

AN EVALUATION OF THE MICHIGAN CHILDHOOD IMMUNIZATION
REGISTRY

THESIS

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INTRODUCTION

Although a high level of age-appropriate childhood vaccination coverage exists, pockets of children who are under-immunized threaten the success of the most recent Childhood Immunization Initiative. Centers for Disease Control and Prevention (CDC) National Immunization Program staff are concerned that the increasing complexity of recommended immunization schedule, coupled with provider complacency for timely immunizations, may increase missed opportunities for immunization (Centers for Disease Control and Prevention, 1998). An important outcome of the Initiative is to build a sustainable system to maintain high immunization coverage. In July 1997, President Clinton directed the Department of Health and Human Services Secretary to work “with the states on an integrated immunization registry system” (National Vaccine Advisory Committee, 1999). As a result, the National Vaccine Advisory Committee (NVAC) developed the Initiative on Immunization Registries. NVAC defines immunization registries as “confidential, computerized information systems that contain information about immunizations and children” (National Vaccine Advisory Committee, 1999). Immunization registries are designed to be much more than a repository of information regarding childhood immunization status- they facilitate interventions proven to increase immunization rates such as reminder/recall systems, assessing immunization coverage and exchanging information with providers and managed care partners, Special Supplemental Nutrition Program for Women, Infants, Children program (WIC) linkages, and provider education through incorporating decision rules based on Advisory Committee on Immunization Practices (ACIP) standards (Centers for Disease Control and Prevention, 1999). Immunization registries can automatically produce immunization

coverage reports by providers, age groups, and geographic areas in order to better quantify pockets of under-immunization and target interventions more cost-effectively.

The CDC estimates that over 70% of immunizations are now given in the private sector which makes public and private links critical for the prevention of vaccine-preventable diseases (National Vaccine Advisory Committee, 1999). Ensuring provider participation is one of the four issues that underlie the Immunization Registry Initiative:

1. Overcoming technical and operational challenges
 2. Ensuring provider participation
 3. Protecting the privacy and confidentiality of information
 4. Determining resources needed to develop and maintain immunization registries
- (National Vaccine Advisory Committee, 1999). These four issues will serve as the evaluation framework.

Purpose:

The purpose of this study is to examine the relationship of the Immunization Registry Initiative on the establishment of an operational population-based immunization registry. The CDC defines operational registries as those that enroll at least 95% of the children ages 0-5 in a given geographical region (Department of Health and Human Resources, 1999). This study will limit the evaluation to only those state-based and the District of Columbia immunization registries that have progressed beyond the planning stage. The primary purpose of the MCIR is to increase immunization rates across the state of Michigan.

According to the National Immunization Program's System Development Branch Annual Registry Report, the MCIR was designed initially as an independent system, with

integration with other state systems planned once the registry became operational by enrolling providers. The MCIR has added links with the Special Supplemental Nutrition Program for Women, Infant, and Children (WIC), Early Periodic Screening and Developmental Testing (EPSDT- part of the Medicaid program), Head Start, and registered day cares. Linkages with the public school system are being implemented this year (D. McLaury, personal communication, August 24, 1999).

The state is divided into 6 regions, each with a regional contractor. SE Michigan /Region 1 (Detroit Metro) represents approximately 50% of the population, while SW Michigan/Region 2 contains ~ 25% of the state's population (Michigan Department of Community Health, 1998). Regional contractors help facilitate MCIR functions by conducting training sessions, operating the help desk, promoting MCIR to providers and parents, overseeing MCIR registration and administration, and clarifying MCIR policies. The regional contractor also plays a pivotal role in facilitating immunization coalitions that work with the local health departments by performing community immunization assessments as well as target provider recruitment and retention (Michigan Department of Community Health, 1998).

One of the most challenging technical/operational issues of immunization registries to overcome is the aspect of data quality assurance, which includes matching and de-duplication of patient records. Accurate and complete records de-duplication is a crucial precursor in order to accurately assess an individual's vaccination status based on ACIP guidelines and administer the appropriate vaccinations to ensure high immunization coverage levels (National Vaccine Advisory Committee, 1999). A computer-based algorithm that utilizes a probabilistic approach to de-duplication, with scores assigned for

levels of probable, possible, and non-matches, can significantly reduce manual review and hence is a crucial aspect of large, state-based immunization registries. Patient record matching through queries require a minimum of two specified fields: Child's name (last, first, middle), Date of Birth (DOB), Mother's maiden name, Responsible party's name (last, first, middle), Responsible party's phone number. The database utilizes a probabilistic algorithm to match records based on these queries. Likewise, queries generated through unique identifiers use a probabilistic match to account for errors: Medicaid number, WIC personal identifier (ID), Social Security number (SSN), and/or MCIR ID. The MCIR will transmit a request for additional information if multiple matches occur. Once a single match has occurred, the user authenticates the match through review of demographic data by keystroke or mouse click (for electronic data transmission), or touch-tone phone (through the Interactive Voice Response system) to confirm that the MCIR match is correct (Michigan Department of Community Health, 1998).

Patient data enters the MCIR in one of two ways:

1. Newborns: electronic birth certificate transmission from Vital Records within 14 days after birth.
2. New patients and immunization updates at the provider level through computer access or standardized paper forms (mail or fax).

Providers that utilize the MCIR are required to submit immunization data within 72 hours. The information can be submitted by mail (paper forms or diskettes), fax, or electronically. Providers who submit electronically use the proprietary software developed by Vector Research, Inc. Those providers who choose to submit immunization

histories electronically must verify that the information meets data quality, format, security, and timeliness standards developed by the state health department, the Michigan Department of Community Health (Michigan Department of Community Health, 1998). Currently, the standards do not include data encryption standards for electronic transmission (D. McLaury, personal communication, August 24, 1999). This will need to be instituted in order for the registry to comply with proposed registry certification. Those providers not using electronic submission will need to use the MCIR Child Data Scan Forms.

Providers can register with the MCIR either as individuals or as members of a group practice or health maintenance organization (HMO) as an organization. Providers in group practices and HMO's have the ability to also register as individuals. The medical officer of the organization has the responsibility to oversee MCIR confidentiality and security policies for the organization. Physicians who practice in neighboring states but treat Michigan residents can also register with the MCIR. The MCIR will only accept immunization histories for those children who reside in Michigan. Other stakeholders can have limited access to the MCIR once a user agreement has been signed. WIC, day care facilities, and schools have read-only access to MCIR either through MCIR Link View software or a telephone and fax machine in order to obtain an official immunization record on a child (Michigan Department of Community Health, 1998).

The System Development Branch of the CDC's National Immunization Program is responsible for developing and monitoring minimum registry attributes. Compliance with these attributes is expected in the development of a certification process for registries, which is currently under development with the Technical Working Group for

Immunization Registries. Most of the minimum attributes have components of privacy, confidentiality, and security of information; measures to increase provider participation; and technical and operational challenge issues. Certain attributes have more benefit for providers and hence may influence provider participation (Table 1).

MINIMUM REGISTRY ATTRIBUTES	BENEFIT
1. Electronically store data on all NVAC approved core data elements.	
2. Establish a registry record within 2 months of birth for each newborn child residing in the catchment area.	
3. Enable providers to retrieve information from the registry on all immunization records at the time of encounter.	X
4. Ensure that providers submit information on all immunization encounters within one month of vaccine administration.	
5. Protect confidential medical information (confidentiality and security measures).	X
6. Recover lost data (disaster recovery).	
7. Exchange immunization records utilizing Health Level 7 (HL7) standards.	
8. Automatically determine the immunization(s) needed when an individual presents for vaccination, based on current ACIP recommendations.	X
9. Identify individuals late for immunization to enable the production of recall notices.	X
10. Automatically produce immunization coverage reports by providers, age groups, and geographic areas.	X
11. Produce authorized immunization records.	X
12. Consolidate all immunization records from multiple providers using deduplication and edit checking procedures to optimize accuracy and completeness.	X

Table 1. Minimum Registry Attributes

Hypothesis:

State-based immunization registries with higher compliance with the minimum attributes are more likely to have either a higher percentage of children under 6 years of age enrolled or a higher number of providers participating in the registry.

METHOD

Subjects:

The 34 state-based registries and the District of Columbia that are able to provide consolidated immunization histories to registered providers and hence have advanced beyond the planning stage were utilized in this study. Michigan was chosen as a convenience sample to quantify the impact of the Immunization Registry Initiative on state-based registries.

Design:

The relationship between comprehensiveness of registry attribute compliance by inclusiveness of the target population was examined utilizing a chi-square test for independence. Provider participation was utilized as a surrogate for inclusiveness because the MCIR was unable to determine the patient population at the time of the Registry Annual Report due to technical problems. The Director of Immunization for Michigan estimates that approximately 700,000 children ages 0-5 are enrolled in the MCIR with at least one vaccination recorded (G. Stoltman, personal communication, August 24, 1999). Each individual registry attribute category has previously been assigned a score of "10" by registry staff for a total of 120 possible points. The MCIR achieved the highest attribute score for a state-based registry at 82.4%. Provider participation was 79% of the target minimum enrollment (95% or greater) for a functional registry, which placed Michigan's registry in the "middle" development category, along with most of the other state-based projects that have progressed beyond a planning stage (Figure 1).

State-based Immunization Registries

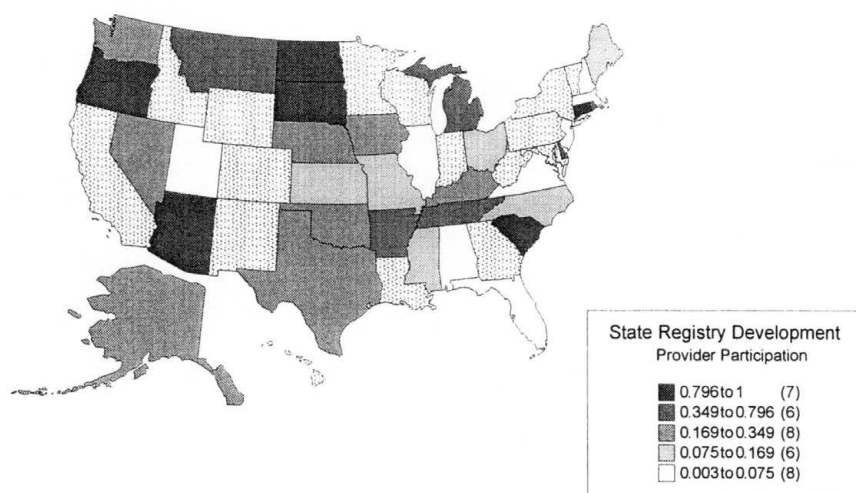


Figure 1. State-based Immunization Registries

Cut-off scores for the categories were based on cumulative frequencies of the minimum attribute score and the percentage providers enrolled in the 34 state-based immunization registry projects that have advanced beyond the planning stage. The median value for attribute score was 69.7% with a range from 37.1 to 82.4%. The standard deviation was 12.8%, reflecting the wide range. The median value for enrolled providers was 21.4% with a range from 0.4 to 100%. The standard deviation was higher at 35.7%, which may be in part reflective of the states' enrollment strategy of targeting public providers first (Appendix A). The states were categorized as a medium-high registry if the provider participation percentage was greater than or equal to 21.4% and the registry minimum attribute score was greater than or equal to 69.7%. The MCIR and 7 other state-based projects were hence classified in the medium-high category (Table 2).

RESULTS

The scores of the two groups were compared utilizing the chi-square test for independence. Two by two contingency tables were constructed with one degree of freedom. The result is not significant at one degree of freedom ($p > .50$), suggesting there is no difference between a low-medium developmental stage and a medium-high developmental stage immunization registry based on comprehensiveness of registry attributes by inclusiveness of the population.

Observed				versus		Expected			
Attribute	Provider enrollment					Attribute	Provider enrollment		
	Med-High	Low-Med					Med-High	Low-Med	
Med-High	8	11	19			Med-High	9.8	9.2	19
Low-Med	10	6	16			Low-Med	8.2	7.8	16
	18	17	35				18	17	35
Result 0.678						$p > .50$			

Table 2. Chi-square Test for Independence

This suggests that the minimum registry attributes alone cannot be categorized as influencing provider participation and hence children ages 0-5 enrolled. Two other key components, legislation and costs, are discussed below.

DISCUSSION

The interaction between the issues that underscore immunization registry development is complex in nature. Further research is needed to determine the nature of the relationship of each of the attributes to improving enrollment. Recall bias, which is inherent in self-reported data, limits the comparability of the state-based immunization registries. Biannual site visits are planned to verify Annual Report data and provide technical assistance for the Immunization Registry Initiative. The CDC's National Immunization Program is committed to immunization registry development as a critical system that will sustain high immunization coverage levels in children.

The Michigan Child Immunization Registry (MCIR) was established as an Amendment to Public Act 540 of 1996 to record immunization information from birth to age 18 in response to low immunization rates of children in the 1990's. The law also specifies that records be deleted from MCIR once a child reaches age 20 (Michigan Department of Community Health, 1998). The law mandates provider reporting yet does not impose sanctions for non-compliance. Hence, enlisting private provider participation requires marketing the benefits of immunization registries in increasing age-appropriate immunizations, as well as decreasing over-immunization. The Act specifies implied consent with the parents having an "opt out" option (Centers for Disease Control, 1998). Notice of inclusion into the registry is typically given at the birth hospital with the first Hepatitis B vaccination. Providers are responsible for registry consent for those children born at alternative sites or in another state. The providers submit the consent forms to the regional contractor (generally, a specified local health department) for further processing.

The Health Care Portability and Accountability Act of 1996 (HIPPA) mandates provisions for a federal privacy law, as well as provisions for security standards and electronic transaction standards under the administrative simplification provision (Department of Health and Human Services, 1998). Protection of patient privacy is under the purview of informational privacy, which concerns “the interest of the individual in controlling the dissemination and use of information” about oneself (National Research Council, 1997). According to the Institute of Medicine, protection of the confidentiality of sensitive information “implies controlled access to and protection against unauthorized access to, modification of, or destruction of health data.” (National Research Council, 1997). Threats to data security can occur during the collection, storage, usage, and transmission of electronic health care information (Donaldson and Lohr, 1994). Implementation of privacy and confidentiality protection involves system security-both administrative and technical security safeguards. Administrative or organizational practices include policies and procedures governing user access, training policies and plans to heighten security awareness, and policies detailing sanctions against unauthorized access. Technical practices include physical security and disaster recovery. Disaster recovery plans cover both harm from unintentional (such as physical disaster) and intentional threats such as hacking. Technical practices also include operational access controls such as a unique log-on identifier and password, audit trails of system users, virus-checking software, and physical equipment security (Federal Register, 1998). System security hence protects the confidentiality of individuals in the registry. Although the MCIR has successfully tested a disaster recovery plan from environmental disasters, the MCIR administrative staff has not conducted a formal vulnerability assessment for

intentional threats. The MCIR complies with the other suggested technical practices except up-to-date virus checking programs. The CDC is in the process of drafting minimum privacy, confidentiality, and security standards for state and local registries. These guidelines may need to be revised once the HIPPA final rule on data security is released next year.

The confidentiality of personal identifiable information is subject to federal, state, local and organizational laws or regulation. The Federal Privacy Act of 1974 protects the release of personally identifiable information by the Federal Government without the consent of the individual to disclose the information (National Research Council, 1994). Protection of patient confidentiality in the MCIR exist under the Michigan Childhood Immunization Registry Law (Public Act 540), the Vital Records Law (Public Act 333), and the Michigan Computer Crime Law (Public Act 752). Both the Vital Records Law and the Computer Crime Law detail sanctions associated with violations to include fines and/or imprisonment (Michigan Department of Community Health, 1998).

The State of Michigan does not have a law addressing the sharing of healthcare information between providers. Security standards for data encryption are being developed at the national level for electronic transmission of potentially sensitive information. Policymakers expect that both parties involved in data transmission of potentially patient identifiable information have minimum data protection. Interstate electronic exchange of personally identified information presents both legal and technical challenges for immunization registries. Currently, no state or local registry electronically exchanges registry information with other states utilizing communication standard protocols (S. Abernathy, personal communication, September 15, 1999).

Michigan's Public Act 540 establishing the MCIR and mandating provider reporting should facilitate provider participation if providers are educated towards immunization registry benefits. Implied consent or parental "opt out" has been documented to be preferred over informed consent by those providers that participated in immunization registry focus groups (National Vaccine Advisory Committee, 1999). The MCIR has achieved "reasonable" protection of patient privacy and confidentiality via state legislation, technical security measures, and strong policies and procedures with sanctions detailed in the user agreement. The MCIR staff initially targeted Vaccine for Children Providers to include public health clinics as well as private providers who serve the medically indigent. The challenge for the MCIR administration is enlisting and retaining private provider and parental support in Southern Michigan, where ~75% of the population resides. The regional contractors and the immunization coalitions will need to capitalize on the support of the state government in order to be successful.

Costs associated with planning, implementing, and maintaining immunization registries should be discussed with the registry's benefits for parents, providers, managed care plans, communities, and public health officials. The reminder/recall function in immunization registries reduces missed opportunities for vaccination, hence increasing the target population's immunization coverage rate. Registries can offset many costs associated with ongoing record reviews by plans for the value of the childhood immunization Health Plan Employer Data Information Set (HEDIS) indicator (National Vaccine Advisory Committee, 1999). Other benefits of a population-based registry include minimizing the cost associated with the yearly National Immunization Survey, the primary method for community immunization assessment. Moreover, registries

produce authorized immunization certificates, a benefit useful to parents, providers, day cares, and schools (National Vaccine Advisory Committee, 1999). An All Kids Count study among private-sector organizations with high immunization utilization (more than 100,000 immunizations per month) examined the costs associated with manual record review at providers' offices for school entry. The study determined that the average cost per review was \$ 14.50. The study concluded that registries could save approximately \$58 million per year (based on an estimated 4 million children entering the school system each year) in costs now associated with manual retrieval (Wood, Saarlal, Inkelas, & Matyas, 1999).

Cost studies are currently being pilot-tested in CDC funded state and local registries. The average cost-estimate per child ages 0-5 in the MCIR database for Fiscal Year 1998 based on the estimated 700,000 children ages 0-5 enrolled was \$4.32 per child (Appendix B). This estimate is within the range of average cost per child of \$3.38-\$6.15/year that was determined from initial registry cost analysis conducted by CDC staff. The later range translates into costs ranges of \$67.6-123 million per year nationally to enroll all children ages 0-5 in a fully operational registry based on 1998 U.S. Census estimates (National Vaccine Advisory Committee, 1999).

Long-term funding of registries is likely to involve partnerships between several entities: private foundations, managed care organizations, Medicaid, schools, parents and providers, and local, state, and federal governments. Options under study include a vaccine surcharge to maintain immunization registries, surcharge on HEDIS indicator reporting, financial partnership with Medicaid managed care and the Medicaid information systems, and a possible school entry surcharge for an authorized

immunization certificate (G. Urquhart, personal communication, September 15, 1999).

Stakeholder involvement in immunization registry maintenance as well as ongoing cost-benefit analysis are key issues facing the financial sustainability of immunization registries.

SUMMARY

The MCIR has made impressive strides towards becoming a fully functional registry since its inception 3 years ago. The partnership with Vector Research has proven to be beneficial in achieving this goal. The MCIR standardized forms have been streamlined to increase provider participation for those without reliable computer access. Key state registry legislation has been enacted. The State funds the majority of registry functions in part through a Healthy Michigan tobacco tax fund. Enlisting private providers in the most populous regions appears to be the hardest challenge for the MCIR.

Working with stakeholders in both the private and public sector is the key component in successful implementation of an immunization registry. Parents must be assured access to their child's information via electronic audit logs of authorized users. Parents and providers benefit from a consolidated immunization record and decision support rules to ensure that over-immunization does not occur. Parents, providers, and other agencies such as schools, day cares, and camps benefit from a computerized official immunization certificate. Parents and providers benefit from the reminder/recall function, which emphasizes the importance of preventive services. In addition, providers, managed care organizations, and public health agencies benefit from automated immunization assessments of children in a specified geographic location.

Adequate funding of immunization registries depends on the support from the public health sector, business sector via children's hospitals and managed care plans, private philanthropic organizations, and state government. Further research is planned to ascertain determinants of provider and managed care participation in immunization registries. The State of Michigan has realized the importance of immunization registries

to ensure high immunization coverage levels via public legislation and implied consent policy. Immunization registries can play an important role in improving data collection, analysis, and communication of preventive services for children, all of which will ultimately improve the delivery of health care to children.

APPENDIX A: Results of State-based Immunization Registries

STATE	PROVIDER	ATTRIBUTE	CHILD <6
Alabama	2.3%	68.6%	68.9%
Alaska	19.3%	69.7%	39.7%
Arizona	100.0%	81.3%	90.6%
Arkansas	75.8%	69.0%	92.4%
Connecticut	99.5%	37.2%	6.8%
Delaware	45.7%	63.6%	91.9%
District of Columbia	100.0%	55.8%	112.2%*
Florida	0.4%	74.9%	0.0%
Illinois	4.9%	62.5%	31.3%
Iowa	34.9%	71.1%	39.3%
Kansas	8.2%	69.6%	25.3%
Kentucky	21.4%	47.7%	35.4%
Maine	12.0%	76.2%	0.0%
Massachusetts	1.3%	73.7%	2.4%
Michigan	71.2%	82.4%	0.0%
Mississippi	15.2%	57.2%	85.0%
Missouri	9.1%	80.6%	46.8%
Montana	65.8%	66.0%	66.3%
Nebraska	19.5%	70.2%	27.1%
Nevada	34.0%	70.2%	0.0%
New Hampshire	2.5%	76.2%	1.7%
New Jersey	2.9%	58.6%	9.2%
North Carolina	10.2%	36.5%	51.8%
North Dakota	94.6%	56.2%	96.5%
Ohio	15.6%	71.1%	3.6%
Oklahoma	32.2%	67.2%	73.9%
Oregon	94.1%	42.7%	101.1%*
Rhode Island	64.1%	75.0%	20.9%
South Carolina	79.6%	45.4%	84.5%
South Dakota	100.0%	74.3%	90.0%
Tennessee	45.2%	67.6%	61.8%
Texas	24.7%	81.3%	47.9%
Utah	7.5%	46.1%	22.6%
Virginia	1.1%	78.9%	10.3%
Washington	16.9%	77.8%	24.8%

*Includes duplicate records

APPENDIX B: Cost per Child in MCIR, 1998

MICHIGAN COST DATA 1998

FUNDING CATEGORY			
	Federal 317	State	TOTALS
Personnel	\$148,909	\$200,000	
Fringe benefits (42.3%)	62,988		
Contractors (Cost)		2,351,400	
Equipment		50,000	
Communication (WAN)	2,236	200,000	
Supplies	6,692		
Indirect:			
Travel	4,100		
TOTAL EXPENSES	\$224,925	\$2,801,400	\$3,026,325

Estimated children 0-5 enrolled: 700,000

Average Cost per child: \$4.32

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VITA

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