

Implementing Immunization Registries in Minnesota

Phase II — Consolidating and Unifying Registries Statewide

November 1, 1999

Final Version

Executive Summary

The period of 1993-1999 has been one of experimentation, growth, and evolution for immunization registries in Minnesota. In 82 counties throughout the state, immunization registries are in some stage of planning or development. We are now entering a second phase of registry development. During the next five years, our goal is one of consolidation, based upon the lessons of the first six years. This planning document lays out a road map for community immunization registries in Minnesota through the year 2005. It builds upon the original vision of inter-connected community registries linked to a state hub.

This document includes:

- The state vision for development and implementation of immunization registries during 2000-2005 (Phase II) and 2006-2010 (Phase III);
- Minimum standards and functions for immunization registries throughout the state;
- A description of the statewide model of registries, including the model of regional, community-based, locally-controlled registries;
- Technology standards and guidelines, including those related to data security and the capacity for data exchange;
- Funding guidelines, including the anticipated cost of registries, cost-benefits, and the state plan for pursuing long-term, continuous funding;
- Recommendations concerning policy and legislation related to data privacy and limited access only by authorized individuals; and
- Discussion of state responsibilities and models for a state hub.

Each area addresses:

- Where do we want to be?
- Where are we now?
- How will we get there and who will we work with?

Like all plans, this document is expected to evolve, change and expand as new circumstances and opportunities present themselves. The ultimate goal of this document is to guide the state towards a full operational, statewide system of immunization registries, which in turn will prevent disease and reduce health care costs.

Table of Contents

Background	1
Vision for Phase II of Implementing Immunization Registries In Minnesota	4
Registry Functions and Reporting	5
Statewide System	7
Technology	9
Funding	11
Policy and Legislation Around Privacy and Access	16
State Hub and Other State Roles	18

Background

Immunization registries exist to prevent infectious diseases. They do this by centrally storing immunization information that would otherwise be scattered across many health care providers. Registries alert patients and providers when shots are coming due or are past due. They can quickly assess the immunization status of a patient, a group of patients, or the entire population in a given area. Immunization registries are a powerful tool to better and more efficiently manage data that is needed by patients, health care providers, schools, day cares, and public health to prevent disease and disease outbreaks.

The vision for immunization registries for Minnesota was first articulated in 1993, then acted and built upon through the present. The vision called for a decentralized and voluntary system consisting of provider-based immunization registries feeding into community (regional) registries, and these community registries linking to a state hub. The vision standardized on data and registry functions, not on hardware and software.

Since 1993, we have been in a period of experimentation, growth, and evolution. Through the hard work and creativity of many public and private partners across the state, we have all learned a great deal about provider needs, the difficulties in merging and managing records from many sources, concerns about privacy, and a broad range of other challenging issues. We've certainly learned that registries are easy to grasp in concept but surprisingly hard to implement in practice.

How far have we progressed since 1993? In addition to the highlights noted in the sidebar, we have community registries operating or in planning in almost every county in the state. In September 1998, based on local Immunization Action Plan (IAP) grant reporting:

- 52 counties (plus Minneapolis and Bloomington) were

Chronology of immunization registry activity in Minnesota

1993 — Robert Wood Johnson registry planning grant

January, 1994 — Registry Work Group convened under the Commissioner's Task Force on Immunization Practices. Work group charged to develop guidelines for provider- and population-based registries.

April, 1994 — Part I of registry guidelines, Background and General Recommendations, completed and approved.

December, 1994 — Part II - Guidelines for Provider-based Registries completed and approved.

November, 1994 — First local health department receives Acclaim ITS software. By 1998, a total of 41 agencies using Acclaim ITS.

1994 - 1996 — Registry demonstration grants.

1995 - 1998 — Statewide Immunization Action Plan grant program

1995 - 1996 — Supplemental funds to local health departments for provider-based registry development.

November, 1996 — Immunization registry conference

1997 — Part III guidelines on population-based registries completed and approved.

Chronology of immunization registry activity in Minnesota (cont.)

September, 1998 — Community Immunization Registry Toolkit released.

1998 — HumanSoft bankruptcy; loss of vendor technical support for Acclaim

March, 1999 — MDH decides to phase out support of Acclaim ITS by March 2000.

April, 1999 — National All Kids Count conference held in St. Paul.

May, 1999 — Meeting of registry operators to begin discussion of Phase II state plan.

July, 1999 — Meeting of registry operators to set minimum functions for registries.

August, 1999 — Meeting of registry stakeholders to discuss ongoing funding strategies.

involved in planning or implementing regional registries in five areas of the state;

- 10 counties had partially operational registries for their county only;
- 4 counties were in the early design and implementation stages of a county-wide registry;
- 16 counties were in the early planning stage; and
- 5 counties had no current plans for registries.

We're are now entering a second phase where we need to solidify the best practices from the first phase in order to create more uniformity and consistency across registries. We also need to move toward more regional systems and clarify the functions and design of the state hub.

Taking these steps toward greater statewide uniformity are important for a number of reasons, including:

- demonstrating to potential funding sources that a statewide system exists and that their clients will receive similar services no matter where they live or receive health care in the state;
- creating greater efficiency in registry planning and implementation by adopting a core set of uniform functions and more readily learning from each other's experiences; and
- responding to national surveys on the status of registry progress in Minnesota.

This planning document lays out a road map for community immunization registries in Minnesota through the year 2005. It builds upon the original vision of a mosaic of inter-connected community registries linked to a state hub but provides additional detail in many areas based on the experience and needs of registries to date.

The plan includes an overall vision for the year 2005, and addresses six major topic areas: Registry Functions and Reporting, Statewide System, Technology, Funding, Policy and Legislation, and State Hub.

Each area addresses:

- Where do we want to be?
- Where are we now?
- How will we get there and who will we work with??

Like all plans, especially plans with a technology component, this is fully expected to evolve rapidly and be in a constant state of flux. The plan format is designed for easy and regular updating, and also lends itself to regular reports from MDH on the status of registry progress across the state.

Vision for Phase II of Implementing Immunization Registries in Minnesota

By 2005, Minnesota will have 8 - 12 partially or fully operational regional registries which include every county in the state. These registries will have:

- 100% of local health departments (LHDs) participating;
- at least 65% of private providers actively participating;
- at least 75% of children 0 - 5 years of age enrolled and with immunization records;
- a lead local health department from each region coordinating\directing registry policies and operations;
- a public-private advisory or governing body;
- an "end user" advisory group to help ensure the registry is addressing providers' and other users' needs;
- the ability to meet all the minimum registry functions for Minnesota as defined by MDH (see Attachment A), including notification for enrollees;
- interim or on-going funding in place from a limited number of funding streams; and
- the ability to securely exchange data with other registries, at least two of which can use standard formats such as HL7.

By 2003, Minnesota will have the authority and funding to create a state hub, all policies in place, the design and testing complete, and most functionality implemented.

While Phase II will take us through 2005, it's useful to look beyond at Phase III when we will achieve fully operational status with all registries in Minnesota.

By 2010, Minnesota's regional registries will have:

- 100% of local health departments participating;
- at least 95% of private providers actively participating;
- at least 95% of children 0 - 5 years of age with immunization records;
- a lead agency serving as the registry coordinator;
- a public-private advisory or governing body;
- the ability to meet all the minimum registry functions for Minnesota, including notification for enrollees;
- stable on-going funding from a minimum of different funding streams; and
- the ability to securely exchange data with other registries and the state hub, using standard formats such as HL7.

Registry Functions and Reporting

Where do we want to be?

- By the end of 1999, consensus will be reached among LHDs, the Immunization Practices Task Force, and MDH on minimum registry functions and annual quantitative reporting indicators (see Attachment A). Registry functions will include requirements for maintaining privacy and confidentiality. (See also the section on Policy and Legislation).
- By 2003, every operating registry—whether single county, multi-county or regional—will be implementing all of the minimum functions and be able to report semi-annually on at least 80% of the quantitative indicators.
- By 2003, MDH will have a process in place for quality improvement visits to registries, monitoring the level of registry functionality, and tracking registry costs.
- By 2003, every operating registry will be capable of securely providing data to a state hub for the purposes of surveillance and assessment.
- By 2005, all regional registries will be fully implementing all the minimum functions and capable of reporting semi-annually on all the quantitative indicators.

Where are we now?

- Minnesota registry guidelines (1994 - 1997) provide standards for functionality and the data elements required to implement that functionality.
- The National Vaccine Advisory Committee (NVAC) released its findings and recommendations (April 1999) in the areas of privacy and confidentiality, provider participation, technical and operational functioning, and sustainable funding.
- CDC, in conjunction with states, has developed 12 minimum registry attributes. These attributes, and the NVAC report described above, provide useful and timely recommendations on which to base minimum functions and policies for Minnesota registries (see Attachment A).
- The national All Kids Count program has developed seven quantitative indicators to measure the operational status of registries in a uniform way, no matter their size, level and type of technology. MDH believes adopting these for all Minnesota registries is critical to documenting the status of registry development statewide and to account for funding from public or private sources.
- HL7 and other standards for immunization transactions are being established, tested, and refined nationally.

How will we get there?

- In 1999, MDH will convene LHDs/registry coordinators to reach consensus on minimum registry functions and annual quantitative indicators, both based on standards set nationally. These functions must be able to support both public decision making and clinical quality improvement efforts. Recruiting and retaining clinic participation in registries depends upon registries providing useful and cost-saving benefits to clinic practitioners and managers.
- In 1999, the agreed-upon minimum functions and indicators will be reviewed and approved by the Commissioner's Task Force on Immunization Practices and the Commissioner of Health. Examples of technical support include sample policies, parent/enrollee notification materials, national and state standards and guidelines, algorithms and other routines from other registries, and financial support as available.
- From the time of adoption onward, MDH will provide technical support in ensuring registries can perform the minimum functions and generate reports for the annual quantitative indicators.
- MDH will work with registries operators to develop a quality improvement/site visit protocol to monitor and address issues related to implementing the minimum registry functions. These visits may include peer review by operators from other registries.
- MDH will use the quantitative indicators and financial reports to monitor and report on registry functionality and costs statewide.
- MDH and registry operators will review the minimums and indicators at least annually and modify them as needed to accommodate changes in national standards, changing data or other needs within the state, and changes in law.

Statewide System

Where do we want to be?

- By 2001, natural groupings of counties within regions will have been identified, based on existing health care system delivery patterns and other factors.
- By 2002, a lead local health department will have emerged to coordinate/direct a regional registry in every region of the state, with a public-private advisory or governing body in place.
- By 2005, every region of the state will have a partially or fully operational regional registry in place, representing no more than 12 regions and using four or less different software applications to facilitate efficient technical support and inter-registry data exchange. Providers will only need to report to one registry; it will be up to registries to promptly exchange immunization data on clients who reside in another registry service area.

Where are we now?

- In September 1998, based on IAP reporting:
 - 52 counties (plus Minneapolis and Bloomington) were involved in planning or implementing regional registries in five areas of the state;
 - 10 counties had partially operational registries for their county only;
 - four counties were in the early design and implementation stages of a county-wide registry;
 - 16 counties were in the early planning stage; and
 - five counties had no current plans for registries.
- All regional registries have public-private advisory or governing groups.
- All regional registries have a lead agency identified.
- Two different software applications are being built in Minnesota (Communities Caring for Children (CCC) and Minnesota County Computer Consortium (MCCC)), and two existing applications are being redesigned (metro registry and the Southwest Minnesota Immunization Information System (SIIS)). Most other registries are using either Acclaim ITS or Acclaim/PH. The registry for the Brainerd area has contracted with Scientific Technologies, Inc. in Arizona for registry software and support.

How will we get there?

- MDH will either participate in or host regional meetings (with LHDs, health systems and non-affiliated private providers, health plans, schools and others) to discuss the appropriate boundaries and lead agency for a regional registry.
 - MDH will support regional planning (including issues related to governance, roles

and responsibilities, cost sharing, staffing and IT needs) by, for example, passing on the experiences and planning materials of existing registries or through planning grants (contingent upon available funding).

- Boundaries will take into account natural health care delivery service areas and current LPHA districts.
- MDH will meet with health systems to discuss the benefits of registries, encourage corporate support of clinic participation in registries, and to encourage/support export of immunization data from any clinical information system to a registry.
- MDH and registry operators will establish standards for data exchange among registries and with a state hub.
- MDH has no current plans to introduce a bill mandating provider reporting. This theoretically might be considered at some point in the future when 85% to 95% of all providers are enrolled, and sufficient statewide registry capacity exists to receive, securely maintain, and appropriately use the data. However, even at this point, even considering such a measure would have to be carefully discussed with provider organizations and other involved groups.
- For tasks related to software, please see the following section on Technology.

Technology

Where do we want to be?

- By 2001, all existing registries will have software which meets at least 75% of Minnesota's minimum registry functions (see Attachment A).
- By 2001, all existing registries will have a tested disaster recovery plan in place.
- By 2002, all registries will be receiving/importing timely electronic birth and death data at least monthly.
- By 2002, prediction algorithms will be standardized across registry applications to facilitate uniform incorporation of new vaccine products and schedules.
- By 2003, every operating registry—whether single county, multi-county or regional—will be implementing all of the minimum functions and be able to report semi-annually on at least 80% of the quantitative indicators.
- By 2005, no more than four different software applications will be used by 8-12 regional registries, with technical support provided by the software vendor and/or MDH.
- By 2005, all regional registry applications will feature secure network access using web technology and appropriate security measures.
- By 2005, all regional registry applications will fully meet Minnesota's minimum registry functions, and be reporting semi-annually on all the quantitative indicators.
- By 2005, all registry operators will have the informatics capacity to adequately support registry functions and operations, and to provide appropriate training and support to registry staff.
- Through 2005, MDH will work with CDC and other state registries to assure billing standards for importing and exporting billing data utilized in registries, including ensuring the quality and completeness of the data.
- By 2005, communication standards, such as HL7 messaging, to facilitate inter-registry data exchange will have been implemented by at least two registries.
- By 2010, all regional registries will have the ability to exchange data securely with other registries and the state hub, using standard messaging such as HL7.

Where are we now?

- C Every registry application currently in use in Minnesota is being evaluated by its owner for replacement or rebuilding within the next year.
- C Four separate efforts are currently underway to either develop new registry applications (MCCC and CCC) or to re-design their existing systems (metro registry and S I S). At least two (metro and CCC) will incorporate Web access as the primary method of reporting and/or query.
- C A tested disaster recovery plan is not in place in all registries.

- C A consistent statewide system does not yet exist to provide timely birth and death data to regional registries. A new electronic Vital Statistics Redesign Project through the Center for Health Statistics, MDH, is in process. Presently, regional registries are pursuing interim solutions, for example, working with county registrars to secure some data.
- C Public health informatics training and capacity building is in its infancy.
- C CDC is working with ACIP to create a prediction algorithm standard all registries can adopt.
- C State and local registries nationally are calling on CDC to work with billing system vendors on a standard for data export to registries.
- C The national HL7 work group is finalizing its standards, with selected state pilot sites. Other national standards for data exchange continue to emerge as well.

How will we get there?

- C MDH will host software demos of applications as they become available so agencies can evaluate them based on needs and budgets. Applications from registries in other states may also be evaluated. MDH can also serve as a neutral party to support registry evaluations of software.
- C MDH will strongly encourage using existing software, discouraging any new software development beyond current efforts (assuming they are successful). The fewer applications in use, the more peer support can occur among registry coordinators and the more likely MDH can provide on-going technical support to registries and users, thus reducing costs to LHDs and registry users.
- C MDH and the LHD consortia developing software will work with their vendors to assure their applications are capable of meeting the minimum functions and generating the operational indicators.
 - MDH will facilitate the sharing of best practices among registry operators.
 - MDH will assess state and local public health informatics training needs, and develop a training plan to address those needs.
- C MDH will work with LHDs and others to develop a sample disaster recovery plan, including a suggested procedure for testing.
 - By 2002, MDH will work with LHDs and MDH Vital Records to establish statewide system for regional registries to receive complete, accurate, and timely birth and death data.
- C MDH will work with CDC to encourage a national billing system standard for data export to registries.
- C MDH will work with entities who have experience in HL7 other messaging to provide training and to develop a site(s) for registries to test their messaging capabilities.

Funding

Where do we want to be?

Estimated operational costs:

Operational costs are based on a number of factors, including: administrative personnel to coordinate and operate the registry, and to interact with providers; technical personnel to enter data, program, and coordinate hardware and software issues; equipment, including computers; and telecommunications costs; the number of users, the size of the population enrolled, the type and level of technology, and the number and type of functions performed (such as reminder/recall).

Based on a number of local and national studies conducted to date, a reasonable working estimate for fully functional operational registries in Minnesota during 2000 is \$5.00 per year per child age 0-6 years. The estimated cost of enrolling all children age 0-6 in an immunization registry would therefore be approximately \$1,950,000, or $(\$5.00/\text{child}/\text{year}) \times (65,000 \text{ children born}/\text{year}) \times (6 \text{ years})$. This represents operational costs for registries being conducted at the local level. If the state vision is also to support coordination of activities between registries, sharing of technology and data, training, and (for purposes of reimbursement) monitoring based on agreed upon uniform standards and minimum functions, operating costs may be increased by another 25%-30%.

The annual total cost (in 1999) of having fully operational registries across Minnesota would therefore be approximately \$2,500,000.

By the year 2005, if the annual birth cohort in Minnesota is conservatively estimated at 70,000 children per year, and the estimate for fully functional operational registries in Minnesota is \$6.00 per year per child, the estimated cost of enrolling all children age 0-6 in fully operational immunization registries would be approximately \$2,500,000 in local operational expenses, and **approximately \$3,200,000 in total costs per year.**

These estimates may be conservative for several reasons:

- The benefits of immunization registries do not end by the age of 6. Children will continue to need reviews of immunization status if they change providers, and for attendance at schools (including colleges) and camps. There are no data comparable to the analyses described above of the cost per child per year for those over the age of 6 years, although maintaining records on school-aged children and adults are expected to be considerably less costly than for pre-schoolers because the level of reminder-recall, outreach, and other interventions is considerably less costly with older children. An exception to this would be if a registry decided to keep all addresses on school-aged children current in case of an outbreak — a potentially costly maintenance activity.
- The cost estimates described above are for fully operational immunization registries. Development costs are variable, but are typically more than the costs once the registry is up and running. Currently, development and operational costs not always

well differentiated, making it difficult to know what the actual ongoing financial needs for registries will be. Also, because information systems are continually being refined and upgrade, development costs seldom ever completely go away. Changes in clinical information systems, such as electronic medical records, will have a big impact on registries technology and funding needs as they continually match technical improvements in the clinical setting.

State Goals:

Goals for immunization registries as part of the Minnesota state plan for 1999-2005 are:

- During 1999, immediate sources of interim funding will be identified to help keep existing registry efforts from dying. At the same time, MDH and other partners will be vigorously pursuing more long-term, sustainable sources of funding.
- During 1999, an operational strategy to obtain interim and long-term statewide funding based on a cost-sharing formula will be finalized. This plan will be collaboratively developed based on discussions with other state agencies, local health departments, and private sector representatives.
- By 2005, statewide interim and/or long-term funding will be in place from a limited number of different funding streams. These may be supplemented by other funds individually sought by registries from local foundations or other sources.

Although this plan focuses on 1999-2005, it is expected that by 2010, on-going, stable statewide funding will be in place from a limited number of different funding streams. This is the ultimate goal.

Where are we now?

Funding remains one of the most critical issues currently facing immunization registries and one of the largest barriers to continued registry development in Minnesota. Critical issues include the following:

- **There is no stable, ongoing, consistent source of statewide registry funding.** Past support has typically been short-term and piecemeal, from a combination of federal, local, and health plan foundation support, plus the significant in-kind efforts of many private and public organizations. Although the Minnesota State Legislature provided funds specifically earmarked for purchase of vaccine, this funding does not support the vaccine delivery infrastructure, including registries. No dedicated state funding currently exists.
- **Many of the previous sources of funding are “drying up”**

For the past five years, MDH has seen continued reductions in the federal 317 immunization grant. From 1998 to 1999, there was a 28% decrease in grant funds for immunization activities, with a loss of more than one million dollars in 317 funding. Local governments are feeling the same financial pressures, with decreased funding for an increased number of competing public health activities. In particular, 1998 marked the last year of local IAP grants, begun in 1993-1994, which supported most local registry development efforts, as well as other collaborative efforts to raise immunization levels. The Robert Wood Johnson Foundation/All Kids Count operational funding is scheduled to end in mid-2000.

- **Current data support the cost-benefit of registries to public health and the health care system**

Benefits include prevention of serious illnesses by improving immunization rates, more efficient management of disease outbreaks, preventing the cost of manual record pulls, improved record management, more efficient assistance with audits and assessments such as HEDIS reports, improved vaccine management, prevention of over-immunization because accurate records are not available, and cost savings to schools in enforcing state immunization law. (See Attachment B — *Financing Community Immunization Registries in Minnesota* for more detail on the costs and benefits of registries.)

How will we get there?

During 1999, a state strategy and operational strategy to obtain interim and long-term statewide funding based on cost-sharing formula will be finalized.

As of September 1, 1999, this process is already well underway. Planning meetings have been held with the Health Commissioner, local public health officials, other state agencies, private physicians and representatives of health plans. A cost formula that assesses the cost per child for children 0 - 18 (perhaps including adult populations as well) needs to be developed in conjunction with CDC/All Kids Count. This will better measure the actual costs of registry operations.

A number of potential funding sources are currently being explored, including the following:

- **State support from legislative appropriations:**

Because the state has an obligation to control vaccine-preventable diseases, a state legislative appropriation is an appropriate source of on-going support for registries. This request is also consistent with statewide and national public health goals. The governor's biennial budget for 1999-2000 has just been passed, and the likelihood of new major initiatives for 2000 seems small. However, it is reasonable to begin

planning now for the next biennial budget. Building support would need to start in 2000 for the 2001 budget session, and would need to include a broad array of supporters.

- **State support from Medicaid funds:**

The Department of Human Service (DHS) administers Minnesota's Federal Early Periodic Screening, Diagnosis and Treatment program, or the Child and Teen Checkups (CTC) program. This program offers comprehensive health screening for children and teens under Medical Assistance and MinnesotaCare. Federal regulations stipulate that CTC services must be coordinated with other children's programs including immunization programs. At the federal level, HCFA has indicated their willingness to allow Medicaid funds to be used to help support immunization registries. MDH and DHS are currently engaged in active discussions as to how CTC administrative funds could be used to support immunization registries. After this issue is resolved, other approaches to using Medical Assistance administrative will be explored as a long-term funding strategy.

- **Provider taxes:**

This concept is based on the fact that physicians and other health care providers benefit from immunization registries. Because provider participation is essential for any immunization registry to succeed, specific user fees might be a disincentive for provider or clinic participation. An alternative source of revenue would be from the state's Health Care Access Fund. The appeal with this fund is that all providers already pay the tax, and may be supportive of it supporting a service which benefits their practice and their patients. Issues that would have to be addressed include the opposition of some groups to taxes to support this fund, competing priorities for use of these funds, and the anticipated balance between revenues and expenditures. Issues that need to be addressed include whether, given these considerations, the Access Fund represents a likely source of continuous, long-term stable funding.

- **Health plans, managed care organizations, and private payers:**

Health plans benefit from registries in a number of ways including improved quality of care, more efficient record management, and timely immunization coverage reports. Practical logistical issues in requesting funding from specific health plans include whether health plan funding will be stable and long-term; how to communicate with large number and diversity of health plans throughout the state; and how to coordinate funding, since some health plans may elect to support a specific registry or geographic area. Clearly, having a major health plan not contributing its "fair share" financial contribution would have a big impact on the registry and potentially increase the burden on the remaining partners. The issue of whether a registry should be largely publicly-funded or on a "pay to play" basis is a difficult one and will likely be a focus of continued discussion in Minnesota and nationally. MDH will be

meeting with the Council of Health Plans and others in the private sector to discuss the most appropriate involvement of these organizations, and how they can best provide assistance.

- **Federal funding:**

Potential sources of federal funding include the 317 immunization grant, as well as additional federal awards that might be announced. MDH has received continued reductions in the 317 award; in our most recent application, we requested restoration of these funds to provide support to local health departments for immunization activities including registries. If this funding is not provided, MDH will continue its policy of making smaller, more focused awards to specific regional registries to help promote registry development activities. In-kind technical and other support through grant-funded staff at MDH will also continue. MDH will also actively seek additional federal funds as they become available.

- **Local public health funding:**

Local health departments have and continue to contribute varying amounts in support of immunization registries. Considerable in-kind support has also been provided. It is not reasonable to expect local health departments to assume a major financial burden of immunization registries, especially given the limited budgets that many work with. However, it is reasonable, as part of the shared responsibility and commitment, for them to assume a small portion of the financial burden from any available source, be it local, state, or federal dollars.

- **Pharmaceutical companies:**

There are potential benefits and concerns about this approach. Many companies have considerable resources, and have expressed interest in helping to fund immunization activities. On the other hand, because these companies manufacture vaccines, their involvement could raise conflict of interest issues. There may be ways to address these concerns, such as if all companies contribute to a common fund. MDH will cautiously initiate conversations with pharmaceutical companies to explore in more detail the feasibility and implications of pursuing this option.

- **Foundations:**

The Robert Wood Johnson Foundation, through the All Kids Count program, has in the past funded immunization registries throughout the country; however, such funding will not be available in the future. The Blue Cross Foundation has expressed interest in supporting registries, and is currently developing a specific proposal for providing such support. Because some foundation awards are one-time or short-term, such support, though valuable, is not expected to provide a long-term, continuous source of funding. Despite the potential limitation of foundation funding, MDH will actively be on the look-out for and seek additional foundation grants as they become

available.

- **Other sources** of funds that have been suggested include educational funds (given the cost-benefit of registries in enforcing school law) and vaccine surcharges (on public sector and/or private sector vaccine). Although these are possibilities, a number logistical, administrative, and/or financial concerns have been raised.

In summary, no single source of funding can be expected to carry the entire burden of funding registries in Minnesota. Funding will have to be a shared responsibility, with the state taking an active lead role. MDH will actively work with all parties to develop a reasonable cost-sharing strategy which will become our blueprint for seeking continuous, long-term funding in 2000 and beyond. This will be one of our highest priorities, and will require the support and assistance of all registry partners.

Policy and Legislation Around Privacy and Access

Where do we want to be?

- By July, 2001, the Minnesota Legislature will recognize notification with an opt-out option as a reasonable approach to assuring registry enrollees know of the information in the registry, how it is used, and how they can withdraw if they so choose.
- By July, 2001, legislative approval to operate a state hub will be obtained, if needed.
- By July, 2001, either standards established by MDH or statutory language will exist to govern the allowable uses of registry data.
- By 2003, legislation will be in place authorizing inter-registry and inter-state exchange of immunization data, if needed.

Where are we now?

- Heightened concern exists across the country about electronic data obtained and used without individuals' knowledge and of the adequacy of security measures to protect confidentiality. These concerns include health data, and opponents of immunization registries often see registries as the first step to comprehensive, "cradle-to-grave" electronic records that can easily be mis-used.
- Health data confidentiality was a major concern during the 1997 legislative session in Minnesota. Opponents of registries seemed particularly concerned about a state hub/statewide database. A small number of legislators argued effectively for written consent to be in a registry; proposals which were only narrowly defeated.
- The current immunization data sharing law (M.S. 144.3351) allows for sharing of immunization data without consent (or notification) "if the person requesting access provides services on behalf of the patient." Most interpretations of this phrase in the law assume registries are clearly included because they provide service to the patient. Privacy advocates state this is too broad an interpretation and beyond what the Legislature intended. An amendment to this or another law specifically stating registries can share immunization data without consent would resolve this debate.
- Different states have different privacy laws, and clarity is needed on whether such laws authorize data exchange between states. This is important both for people who reside in one state but receive health care in another, and for migrant families who regularly travel back and forth between Minnesota and other states/countries.

- The Minnesota Government Data Practices Act (M.S., Chapter 13) governs governmental use of health and other data, but does not address immunization registries issues specifically. The Immunization Data Sharing Law (M.S. §144.3351) allows for sharing of immunization data without consent but also does specifically address the issue of registries.

How will we get there?

- Minnesota will continue to monitor and work with others to implement national and state standards related to data privacy and security. Such standards will likely evolve continually and require constant evaluation, technical adjustments, and financial resources to implement.
- MDH will work with registry operators, local public health agencies, and other registry supporters to build grassroots support for registries. Strategies will include a wide variety of written and verbal communications with legislators, including one-to-one meetings with key legislators, legislator visits to registries sites, letter writing campaigns, testimony, and other means.
- MDH will provide cost estimates of a notification/opt out process versus written consent, as well as information on the number of families who have opted out of registries to date.
- MDH will obtain an opinion from the Attorney General's Office on whether any amendments are needed to §144.3351 or other statutes to clearly authorize data exchange between registries and a state hub and between registries in other states.
- MDH will obtain an opinion from the Attorney General's Office on whether specific legislative authorization is required to establish and operate a state hub. If such authorization is needed, a legislative strategy will be implemented in conjunction with the strategy discussed above for notification.
- MDH will work with the Attorney General's Office, registry operators, and registry supporters and opponents to establish whether existing law and state guidelines adequately address the issue of allowable uses of registry data, or whether additional statutory language is needed.
- MDH will jointly develop principles with other states on inter-state data exchange (including immunization, birth and death data), and address legal or other barriers to routine and timely data exchange.

State Hub and Other State Roles

Where do we want to be?

- By March, 2000, a feasibility study will be completed that examines alternative models for a state hub and the financial, technical, policy, political, and security issues associated with each.
- By December, 2000, a design for the state hub will be completed, functions identified, and the question of whether MDH needs specific legislative authorization to proceed will be resolved.
- By July, 2001, legislative approval to operate the hub, if needed, will be obtained.
- By January, 2002, a prototype of the state hub will be built and testing begun.
- By July, 2002, the state hub will be ready for operation; policies will be in place around security, access to data, and uses of data; and on-going funding will be secured.
- By September, 2002, community registry data will have begun being uploaded or indexed, and state hub functionality implemented.
- By 2001, all registries will be capable of importing birth records. Complete and accurate records will be sent by MDH to the registries at least monthly.
- By 2004, at least 60% of data needed for the quadrennial statewide retrospective assessment of immunization coverage levels will come from registries. By 2008, at least 90% of the data will come from registries.
- Through 2005, registries will receive the technical support they need to meet the minimum registry functions and adequately safeguard registry data.

Where are we now?

- General discussions of possible models for the hub have occurred within MDH.
- There is a legislative reticence to create statewide databases of children. A state hub will likely be a lightning rod for concerns about database security and privacy.
- No funding has been dedicated to building, testing and operating a state hub; priority has been given to supporting community registries.
- Birth records are being sent to registries quarterly but the process occurs on a registry by registry basis.
- The experience of other MDH and state agency information systems will be helpful in designing a state hub that meets data practices and other statutory requirements.
- The process for developing policies addressing authorized access to and uses of state hub data has not yet begun, although much of this is determined by existing law.

- Retrospective immunization data has been largely collected manually by local public health and schools across the state. Only one registries has been in existence long enough to now have complete data on kindergarten enterers.
- Technical support from MDH to date has consisted of guidelines, conferences, sample materials and resources (the *Community Immunization Registry Toolkit*), statewide conference calls, regional meetings, software support and training, and one-on-one consultation.

How will we get there?

- By December, 1999, MDH will solicit input from community registry operators, local public health agencies, health systems, health plans, schools, the Task Force and others on the desired features of a state hub.
- By December, 1999, MDH will work with the Attorney General's Office to determine whether specific legislative authorization is required to initiate a state hub.
- By March, 2000, alternative models for the hub will be examined for their feasibility, based on the experiences of registries nationally, data practices standards in Minnesota, border state data exchange requirements, and other pertinent factors.
- By April, 2000, a detailed specifications document will be drafted, reviewed by stakeholders, and approved by the Task Force.
- By 2001, MDH will work with LHDs and MDH Vital Records to set up a timely statewide system for regional registries to receive complete and accurate birth and death data.
- Through 2005, MDH will provide, either directly or under contract, timely technical support to registries in all aspects of registry development and operations, especially in implementing the minimum functions, evaluating software options, data exchange, and data practices.

Attachment A

Minimum Functions for Community Immunization Registries in Minnesota

Minimum Functions for Community Immunization Registries in Minnesota

The following minimum functions and reporting capabilities for community immunization registries were adapted from three national documents: the National Vaccine Advisory Committee (NVAC) recommendations for immunization registries, Attributes that Constitute the Minimum Necessary Elements of an Operational Immunization Registry from the Centers for Disease Control and Prevention, and the All Kids Count Quantitative Indicators. The adapted minimum functions, and the corresponding implementation steps for each function, were recommended by an ad hoc immunization registry functions advisory group to MDH that met in July, 1999. Final review and approval was provided by the Commissioner's Task Force on Immunization Practices in September, 1999.

Function #1: Involve providers and the community

All community registries will have an overall advisory or governance group that includes private providers and public health. Other stakeholders may include schools, health plans, and consumers. This group will be involved in both registry planning and on-going operations.

Function #2: Store core data set

All community registries will be able to electronically store data on the core data elements established by MDH. These elements are:

- Patient name
- Patient birth date
- Patient gender
- Mother's name
- Address, city, zip code
- Vaccine type
- Vaccine manufacturer
- Vaccination date
- Lot number
- Name of medical clinic providing immunization/immunization event record location
- Immunization adverse reaction indicator (checkbox only)
- Contraindication indicator (checkbox only)
- Patient birth state/county (This is a core data element recommended by NVAC.)

Function #3: Establish records on all newborns

A registry will establish a registry record within 2 months of birth for each newborn child residing in the registry catchment area.

Function #4 — Notify all individuals included in the registry

All community immunization registries will:

- Ensure that patients/parents are notified of the existence of the registry and of the information contained in the registry within 30 days of the registry receiving birth or immunization data on a new patient. The notification will include information on the purpose and potential uses of the registry.
- Permit patients/parents to review and amend their own information in the registry.
- Accept responsibility for reliability and protection of registry information.

Function #5 — Permit parent/individual right to opt out without penalty

Parents/individuals must be given the option to decide whether or not they or their children will participate in a registry. If they choose to participate, they still have the right to withdraw at a later time. No one should be penalized for choosing to not participate in a registry for religious, philosophical, privacy, or other reasons.

Function #6: Establish record access; audit trails

Registry developers will limit access to registry information to those persons and entities authorized in the Immunization Data Sharing Law (M.S. §144.3351), and maintain audit trails to monitor access to records. Individuals should have access to their own records and to these audit trails, available either through the registry and/or their health care provider (decided locally).

Function #7: Ensure timely provider reporting

Ensure that providers submit information on all immunization encounters within one month of vaccine administration. The modes include:

- Electronically through a web interface
- Electronically through dial-in modem in real time
- Electronically through dial-in modem by batch mode
- By mailing a computer diskette
- By encrypted e-mail
- By mail or fax using paper forms
- By phone using touch-tone entry, computer voice response, or speaking with registry staff

Function #8: Enable timely provider retrieval

Enable providers to retrieve information from the registry on all immunization records at the time of encounter. The methods could include any combination of :

- Electronically through a secure web interface
- Electronically through dial-in modem in real time
- Electronically through dial-in modem by batch mode
- By fax or mail using paper forms
- By phone using touch-tone entry, computer voice response, or speaking with registry staff

Function #9: Authorize uses of immunization registry data

Community immunization registry data may only be used to improve immunization services to individuals and for summary reports. Use of registry data in any other manner, including sharing the demographic data with other entities who serve the same individuals and families, is not authorized unless specific prior consent is obtained. Use of registry data in a manner that is punitive to patients/parent (e.g., denial of health insurance or an increase in premiums, INS tracking of immigrants, other law enforcement purposes) is also a violation of Minnesota data practices law.

Registry information can only be used to:

- assess a person's immunization status and determine needed vaccines;
- issue reminder notices to people due for immunizations and recall notices if they are past due;
- notify persons of a vaccine-preventable disease outbreak to which they may be susceptible;

- produce individual immunization reports for school admission, child care enrollment, or other enrollments that require an immunization history; or
- prepare summary reports of immunization levels in a population (this must be done in a way that no individual (patient or individual health care provider) can be identified).

Function #10: Protect confidential medical information

Registry confidentiality and security measures would minimally include:

- Written confidentiality policies detailing the administrative procedures in place to protect confidentiality
- Confidentiality agreements with providers and other users of the registry.
- Penalties for unauthorized disclosure or use of registry data (contained in the Government Data Practices Act, M.S. §13).
- Written security policies detailing the technical security measures and physical safeguards in place.
- Formal system vulnerability assessment conducted to identify security weaknesses/ability to break into system.
- Unique user IDs assigned at both central and provider levels.
- Individually-assigned passwords required to gain access to system at both central and provider levels.
- Levels of access controls that limit users’ access to only that information for which they have a legitimate need, e.g., read only, update, or full access.
- Audit trail that logs all access to information.
- Remote access to central server(s) protected by firewall.
- Encrypted computerized information that passes over telephone lines.
- Up-to-date virus checking.
- Central server located in locked room, with limited access.

Function #11: Provide data privacy training

All staff with access to registry data must receive periodic training on data privacy and confidentiality based on the Minnesota Government Data Practices Act (M.S. §13).

Function #12: Predict immunizations

Automatically determine the immunization(s) needed when an individual presents for a vaccination, based on current ACIP recommendations.

Function #13: Have reminder/recall capability

A community immunization registry will have the *capability* to send reminder and recall notices to both parents and providers based on the MDH/national harmonized immunization schedule. At a very minimum, registries will send recall notices to providers when their patients are more than two months behind on their shots and send an alert/recall notice to the public health agency of residence at the same time.

Beyond that minimum, the combination of reminders and/or recalls to providers and/or parents a specific registry provides is a local decision based on factors such as whether any providers are willing to conduct reminder and/or recall themselves, available registry resources, and the ability to maintain accurate address information.

Function # 14: Produce registry reports

Automatically produce summary immunization coverage reports by clinics, vaccines, age groups, and

geographic areas.

Function #15: Produce individual immunization records

Produce authorized immunization records (copy of an individual's immunization history on a form that serves as an official immunization record).

Function #16: Merge and deduplicate immunization records

Consolidate all immunization records from multiple providers using de-duplication and edit checking procedures to optimize accuracy and completeness. Procedures would include:

- Verification through clinic chart audits
- Allowing entry of historical immunization information
- Dependable and efficient processes in place for preventing, identifying, and resolving duplicates
- Consolidation of information from multiple providers on an individual into a single, unduplicated record
- Minimum data quality assurance checks

Function #17: Plan for recovering lost data

Disaster recovery measures would minimally include:

- Daily backup
- Secure storage of backup media
- Successfully testing the disaster recovery plan at least annually

Function #18: Exchange records securely

Exchange immunization records using Health Level 7 (HL7) standards.

Additional Expectations of Community Immunization Registries in Minnesota

Report bi-annually to MDH on the registry's status using standardized operational indicators and cost reports

The following indicators were developed by the national All Kids Count (AKC) program as a way to consistently measure performance across the 16 diverse AKC-funded projects. These indicators are the best measure developed to date nationally for assessing how fully functioning a community immunization registry is, so were adopted by Minnesota as part of statewide bi-annual reporting.

Operational Indicators:

Indicator #1:

Percent of births within catchment area entered into the registry by #42 days, 43 – 90 days, and >90 days of age for births occurring between <date> and <date>.

Indicator #2:

Percent of resident children #24 months of age with immunization events in the registry.

Indicator #3:

Percent of doses administered entered into the registry #7 days, 8 – 30 days, and >30 days during the period <date> and <date>.

Indicator #4:

Percent of public providers who submitted immunization data during the previous six month period.

Indicator #5:

Percent of private providers within catchment area enrolled (that is, have committed to be part of the registry and are at least working with the registry on data exchange\data quality issues).

Indicator #6:

Percent of private providers within catchment area who submitted immunization data during the previous six month period.

Indicator #7:

Percent of resident children in the registry during the six-month period prior to the report date who were up-to-date (4:3:1:3:3) at 24 months of age.

Report registry cost data at least annually.

Cost reports will include registry costs and reflect all sources of direct support. Showing in-kind support will be optional. A standardized expenditure report may be necessary to accurately summarize cost data statewide.

Work with MDH and CDC to characterize start-up and maintenance costs of registries and

compare these costs to alternative systems. Work with MDH, CDC and others to gather and evaluate information about funding to partially or fully support immunization registries.

Work with MDH, CDC, and other groups in developing and implementing standards pertaining to immunization registries, including:

- Defining essential registry functions and attributes.
- Defining core data elements.
- Participate in any national or state certification process for the registry's clinical decision-support function.
- Participate in any national or state certification process for the registry's ability's to consolidate multiple records on the same individual.
- Participate with MDH in the testing and implementation of intra- and inter-registry record exchange with standard (e.g., HL7) messages, incorporating these capabilities into the registry application.
- Participate with MDH and CDC in setting and adopting system security standards to address both technical and administrative issues and to ensure that access is limited to authorized persons.
- Participate in any state or national process to certify registry functions.

Work with MDH and community registries to develop a site visit protocol to review registry adherence to the minimum functions and to develop strategies to enhance registry operations and services to the user and the community.

- The site visit team would include at least one other registry operator.
- Annual site visits would be the preferred schedule.
- The site visit would be to the lead agency/registry operator only, not agencies participating in a regional registry.

Attachment B

**Financing
Community Immunization Registries
in Minnesota**

(See separate entry)