

Immunization Registries: Progress and Challenges in Reaching the 2010 National Objective

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Immunization registries are confidential, population-based, computerized information systems that contain data about children's immunizations and have been described as the cornerstone of immunization delivery in the 21st century. Work to ensure the privacy of registry participants and the confidentiality of their information, recruit provider participation, overcome technical and operational challenges, and identify sustainable funding streams has resulted in 24 percent of children less than 6 years of age currently in an immunization registry in the United States. New solutions will be needed before reaching the national health objective of increasing the proportion of children to 95 percent in a fully operational immunization registry by 2010.

Key words: *immunization, information systems, registries*

Despite record high rates of immunization coverage in the United States, each year approximately 300 children die from diseases that can be prevented by vaccines. One million 2-year-old children need at least one additional vaccine dose to be fully immunized.¹ The lowest rates of coverage are in urban and low-income “pockets of need.”

Currently, the Advisory Committee on Immunization Practices recommends 16–20 vaccine doses by 18 months of age.² While parents^{3–8} and providers⁹ already find it difficult to interpret the complex vaccine schedule, the number of recommended vaccines may triple by 2020.¹ Studies have shown that providers overestimate the immunization coverage in their practice.^{10–12} For example, in Massachusetts, providers estimated 85 percent to 100 percent coverage in their practices. Measured coverage rates were as low as 19 percent.

Making appropriate immunization decisions may be compounded by the administrative challenge of assembling a complete and accurate immunization history. More than 20 percent of children have seen more than one provider by 2 years of age.^{13,14} In many states, Medicaid participants are allowed to change managed care plans every 30 days. Unless immunization data are shared, no one of these providers will have the information needed to make appropriate immunization decisions.

Children who receive care from multiple providers may receive too many immunizations.¹⁵ The effort required to assemble a complete and accurate immunization history can further burden already overburdened office staff and may foster the attitude of “when in doubt, vaccinate.” Approximately 21 per-

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cent of children 19–35 months of age receive at least one unnecessary dose of vaccine, and costs associated with these duplicative immunizations are estimated to be \$26.5 million each year.¹⁶

Several strategies have proven effective in ensuring optimal immunization delivery: (1) reminder and recall systems used to notify parents and providers when immunizations are due or overdue; (2) “AFIX” evaluations to Assess provider coverage, provide Feedback on findings, supply Incentives to improve practice, and eXchange information to boost coverage; and (3) linkages between immunization programs and the Special Supplemental Nutrition Program for Women, Infants, and Children to identify

and refer inadequately immunized children back to their medical home for needed vaccinations.^{17,18} Nonetheless, only 35 percent of pediatricians and 23 percent of family physicians routinely operated reminder/recall systems in 1995, and only 48 percent of public and 6 percent of private clinics conducted AFIX evaluations in 2000.^{1,19} The administrative burden associated with these activities may be a barrier to their use in addition to an inadequate information infrastructure.^{1,17}

Community- and state-based immunization registries overcome these ongoing challenges by providing automated immunization information tools that decrease record scattering, enable providers to easily

Table 1.

Potential benefits of immunization registries

Group benefited	Potential immunization registry benefits
Parents	<ul style="list-style-type: none"> • Assemble in one site a record of all immunizations a child has received to create an accurate and complete immunization history. • Help ensure that a child’s immunizations are up-to-date through computerized decision support. • Provide reminder and recall notices when an immunization is due or late. • Prevent unnecessary (duplicative) doses of vaccine. • Produce an accurate, official copy of a child’s immunization history for personal, day care, school, or camp entry requirements.
Providers	<ul style="list-style-type: none"> • Consolidate immunizations from all providers into one record to serve as a source of complete and accurate immunization histories for any child, whether a new or continuing patient. • Help interpret the complex immunization schedule by providing computerized immunization decision support. • Identify immunizations due or overdue, and produce reminder and recall notices. • Produce official immunization records for schools, camps, and day cares. • Reduce a practice’s paperwork. • Facilitate introduction of new vaccines or changes in the vaccine schedule. • Help manage vaccine inventories. • Generate quality assurance reports (e.g., Health Plan Employer Data Information Set [HEDIS] for managed care organizations). • Reinforce the concept of the medical home by facilitating vaccination and referral back to the medical home.
Public health officials	<ul style="list-style-type: none"> • Help control vaccine-preventable diseases. • Provide information to identify unimmunized and under-immunized populations, target interventions and resources, and evaluate programs. • Promote reminder and recall of children who need immunizations. • Reduce missed immunization opportunities by ensuring providers follow the most up-to-date recommendations. • Integrate immunization services with other public health functions.

Source: Adapted from the Report on the Development of Community- and State-based Immunization Registries, National Vaccine Advisory Committee, Department of Health and Human Services, 1998.

implement strategies known to improve coverage, decrease unnecessary immunizations and missed immunization opportunities, and increase office efficiency. These systems have been described as the “cornerstone of immunization delivery in the 21st century.”²⁰ Potential benefits they provide to parents, providers, and public health officials are described in Table 1.

Since 1994, the Centers for Disease Control and Prevention’s (CDC’s) National Immunization Program (NIP) has allocated \$181.3 million for the development of immunization registries. A national immunization health objective for 2010 is to increase to 95 percent the proportion of children (0 – < 6 years) in a fully operational immunization registry (objective 14.26).²¹

Definition of Immunization Registries

Immunization registries are confidential, population-based, computerized information systems that contain data about children’s immunizations.²² Commonly, after obtaining parental consent, a child is enrolled in an immunization registry at birth, possibly through linkage with an electronic birth certificate or at first contact with the health care system. Demographic and immunization data are recorded at enrollment and electronically transferred from the provider office to a central registry database. At each immunization encounter, the child’s history is located in the registry’s database with the help of a patient identification algorithm and electronically transferred to the provider’s office. The provider can have confidence that the record is complete and accurate as the registry will have assembled all immunizations the child has received, regardless of when and where they were administered. Automated registry functions enable immunization decision support, “push button” reminder/recall notice generation, and provider coverage assessment and feedback. Official immunization records also can be generated, saving office time and resources required to document immunization histories for school entry requirements.

Survey data collected by the NIP in 2000 indicated that 39 (61%) of NIP’s 64 projects that receive federal immunization funds under the Public Health Service Act (50 states, the District of Columbia, Chicago, Houston, New York City, Philadelphia, San Antonio,

American Samoa, Guam, Marshall Islands, Micronesia, Northern Mariana Islands, Palau, Puerto Rico, and the U.S. Virgin Islands) operated population-based immunization registries that targeted their entire catchment areas.²³ An additional four (6%) projects reported the presence of independent population-based registries covering segments of their catchment areas, and 21 (33%) reported that they planned to develop registries. Data from the 29 projects that operated population-based registries indicated that approximately 11.4 million children in those catchment areas were enrolled in a registry, or approximately 24 percent of all U.S. children.

NIP plans to validate these self-reported survey data through annual site visits beginning in 2001. Nonetheless, before reaching the national registry health objective, more work is needed in the areas of ensuring the privacy of individuals and the confidentiality of registry information, overcoming technical and operational challenges, increasing provider participation in registries, and identifying and securing needed registry resources.

Ensuring the Privacy of Individuals and the Confidentiality of Registry Information

Public health practice often requires access to health information on individuals. Balancing the public health need for this information with the need to protect the privacy of these individuals is one of the greatest challenges in registry development.

To assist registry projects, NIP and partner organizations developed minimum privacy specifications, which were approved by the National Vaccine Advisory Committee in 2000.²⁴ These recommendations are consistent with privacy regulations now required by the Health Insurance Portability and Accountability Act of 1996,²⁵ and cover the following areas:

- *Confidentiality policies:* All registries must have a written confidentiality policy that applies to everyone with registry access. This policy must be consistent with applicable federal, state, and local regulations.
- *Agreements to protect confidentiality:* Authorized users must agree in writing to comply with the registry confidentiality policy.
- *Notification:* Parents must be notified of the existence of the registry. They must be told what data will be stored, how they will be used, with

whom they will be shared, and how they can be reviewed and corrected.

- *Choice:* Parents must be given the choice of whether to participate in the registry and must be allowed to modify this decision at any time. There must be no penalties for choosing not to participate.
- *Use of registry information:* Registry information must be used only for its intended purpose.
- *Access to and disclosure of registry information:* Policies must specify who has registry access and to what information this access provides. Law enforcement access to registry information must be limited to extraordinary circumstances.
- *Penalties for unauthorized disclosure of registry information:* Confidentiality breaches and resulting penalties must be defined. Penalties must be enforced.
- *Data retention and disposal:* Policies must specify the length of registry data retention and what will happen to the data at the end of that period.

As of October 2000, 14 (27%) of the 50 states and the District of Columbia required explicit consent to be in a registry, 35 (69%) allowed implied consent, and the remaining two (4%) jurisdictions had not yet addressed this issue.²⁶ Of these 51 jurisdictions, 35 (69%) provided or were planning to provide notice

of the registry to parents. However, 13 (25%) of these jurisdictions did not provide notice and three (6%) had not yet addressed the issue of notice.

While the confidentiality policies of several states are being modified to comply with the specifications, it will be critical to ensure conformity of the minimum specifications with future federal privacy regulations. Work is also needed to enable interstate exchange of immunization information; because federal legislation will not preempt stricter state laws,²⁷ interstate exchange of registry information between two states with different levels of legislative stringency may be problematic. Solutions are needed that ensure provider access to complete and accurate immunization histories, even when this requires sharing immunization information across state lines.

Overcoming Technical and Operational Challenges

Early efforts to develop infant immunization tracking systems in the 1960s failed because systems were primarily manual, expensive to maintain, and not integrated within the broader public health delivery system. Among the lessons learned from development efforts in the 1980s was the vital role that end users and management staff play in the development process. Ease of use and integration with office rou-

Functional Standards of Immunization Registries

1. Electronically store data on all NVAC-approved core data elements.
2. Establish a registry record within six weeks of birth for each newborn child born in the catchment area.
3. Enable access to and retrieval of immunization information in the registry at the time of encounter.
4. Receive and process immunization information within one month of vaccine administration.
5. Protect the confidentiality of medical information.
6. Ensure security of medical information.
7. Exchange immunization records using Health Level 7 (HL7) standards.
8. Automatically determine the routine childhood immunization(s) needed, in compliance with current recommendations of the Advisory Committee on Immunization Practices, when an individual presents for a scheduled immunization.
9. Automatically identify individuals who are due/late for immunization(s) to enable the production of reminder/recall notifications.
10. Automatically produce immunization coverage reports by providers, age groups, and geographic areas.
11. Produce official immunization records.
12. Promote accuracy and completeness of registry data.

Source: Data from Centers for Disease Control and Prevention. "Progress in development of immunization registries—United States, 2000." *MMWR*, 2001, 1:3–7.

tines were critical to immunization tracking system acceptance.

Today's concerted developmental activity was motivated by a nationwide resurgence of measles in 1989.¹ Because of the difficulty in estimating measles vaccine coverage in the population, experts convened by CDC recommended that immunization registries be created to track immunizations.²⁸ Since 1993, NIP has encouraged the development of community- and state-based immunization registries that meet local needs. While flexible, this approach has resulted in registry systems that differ in functionality and operate in different electronic environments using a variety of front-, middle-, and back-end technologies.

To facilitate registry development and enable secure, inter-registry data exchange, technical functional standards were identified in 1997 (see box "Functional Standards of Immunization Registries"). One standard is the storage of required core data elements (patient name, patient birth date, patient sex, patient birth state/country, mother's name, vaccine type, vaccine manufacturer, vaccination date, and vaccine lot number) considered essential for the record exchange process. Data from 2000 indicate that only 18 population-based registries store data on each of these data elements.²³

Also included in the technical functional standards is the ability of a registry to automatically determine vaccine(s) needed based on a registry's electronic immunization record. Despite NIP's release of the *Programmer's Guide to the Automated Immunization Evaluation Process* in 1995,²⁹ creation of computerized algorithms by registry developers has been problematic due to nonuniform immunization recommendations (e.g., "month" is not defined). However, in 2000, NIP developed and released a public domain algorithm as an ActiveX component.^{30*} A corresponding set of test cases also was released to validate recommendations made by algorithms already created by registry developers.

NIP also has helped facilitate registry data exchange through the use of standard codes and transmission rules identified by the Health Level 7 (HL7) organization. In 1999, NIP collaboration with six reg-

istry developers resulted in an HL7 implementation guide for immunization data exchange.³¹ While only four population-based registries in the United States currently are able to exchange records using these standards,²³ the Committee on Immunization Registry Standards and Electronic Transactions (CIRSET) may increase this capacity. CIRSET was created by registry developers who actively are developing data exchange capability and who have agreed to follow the HL7 implementation guide. CIRSET intends to establish common HL7 implementation policies and provide HL7 technical assistance to other developers. To assist with CIRSET's efforts, the National Vaccine Program Office has provided NIP with funds to develop and distribute a public domain HL7 parser in 2001.

NIP also is developing a set of test cases to evaluate deduplication methods. Duplicate registry records pose a serious challenge to the integrity of registry databases. While many population-based registries have methods in place for ensuring that only one record exists on each individual,²³ there are no criteria for assessing the effectiveness of these methods. Test cases should enable NIP to evaluate levels of sensitivity and specificity for deduplication methodologies.

Currently, key elements associated with each of the technical functional standards are being developed. These measurable criteria will be collected during annual registry visits conducted by NIP and used to monitor progress at reaching the national registry health objective.

Increasing Provider Participation

Focus group research indicates that barriers to registry use in provider settings include staff concerns about dual record systems, slowing of patient flow, and the high costs for small practices with high staff turnover.^{32,33} Other studies indicate that providers are willing to use registries if: (1) registry data are accurate; (2) participation costs are offset by cost savings;^{34,35} (3) registry data are kept confidential;^{36,37} (4) the time required for personnel to enter and retrieve immunization data is not significant;³⁸ (5) there is no liability for data entry errors;^{1,32} (6) the data are useful in improving clinical practice;³⁸ and (7) providers understand the purposes and benefits of the registry.³⁸

*The algorithm is available upon request by calling 404-639-8739, or by e-mail at CASAINFO@cdc.gov.

Much of NIP's effort to increase provider participation involves improving registry data quality.

Much of NIP's effort to increase provider participation involves improving registry data quality. NIP currently is comparing immunization coverage estimates generated from registry databases with estimates generated from the National Immunization Survey, a nationwide, random digit-dial survey of children's immunization coverage in states and selected large metropolitan areas.^{39,40} High concordance rates between registry estimates and these "gold standard" estimates should identify registries with complete and accurate data.

Related to this effort is NIP's identification of eight "sentinel site" registries that include a large proportion of their population or subset of their population and are thought to have high-quality registry data. If these sites can demonstrate that registries with high data quality are useful in providing valid and reliable estimates of vaccine coverage, providers may begin to rely on registries as authoritative sources of immunization histories.

Identifying and Securing Needed Registry Resources

Federal funds for registries have declined from a high of approximately \$50 million in 1995 to approximately \$15 million in 2000 (K. Lane, Acting Associate Director for Management and Operations, NIP, personal communication, April 11, 2001). Estimation of registry costs and cost savings should assist in identifying stable funding sources.

NIP estimated a mean registry cost per child (less than 6 years of age) per year of \$5.18⁴¹ similar to an earlier estimate of \$3.91 per child per year based on data from 16 registries.⁴² Based on NIP's estimate, reaching the national registry health objective will require approximately \$124.3 million annually.

States and communities have used different approaches to generate sufficient registry funds, including creating a private, nonprofit corporation to

help underwrite registry costs, using tobacco tax revenues to supplement registry funds, and charging providers for registry services such as generation of immunization coverage reports, HEDIS measures, and lists of children who need immunizations.^{37,43-45} In 2000, the Center for Medicare and Medicaid Services (formerly the Health Care Financing Administration) agreed to fund up to 90 percent of registry development costs for its Medicaid population.⁴⁶

Estimated fiscal savings to the United States of \$270 million per year have been associated with registries, including costs saved by avoiding manual record pulls for school/day care entry (\$58 million), changes in immunization providers (\$16.2 million), and managed care reporting requirements (\$2 million); preventing unnecessary doses of vaccine (\$26.5 million), and negating the necessity to review vaccination records for school entry requirements compliance (\$168.0 million).^{16,23,47} Other cost savings not accounted for here include decreased no-show appointment rates through the automated use of reminder/recall notices and decreased rates and complications associated with vaccine-preventable diseases.

Conclusions

While much progress has been made toward developing a nationwide network of state- and community-based immunization registries, much work is needed before achieving the *Healthy People 2010* national registry health objective. The success of these efforts will depend on the creation of a vocal demand for registries. Parents must continue to appreciate the benefits of vaccines and become convinced that registries are critical tools for getting their children immunized on time. Providers must recognize the value of automated medical information systems and incorporate these tools in their office settings. Registry developers must understand the importance of seamless integration of their products into pre-existing office software, and develop systems that maintain the highest quality of data and reduce the burden of providing immunization services in the medical home. Political leaders must understand that immunization registries are essential for sustaining record-breaking levels of immunization coverage in the United States and that registries save more money than they cost. Adequate

resources must be committed to develop and maintain this immunization infrastructure.

Even with this demand, the sustainability of immunization registries may be dependent on their ability to integrate with other health information systems. "Silo" systems supported by categorical program funds are only one more challenge to the overburdened health care provider. Children have multiple health needs that could benefit from integrated, electronic health information systems.

Immunization registries have been described as the first step in creating such integrated systems. Population-based health registries could be used to ensure that children get the immunizations they need while being assessed for a variety of non-immunization related public health interventions. These electronic tools could make it easier for public health practitioners to fulfill their mission to assess the health of the public, ensure their access to health care, and develop effective policies to ensure a healthy population.

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