

THE CHALLENGE AND POTENTIAL OF CHILDHOOD IMMUNIZATION REGISTRIES

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■ **Abstract** Recent efforts to attain near-complete coverage of child populations by recommended vaccines have included initiatives by federal and state agencies, as well as private foundations, to develop and implement statewide or community-based childhood immunization registries. Plans for a single, national registry have been set aside in favor of a national network of local and state registries linked through the use of common definitions and unique child identifiers. However, both operational/technical and financing difficulties have slowed their development. The experience to date in selected areas has provided useful lessons for further development of a registry system and has underscored the potential of such systems to assure the success of childhood immunization initiatives.

INTRODUCTION

Immunizations have been shown to be among the most efficacious and cost-effective strategies for the prevention of disease in human populations. Assuring the availability and coverage by this most effective preventive intervention has proven, however, to be a never-ending problem for both developed and developing nations. The 1989–1991 measles epidemic brought focus to the problem of under-immunization. During 1990, the peak of the epidemic, more than three quarters of the measles cases occurred in persons who had not received measles vaccine or who, in many fewer cases, had been vaccinated too early (7). A landmark report, subsequently known as the Measles White Paper, identified the failure of the immunization delivery system as a major contributor to the outbreak (20). Myriad public and private programs were launched following the measles outbreak to improve the rate of immunization coverage in the United States. The development of childhood immunization registries was one intervention targeted to expand immunization coverage by improving the immunization delivery system.

Why Registries?

Childhood immunizations represent a basic public health strategy for disease prevention, responsibility for which is assumed by child health care professionals and health care organizations in the private sector, which provide the bulk of immunizations, and public providers, the traditional safety net in providing care for many children. Hence, an effective public health program to protect young children from vaccine-preventable diseases must involve public-private sector collaboration.

Immunization coverage rates, while considered a fundamental component of population-based approaches to disease prevention, require constant vigilance and programmatic infrastructure if they are to assure high levels of protection from vaccine-preventable diseases. Moreover, strategies are needed that can offset the negative influence of health care system fragmentation. Such is the role of immunization registries at the state and community levels.

Three factors are particularly relevant to the need for childhood immunization registries. Since 1985 there have been 23 changes to the recommended immunization schedule (17). Changes include the introduction of new vaccines, new age groups for which existing vaccines are now recommended, and replacement of vaccine with new formulations. Parents and providers may mistakenly believe that a child's immunizations are up-to-date. Scattered immunization records for children who see multiple providers make assessment of need for immunization at well and acute visits difficult and increase the risk for missing opportunities to immunize. These barriers led to the national effort to develop computerized record systems of immunization information for preschool children in defined (usually geographic or health system) populations. These efforts to use conventional technologies of information infrastructure to perform essential public health assessment and assurance functions have had variable levels of success, depending on the availability of such technology, the financial and personnel resources to support information system development, and the willingness of health care providers to use these systems for monitoring the immunization status of their child populations.

What is an Immunization Registry?

By definition, immunization registries are confidential, population-based, computerized systems for maintaining information regarding children's vaccinations. There have been two systematic efforts to define and describe the essential components of an immunization registry system for children. The first of these was offered in 1996 by the *All Kids Count* Childhood Immunization Registry Initiative sponsored by the Robert Wood Johnson Foundation (RWJF) (26). The second was specified by the National Immunization Program (NIP) of the U.S. Centers for Disease Control and Prevention (CDC) in 1997 through a review process involving immunization program managers. The 13 original functions identified in 1997 have since been modified to 12, and the most recent iteration of these

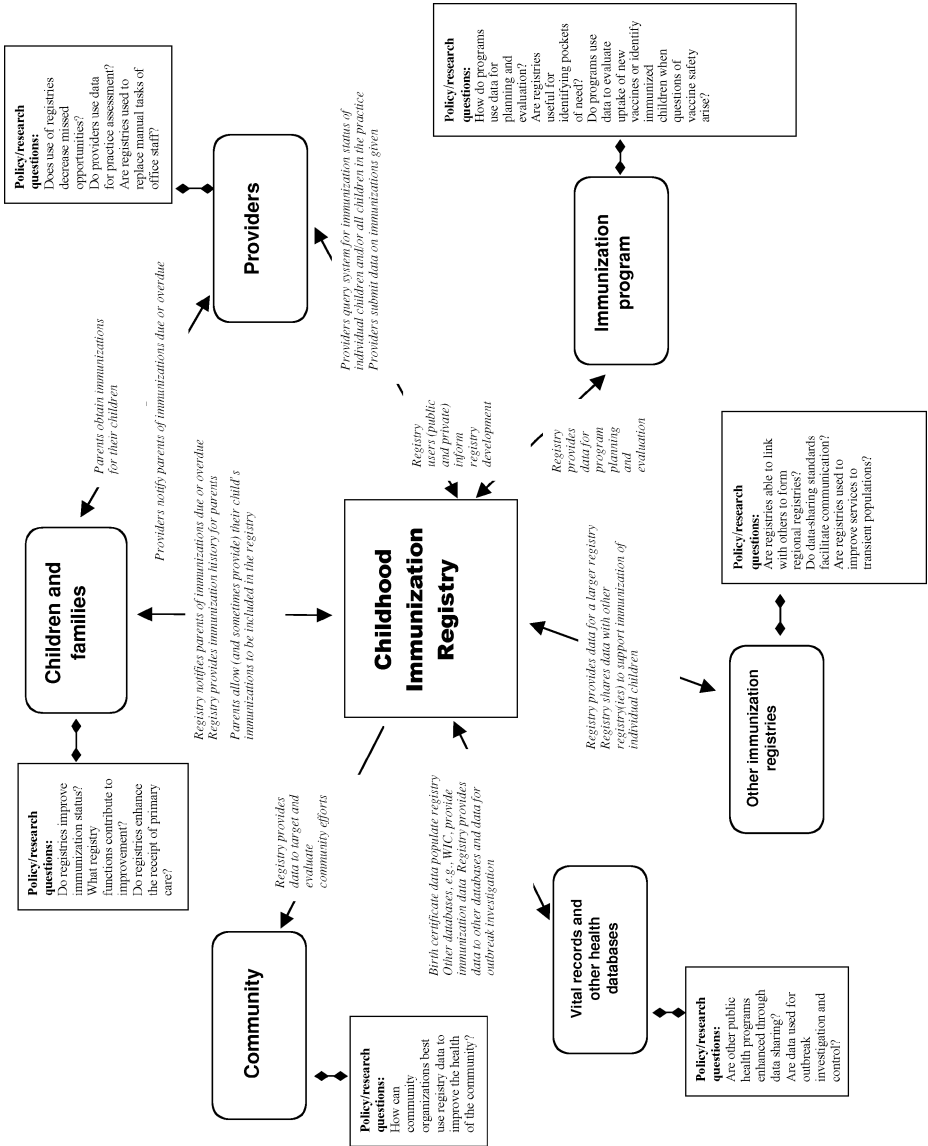
guidelines, now known as Immunization Registry Minimal Functional Standards, was approved by the NIP in 2001 (8). Basically, an immunization registry system has both structural/enabling components and specific capacities to perform certain functions relative to immunization coverage initiatives in defined populations.

The 12 minimal functional standards for an immunization registry include:

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. Retrieve and process immunization information within 1 month of vaccine administration.
5. Protect the confidentiality of health care information.
6. Ensure the security of health care information.
7. Exchange immunization records using Health Level Seven (HL-7) standards.
8. Automatically determine the routine childhood immunization(s) needed, in compliance with current ACIP recommendations, when an individual presents for a scheduled immunization.
9. Automatically identify individuals 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.

An immunization registry has several basic functions, each performed in relation to and for the benefit of different “users” of registry-based immunization data. Figure 1 attempts to identify these functions and potential users of each, as well as a number of policy questions of importance to the future development of a national network of immunization registries in the United States. While one most immediately thinks of immunization providers and parents as the two primary users of registry-based information, it is important to recognize the potential uses of such data by community health planners, vital records and public health information systems, and by other registries serving other geographic areas or health care organizations. Immunization registries therefore have a wide spectrum of implications for child health services and the achievement of child health goals in defined populations. Though there are limited examples of fully implemented registry systems, the potential uses of these systems were they to become a nationwide reality is increasingly well recognized.

Another facet of immunization registries illustrated by this diagram is the important interactive nature of registry construction and use. Not only do parents



and providers contribute data to these registries, they extract personalized reports and summaries of immunization coverage from the registry data in the form of reminders, recalls, or evaluations of organizational efforts in the protection of child populations from vaccine-preventable diseases.

IMMUNIZATION REGISTRY DEVELOPMENT IN THE UNITED STATES

Delaware created the first population-based registry in 1974 (23). Registry development continued in the 1980s but was primarily centered in large managed care organizations rather than being population based (33).

The development of population-based immunization registries received a major boost when the RWJF initiated its *All Kids Count* program in 1991. The Foundation awarded grants to 23 applicants to support their planning of registries. One year later, 14 of the original grantees were awarded implementation funds ranging from one to four years. Other philanthropies including the Annie E. Casey Foundation, Skillman Foundation, Flinn Foundation, Lucile and David Packard Foundation, and California Wellness Foundation joined RWJF with financial support for registry development, and the entities funded by these various philanthropies formed a loose coalition of immunization registries. Registry development by these pioneer projects proceeded more slowly than expected, however, and the RWJF, through a new competitive process, awarded grants to 16 promising registries, the *All Kids Count II* projects, to enable them to complete their development.

Federal support for immunization registries also became available when President Clinton included immunization registries in his Childhood Immunization Initiative in 1993. Funds from Section 317 immunization grants can be used for registry development and grantees are, in fact, required to include registry development as part of their immunization program activities.

It is not easy to obtain a comprehensive and detailed picture of the current status of immunization registry development in the United States. The development of state-based registries has been promoted by the National Immunization Program of the Centers for Disease Control and Prevention. Other registries, some state-based and some regional, county, or urban in scope, have been supported by funds from private philanthropies. Other registries are operating as part of private health care delivery systems. There is little published information regarding the nationwide status of registry development and implementation in the United States. Frequently, what can be determined must be gleaned from the proceedings of conferences and informal briefings and newsletters.

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Figure 1 Childhood immunization registry connections to children, providers, and programs.

The CDC collects information on registry development from Section 317 immunization program grantees in an Immunization Registry Annual Report (IRAR). Their most recent survey was completed by grantees in all 50 States and the District of Columbia (11). Of those grantees, 32 States reported having an operational population-based registry involving their entire geographic catchment area. The remaining 19 states reported having a registry in the pilot phase (limited to specific counties or regions) or in the development phase. Grantees reported progress in the major development functions, such as populating the registry with children and their immunizations and enlisting the participation of immunization providers. Overall, 49% of the children under six years of age in the catchment areas of the 32 statewide registries have at least two immunizations recorded. These data reflect the participation of an average of 56% of all public immunization providers and 41% of all private providers.

Other population-based immunization registries that cover smaller jurisdictions have been successfully developed but are not detailed in any statistical report on the nationwide status of registry development. The largest group of population-based registries participating in systematic assessment of their development was the group of registries funded as part of the *All Kids Count* childhood immunization registry initiative described above. As noted above, 16 “almost complete” registries were funded in 1998 to accomplish the tasks necessary to become fully operational. These registries (which include eight state-based registries that also are included in the CDC’s IPAR) were monitored on a regular basis by the *All Kids Count* National Program Office at the Task Force for Child Survival in Atlanta, Georgia. Many of these projects, which had been under development for some time and had benefited from philanthropic funding in addition to their Section 317 grants, had made significant progress by the end of their Foundation funding in June 2000 (1). Overall, 97% of children younger than age two in target areas served by *All Kids Count* registries had records established in the registries, with most registries reporting at least 90% of children enrolled. By a more stringent measure of enrollment, i.e., children in the registry with at least one immunization other than hepatitis B administered at birth in hospitals, almost two thirds (64%) of the children in the 16 *All Kids Count II* target areas were included in the registries.

To fully implement a registry and thereby maximize its utility, participation by all immunization providers is required. The *All Kids Count II* projects made significant progress in the public sector by the end of their funding with all registries reporting near 100% participation by public providers. More disappointing was an overall rate of 59% participation by private providers. Although these projects had made substantial progress in building their registry foundations, these steps were but the first toward realization of the full potential of childhood immunization registries. Even these *All Kids Count* projects funded in Phase II because of their potential to become fully operational by the year 2000 were unable to claim full success with regard to the critical measure of private provider participation.

Another measure of registry development is how well registries meet the 12 functional standards outlined by the CDC and described above. Data from the

2000 IRAR indicate that 14 of the Section 317 grantees had met more than 11 of the then 13 standards (11). The Technical Working Group of the American Immunization Registry Association (AIRA) has developed certification standards for immunization registries requiring that registries meet all 12 functional criteria to become certified (4). The National Immunization Program will pilot test the standards with a small group of functioning registries. Once pilot tested and revised as necessary, the certification standards will become yet another way by which the implementation of registries can be measured.

Finally, NIP has established a group of eight sentinel sites (22, 27). These eight sites, which must meet most of the 12 functional standards and contain information for a significant number of children in their respective geographic areas, will provide periodic reports on immunization coverage levels in their area as well as answer other questions of relevance to vaccine administration. The ability of these registries to answer important immunization questions can serve as an impetus for those still in the development phase.

LESSONS LEARNED ABOUT REGISTRY IMPLEMENTATION

Through the synthesis of experience gained from registry development funded by public and private sources, a great deal can be learned about how such information systems may be initiated at either the state or community level, as well as identifying common barriers to registry system progress. We have organized a summary of some of these experiential lessons under headings reflecting the “step-wise” mode with which most registries have tended to evolve. Many of the lessons summarized here are drawn from our several years of conducting the national evaluation of the RWJF’s *All Kids Count* program. Although there is no one best way to initiate or develop an immunization registry, most of the challenges described under each of these several topical headings will confront those who undertake to develop a registry system.

Assessing Need and Garnering Support for a Registry

Among the requirements for *All Kids Count* grantees was the development of an advisory group or coalition to guide registry development. In some areas, such coalitions were already in place, having been instituted in response to the measles outbreak in the late 1980s and to the discovery of inadequate local immunization rates. Development of an advisory group or consortium not only helps identify the need for a registry but also encourages the buy-in of critical participants in the registry. For example, the early and continuing involvement of the Arizona Partnership for Infant Immunization has been frequently cited as critical to the success of the Arizona statewide registry. It also guided the development of this registry, which took a “business” approach to identifying needs of private providers in particular and developing a product to meet those needs.

Technical Aspects of Registry Development

Immunization registries that can offer essential informational services in a timely way to both parents and participating providers are dependent on an integrated, user-friendly, comprehensive, computer-assisted information system. Registry developers face the choice of designing a technical system in-house, contracting with an outside consultant for a custom design, purchasing and implementing an existing system, or acquiring a system that can be modified to suit local needs. Early efforts at registry development were thwarted in some areas by the withdrawal from the market of a software vendor with whom several registries had contracted for their registry system. In other areas, failure of a locally developed system led to expensive redevelopment of a replacement system. Experience has shown that it is better not to reinvent the wheel. Registry development costs are highest in registries where significant human resources are used to develop and sometimes redevelop these information technology systems. Several registries, aware of the financial risk of developing information management systems from scratch, have sought to borrow from the experience of other registries and import existing and tested registry technology. In this way, some of the earliest and most successful registries have become “lighthouse” examples for others. Michigan’s registry software, for example, is free to others who want to use it and was recently acquired by Connecticut. Others are waiting until Michigan’s software is web-enabled to adopt it as their model (T. Hoyle, personal communication). In California, where county-based registries are being merged into regional registries with the goal of a statewide system, state health department staff reviewed six locally developed registry programs and selected the registry software from Contra Costa County for replication in other areas. This registry model has been implemented in five California regions and is now known as the California Automated Immunization Registry (CAIR) (A. Gill, personal communication). CDC has contributed to making acquisition of immunization registry software easier by contracting with four registry software vendors whose product meets minimum functionality requirements. Registry developers can use Section 317 direct assistance immunization funds to purchase software from one of these vendors (22).

Technical and operational challenges have been described as one of four major barriers to registry development (21). Use of standardized systems will assist in the ability to develop a community-based registry by allowing communication between the central registry and providers who contribute and use the immunization data. Standardization will also enhance the ability to link registries in areas where county- and regional-based registries are being developed to form a statewide registry. Finally, standardization will allow sharing of data across states in areas where populations are particularly transient and frequently cross state borders for health care. Guidelines for sharing information using Health Level 7 (HL-7) protocols have been developed and will facilitate data sharing and thus mitigate this major barrier to participation in the registry (22).

Pilot Testing

Given the complexities of design and implementation of registries, pilot testing is valuable on several fronts. Whereas planning is complex regardless of the size of the target child population and provider base, rollout is easier in a smaller geographic area. Fewer providers need to be contacted and recruited and when inevitable changes in the system occur they are more easily implemented with a smaller provider base. In addition, the goodwill created with providers is more easily maintained with a smaller provider base when technical assistance is required or repeated modification and adjustment of the system become necessary.

Rollout of a registry system in a small area does not obviate the need for comprehensive planning that takes into consideration the variety and complexity of the local system for health care delivery. It has been customary in most areas to implement the registry in the public sector first, as most registries are being developed by and based in the county or state public health department. Some areas have existing public health information systems on which to base the immunization registry. It may not be adequate, however, to consider implementation of the registry in the public sector as a pilot test of the system. Implementation of the registry in the private sector will be more or less complex depending on the hardware and software capabilities of private providers and the flexibility of the registry in allowing data exchange from office-based computers, managed care plans, and billing systems.

In a large state, registry implementation may best be accomplished by substate regionalization through which contiguous areas/counties represent the geographic catchment area served by a registry. The aggregation of coverage data across these substate regions enables the creation of a statewide registry database. The Michigan Childhood Immunization Registry (MCIR) was developed in this manner and currently includes the participation of 97% of that state's private providers (T. Hoyle, personal communication). California is also using this approach to unify multiple level registry systems in a large and diverse state.

Provider Enrollment and Participation

Implementation of immunization registries is not simply a matter of "build it and they will come." Although most public and enthusiastic private providers might sign on early by choice or mandate, obtaining the participation of all providers of immunizations to children remains a time-consuming promotional task. Calling upon the expertise of more than two dozen leaders in the field of immunization development, a private provider workgroup of the *All Kids Count* immunization registry projects developed and published guidelines for the recruitment of private providers (24). The workgroup identified six steps within this process.

Before provider recruitment strategies are planned, the workgroup suggests two preliminary steps. First, know the environment within which the registry will be developed and, second, know the "customers" who must be recruited for the

registry to be effective. Once both are specified, that information can be used to develop reasonable objectives for recruitment of providers and tailor strategies to the environment and customer base that have been identified. Next, a recruitment plan must be implemented. Finally, although rarely a terminal process, the plan and its results are evaluated and modified as necessary based on information obtained in the implementation phase. This iterative process is important in program planning and evaluation and can be expanded to the maintenance phase required for provider retention.

Oregon was among the first states to implement a statewide registry and remains on the cutting edge in the use of their registry for support of immunization activity. Among the early strengths of the Oregon ALERT system was the flexibility of allowing providers to report immunizations by attaching barcoded stickers to report sheets that were sent to the central registry for scanning into the database. This flexibility encouraged the participation of private providers regardless of the level of information technology available to them. As computer capability has increased in the health care community, the barcode system has been largely replaced. Similarly, the New York City registry project facilitated the participation of immunization providers by allowing paper (or hard copy) submissions. The cost of these labor-intensive methods must be weighed against the benefits of increased private provider participation.

Maximize Utility of the Data

Immunization registries are valuable at their most fundamental level when they contain sufficient numbers of children with immunization histories to allow health care providers to easily assess the need for an immunization at a child's preventive health care or acute care visit. Consolidation of immunization records for children who receive care at multiple sites can both save time in medical offices and reduce potential error when assessment must be done from scattered written records. These systems can also avoid the problems of both over- and underimmunization.

Immunization registries can be beneficial to multiple public health functions, as is illustrated in Figure 1. Some of the most advanced registries are beginning to use their data in many of the ways described previously in Figure 1. In the following paragraphs, reference is made to some of the links illustrated in Figure 1, which many registries have strengthened through the use of these information systems.

LINKS TO CHILDREN AND FAMILIES As registries become fully populated with "sufficient" immunization data for a "sufficient" number of children, they are increasingly being used to identify children to be recalled because they have missed immunizations. New York City and Oregon have implemented similar systems that identify children who are not up-to-date and notify the provider of record who then has the opportunity to report additional immunizations to the registry before a notice is sent to the family, thus improving the completeness of registry data. Other registry reminder/recall functions range from those for which the central

registry assumes all responsibility for this important function to those where reminder/recall is at the discretion of the individual provider. The San Bernardino County registry used their reminder/recall function to improve MMR (measles, mumps, rubella) coverage for children in their community. The average age of receipt of MMR decreased substantially after implementation of notices to parents (22).

LINKS TO IMMUNIZATION PROGRAMS Oregon has used its well-established immunization registry, Oregon ALERT, to support many aspects of its immunization program (5). For example, registry data are used to analyze trends in the percentage of children who receive specific immunizations or specific doses of immunizations as the recommendations for immunizations have changed and new vaccines are introduced. Among the vaccines they have tracked are uptake of hepatitis B at birth, uptake of PCV7 after introduction, uptake of varicella vaccine, and administration of hepatitis A vaccine among preschool children and adolescents. These uses of the Oregon registry data illustrate the ability of a fully implemented registry to evaluate acceptance of new vaccines or serve as an early warning system as vaccine coverage wanes.

The Connecticut Department of Public Health used the Connecticut Immunization Registry and Tracking System (CIRTS) to assess the benefit of adding registry information to chart review to enhance assessment of immunization coverage of a cohort of 7-month-old inner-city infants (29). From record review alone, the up-to-date immunization rate for these infants was 53%. By adding information obtained from data in the immunization registry, the up-to-date rate increased to 58%. In the group of children for whom record review indicated they were not up-to-date and for whom records were found in the registry, 30% had changed providers since their birth, emphasizing the value of a registry in tracking immunizations in a mobile population.

Registries play a role in promoting and assuring vaccine safety. Recording vaccine lot numbers in their registry enabled Kaiser Permanente to identify and recall children who had received doses of Tripedia™ that were later recalled. Similarly, Arkansas was able to identify and recall children who had received vaccine that had expired (22).

LINKS TO VITAL RECORDS AND OTHER HEALTH DATABASES Data from the June 2000 National Registry Report indicate that more than three quarters (77%) of registries share data with vital records systems. Other health care organizations with which data are shared include Community Health Centers (70%), hospitals (53%), and Indian Health Service (32%). Data are shared with clinic billing systems, both public (53%) and private (47%). WIC linkages are reported by 47% of registries. Other linkages include managed care organizations (40%), Medicaid Management Information System (38%), and schools (34%) (22). Oregon has used their registry data to support activities in disease surveillance (6). To ensure appropriate care for children with perinatal exposure to hepatitis B, the registry was used to identify

the last provider seen by these children to enable follow-up to assure that they had received hepatitis B vaccine and postvaccine serology, if appropriate. In another use of ALERT data, over 90% children in a case-control study to assess the efficacy of pneumococcal conjugate vaccine had immunization records in the registry and could be linked to disease surveillance data.

LINKS TO COMMUNITY The Department of Public Health in Philadelphia used data from its immunization registry to identify children for a randomized, controlled trial of community-based outreach (32). Children in the outreach group were more likely to have received an immunization during the study period than were control children. Children with multiple risk factors for underimmunization determined from their immunization history were also more likely to have been immunized. This study demonstrated the importance of registry data in identifying children at risk for underimmunization so that outreach interventions could be effectively targeted.

LINKS TO PROGRAMS OF PRIMARY MEDICAL CARE FOR CHILDREN In Michigan, data in the Michigan Childhood Immunization Registry (MCIR) were used to examine the effect of closure of an urban primary care clinic (18). The up-to-date immunization rate for 474 children served by the clinic was calculated at the time the clinic closed and then again 12 months later. Prior to closure, 53.2% of the children were up-to-date. One year later, the MCIR indicated that only 14.5% were up-to-date. Because the missing immunizations could have actually been given, but not reported to the registry, the need for continuing provider education for reporting to the MICR was emphasized. The study also demonstrates another use of registry data, i.e., an early warning system for young children in particular who lose their primary care provider and may not get connected to another medical care home.

Cross-Cutting Issues in Registry Development

PROTECTING THE PUBLIC'S PRIVACY Protection of privacy and confidentiality of immunization data has always been an important component of immunization registry planning and implementation. The National Vaccine Advisory Committee's 1999 report on the development of immunization registries included protection of confidentiality as one of four areas of emphasis (21). The Committee made specific recommendations including, first, the need to recognize and acknowledge the essential nature of protecting privacy and confidentiality with specific mention of immigrant communities. Registry data should not be used in any manner that punishes parents. Information and education to parents about their child's inclusion in a registry was another recommendation, together with a specific recommendation that parents be able to opt out. Registries should limit access to the data, monitor that access, and include and enforce penalties for improper use. Development of standards was strongly encouraged. Protection of privacy and confidentiality

should extend to those systems integrated with larger public health information systems and should be reviewed on an ongoing basis.

The Health Insurance Portability and Accountability Act (HIPAA) of 1996 has particular relevance to immunization registries. Among its Administrative Simplification Provisions are sections that require the development of regulations to protect the privacy of health information and standards for data transactions and data security (14). The NVAC has subsequently revised earlier work on confidentiality standards and produced a guidance document outlining minimum specifications for the protection of privacy and confidentiality that are consistent with HIPAA requirements (22). CDC has promoted the use of these standards with its immunization grantees.

Immunization registry legislation (at the state level) is an important part of safeguarding privacy and confidentiality and may be an important adjunct for the successful implementation of registries. Legislation has been used to authorize development of a registry and the collection of personal health care information. Legislation can address consent for participation in the registry. Finally, registry legislation can support registry implementation by mandating reporting of immunizations and, thus, encouraging the participation of private providers.

The National Immunization Program conducted a survey of immunization program managers in all 50 states and the District of Columbia regarding registry-related legislation in their states. The results of this 1997–1998 survey were tabulated and have been periodically updated as new information is received (10). Almost half (25 states) of the states have a law or rule authorizing an immunization registry. Four states had plans to introduce legislation related to immunization registries. Of those states with laws authorizing immunization registries, one half also have laws mandating reporting, although one state mandates reporting only by public providers. Ten states with no law authorizing an immunization registry do have a law addressing the sharing of immunization information. All but one state have addressed the question of consent for inclusion in the registry or sharing of information. In the majority of states (36 states), notice is given to parents of their child's inclusion in the registry. In most states (35 states), consent is implied. In 14 states, consent is required and is in most cases written.

REGISTRIES REQUIRE FINANCIAL SUPPORT There have been two principal recent studies of the cost of childhood immunization registry systems. The first, by Slifkin et al., used reports of funds expended to examine the costs of developing four *All Kids Count* registries (28). Overall costs of registry development ranged from \$2.4 million to almost \$7 million over five years. These costs were influenced by the fact that the registries studied were among the first community-based systems to be developed. As such, the cost of development for at least one registry was higher because their technical system had to be completely reconfigured when the original system proved not to be viable. One registry system included not only a collection of immunization information but also a large-scale health information program for parents, thereby adding to the cost of implementation. A significant portion of

the total cost of developing these registries was associated with the development of the electronic data system and its technical specification. Because of these costs, Slifkin et al. recommend that new registry developers use the expertise of others who have broken ground and that registries be developed to serve large rather than small areas to take advantage of economies of scale.

The second study, by Horne et al., also focused on *All Kids Count* registries and estimated an annual cost-per-child to maintain and run fully operational registries (15). Using financial data supplied by the registries, the authors first project a cost-per-child-per-year ranging from \$1.60 to \$6.23. Second, the cost of manually retrieving paper records was estimated in five clinical practices and ranged from \$6.00 to \$19.00. Using the average cost of manual record retrieval (\$14.50) across a projected birth cohort, this study attempted to estimate the costs of various registry system functions that involve record retrieval, including preparation of immunization histories for school, day care, change in provider, or calculation of HEDIS rates, as well as other cost savings including the elimination of the National Immunization Survey and savings associated with reduction in overimmunization. They found the "cost-offset" of an immunization registry in these settings to exceed the cost of registry maintenance by 46% (\$113.8 million in savings versus \$72.8 million in costs). Despite their obvious public health value and cost-benefit, these systems are not inexpensive.

One of the ultimate benefits of immunization registries is efficiency in the provision of immunization services, with registries being able to target interventions where most needed. A third study of relevance to the cost of childhood immunization registries, by Rask et al., examined the costs of four interventions frequently used to improve immunization (25). Of particular interest to this review was the use of a community-based immunization registry to identify children to receive the intervention. Selected children were randomized to receive one of three interventions or to be controls. Interventions included both prospective reminders of immunizations coming due and recall of children who had missed immunizations. Overall, children in the intervention arms of the study had significantly higher rates of series completion than did children in the control or usual care arm. There were no significant differences in rates among the intervention arms of the study. There were differences in cost, however, with the most automated intervention (contact of parents by autodialer) being the least expensive at a monthly cost of \$0.85 per child. Adding personnel costs in the form of outreach worker time to the intervention increased the cost.

Funding of immunization registries has come from federal and state governmental appropriations as well as from private foundations. The *All Kids Count* National Program Office reported in fall 2000 that 42% of registry funds were federal, another 32% came from state dollars, and the remainder from other sources such as foundations (2). The NIP has made available \$181 million for registry development since 1994 (19). Section 317 funding available for registries was at a peak of \$50 million in 1995 but has declined in each year since (22). Another funding stream became available in July 2000 when the Centers for Medicare and Medicaid

Services (CMS) announced the availability of funds to support immunization registries (T.M. Westmoreland, letter to State Medicaid directors, July 6). Enhanced funding at 90% federal financial participation (FFP) for development and 75% FFP for operation is available for registries that are being developed and implemented as components of the state's Medicaid Management Information System (MMIS). If the registry is being developed in another agency, states are eligible to receive funds at 50% FFP for costs associated with inclusion of Medicaid children. As of July 2002, four states had been approved for enhanced funding and three states receive funds at the 50% level (J. Goldwater, personal communication). Another 13 states have indicated that they plan to apply for CMS funds.

The NVAC report on the development of immunization registries included several options for long-term immunization registry funding including federal funds, vaccine surcharges, and incorporating funding into health care financing systems such as Medicaid and SCHIP (21). Among their specific recommendations was a short-term federal appropriation for registry development and implementation. Other suggested funding mechanisms include Vaccines for Children (VFC) operational funds; other federal programs such as newborn screening, whose data systems are potential links with immunization registries; health plans; fee-for-service; additional funds from state and local government; and renewed funding from foundations (22). Among the proposed options, commitment of public funds is the most promising with continuing availability of Section 317 funds, the new funding stream from Medicaid, and possible use of VFC funds. Recent demands on public health dollars, not the least of which involve preparation for potential bioterrorist attacks, have made the quest for financial support for immunization registries more difficult, and funds from other stakeholders probably are essential.

REGISTRIES IN THE FUTURE

Registries were initially seen as a way to increase immunization coverage. When many of today's immunization registries were launched, however, there were other interventions designed to improve childhood immunization rates and significant public and provider education regarding the importance of all immunizations as well as education regarding new immunizations and other changes to the immunization schedule. Data from the 2000 National Immunization Survey (NIS) indicate that the percentage of 19- to 35-month-old children who have completed the immunization series 4:3:1:3 (4 diphtheria-tetanus-pertussis, 3 polio, 1 measles containing vaccine, 3 *Haemophilus influenzae* type b) is 76.2%, down from a high of 79.2% in 1998 (9). State-specific coverage ranged from 68.2% to 86.9%. National rates of series completion for more recently recommended vaccines such as hepatitis B (HBV) and varicella continue to improve, with HBV coverage at 90.3% and varicella coverage at 67.8%. Immunization rates have improved since data were first reported from the NIS in 1995, but this improvement can hardly be credited to one intervention alone, although registries have likely played some role

in some communities. In areas where they have been implemented, the requirement to report immunizations may have made providers more vigilant. However, as immunization coverage rates plateau or even decrease, registries become more valuable in identifying children whom the system has failed to assure they are adequately protected against vaccine-preventable disease.

As childhood immunization registries have been developed, their potential utility of being combined with other child health information systems to form an integrated health information system has gained support. A new *All Kids Count* initiative was funded by RWJF in 2000 to foster development of these integrated systems (1). With the appropriate safeguards for assuring confidentiality in the sharing of health care information, data from other health care databases such as lead, hearing, and metabolic screening programs, as well as WIC, EPSDT, and other public health programs, can be integrated with immunization registries with potential benefits for families and community as well as health care providers, both public and private. In October 2001, *All Kids Count* awarded grants to seven public health agencies to work toward integration of their health information systems (3). Each project will integrate one or more programs, and, like the pioneer developers of immunization registries, their experience will provide valuable lessons to others who wish to do the same.

SUMMARY

It has been almost 30 years since public health officials in Delaware recognized the need for population-based immunization registries and 10 years since population-based registry development began in earnest with initiation of a variety of registry system developments all over the United States. Much has been learned about registry development, not the least of which is that it is a complex, labor-intensive, and expensive process at every step. Registry developers in the past decade have been pioneers in this regard and those who follow have benefited from the experience of early work of the *All Kids Count* registries and others. Other developments in the way of standardization in the past five years have also contributed to the ease with which registries might begin to flourish. Specifically, there is widespread agreement that such steps as setting out specific criteria that registries must meet in order to be considered a registry, the development of software that meets certain functionality guidelines, or making software readily available and easily modified for use in other areas can contribute to the the success of registry development. Guidelines for protection of confidentiality provide guidance and can give assurance to others recruited to the registry effort, such as providers and parents. There are protocols for data transfer using HL-7 standards. All of these accomplishments have led to the current point where half of America's children have records in an immunization registry, more than halfway to the Healthy People 2010 goal of participation of 95% of the nation's children under six years of age in a fully operational, population-based immunization registry (30).

Individual immunization providers, health maintenance organizations, state immunization programs, and the National Immunization Program are beginning to use the data in immunization registries. The potential benefit of registries encompasses much more than assisting the busy pediatric practice with determining what immunization to give a child. As illustrated in Figure 1, registries are a central feature of comprehensive public health information systems, facilitated by the input of both public and private sector programs and providers, and enabling the more effective performance of both public health and private child health care providers.

It may have been considered ambitious at the outset to expect immunization registries to identify immunizations needed when a child is presented for care, to send notices to parents that their child had an immunization coming up and/or had missed one, and to collect population-based data to calculate population coverage rates to measure success in protecting our children's health. Along the way, new prospects for day-to-day management of immunization programs using registries have been identified. Immunization registries can serve as early warning systems. By monitoring rates for specific doses of specific antigens, they can be used to detect drop-offs in provision of immunizations and assess the repercussions of news regarding immunizations such as concerns about thimerosal preservatives or reports in the popular press of chronic childhood conditions purportedly associated with vaccine use. The recent shortage of some vaccines led to changes in the recommended schedule, with providers instructed to delay administration of certain doses and to keep a list of children whose immunizations are delayed. Registries already keep a "list" of children missing certain immunizations and can produce them with minimal effort.

Despite these positive developments, which clearly demonstrate the feasibility of childhood immunization registries, there remains an overarching (and as yet unanswered) question: Why have registries proven so difficult to implement? Surely the answer is not so simple as our failure to overcome the four barriers to successful implementation described in this paper (namely, funding, provider participation, technical challenges, and privacy concerns). Strategies for addressing each of these have been proposed and tried with some success. But, despite the ability of some existing registries to overcome each of these barriers, complete success is rarely easy.

Proponents of immunization registries must acknowledge that there may be other, thus far unidentified, barriers to success that now need our attention if these information systems are to deliver the kind of benefit assumed to be potentially available. In this regard, immunization registry systems (both fully operational and those still struggling to reach these goals) have not been adequately evaluated. Were such evaluations to take place, we might be able to determine whether there are options to the centrally located, public health department-initiated systems that are the predominant models. At present, a clearly inadequate amount of time and resources is being given to evaluation to identify factors limiting the potential benefit such registries may offer. Such evaluations should include measures not only of process but more importantly of outcome in terms of coverage levels and

the use of registries to address questions such as the impact of vaccine shortages on coverage. Given the limited evidence available thus far, we cannot point to evaluative data on the implementation or the outcomes in making the case for further support of registries. Such information, were it available, would be a powerful argument for further investment of public or private funds in registry system development.

Another challenge is whether we can afford to continue to develop and support registries, and if so, how we will pay for them. In a slowing economy with increased demands on public health dollars, more funds than are currently available must be committed to allow the continued operation of those registries that are functioning at a fully operational status and complete the implementation of those still in process. The Centers for Disease Control has committed a portion of Section 317 funds to the process and other federal dollars have been identified and offered. More money, from diverse sources (both public and private), will be necessary if these goals are to be reached. It is time for a new national coalition of public and private sector organizations with a commitment to national immunization goals (public health, private health care providers and health plans, and pharmaceutical companies) to address these issues and identify ways in which a mixture of public and private support can assure the availability of these vital health information systems in every American community.

Progress over the past 10 years has been remarkable, demonstrating the effectiveness and utility of childhood immunization registries and developing the technical know-how to make these systems work efficiently in community- and state-level immunization endeavors. It is now time to finish the job. National programs of this magnitude cannot be assumed to be the sole responsibility of underfunded public health agencies alone. This is an area crying out for public-private sector collaboration. The fact that the focal intervention is now fully demonstrated and technically feasible makes the task that much easier.

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