

Frequently Asked Questions About Immunization Registries

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Note: Some of the following information was taken directly from the NVAC Report entitled *Development of Community- and State-Based Immunization Registries* (1/12/99).

1. What are immunization registries?

Immunization registries are confidential, population-based, computerized information systems that contain information about immunizations and children. A “fully operational” registry includes =>95% enrollment of all catchment area children <6 years of age with 2 or more immunization encounters administered according to ACIP recommendations.

Children typically are entered into a registry at birth, often through a linkage with electronic birth records or at first contact with the health-care system. If a registry includes all children in a given geographical area and all providers are reporting immunization information, a registry can provide a single data source for all community immunization partners. Such a population-based immunization registry can make it easier to carry out the demonstrably effective immunization strategies (e.g., reminder/recall, AFIX, and WIC linkages) and thereby decrease the resources needed to achieve and maintain high levels of coverage. Immunization registries also can be used to enhance adult immunization services and coverage.

The concept of immunization registries is not new. Many individual practices and health plans have developed information systems to keep track of immunizations given to their patients. Often these are based on computerized information systems designed for other purposes such as billing. There also is a growing movement toward development of totally computerized patient medical records. These site- or plan-specific registries cover only immunizations administered by participating providers to covered patients. Only population-based immunization registries can provide information on all children and all doses of vaccines administered by all providers.

2. Why is NIP supporting the development of immunization registries?

Every year, 4 million babies are born in the United States. This means that every day, a new cohort of 11,000 infants is born having zero coverage and needing protection against vaccine-preventable diseases. Current success does not guarantee future success. Maintaining high immunization rates is a continuing challenge that is threatened by:

- an increasingly complex childhood immunization schedule (e.g., a minimum of 13 doses are recommended by 24 months of age), and new vaccines continue to

- be added to the already complex immunization schedule;
- incomplete immunization records scattered across healthcare providers (e.g., ~20% of children move by age two, thus change providers);
- missed opportunities to vaccinate because effective office practices such as reminder/recall systems are not used;
- inaccurate assessment of immunization status both by parents and providers;
- declining resources to support demonstrably effective, but resource-intensive immunization strategies (e.g., reminder/recall systems); and
- growing public complacency about the need for childhood immunizations as a result of the record low levels of vaccine-preventable disease.

Together, these factors are making it more and more difficult for parents and health-care providers to know at a glance the immunization status of any given child and to ensure that each child gets the needed vaccines. Nonetheless, families, providers, and communities need, and want definitive documentation of childhood immunizations. Immunization registries can provide such a solution.

3. What are some of the benefits of immunization registries?

Immunization registries can be extremely helpful, if not essential, to maintaining the current high immunization coverage. This is particularly true since disease levels are at record lows and do not serve as a constant reminder to patients/practitioners of the need for timely immunization. Studies consistently have shown that both parents and providers overestimate coverage, which can lead to complacency. A detailed listing of the benefits of registries to parents, providers, communities, and public health officials follows.

For parents, immunization registries:

- consolidate in one site all immunizations a child has received;
- provide an accurate, official copy of a child's immunization history for personal, day care, school, or camp entry requirements;
- help ensure that a child's immunizations are up to date;
- provide reminders when an immunization is due;
- provide recalls when an immunization has been missed;
- help ensure timely immunization for children whose families move or switch health-care providers; and
- prevent unnecessary (duplicative) immunization.

For communities, immunization registries:

- help control vaccine-preventable diseases;
- help identify high-risk and under-immunized populations;
- help prevent disease outbreaks;
- provide information on community and state coverage rates; and

- streamline vaccine management.

For providers, immunization registries:

- consolidate immunizations from all providers into one record;
- provide a reliable immunization history for any child, whether a new or continuing patient;
- provide definitive information on immunizations due or overdue;
- provide current recommendations and information on new vaccines;
- produce reminders and recalls for immunizations due or overdue;
- complete school, camp, and day-care immunization record requirements;
- reduce a practice's paperwork;
- facilitate introduction of new vaccines or changes in the vaccine schedule;
- help manage vaccine inventories;
- generate HEDIS reports for managed-care organizations; and
- reinforce the concept of the medical home.

For public health officials, immunization registries:

- provide information to identify pockets of need, target interventions and resources, and evaluate programs;
- promote reminder and recall of children who need immunizations;
- ensure providers follow the most up-to-date recommendations for immunization practice;
- facilitate introduction of new vaccines or changes in the vaccine schedule;
- integrate immunization services with other public health functions; and
- help monitor vaccine-associated adverse events.

4. What is the commitment to immunization registries at the National Level?

In 1998, the National Vaccine Advisory Committee (NVAC) formed a Workgroup on Immunization Registries which included representatives of provider organizations, managed care plans, state and local health departments, parent and consumer groups, and the health information system community. This Workgroup was staffed and supported by the Centers for Disease Control and Prevention (CDC). By focusing on new demands and lessons learned over the past four years, the Workgroup continues the work of the 1994 Subcommittee on Vaccination Registries. To achieve the goal, the Workgroup considered four critical issues:

- privacy and confidentiality;
- ensuring provider participation;
- technical and operational issues; and
- resource issues.

5. What progress has been made?

In 1997, the National Immunization Program (NIP) assembled a planning task force which consisted of staff from NIP, All Kids Count (a Robert Wood Johnson Foundation-funded activity focused on developing community-based immunization registries), and the National Vaccine Program Office (NVPO). This task force reviewed ongoing immunization registry development efforts and considered various alternatives to address registry challenges. The NVAC was asked to take the lead on this effort, which was named the Initiative on Immunization Registries. The NVPO provided the leadership and NIP provided staff support for the Initiative. Four NVAC members were named to the Workgroup on Immunization Registries and stakeholder organizations were invited to participate as consultant members.

On March 13, 1998, the Initiative's "kick-off" meeting was held in Houston, Texas. At this meeting, goals of the Initiative were formulated, the process to develop an Immunization Registry Plan of Action was defined, and a tentative date to launch the Plan was identified.

To ensure input from stakeholder groups and the general public, the Workgroup held four public meetings in New Orleans (April 6, 1998), Washington, D.C. (May 13-14, 1998), San Francisco (June 18-19, 1998), and Atlanta (July 16-17, 1998). A total of 104 persons provided testimony at these meetings representing health care providers, academia, institutes of privacy and confidentiality, health plans, school nurses, community-based organizations, numerous national associations, public health agencies, the information technology industry, vaccine manufacturers, private foundations, federal agencies, and parents. Approximately eight invited speakers per public meeting provided testimony on each issue (i.e., privacy and confidentiality, ensuring provider participation, technical and operational issues, and resource issues). However, only the privacy and confidentiality issue was discussed in New Orleans.

At each meeting, time was scheduled for the public to comment on the Initiative and to question the invited speakers. All meetings were advertised in the Federal Register. More than 400 people attended the public meetings. Of these, 12 individuals provided public comment on their own behalf or that of a special interest group or agency.

To ensure a broad cross-section of input from parents, NIP was asked by the Workgroup to conduct parent focus groups. A total of 21 focus groups, including one pilot, were held throughout the country from September - October 1998 that included a cross-section of African American, Non-Hispanic White, Hispanic, Native American, and Asian populations. Focus groups were conducted in Baltimore, Maryland; Miami, Florida; Portland, Oregon; Ankeny, Iowa; Tucson, Arizona; Tulsa, Oklahoma; and Los Angeles, California. These locations were selected based on the racial make-up and urban/rural characteristics of the communities.

The results of this focus group research are available at the following web address:
http://www.cdc.gov/nip/registry/i_fgmenu.htm.

The final report, including recommendations, was approved by the NVAC on January 12, 1999.

6. How much federal money has been spent on the development of immunization registries?

The U.S. Centers for Disease Control and Prevention (CDC) provided funding to support immunization information and registry development projects. With federal support, community- and state-based registries are proliferating across the country. As of April 2000, 62 of 64 (99%) federal immunization grantees (states, territories, commonwealths, and cities) were developing or implementing registries. Twenty-two areas were reported as operating independent registries. An estimated \$172 million in 317(j)(1) categorical immunization grant funds have been awarded in support of immunization registries since 1994.

7. What is the cost of developing and implementing an immunization registry?

Immunization registries automate the three successful strategies that played a major role in achieving the currently high coverage (i.e. reminder/recall systems, the AFIX evaluation system, and linkage between immunization programs and WIC). In a large managed care setting in California, recent registry data suggest a 20% increase in worker productivity and cost-saving ratios of 1:8. Registries also can enhance adult immunization delivery and other public health programs. Data from Rhode Island suggest an increase of 60% in lead screening after electronic public health information system data were used to identify at-risk children.

The limited information available on registry costs includes a recent study of the 16 All Kids Count II (AKC) immunization registry projects. Findings indicate that the cost of maintaining immunization registries would be approximately \$3.91/child/year, or approximately \$78 million/year nationally to enroll all children and keep them in the registry through the first five years of life. CDC has developed other estimates based on visits to three immunization projects (Florida, Oregon, and San Antonio). Analysis indicates an average annual cost per child of \$3.38-\$5.03/year, translating to national costs of \$67.6-\$100.6 million/year. These studies also identified a range of funding sources for current registry efforts, including local and state governments, federal 317(j)(1) funds, Robert Wood Johnson Foundation, Medicaid, and managed-care organizations. Additional cost data from 23 registries of varied design and development status have been collected by CDC. These data are expected to be available in 2000.

Any analysis of registry costs also should include savings derived from registry use. In addition to savings related to prevention of vaccine preventable diseases, fully functional immunization registries can offset many costs presently being borne by patients, providers, and carriers, such as the costs of manual review of individual records. An All Kids Count II (AKC) study queried five private-sector providers, who administer more than 100,000 immunizations each month, about the cost to retrieve manually and review

an immunization record, provide the information to a nurse or physician, update the record, and refile it. The average cost per review was \$14.50. This cost is equivalent to more than three times the average annual cost of maintaining a child in a registry. Since each child must have a record pulled and reviewed at least once for school entry, automatic generation of the records by registries would save approximately \$58 million/year (\$14.50 x 4 million children). In addition, 22% of American children see two immunization providers in their first two years of life and an additional 3% see three or more (S. Stokley, personal communication). Each change in provider necessitates a manual record pull and review (total annual cost approximately \$16 million); these costs also would be offset by use of a fully functional immunization registry.

Other cost-saving benefits of registries include: avoiding unnecessary (duplicative) immunizations, reducing “no show” rates (through the use of reminders), reducing vaccine wastage, avoiding manual generation of immunization certificates, avoiding manual review of multiple records to establish HEDIS indices, and avoiding part or all of the cost of the National Immunization Survey (currently the primary method for assessing coverage levels of communities). Data from the National Immunization Survey indicate that 21% of 19-35 month-old children had received at least one dose of vaccine they did not need. The estimated cost of this vaccine (without considering administration) was \$15 million (S. Feikema, personal communication). These savings need to be considered in assessing the cost-benefit of registries and possible sources of funding.

8. What’s the status of registry development in the U.S.?

Our latest survey data suggest that 62 (97%) of our 64 federal immunization grantees (states, territories, commonwealths, and cities) are developing or operating registries. An additional 22 registries were reported to be operating independently at the local level.

While much registry activity is occurring in the United States, registry development also can be measured by the maturity of these registries. A fully mature registry is one that records all shots for all children, includes all providers, and also has implemented all of the Minimum Functional Standards for immunization registries.

Many registries are capturing and distributing large amounts of immunization data on a daily basis, but most (states and the District of Columbia) still focus primarily on public sector providers. Several states have registries covering their entire area and include information on a large number of children and providers.

9. What are the Minimum Functional Standards for immunization registries?

- 1) Electronically store data on all National Vaccine Advisory Committee (ACIP)-approved core data elements
- 2) Establish a registry record within 6 weeks of birth for each newborn child born in

- the catchment area
- 3) Enable access to immunization information in the registry at the time of encounter
 - 4) Receive and process information within 1 month of vaccine administration
 - 5) Protect the confidentiality of medical information
 - 6) Ensure the security of medical information
 - 7) Recover lost data (disaster recovery)
 - 8) Exchange immunization records using Health Level 7 (HL7) standards
 - 9) Automatically determine the immunization(s) needed, in compliance with current ACIP recommendations, when an individual presents for a scheduled encounter.
 - 10) Automatically identify individuals due/late for immunization(s) to enable the production of reminder/recall notifications
 - 11) Automatically produce immunization coverage reports by providers, age groups, and geographic areas
 - 12) Produce authorized immunization records
 - 13) Consolidate all immunization records from multiple providers, using deduplication and edit checking procedures to optimize accuracy and completeness.

In addition to the Minimum Functional Standards, a registry also could document vaccine contraindications, monitor/report adverse events following immunization, manage vaccine inventories, generate reports for the Vaccines for Children Program, and integrate into a broader public health information system.

10. How is the confidentiality and security of patient information being handled?

Because of concerns regarding privacy and confidentiality issues voiced by our registry partners, NIP worked with the All Kids Count Program to produce a publication entitled *Community Immunization Registries Manual*. This Manual was approved by the National Vaccine Advisory Committee (NVAC) in 1997. A recently revised chapter on confidentiality (<http://www.cdc.gov/nip/registry/cirman2.pdf> or <http://www.cdc.gov/nip/registry/cirman2.wpd>) recommends that each registry have a written policy on privacy and confidentiality in place at the time of registry development. This chapter was revised and updated in light of several significant events, including the enactment of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Information on HIPAA is available on the web at <http://www.cdc.gov/nip/registry/legisreg.html>.

In 1998, the Initiative on Immunization Registries was undertaken by the NVAC, with support from the NIP and the National Vaccine Program Office. Four public hearings and 21 parent focus groups were held as part of the Initiative. One hundred and four persons provided expert testimony on 4 key issues including confidentiality. On January 12, 1999, the NVAC approved the report entitled the *Development of Community- and State-Based Immunization Registries* (http://www.cdc.gov/nip/registry/i_recgs.htm).

The NVAC report recommends that a workgroup develop minimum specifications for

the protection of privacy and confidentiality. This workgroup recently was initiated and began to address this important registry issue. The updated confidentiality chapter of the Manual contains minimum specifications for the protection of the privacy of registry participants and the confidentiality of information contained in a registry. This chapter also contains guidelines for implementing the specifications in a manner that is consistent with community values of the population served by the registry. The NVAC approved the updated chapter on February 28, 2000.

11. How are confidentiality/consent issues affected by State legislation?

Public health agencies historically have shared immunization information with providers and schools on a need to know basis. The development of technology and the ability to access large amounts of data has increased concerns about confidentiality as well as providers' liability concerns. Several states, including those with high immunization coverage rates, have felt the need for clear legal authority to establish an immunization registry or to share immunization information.

In many states, immunization information is considered part of the medical record, and it cannot be shared without consent. Some states find consent expensive and burdensome; others consider it necessary for parents and providers to provide information and to address liability concerns. Specific provisions in certain state laws limit immunization registries' ability to share information. For example, in one state information can be shared with those involved in service delivery, but it can not be shared with those that do not provide service directly, such as the health department.

Some important factors that have helped facilitate immunization registry development are as follows.

- Laws specifically authorizing the Department of Health to establish and maintain an immunization registry. Some laws require reporting to the registry; other laws allow reporting. Both types of laws may address liability concerns.
- Statutory provisions providing immunities from civil and/or criminal liability for providers who make good faith disclosures to immunization registries or rely on information in immunization registries.

Other important statutory provisions include:

- penalties for improper disclosure of information;
- provisions defining with whom immunization information can be shared (e.g., providers, schools, health department); and
- provisions allowing parents to opt out or limit access to immunization registry information.

While opt out and consent provisions are particularly important to some religious groups, victims of domestic violence, and others, in fact only a small percentage of people

exercise these options.