge data and vital statistics (e.g., birth records). In these states, all hospital discharge information is located in one convenient, central location. They may also link databases from the Medical Assistance program, service programs, and other programs or institutions that collect data on children with birth defects. Again, because these data are often assembled for purposes unrelated to birth defects surveillance, the data may or may not be reliable, accurate, or current.

In an active case-finding system, field staff from the system visit hospitals, clinics, or other health care facilities to identify children with birth defects. These staff are responsible for setting up methods to work within the existing structures. They have substantial knowledge about birth defects and are able to make many decisions regarding eligibility while in the field. They might review logs from a neonatal/pediatric intensive care unit or use hospital discharge information to identify charts for review. Hospital staff may need to pull charts, but the field staff conduct the record reviews and fill out any applicable forms. In an active case-finding system these activities are conducted in addition to obtaining easily available information from databases such as birth certificates, death certificates, and fetal death certificates. This approach, used by Metropolitan Atlanta, California, and Arizona, is generally considered to be the most comprehensive and accurate, but it is also the most expensive.

RECOMMENDATIONS OF THE TECHNICAL ADVISORY WORK GROUP

The first activity of the Technical Advisory Work Group was to agree on a set of guiding principles, goals, and objectives for the Minnesota Birth Defects Information System. These guidelines were used to make recommendations about the case definition, data collection, services, data privacy, and legislation. In the future, these guidelines can be used to direct planning and facilitate decision-making.

Principles:

- The Birth Defects Information System should be population-based. That is, complete ascertainment of defined birth defect diagnoses must be obtained from a population of known size and demographic characteristics. The methods for finding cases must ensure a high level of case identification.
- The system should be based primarily upon diagnoses for which medical criteria are well defined.
- The system should provide for prompt identification of defined birth defects once they have been diagnosed and rapid computer processing of incoming information.
- The core data of the system should meet three criteria: usefulness, scientific validity, and economic feasibility. Data should be collected in an efficient and cost effective manner. Data on each case that could only be acquired through patient contact should not be part of the core surveillance system.
- The system should be designed for close collaboration with research, treatment, and service programs. It is through this collaboration that effective new knowledge for the prevention of birth defects and education and support for families can be developed.
- The design of the system should be flexible enough to facilitate modifications and extensions that take advantage of new technologies (including new methods of case identification), or that address newly identified needs of health professionals, families affected by birth defects, and researchers.

- The system must provide strict confidentiality for families affected by birth defects and their surveillance records. The system should maintain records that could be used to identify individual patients separate from medical information.
- Information in existing databases should be used whenever possible to maximize the efficiency of operation of the system.
- Data collection methods should be designed to have a minimal impact on data providers.

Goals and Objectives:

Monitor the occurrence of birth defects in Minnesota and describe the risks of having a birth defect

- Identify at least 95 percent of defined cases through case ascertainment methodology.
- Identify defined cases within six months of diagnosis.
- Determine population rates for birth defects.
- Respond to reports of birth defect clusters.
- Provide data for approved epidemiologic and basic research into the causation and prevention of birth defects.
- Monitor the effectiveness of public health intervention efforts through analysis of trends of specific outcomes.

Inform health professionals and educate citizens regarding birth defects in Minnesota

- Publish a biannual report describing and summarizing BDIS activities and the occurrence of birth defects in Minnesota.
- Respond to requests for information on birth defect rates or birth defect risks.
- Provide outreach education through newsletters, presentations, electronic media, and published articles.

Provide information for service and resource planning

- Provide information to local, county, regional, state, and federal programs to facilitate needs assessment and allocation of resources.
- Assist providers by facilitating linkage between families and available child health and social services.

Following are the specific recommendations made by the Technical Advisory Work Group regarding development and implementation of a BDIS.

1. Case definition. The case definition should include children with selected major and minor structural congenital defects whose mothers are Minnesota residents. Children must have signs or symptoms related to a birth defect prior to one year of age, but may be diagnosed by a health care provider at any time before their sixth birthday. The case definition should also include children who are diagnosed with infantile spasms. Following establishment of the BDIS, a work group should be formed to determine whether the system should also conduct surveillance for developmental disabilities (in approximately 5 years).

Rationale: Major congenital defects form the backbone for every birth defect information system in the U.S. and include such conditions as heart or neural tube defects (i.e., spina bifida). In addition, some systems collect information on minor congenital defects; this inclusion, however, comes at a cost. In comparison to major congenital defects, there is a high incidence of minor congenital defects and there is poor reliability in identifying them. Collecting population-based data on all minor defects could quickly overwhelm a system, especially in the beginning stages of development. Because of this, the Work Group recommends that the BDIS collect information on major congenital defects and a specified subset of minor congenital defects of special interest. Specific defects for inclusion will be selected in the next year, but will start with the list used by the Metropolitan Atlanta program.

The Work Group was also interested in including seizures in the case definition. Because of the difficulties in arriving at a definition that could be operationalized for case-finding purposes, and the lack of a model for conducting surveillance for these conditions, the Work Group decided to include the diagnosis of infantile spasms in the case definition. This allows the system to gain experience in collecting data on a neurologic disorder that is important and has widely accepted diagnostic criteria. A decision about including other neurologic disorders can be deferred until this experience is evaluated.

The rationale for the age criteria is that approximately 80 percent of children with birth defects are identified during their first month of life. They may not, however, be given a definitive diagnosis for several years. Including children diagnosed with a birth defect until their sixth birthday increases the system's ability to identify every child with a birth defect. This definition is consistent with that used by the Metropolitan Atlanta Congenital Defects Program.

Developmental disabilities, including conditions such as hearing and vision loss, cerebral palsy, and mental retardation, have also been included in the surveillance efforts of several states. There are unique benefits and difficulties which accompany this effort. Many service programs would like to have more information on conditions, such as mental retardation, to aid with service planning and enrollment. There are major difficulties, however, in obtaining an accurate diagnosis, and also in identifying these children, since the diagnosis is often not made until the child is in school. For example, a diagnosis of mental retardation is often based on an IQ test, a test which is not administered until the child is in school. Because of these difficulties, the Centers of Disease Control set up a completely separate surveillance system for this activity. After discussions with other experienced states, the Work Group decided not to include surveillance of developmental disabilities into the initial case definition. There was, however, a decision to revisit this issue once the system had been established for several years.

2. Data to be collected. The system should collect available information on the infant/child, mother, and father. This information can be used to: (1) make sure that each individual only appears once in the database, (2) determine the most accurate diagnostic code for the birth defect, and (3) provide necessary information for education, service planning, and research.

Rationale: Some of this information is already available on the birth certificate, such as name, date of birth, and address information; other diagnostic information can be collected from the medical record. Data that would require parent contact to obtain would greatly increase the cost to the system and might well be perceived as intrusive by parents. Such data is better collected as part of a specific targeted research study. A complete list of data items that should be collected is included in Appendix C.

3. Data collection methodology. The data collection methodology should consist of either active case-finding methods or linkage of currently available databases such as birth certificates or hospital discharge information. Active case-finding methods should include the use of field staff to identify children with birth defects at Minnesota hospitals/clinics. These staff would receive in-depth training about birth defects and are able to interact on a one-to-one basis with their institutions. The cost and completeness of each method should be evaluated in the first two years of the implementation of the system.

Rationale: The Work Group strongly believes that the majority of the costs of the BDIS should not be borne by the institutions and individuals who are required to report the data. Thus a passive reporting system, where institutions are required to fill out abstract forms and submit them to the system, was conclusively rejected.

Thus the remaining possibilities for data collection are either an active case-finding approach or linking available datasets. In an active system, field staff from the system visit hospitals, clinics, or other health care facilities to identify children with birth defects. They are responsible for maintaining relationships with these institutions and setting up methods to work within the existing structures. This method is consistent with that used by the Metropolitan Atlanta Program.

Linking available datasets has also been used to identify children with birth defects. One example of linking available datasets would be to connect hospital discharge data to birth certificates. Since hospitals already compile discharge databases for billing purposes, they could submit the database directly to the system. Alternately, since 114 out of 144 hospitals already submit their databases to the Minnesota Hospital and Healthcare Partnership (MHHP), hospitals might choose to submit the databases through the MHHP. There is currently some question about whether there is sufficient identifying information in the discharge databases to permit linking them to birth certificates, since the data submitted to MHHP does not contain personal identifiers, but at least one state (North Carolina) has developed an algorithm that permits this linking even in the absence of personal identifiers.

The two major considerations that need evaluation in deciding between the two approaches are cost and completeness. Linking databases is likely to be substantially less expensive, but also likely to result in under-reporting of an unknown magnitude. It is impossible to quantify the tradeoffs involved without implementing the two approaches side by side and comparing the results.

4. Uses of data. The BDIS would offer a new opportunity for data to be used for research and epidemiology, education and for services, as described in the goals and objectives. The exact form in which the data could be used for services needs further evaluation. At a minimum, it should be provided to service planners on an aggregate basis, with no personal identifiers.

Rationale: The uses of the data for research and epidemiology, education, and service planning are consistent with the goals and objectives that were established early in the Work Group deliberations. The BDIS may act as a central resource for information on birth defects through information on the rates and trends of birth defects within Minnesota. This information would be useful for both parents and health care providers in describing the impact of birth defects. It may also facilitate the planning efforts of counties or the state in determining where services are needed. Research efforts may help families by finding new ways to prevent birth defects from occurring or could help with evaluating methods that are currently in place (e.g., use of folic acid to prevent spina bifida).

The Work Group did not reach consensus on if, how, or when the BDIS should be used to provide individual referral to service programs. Some members felt that a decision could not be made without more information on the potential "gaps" that currently exist for connecting families to available services. In addition, the MDH did not have time to form discussion groups with all relevant stakeholders, including families of children with birth defects, health care providers, and service programs to explore how they feel about this issue.

The Work Group did agree that this issue was important enough to continue its evaluation. One of the first steps will be to form these discussion groups to get their input. During the first two years of implementation, the BDIS should also try to obtain some quantitative data on the referral patterns within the state and determine to what extent families of children with birth defects receive appropriate referrals. Before any type of individual referral system is put into place, a second work group should be formed to review the data and experience of the BDIS and to provide recommendations in this area. However, this referral system would never replace existing structures within the state; it would only be used to augment the structures that are already in place.

5. Data privacy issues. The data must be legally protected and access to the data must be strictly controlled. The data should be classified as private, non-public, meaning only the MDH and the citizens in the database will have access to their data.

Rationale: There is always a trade-off between an individual's right to privacy and the need of data for public health activities. Because the collection of these data are clearly important for the effort to prevent birth defects, the Work Group felt that collecting these data without the permission of the individuals or their families was justifiable. Collecting data from individuals or parents would significantly increase the cost of the system and decrease the quality of the data. However this places a substantial burden on the BDIS to assure that the data are protected and data access carefully controlled.

Much of the approach of the Minnesota Cancer Surveillance System (MCSS) to the protection of data would be applicable for the BDIS. It is illegal for MCSS to release information for any purpose other than that stated in law. Their policy is to hold themselves to the same standard of access to data (even within the same section of the MDH). All use of data for research must pass the approval of a peer review committee. In addition, researchers are strongly encouraged to have their protocol approved by an Institutional Review Board before submitting it to MCSS for review. Intersectional or interagency agreements may be written if they are approved and adhere to state law.

6. Staged implementation. Implementation of the system should take place in two stages. During the first two years (1997-1999), the BDIS will evaluate methods for collecting data in three areas of the state. Statewide implementation should take place starting in the year 2000.

Rationale: Starting statewide implementation immediately, before methods are pilot-tested and established, is likely to be unnecessarily burdensome and lead to cost inefficiencies. The three areas of the state to be evaluated in the first two years should be: (1) the seven counties surrounding Minneapolis/St. Paul, (2) Olmsted County, and (3) northwest area of Minnesota (i.e., Kittson, Roseau, Lake of the Woods, Marshall, Beltrami, Polk, Pennington, Red Lake, Clearwater, Norman, Mahnomen, Becker, and Hubbard counties). The rationale for these areas are that the MDH is located in the metropolitan area, and thus, while there are many institutions, contacting and visiting them will be facilitated by their proximity. Olmsted County was chosen because of the excellent database maintained by the Rochester Epidemiology Project at the Mayo Clinic. The northwest area of the state was chosen because it is rural and will require establishing relationships with institutions in North Dakota, which will probably take some time and be a valuable experience for the BDIS staff. The system should then expand to cover the entire state in the year 2000. Because the data would be collected in a pilot-testing mode for the first two years, it will not be considered reliable, valid, or useful for answering specific questions.

During these two years, the BDIS should explore linking existing datasets such as birth certificates, death certificates, claims data, hospital discharge data, newborn screening, and possibly service programs to identify children with birth defects. In addition, the BDIS should pilot test an active case ascertainment method with hospitals, large clinics, managed care organizations, and other health care facilities. These two approaches should be run in parallel, and the quality and completeness of the data should be evaluated for each.

7. Enabling legislation. The Work Group agreed on a number of general principles for a statute regarding Minnesota Birth Defects Information System.

Purpose

The purposes of the system are to:

- Monitor the occurrence of birth defects in Minnesota and describe the risks of having a birth defect through a statewide population-based information system.
- Inform health professionals and educate citizens regarding birth defects in Minnesota.
- Provide information for service and resource planning.

Rules

The commissioner should adopt rules to administer the system, collect information, and distribute data. The rules should include, but not be limited to, the following:

- The type of data to be reported.
- Standards for reporting specific types of data.
- Payments allowed health care providers and systems to defray their costs in providing information to the system.
- Criteria relating to contracts made with outside entities to conduct studies using data collected by the system.
- Specification of fees to be charged.
- Establishment of a committee to assist the commissioner in the review of system activities.
- Require preparation of a biennial report for the governor and citizens of Minnesota.
- Allow sharing of data concerning non-Minnesota residents with bordering states' birth defects surveillance systems. They would be required to continue protecting this data as private.
- Allow sharing of data concerning Minnesota residents with other state agencies to facilitate service provision to families of children with birth defects. The agencies would be required to maintain this data as private.

Records and Reports Required Upon the Request of the Commissioner of Health

- Persons practicing healing arts and hospitals, medical clinics, laboratories, and similar institutions should report each case of a birth defect.
- Insurance companies or professional groups may voluntarily report each case of a birth defect.
- Furnishing this information will not subject the person or institution furnishing the information to any action for damages or other relief.

Classification of Data on Individuals

- Data collected on individuals by the Birth Defects Information System shall be private.
- Consent of the individual or their guardian will be obtained by a staff member of the Birth Defects Information System before they can be interviewed by anyone as part of an epidemiologic investigation.

Budget

Our budget estimates (rounded off) for each year are as follows:

FY 1998	$ 670,000
FY 1999	$1,000,000
FY 2000	$1,000,000
FY 2001	$1,000,000

The lower budget in the first year reflects the fact that field abstracters and medical record technicians would not be hired for the first 6 months and several positions would not be hired for the first year. Thus, personnel costs constitute about 50 percent of the first year budget and gradually increases to 75 percent of the budget in the last year. This large personnel complement reflects the level of staffing needed for active surveillance and for adequate management of a computer-intensive system. The next largest budget area is equipment and supplies, which reaches a peak of $189,000 in the second year and substantially declines after that to $75,000 in the last year. The high second year cost reflects the necessity to buy a SUN Sybase Server that year as well as Sun workstations for the staff of the BDIS. The travel budget is about $30,000 a year, the great majority of which is for travel throughout Minnesota for the BDIS staff. Money is included in the first year for rule-making, and every year for the Advisory Committee. Finally, Institutional Development Funds are included for each of the first four years to assist institutions in complying with their reporting requirement.

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APPENDIX A

STATUTES

Chapter No. 451, H.F. No. 1584. Sub. 3. Health Protection -0- 295,000
[BIRTH DEFECTS REGISTRY.] Of this appropriation, $195,000 in fiscal year 1997 is for the birth defects registry system under Minnesota Statutes, section 144.2215. The startup costs shall not become part of the base for the 1998-1999 biennial budget.

Chapter No. 451, H.F. No. 1584. Sec. 6. [144.2215] [BIRTH DEFECTS REGISTRY SYSTEM.]
The commissioner of health shall develop a statewide birth defects registry system to provide for the collection, analysis, and dissemination of birth defects information. The commissioner shall consult with representatives and experts in epidemiology, medicine, insurance, health maintenance organizations, genetics, consumers, and voluntary organizations in developing the system and may phase in the implementation of the system.

Chapter No. 451, H.F. No. 1584 Sec. 63. [REPORT ON THE BIRTH DEFECTS REGISTRY SYSTEM]
The commissioner of health shall submit to the legislature a report by January 31, 1997, on the development of the birth defects registry system, including recommendations for additional statutory authority necessary to implement the system.

APPENDIX B

BIRTH DEFECTS TECHNICAL ADVISORY WORK GROUP

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APPENDIX C

CORE DATA ITEMS FOR THE MN BDIS

Infant

Date of birth (month/day/year)
Sex (male, female, ambiguous, unknown)
Name (including any alias)
Unique health identifier
Date of report (month/day/year)
Source of report (name, phone)
Mother's residence at birth and conception (city, county, state, zip code)
Place of birth (country, city, state, county, zip code, hospital)
Pregnancy outcome (live birth, still birth at > 20 weeks)
Birth weight in grams
Plurality (twins, triplets, etc.)
Gestational age
Diagnosis (description of all defects)
Source and place of diagnosis
Date of each diagnosis
Date of death (month/day/year)
Place of death (county, city, state, zip code, country, hospital)
*Cytogenetic studies
Autopsy performed (yes, no, unknown)
Physicians of record (name and phone of pediatrician/obstetrician/family physician)

Mother

Date of birth (month/day/year)
Race
Ethnicity (collected separately from race)
Name (including maiden surname for matching)
*Occupation and Industry
Education
Summary totals of mother's previous pregnancies (total of previous pregnancies, live births, still births at >20 weeks, spontaneous abortions, induced abortions, total deaths, total number of pregnancies)
*Risk factors for the current pregnancy

Father

Date of birth (month/day/year)
Race
Ethnicity (collected separate from race)
Name

*To be further evaluated by the BDIS.

APPENDIX D

CURRENT INFORMATION ON CHILDREN WITH BIRTH DEFECTS

Information concerning the health of Minnesota children exists in bits and pieces within a variety of settings (e.g., federal programs, state agencies, local providers, and health care providers). None of the sources can be used as a substitute for a birth defects information system. Each program was developed for a special purpose and is directed at a specific group of children or families. Because of this, these programs may each contribute some information to a birth defects information system. Coordination with a birth defects information system would need to accommodate the definitions, rules, and statutes which are applicable to each setting.

Vital Statistics:

The Center for Health Statistics collects information on birth certificates, late term fetal death certificates, and death certificates. There were 63,259 live births, 427 infant deaths, 255 neonatal deaths, and 364 fetal deaths reported to Minnesota residents in 1995. Congenital anomalies were reported for 1.3 percent of all births and abnormal conditions of the child were reported for 4.5 percent. Birth certificate information would provide denominator information for calculation of birth defects rates among Minnesota residents.

Newborn Metabolic Screening:

Newborn metabolic screening is currently conducted on approximately 98 to 99 percent of babies through the MDH, in cooperation with Minnesota hospitals and medical practitioners. Since the vast majority of babies are tested before leaving the hospital, many of the 1 to 2 percent of babies that are not tested are born at home. Newborn metabolic screening is designed to detect rare and serious conditions that affect some babies who seem healthy at birth but may have a hidden rare disease. These diseases include phenylketonuria (PKU), galactosemia, hypothyroidism, hemoglobinopathy, and adrenal hyperplasia. If one of these diseases is found and treated early, serious health problems such as mental retardation, eye problems, liver damage, small body size, sickle cell disease, abnormal sexual development, hormone problems, or death may be minimized or prevented.

Newborn Hearing Screening:

Newborn hearing screening is now possible and cost effective. The Minnesota Department of Health is committing dollars and staff to explore the opportunities and issues surrounding Universal Newborn Hearing Screening. The MDH, along with the Department of Human Services, is convening interested parties to investigate establishing Newborn Hearing Screening as a standard of care for Minnesota infants. This program may be in place within the next several years.

Managed Care Organizations:

In 1994, over 75 percent of Minnesota residents were enrolled in a health plan that used managed care. This increased from 60 percent in 1990 and is continuing to rise. A potential source of information about children with birth defects might be found in claims data for managed care organizations. As more and more people become part of these organizations, they could become an important source of information. The potential usefulness of claims data for conducting case-finding activities has not been evaluated, however.

Hospitals:

Hospitals have traditionally been a rich source of information for birth defect surveillance systems. One of the main sources of information used is the hospital discharge summary. There is no centralized repository for this information on all hospitals at the current time. Most hospitals send their UB92 billing form information to the Minnesota Hospital and Healthcare Partnership (MHHP), but there are no personal identifiers in this database.

Other sources of information within a hospital can be found through a manual or computerized search of records including: obstetric logs, nursery logs, neonatal intensive care unit logs, pediatric logs, postmortem logs, surgery logs, cardiac catheterization laboratory logs, stillbirth reports, disease indices, discharge summaries, cytogenetics laboratory logs, laboratory logs, or cardiac clinic logs. Each hospital will be different, both in its patients and in its record-keeping procedures.

Service Programs:

Minnesota Children with Special Health Needs (MCSHN):

MCSHN is a public program which seeks to improve the quality of life for Minnesota children with special needs and their families. MCSHN pays for diagnostic services and medical care for eligible children. If a child lives in Minnesota, is under age 21, meets income requirements, and has an eligible medical condition, they could receive financial assistance for medical treatment. Adults with cystic fibrosis or hemophilia may also qualify. If a child has a suspected medical disability or chronic illness, they could receive financial assistance for the diagnostic evaluation. A child may also be eligible for services provided by one of the MCSHN special clinics including: cardiac, developmental learning, diabetes, facial dental, habilitation technology, hemophilia, neurology, physical rehabilitation, speech, and transition.

A number of chronic illnesses and disabilities will make a child medically eligible for the MCSHN treatment program. Some of these include seizure disorders, cardiac conditions, cleft lip and palate, hearing problems, orthopedic conditions, leukemia and other cancers, cystic fibrosis, hemophilia, spinal bifida, cerebral palsy, and diabetes.

Part H:

Part H is a voluntary program for all eligible young children with disabilities, birth through 2 years of age. To be eligible,[1]

(1) the child must meet the criteria of one of the disability categories; or
(2) the child meets one of the criteria in unit (a) in addition to criteria in units (b) and (c):
    (a) The child:
        (i) has a medically diagnosed syndrome or condition that is known to hinder normal development including, but not limited to, cerebral palsy, chromosome abnormalities, fetal alcohol syndrome, maternal drug use, neural tube defects, neural muscular disorders, cytomegalovirus, grades III and IV intracranial hemorrhage, and bronchopulmonary dysplasia (BPD);
        (ii) has a delay in overall development demonstrated by a composite score of 1.5 standard deviations or more below the mean on an assessment using at least one technically-adequate, norm-referenced instrument that has been individually administered by an appropriately trained professional; or
        (iii) is less than 18 months of age and has a delay in motor development demonstrated by a composite score of 2.0 standard deviations or more below the mean on an assessment using a technically-adequate, norm-referenced instrument. These instruments must be individually administered by an appropriately trained professional.

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[1] Early Childhood Criteria Chapter 3525.2335 - Rules

(b) The child's need for instruction and services is supported by at least one documented, systematic observation in the child's daily-routine setting by an appropriate professional. If observation in the daily-routine setting is not possible, the alternative setting must be justified.

(c) Corroboration of the developmental or medical assessment with a developmental history and at least one other assessment procedure that is conducted on a different day than the medical or norm-referenced assessment. Other procedures may include parent report, language sample, criterion-referenced instruments, or developmental checklist.

In Minnesota, three agencies coordinate Part H activities including the (1) Department of Children, Families & Learning (lead agency); (2) Department of Health; and (3) Department of Human Services. These three agencies are coordinated through a State Agency Committee. In addition, the three agencies have formed a State Early Intervention Team (SEIT) with works with the local Interagency Early Intervention Committees (IEICs).

Early intervention services play a key role within Part H. As part of this, each eligible child must receive multidisciplinary assessment, a written Individualized Family Service Plan (IFSP) developed by a multidisciplinary team and the parents, and case management. Services which may be provided, if deemed appropriate, must be designed to meet developmental needs and may include: audiology, family training, counseling and home visits, health services necessary to enable the infant or toddler to benefit from other early intervention services, medical services only for diagnostic and evaluation purposes, nursing services, occupational therapy, physical therapy, psychological services, social work services, special instruction, speech-language pathology, and transportation necessary to enable the child and family to receive early intervention services. This list is not exhaustive.

Follow Along Program:

Follow Along is a computer assisted child find system for children and families ages birth to 48 months. Research shows that the first years of a child's life are the best time to begin intervention. The purpose of the Follow Along Program is to improve the identification of children who may experience health or developmental problems as a result of medical or environmental risks.

Part H funds enabled the software to be developed and piloted in an 18-county area in rural Minnesota in the early 1990s. There are two components to the system. The first part is a home visit and enrollment through a local public health nurse. The second part is completion of an Ages and Stages Questionnaire.

Fetal Alcohol Syndrome:

The Fetal Alcohol Syndrome and Fetal Alcohol Effects Prevention Program is working to help with screening and identification as well as an evaluation of services. They are working with the Minnesota Children with Special Health Needs (MCSHN), and a group of medical providers, researchers, and social services agency representatives to achieve this goal. Studies to date indicate that full FAS occurs in about two of every 1,000 live births. An estimated 200 - 800 children are born with FAS or FAE in Minnesota each year.

Women, Infants and Children (WIC):

WIC is a nutrition education program that provides supplemental foods to promote good health for pregnant, breast-feeding, and postpartum women, infants and children up to age 5. WIC services are free and serve approximately 100,000 individuals in Minnesota. Three hundred and one WIC clinics are held across the state. Identification of children with disabilities would be difficult through WIC, but children "at risk" could potentially be found through their medical or nutritional status. It is unclear whether the WIC program could help the Birth Defects Information System identify children with disabilities.

Tax Equity and Fiscal Responsibility Act (TEFRA):

TEFRA provides Medical Assistance (MA) eligibility to disabled children who live with their families. Only the child's income and property are counted when determining MA eligibility. Eligibility requirements include: (1) age 18 or younger; (2) found to be disabled by the State Medical Review Team (SMRT); (3) the child will need a certain level of home health care if he or she is to stay at home; and (4) the cost to the Medical Assistance Program for home care is not more than they would pay for care in a medical institution.

TEFRA is able to help pay for services such as home health services, therapy services, personal care services, private duty nursing, medical supplies and equipment, and prescribed drugs. Under the TEFRA option the child will be able to have all medically necessary services paid for up to the state's payment limits.

Head Start:

Head Start is a federal/state program for children age 3 to 5 years that meet strict income requirements. Children with disabilities constitute approximately 10 percent of their caseload. Their definition of a disability is quite broad, however, and includes both developmental problems (such as asthma or speech impairments) as well as congenital disabilities. Referrals into this program come from many areas including health professionals, churches, posters, and word of mouth.

Other Service Programs:

A number of other service programs are in place to help families with children. These include, in part, AFDC, ECFE, ECSE, case management services, child and teen check-ups (EPSDT), child protection services, deaf services, family subsidy, food stamps, foster care, general assistance, home and community based services waiver, medical assistance, MinnesotaCare, Minnesota Supplemental Aid, Mothers and Children (MAC), permanency planning funds, prenatal care initiative, public health nursing, services for the blind & visually handicapped, social security, social security disability income, speech/language, occupational therapy, physical therapy, supplemental security income, Title XX, and waivered services (CAC, CADI) which help with hospital, nursing home, and respite care.

APPENDIX E

LETTERS OF SUPPORT

A large number of Minnesota citizens have expressed interest in having a birth defects information (surveillance) system. These people/institutions include parents, volunteer or support groups, physicians and other health care providers, hospitals, health care associations, and state, county, and federal programs. The following individuals chose to write letters of support for the establishment of a birth defects information system.

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Birth Defects Information System

This information will be made available in alternative format, such as large print, Braille, cassette tape, upon request.

To receive a copy of this Legislative Report, receive information about the Birth Defects Information System, or request an alternative report format, please contact:

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