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*Recommendations  
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## **Development of Community- and State-Based Immunization Registries**

**CDC Response to a Report  
from the National Vaccine Advisory Committee**

**U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES**  
Centers for Disease Control and Prevention (CDC)  
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# Development of Community- and State-Based Immunization Registries

## CDC Response to a Report from the National Vaccine Advisory Committee

### *Summary*

*Immunization registries are confidential, population-based computerized systems that contain information regarding children's vaccinations. Registries provide a critical tool for increasing and sustaining vaccination coverage. A national health objective for 2010 is to increase to 95% the proportion of children aged <6 years who participate in fully operational population-based immunization registries. According to 2000 data, 24% of U.S. children are participating in population-based immunization registries. In 1998, to facilitate community- and state-based immunization registry development in the United States, the National Vaccine Advisory Committee (NVAC) launched the Initiative on Immunization Registries. Through public hearings and parent focus groups, NVAC identified four concerns that needed to be addressed to increase registry participation: a) protecting each person's privacy and the confidentiality of registry information; b) ensuring participation of vaccination providers and recipients; c) overcoming technical and operational challenges; and d) determining resources needed to develop and maintain immunization registries. In January 1999, NVAC approved the report Development of Community- and State-Based Immunization Registries (available at <<http://www.cdc.gov/nip/registry/nvac.htm>>; accessed July 30, 2001). The following report summarizes NVAC's recommendations and describes CDC's National Immunization Program activities in response to NVAC's recommendations.*

## **BACKGROUND**

Vaccinations are a critical public health tool: They save lives, reduce health-care costs, and improve the quality of life for persons of all ages. After safe and effective vaccines were introduced, the United States and the majority of other developed countries have experienced  $\geq 95\%$  reductions in cases of childhood vaccine-preventable diseases, compared with prevaccine-era levels (1). Reported cases are at record low levels; however, vaccine-preventable diseases will return if vaccination coverage levels decrease (2).

## Reaching and Maintaining Increased Vaccination Coverage Levels

Three successful strategies, implemented nationwide during the 1990s, have boosted vaccination coverage to the highest levels ever (3). These strategies include

- reminder or recall systems maintained by health-care providers to notify parents or guardians of preschool children of needed vaccinations;
- the AFIX evaluation system implemented by public health departments to Assess providers' vaccination coverage, provide Feedback regarding results, provide Incentives, and eXchange information to boost coverage and avert missed vaccination opportunities; and
- links between vaccination programs and the U.S. Department of Agriculture's Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) to ensure that a child's immunization status is assessed at every WIC visit.

Maintaining increased vaccination coverage rates is a continuing challenge. In the United States, an average of 11,000 infants are born daily, and each child needs protection against vaccine-preventable diseases. Multiple factors threaten continuing success, as follows:

- New vaccines continue to be added to the already complex vaccination schedule. Approximately 16–20 vaccine doses are recommended by age 18 months (4). In addition, new vaccines and new combinations of vaccines will probably become available (5).
- In our increasingly mobile society, families relocate and change medical providers or health insurance coverage with increasing frequency. This mobility leaves medical and vaccination records scattered among different caregivers, clinics, and offices, and results in incomplete records, unnecessary vaccinations, or missed opportunities for vaccination administration (6–10).
- A limited number of providers use reminder or recall systems that notify parents or guardians when their children need vaccinations (11,12).
- Both parents and providers overestimate vaccination coverage (13–15).
- Because the percentage of the population who receive vaccinations from private providers has increased, the public health infrastructure designed to administer vaccinations has declined (16).
- Vaccine-preventable diseases are at record low levels; hence, disease occurrence no longer reminds patients and providers of the need for vaccinations.

Together, these factors cause difficulty for parents and providers in determining a child's immunization status and ensuring that each child gets needed vaccinations. Families, providers, and schools need definitive documentation of childhood vaccinations, and communities and public health programs require accurate coverage estimates. Community- and state-based immunization registries are a critical tool for increasing and sustaining vaccination coverage; therefore, one Healthy People 2010 objective is to increase to 95% the proportion of children aged <6 years who participate in fully operational, population-based immunization registries (17).

## INTRODUCTION

### What Are Immunization Registries?\*

Immunization registries are confidential, population-based, computerized systems for maintaining information regarding children's vaccinations. A population-based registry includes the majority of children in a geographic area, regardless of health-care source. Children's names can be entered into the registry at birth (e.g., through a link with electronic birth records) or at first contact with the health-care system. If a registry includes all children in a geographic area and all providers report vaccination and immunization data, the registry can provide a single data source for all community vaccination partners. Registries enable implementing vaccination strategies, and they decrease resources needed to measure, achieve, and maintain increased levels of vaccination coverage. Immunization registries offer potential benefits to parents, communities, health-care systems, and the public health system (Box 1).

#### BOX 1. Potential benefits of immunization registries

Parents benefit because registries can

- consolidate into one database all vaccinations a child has received;
- help ensure that a child's vaccinations are current with recommended schedules;
- provide reminders when a vaccination is due;
- provide recalls when a vaccination has been missed;
- help ensure timely vaccinations for children whose families move or switch health-care providers;
- prevent unnecessary (duplicative) vaccinations; and
- provide an accurate, official copy of a child's immunization history for personal, day care, school, or camp entry requirements.

\*In addition to tracking the vaccinations children receive, fully operational immunization registries can improve vaccine delivery by a) avoiding duplicate vaccinations, b) limiting the cost of missed appointments through the use of reminder or recall notices, c) reducing vaccine waste, and d) reducing staff time required to find or produce immunization records or certificates. In certain regions, immunization registries provide programs a rapid and reliable mechanism for evaluating their vaccination coverage and patterns of use for specific vaccines. Also, registries can assist in vaccine safety efforts and can be used for vaccine ordering and inventory control. Therefore, the term *immunization registry* is used throughout this report, rather than *vaccination registry*, to better reflect their capabilities.

**BOX 1. (Continued) Potential benefits of immunization registries**

Communities benefit because registries can

- help control vaccine-preventable diseases;
- help identify populations at high risk and persons who are undervaccinated;
- help prevent disease outbreaks;
- when authorized, be linked with other health databases (e.g., screenings for newborn metabolic diseases or lead) or other state registries;
- provide information regarding community and state vaccination coverage rates; and
- streamline vaccination program management.

Health-care providers, health plans, and health-care purchasers benefit because registries can

- consolidate vaccinations from all providers into one record;
- provide an accurate immunization history for any child, whether a new or continuing patient;
- provide data regarding vaccinations due or overdue;
- provide current vaccine recommendations;
- produce reminders and recalls for vaccinations due or overdue;
- complete required school, camp, and day care immunization records;
- reduce physicians' paperwork;
- facilitate introduction of new vaccinations or changes in the vaccination schedule;
- help manage vaccine inventories;
- generate vaccination coverage reports for managed care and other organizations; and
- reinforce the concept of the medical home (i.e., a primary care practice in which the patient has a relationship with one provider who is familiar with all aspects of that patient's medical care and accountable for coordinated, comprehensive care).

Public health officials benefit because registries can

- provide data for targeting interventions and evaluating programs;
- promote reminder and recall of children who need vaccinations;
- ensure that providers follow the most current recommendations for vaccination practice;
- facilitate introduction of new vaccinations or changes in the vaccination schedule;
- integrate vaccination services with other public health functions; and
- help monitor adverse events.

## Efforts to Build U.S. Immunization Registries

In 1993, CDC began awarding planning grants to develop immunization registries in every state. These systems were intended to collect immunization histories on all children residing in the states. In 1994, NVAC's Subcommittee on Vaccination Registries recommended expanded funding and new federal policies for a system of immunization registries to support national goals. Since 1994, CDC has allocated \$181.3 million for the development and implementation of a nationwide network of community- and state-based immunization registries to its 64 immunization grantees (i.e., 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) that receive federal vaccination funds under section 317 of the Public Health Service Act. Private foundations have also contributed funds for immunization registry development, including approximately \$20 million from the Robert Wood Johnson Foundation.

As of December 2000, a total of 39 (61%) of 64 grantees reported operating population-based immunization registries that targeted their entire catchment areas, and an additional 25 (39%) grantees reported developing population-based immunization registries. In 2000, an estimated 24% of children aged  $\leq 5$  years participated in a population-based immunization registry (CDC, unpublished data, 2001).

## NVAC's Initiative on Immunization Registries

In 1998, NVAC launched the Initiative on Immunization Registries to facilitate community- and state-based immunization registry development in the United States. Through public hearings and parent focus groups, NVAC's members and consultants to the Initiative on Immunization Registries identified four challenges that needed to be addressed to increase registry participation and to provide a framework for their recommendations:

- **Protecting each person's privacy and the confidentiality of registry information.** Public health practitioners must consider each person's autonomy, including privacy, confidentiality, and consent. In developing immunization registries, these concerns become complex challenges. One difficult challenge is balancing the need to gather and share immunization information with the need to protect patients' and families' privacy.
- **Ensuring participation of vaccination providers and recipients.** Registries will be most useful if they have active participation from the majority of public and private vaccination providers. Private provider adoption of systems has been a slow process. Because of the shift in vaccination delivery from the public to the private sector, registry projects need to enhance efforts to recruit private providers. Educating recipients regarding the benefits of immunization registries should encourage their participation. Recipient demand for registries should encourage providers to participate.

- **Overcoming technical and operational challenges.** State and local communities have developed multiple systems that cover different jurisdictions, operate in different hardware and software environments, use different software packages, and vary in functionality. These systems should collect complete immunization information regarding children and securely exchange this information with other immunization registries, when appropriate.
- **Determining resources needed to develop and maintain immunization registries.** Information is needed regarding the initial and long-term costs of developing and implementing registries, their cost-effectiveness, and the consequences and costs of not developing registries. Sustainable funding sources, which are based on that information, need to be identified.

In January 1999, NVAC approved the report resulting from the Initiative on Immunization Registries (18). The following sections summarize NVAC's recommendations and CDC's National Immunization Program activities in response to those recommendations.

## RECOMMENDATIONS AND CDC ACTIVITIES

### Protecting Privacy and Confidentiality

#### *NVAC Recommendations*

- Protecting privacy and maintaining confidentiality are essential to developing immunization registries. Moreover, registry developers must consider privacy and confidentiality concerns in light of their communities' values and special needs.
- The privacy and confidentiality concerns of immigrant communities must be considered.
- Federal legislation is needed to establish minimum privacy and confidentiality standards. Moreover, the federal government should work with key stakeholders, including NVAC, CDC, and the National Committee on Vital and Health Statistics, to develop and disseminate model policies and legislation for registries that enable exchanging information while protecting privacy and confidentiality.
- At a minimum, registry developers and operators should
  - ensure that patients and parents are notified of the existence of the registry and of the information contained in the registry;
  - inform patients and parents of the registry's purpose and potential uses;
  - permit patients and parents to review and amend registry information; and
  - accept responsibility for registry information protection and reliability.

- Parents must be given the option to decide whether their children will participate in a registry. In certain communities, parents are informed of the registry, its purposes, and potential uses during routine educational sessions offered at the birth hospital. During such education sessions, or at any later time, parents should be allowed to opt out of a registry. In communities where explicit consent is preferred, the opting in or informed consent approach should be offered. Parents should never be penalized for not participating in a registry.
- Registry developers should limit access to registry information and maintain audit trails to monitor records access. Each person should have access to his or her own records and to audit trails.
- Strong penalties for the unauthorized use of registry data should be in place and consistently enforced.
- Using registry data in a punitive manner against parents or patients (e.g., denial of health insurance coverage; U.S. Department of Justice, Immigration and Naturalization Service tracking of immigrants; or other law enforcement purposes) must be prohibited.
- If registries are to be integrated with more substantial health information systems, protecting privacy and confidentiality must be ensured.
- The government should support an ongoing independent assessment of the benefits, risks, and costs of registry development and implementation with regard to privacy and confidentiality concerns.

### ***CDC Activities***

In response to these recommendations, a CDC-led Privacy and Confidentiality Implementation Team with representatives from the National Vaccine Program Office (NVPO), state health departments, and the All Kids Count (AKC) program, developed minimum specifications for protecting the privacy of registry participants and the confidentiality of registry data. Their report was reviewed by privacy consultants and other stakeholders and approved by NVAC in February 2000 (19).

The specifications are based on the following principles:

- An immunization registry is a tool for monitoring and improving population-based health and personal health. The information contained in the registry provides vaccination decision support. Registries do not replace parental or provider responsibility.
- Protecting privacy and maintaining confidentiality are essential to successfully developing immunization registries.
- Confidentiality policies are designed to balance clinical and public health information needs with personal privacy rights.
- Confidentiality policies are based on fair information practice, including each person's right to know what information regarding him or her is in a record and how it might be used and to request amendments or corrections to that record.

- Deciding whether to participate in a registry and deciding whether to vaccinate are separate decisions.
- All immunization registries, including registries that are part of integrated information systems, must ensure privacy protection.

Minimum specifications include, but are not limited to, the following:

- **Confidentiality policies.** All immunization registries must have a written confidentiality policy that is consistent with applicable laws and applies to everyone who has registry access.
- **Agreements to protect confidentiality.** All authorized registry users must sign an agreement indicating that they understand the terms of the confidentiality policy, including the penalties for violations, and that they agree to comply with that policy. An employer can sign the agreement indicating that he or she is responsible for the actions of his or her staff.
- **Notification.** Patients or their parents or legal guardians must be notified of the registry's existence, what information will be contained in it, how the information will be used, with whom the information will be shared, the procedures for review and correction of information, and how to exercise choice regarding participation.
- **Choice.** Parents must be able to choose whether to participate in the registry and to change their decision at any time. Parents and children must not be penalized for not participating. Personally identifiable information of those who have chosen not to participate must be protected.
- **Use of immunization registry information.** Each registry must identify the purposes for which it collects immunization information and inform all authorized users and parents or guardians. Information in the registry must only be used for the purposes for which it was collected.
- **Access to and disclosure of immunization registry information.** Policies must define who will have access to registry information and specify to which information those persons will have access. Policies must ensure that only authorized users can provide information to or receive information from the registry and that procedures are in place for handling requests from persons and organizations that are not authorized users.
- **Penalties for unauthorized disclosures.** Policies must define what constitutes a breach of confidentiality and delineate the legal and administrative policies for the inappropriate use or disclosure of information. Penalties must be enforced.
- **Data retention and disposal.** Policies must address the amount of time the information will be held in the registry and whether it will be deleted or archived at the end of that period. Registries must have a written policy that provides for the storage and disposal of all forms of confidential records.

Reports from states indicate that confidentiality policies are being developed or modified to be consistent with these specifications. CDC continues to provide technical assistance to states regarding these specifications. Additionally, CDC will assess how well the minimum specifications apply to more substantial, integrated information systems and

to data sharing between managed care organizations and registries. CDC and its partners will also explore other privacy concerns, including whether persons reaching age 18 years should be notified that they are in the registry or that their information is being archived.

As registries mature, interstate exchange of immunization information will become more critical. Presently, inconsistent state laws control interstate information sharing. States with stringent legal protections might not allow disclosure to states with less protective laws. Therefore, CDC is facilitating guidelines development for the interstate exchange of information.

## **Ensuring Participation of Vaccination Providers and Recipients**

### ***NVAC Recommendations***

- Providers and interested community groups should be involved throughout registry development and implementation, beginning with the initial planning stages.
- Registries should be simple to use and designed to minimize the administrative burden on vaccination providers. When possible, registries should capitalize on data that providers already collect for billing or other purposes, thereby avoiding duplicate data entry. This can be done by using billing or encounter information systems, although modifications might be necessary to ensure data completeness and quality. Initial and subsequent training should be provided to assist with the technical and administrative challenges associated with seamlessly integrating registry functions into office environments.
- Registries should include reminder or recall functions to improve adherence to recommended vaccination schedules.
- Data in immunization registries should be used to improve vaccination services and coverage; these data should not be used to punish providers whose vaccination coverage is below average.

### ***CDC Activities***

In 1997, to increase registry participation, CDC funded research projects to a) identify strategies to encourage provider participation; b) improve registry data quality by developing generalizable algorithms that ensure only one record per child in a database; and c) assess the feasibility of avoiding duplicate data entry in provider offices by enabling preexisting billing or patient management systems to report vaccinations directly to an immunization registry.

Among the lessons learned from these projects is that provider participation depends, in part, on high quality registry data. Registries must be able to detect whether incoming information is already in the registry or is new. The majority of registries have developed processes for detecting when a registry contains multiple records for one child. Although no national criteria exist for evaluating the effectiveness of registry duplication-reduction algorithms, efforts are on-going to develop suitable evaluation criteria for these algorithms.

CDC is also developing a computerized tool that can examine registry data accuracy and completeness by comparing registry records with vaccination provider records. Furthermore, CDC is evaluating the feasibility of comparing coverage estimates generated from the National Immunization Survey (NIS), which is a nationwide, random-digit-dial survey of children's vaccination coverage in the United States, with estimates based on registry databases. Concordance rates between registry estimates and established standard estimates should reflect the completeness and accuracy of immunization histories recorded in a registry's database. Increased concordance rates should persuade providers and parents that registry data are of high quality.

CDC has also identified registries that collect timely and complete immunization information for a substantial proportion of their target population or a subgroup of their population. Vaccination coverage estimates from these sentinel sites are reported quarterly to CDC and compared with NIS estimates. These sites have been used to monitor new vaccination recommendation implementation and to demonstrate registry data usefulness in focusing public health interventions.

Even when immunization records are of high quality, making appropriate vaccination decisions is difficult because of the complexity of vaccination schedules. In 1995, CDC released its *Programmer's Guide to the Automated Immunization Evaluation Process*, which offered assistance in developing automated decision support algorithms that assess a child's immunization history and determine which vaccinations are needed (20). Subsequently, algorithms were created and incorporated into registries. To evaluate those algorithms, test cases were developed, and a public domain algorithm program that can function on multiple computer platforms is available.\*

CDC is establishing the Provider Participation Team and Work Group to identify concerns and implement solutions to ensure participation of vaccination providers and recipients in immunization registries. Initially, a national survey of pediatricians will be conducted to understand what they think about immunization registries and what would ensure their participation. Then, state vaccination projects will be surveyed to identify current activities to recruit providers and determine best practices.

## Ensuring Registry Functionality

### *NVAC Recommendations*

- CDC, in cooperation with state and local health agencies, provider groups, software and hardware vendors, and national standard-setting organizations, should lead the development, implementation, and maintenance of standards pertaining to immunization registries, including
  - defining essential registry system functions and attributes;
  - defining core data elements;
  - certifying clinical decision-support functions;
  - certifying the registry's ability to consolidate multiple records of the same person;

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\*The algorithm program is available upon request by calling (404) 639-8739 or by electronic mail at <CASAINFO@cdc.gov>.

- enabling intra- and interregistry record exchange with standard messages;
  - adopting system security standards to address technical and administrative problems and to ensure that access is limited to authorized persons; and
  - certifying registry functions.
- The initial target group for inclusion in immunization registries should be children aged birth–<6 years, although registries might need to continue beyond school entry or include other age groups (e.g., adolescents or older adults).

### ***CDC Activities***

In 1994, before these recommendations were made, CDC distributed the first comprehensive description of the general structure and function of an electronic immunization registry. At approximately the same time, CDC, in consultation with immunization grantees and NVAC, also developed essential data elements to identify a person and describe a vaccination event for record exchange. Core data elements include a) patient name (first, middle, and last); b) patient birth date; c) patient sex; d) patient birth state or country; e) mother's name (first, middle, last, and maiden); f) vaccine type; g) vaccine manufacturer; h) vaccination or immunization date; and i) vaccine lot number.

In 1997, because registries were being developed with different capabilities and designs, CDC, in collaboration with immunization program managers, identified the following 12 essential functions for immunization registries to be fully operational:

- electronically store data for all NVAC-approved core data elements;
- establish a registry record within 6 weeks of birth for each child in the geographic catchment area;
- enable access to and retrieval of immunization information in the registry at each health-care encounter;
- receive and process immunization information within 1 month of vaccine administration;
- protect the confidentiality of medical information;
- ensure the security of medical information;
- exchange immunization records by using the Health Level Seven Organization (HL7)\* standard (21,22);
- automatically determine which routine childhood vaccinations are needed, in compliance with recommendations of the Advisory Committee on Immunization Practices, each time a patient visits the health-care facility for a scheduled vaccination;
- automatically identify persons due or late for vaccinations to enable production of reminder or recall notifications;

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\*Health Level Seven (Ann Arbor, Michigan) is an American National Standards Institute-accredited organization that develops specifications or protocols for health-care data management. Additional information is available at <<http://www.hl7.org>> (accessed July 30, 2001).

- automatically produce vaccination coverage reports by provider, age group, and geographic area;
- produce official immunization records; and
- promote accuracy and completeness of registry data.

In 1999, at the recommendation of NVAC, a technical working group (TWG), which included external registry stakeholders and information technology specialists, was formed. The purpose of the group was to a) reach agreement on standard vocabularies and protocols for data transfer; b) serve as consultants to CDC and recommend registry functional standards; c) assist in determining a registry accreditation or certification method and provide ongoing quality assurance monitoring; and d) indicate ways to facilitate the integration of registry functions into existing information systems. Initial TWG accomplishments were their review and agreement with the proposed functional standards, their development of detailed definitions for these standards, and their identification of a method to certify registries on the basis of these standards.

Progress has also been made in enabling registries to exchange data by using standard coding and transmission rules defined by the HL7 standard (21,22). In 1995, CDC began developing the standard HL7 immunization messages and an implementation guide for immunization record transactions. These messages became a part of the final, balloted HL7 standard in 1997. In 2000, CDC received funding from NVPO to develop a computer application that performs HL7 message functions. Plans include placing this application in the public domain so that each registry developer does not have to develop an application independently.

The technical focus of CDC's registry activities is related to identifying methods to ensure reaching the 2010 health objective. CDC is reviewing measurable criteria that have been proposed for each of the 12 functional standards. Standardized site visit protocols addressing these elements were developed to monitor registry progress in achieving the 2010 health objective relating to registries.

## **Ensuring Sustainable Registry Funding**

### ***NVAC Recommendations***

- CDC should further study registry start-up and maintenance costs and compare these costs with those of alternative systems. Prospects for state and local health agencies securing funds to support their immunization registries should also be evaluated.
- NVPO should coordinate discussions regarding recommendations for long-term registry funding mechanisms.
- A short-term (e.g., 3–5 year) federal appropriation should be sought to support further registry development and initial implementation, with cost and benefit analyses integral to these efforts. This funding would provide time to establish a mechanism for long-term funding.

### ***CDC Activities***

Limited information is available regarding immunization registry costs. An AKC study of 16 immunization registry projects in 1997 estimated that the cost of maintaining immunization registries was approximately \$3.91/child/year, or approximately \$94 million/year nationally to enroll all children aged <6 years and keep them in the registry to age 6 years (23). Similarly, a 1998 CDC study of three registries estimated an average annual cost of \$3.38–\$6.15/child/year, or national costs of \$81.1–\$147.6 million/year. Additional 1999 CDC-collected data from 24 registries estimated an annual cost of \$5.18/child, and an annual national cost of \$124.3 million. This study also determined that only 40% of registry costs were funded by federal sources.

Registries offer potential cost savings. Estimated annual fiscal savings of >\$270 million associated with registries include costs of manually pulling medical records in provider offices for school or day care entry (\$58.0 million); costs of manually pulling medical records in provider offices for changes in primary providers (\$16.2 million); costs of duplicative vaccination (\$26.5 million); costs of pulling records to fulfill managed care reporting requirements (\$2 million); and school system review of immunization records (\$168.0 million) (24–26). Registries might also reduce or offset costs by reducing vaccine-preventable disease morbidity and mortality through improved coverage, providing a means for assessing coverage at the local level, and decreasing the incidence of vaccine adverse events through the identification of children who have vaccine contraindications.

Involvement of all stakeholders in considering funding sources for registries will be critical (Box 2). In 2000, the Centers for Medicare and Medicaid Services (formerly the Health Care Financing Administration) agreed to fund approximately 90% of registry development costs for Medicaid recipients. Although certain states have taken this funding opportunity, other sources need to be identified for a long-term funding solution.

## **OTHER REGISTRY-RELATED CONCERNS**

Despite potential benefits of registries to vaccination coverage, program operations, cost-savings, and parental support, immunization registries have critics and opponents. In 1994, a congressional initiative to establish population-based immunization registries throughout the country was proposed. Opponents successfully argued against establishing a national immunization information database. Consequently, efforts to establish state- and community-based immunization registries were begun and have since resulted in the development of state and local registries with different capabilities, legal authority, and success.

Concerns regarding immunization registries and their recommended uses remain, including

- ensuring registry participation by all or approximately all vaccination providers;
- changing vaccination provider practices to rely on registry information for coverage and programmatic data for improving vaccination services among a population;
- developing and applying a standard evaluation protocol to document that each registry meets operational standards;

**BOX 2. Potential funding options for immunization registries**

Potential sources	Pros	Cons
<b>Federal</b>		
Supplemental Section 317d grant program	<ul style="list-style-type: none"> <li>• Grantee system already established.</li> </ul>	<ul style="list-style-type: none"> <li>• Requires substantial federal commitment and additional federal discretionary funding.</li> </ul>
Vaccine excise tax	<ul style="list-style-type: none"> <li>• Excise tax already in place.</li> <li>• Reliable and sufficient funding source.</li> <li>• Vaccine safety promotion.</li> </ul>	<ul style="list-style-type: none"> <li>• Not legislative intent.</li> <li>• Opposed by vaccine manufacturers.</li> </ul>
Centers for Medicare and Medicaid Services (formerly the Health Care Financing Administration) matching funds	<ul style="list-style-type: none"> <li>• Procedures in place.</li> <li>• Reliable funding source.</li> </ul>	<ul style="list-style-type: none"> <li>• State matching funds required.</li> <li>• Amount based on Medicaid population and location of registry.</li> </ul>
<b>Nonfederal</b>		
State or local communities	<ul style="list-style-type: none"> <li>• Ensures buy-in.</li> </ul>	<ul style="list-style-type: none"> <li>• Varies as time progresses and among states.</li> </ul>
Health plans or insurance companies	<ul style="list-style-type: none"> <li>• Facilitates reporting and use by private sector.</li> <li>• Reliable funding source.</li> <li>• Public and private cooperation with coverage assessments and managed care measures.</li> </ul>	<ul style="list-style-type: none"> <li>• Participation viewed as cost-prohibitive.</li> </ul>
Foundations	<ul style="list-style-type: none"> <li>• Established funding history.</li> </ul>	<ul style="list-style-type: none"> <li>• Unreliable and probably insufficient funding source.</li> </ul>
Fee-for-service	<ul style="list-style-type: none"> <li>• Distributes vaccination costs by use.</li> </ul>	<ul style="list-style-type: none"> <li>• Needs system for collecting fees.</li> <li>• Providers or parents might choose not to participate.</li> </ul>

- facilitating data flow from provider settings and local population-based registries into and between state-based systems via the implementation of nationally recognized data standards;
- the implications of including data regarding a child's vaccine-associated adverse events or contraindications to specific vaccines in a registry's database; and
- appropriateness of integrating immunization data with other childhood preventive health service information systems (e.g., blood lead screening or newborn screening for metabolic abnormalities).

## CONCLUSION

Population-based immunization registries, which collect information regarding children within a specified geographic area, can be an effective means for ensuring that children remain current with recommended vaccination schedules. Additionally, registries allow programs to rapidly and completely assess vaccination coverage in defined areas or among specific groups of children. Despite their advantages, registries have developed slowly, and only a limited number of registries are close to meeting the Healthy People 2010 national objective of increasing to 95% the proportion of children aged <6 years who participate in fully operational population-based immunization registries.

In 1998, NVAC held public hearings that produced four recommendations for immunization registries: a) ensure each person's privacy and the confidentiality of the information collected; b) ensure participation by all vaccination providers and recipients; c) ensure functionality; and d) ensure sustainable funding. CDC has worked on each of these recommendations with its partners. Minimum specifications to protect privacy and confidentiality have been developed and approved by NVAC. A set of 12 minimum operational standards have been established for population-based immunization registries, and standardized evaluation criteria to monitor registry progress are being developed. The Centers for Medicare and Medicaid Services plans to share the financial burden of state registries. Although these actions do not guarantee that state and local vaccination programs can develop and implement fully operational registries, this national approach to standardization and shared allocation of substantial resources will facilitate this process.

Ensuring participation by all providers and recipients has been more difficult and is not yet close to achievement. Survey data in 2000 estimate that, nationwide, only 24% of children aged <6 years are participating in an immunization registry (CDC, unpublished data, 2001). Although certain national organizations have formally supported the concept of immunization registries, practitioners still find routine participation difficult to implement. Overcoming barriers to full participation remains the greatest challenge to population-based immunization registries.

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