Development of Community- and State-Based Immunization Registries

Report of the
National Vaccine Advisory Committee (NVAC)

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EXECUTIVE SUMMARY

The Childhood Immunization Initiative of 1993 has resulted in record high levels of immunization coverage in preschool children and record low levels of vaccine-preventable diseases of childhood. The Initiative received unprecedented levels of federal support and involved intensive and extensive efforts by communities and states. Three community-based strategies that were particularly effective in improving immunization levels were the use of reminder/recall systems, assessment of immunization levels (with feedback and corrective action), and linkages between immunization programs and the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC).

An important goal of the Initiative was to build a sustainable system to maintain high immunization coverage. To accomplish this goal, President Clinton directed the Secretary of Health and Human Services (HHS) "to start working with the states on an integrated immunization registry system." As a result, an *Initiative on Immunization Registries* was undertaken by the National Vaccine Advisory Committee (NVAC). A Workgroup was formed to develop a plan to facilitate and coordinate a nationwide network of community- and state-based immunization registries. The Workgroup identified four issues that provide the conceptual framework for the plan: 1) protecting the privacy of individuals and the confidentiality of information, 2) ensuring provider participation, 3) overcoming technical and operational challenges, and 4) determining resources needed to develop and maintain immunization registries.

To identify challenges and solutions related to each of these issues and to ensure input from stakeholder groups and the general public, the Workgroup convened four public meetings attended by more than 400 persons, with 104 persons providing expert testimony. To ensure input from a cross-section of parents, the Workgroup subsequently asked the National Immunization Program (NIP) of the Centers for Disease Control and Prevention (CDC) to sponsor a series of parent focus groups--20 were conducted around the country. This report presents the findings from the public meetings and the focus groups, NVAC's recommendations based on these findings, and action steps to develop the nationwide network of registries. **Immunization registries are confidential, computerized information systems that contain information about immunizations and children.**

NVAC Recommendations

Vision

The **Vision** guiding these recommendations is **a nation with all children appropriately protected against vaccine-preventable diseases**.

Goal

The **Goal** of the recommendations is to outline the **policy directions and major steps needed to establish a nationwide network of community/state population-based registries that are capable of sharing information while maintaining privacy and confidentiality** that will provide the information necessary to achieve the vision and the Healthy People 2010 objective. Achieving this goal will require a series of actions to meet four primary objectives, which are closely related to the four issue areas addressed by the Workgroup on Immunization Registries. These recommendations address the major policy issues and action steps needed to carry out NVAC's recommendations and achieve the goal. Specific implementation plans with time lines will need to be developed for individual components. These implementation plans should be developed as soon as NVAC approves this report and be completed by the time the report is formally released. For each objective there are research needs and opportunities as well as need for evaluation and communications strategies. Some of these are mentioned.

Objectives, recommendations, and action steps

1. Ensure appropriate protections of privacy and confidentiality for individuals and security for information included in the registry.

NVAC Recommendations

1. Protection of privacy and maintenance of confidentiality are essential to the successful development of immunization registries. Registry developers must give careful consideration to privacy and confidentiality issues to reflect the values and special needs of the communities they serve.

2. Registry developers must give special consideration to the privacy and confidentiality needs of immigrant communities.

3. Federal legislation to establish a minimum set of privacy/confidentiality standards would be very helpful. To assist in the development of registries that can exchange data while also ensuring privacy and confidentiality, the federal government should work with key stakeholders to develop and disseminate model privacy and confidentiality policies and legislation for registries.

4. At a minimum, immunization registries should:
   - Ensure that patients/parents are notified of the existence of the registry and of the information contained in the registry
   - Inform patients/parents of the purpose and potential uses of the registry
   - Permit patients/parents to review and amend information in the registry
   - Accept responsibility for reliability and protection of registry information

5. Parents must be given the option to decide whether or not their children will participate in a registry. In some communities, parents are informed of the registry and its purposes and potential uses during routine educational sessions offered at the birth hospital. At this time, or at any later time, parents should be allowed to opt out of a registry. In communities where the "opt in"/informed consent approach is most consistent with community values, this is the option that should be offered. Parents should not be penalized for choosing not to participate in a registry for religious, philosophical, privacy, or other reasons.

6. Registry developers should limit access to registry information and maintain audit trails to monitor access to records. Individuals should have access to their own records and to these audit trails.

7. Strong penalties for the unauthorized use of registry data should be in place and consistently enforced.

8. Use of registry data in a manner that is punitive to parents/patients (e.g., denial of health insurance/coverage, INS tracking of immigrants, other law enforcement purposes) must be prohibited.

9. If registries are to be integrated with larger health information systems, protection of privacy and confidentiality must be ensured.

10. The federal government should support an ongoing independent assessment of the benefits, risks, and costs of registry development and implementation with regard to issues including privacy and confidentiality.

Action steps

1.1 Develop specifications for minimum protections needed with specific guidelines on notification, parental choice, access, audit trails, law enforcement, etc. This should be completed within 90 days and should also address assuring legal authorization for state-to-state exchange of information.

- Convene a workgroup of representatives from NVAC, CDC, and the National Committee on Vital and Health Statistics (NCVHS) Subcommittee on Privacy and Confidentiality to design specifications. The NVAC-approved document on Confidentiality in Community Immunization Registries contains many of these specifications.

- Charge the workgroup to review new legislative proposals and determine if any fill the need (DHHS has already developed positions on existing legislative proposals). If so, develop a DHHS

position paper to support that legislation. If not, propose changes that would make proposal(s) adequate, and convey these to congressional staff. The workgroup should also review and comment on any proposed regulations developed pursuant to HIPAA requirements.

1.2 Develop and disseminate a DHHS-approved policy statement on needed protections to guide states and communities until legislation is enacted. The statement could be based on the recent agreement between the Health Care Financing Agency (HCFA), HRSA, and CDC regarding exchange of information.

1.3 Each immunization registry should have a written policy and protocols on privacy and confidentiality consistent with the specifications in 1.1, and each user of the registry should sign an agreement to abide by the policy. Enforcement mechanisms should be in place and used.

1.4 CDC should continue to monitor privacy and confidentiality developments (including legislation) at state and local levels to identify new issues and to resolve existing issues.

2. Ensure participation of all immunization providers and recipients.

NVAC recommendations

1. Providers and interested community groups should be involved throughout registry development and implementation, beginning at the initial planning stages.

2. Registries should be simple to use and should be designed to minimize the administrative burden on providers. When possible, registries should capitalize on data already being collected and used in providers' practices for billing or other purposes thereby avoiding duplicate data entry. This could be done using billing or encounter information systems, although some modifications might be necessary to ensure data completeness and quality. Initial and subsequent training should be provided; technical and non-technical support should be readily available.

3. Registries should include reminder/recall functions to improve adherence to recommended immunization schedules. Whether both reminders and recalls will be used will depend on local circumstances.

4. Data in immunization registries should be used to improve immunization services and immunization coverage; they should not be used to "punish" providers whose immunization coverage is low.

Action steps

2.1 CDC should take the lead in meeting with major professional organizations (including AMA, NMA, AOA, AAP, AAFP, ACP, ACPM, ATPM, ANA, AMIA, etc.)[1] and health agencies (including ASTHO, NACCHO, CSTE, ASTMCHD, NACHC, APHA, etc.)[2] to assess their needs and develop organizational/institutional support. Special attention should be paid to meeting with managed-care providers and purchasers of care (AAHP, HIAA, WBGH, PBGH, etc.).[3] This should be accomplished within 90 days.

2.2 State and local health agencies and CDC should work with parent, community, and professional organizations to develop educational materials for parents and patients.

2.3 State and local health agencies and CDC should work with professional organizations, health agencies, and managed-care representatives to develop educational materials for providers.

2.4 The Technical Working Group (see 3.1 and 3.2 below) should work with practice management vendors, third party payers, and other information system vendors to make registry use as simple as possible and to facilitate integration of registry functions into existing information systems.

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[1]American Medical Association, National Medical Association, American Osteopathic Association, American Academy of Pediatrics, American Academy of Family Physicians, American College of Physicians, American College of Preventive Medicine, Association of Teachers of Preventive Medicine, American Nurses Association, American Medical Informatics Association, respectively.

[2]Association of State and Territorial Health Officials, National Association of County and City Health Officials, Council of State and Territorial Epidemiologists, Association of State and Territorial Maternal and Child Health Directors, National Association of Community Health Centers, American Public Health Association, respectively.

[3]American Association of Health Plans, Health Insurance Association of America, Washington Business Group on Health, Pacific Business Group on Health, respectively.

2.5 CDC should monitor the level of provider and recipient participation, conduct research on effective means of ensuring participation, and share this information with registry partners.

3. Ensure appropriate functioning of registries.

NVAC Recommendations

1. CDC, in cooperation with state and local health agencies, provider groups, software/hardware vendors, and national standard-setting organizations, should take the lead in developing, implementing, and maintaining 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 on the same individual
   - Enabling intra- and inter-registry record exchange with standard (e.g., HL7) messages
   - Adopting system security standards to address both technical and administrative issues and to ensure that access is limited to authorized persons
   - Certifying registry functions

2. The initial target group for inclusion in immunization registries should be children from birth through 5 years, although many registries will want to continue the registry beyond school entry and/or include other age groups (e.g., adolescents, older adults).

Action steps

3.1 CDC and other stakeholders, including state/local health departments, representatives of managed care, the NCVHS Subcommittee on Standards and Security, informatics associations, etc., should form a Technical Working Group to reach agreement on standard vocabularies and protocols for data transfer as well as other areas listed in recommendation 3.1. This should use information from current efforts and be accomplished within 90 days.

3.2 The Technical Working Group should develop benchmarks and protocols for accreditation or certification and provide ongoing quality assurance monitoring.

3.3 CDC should monitor the implementation of registries and provide technical assistance.

4. Ensure sustainable funding for registries.

NVAC Recommendations

1. CDC should immediately pursue further study to characterize start-up and maintenance costs of registries and compare these to costs of alternative systems. Information about the prospects for state and local health agencies to secure funding to partially or fully support their immunization registries should also be gathered and evaluated.

2. NVPO should coordinate discussions leading to a recommendation about appropriate mechanisms for long-term funding of registries.

3. A short-term (3-5 year) federal appropriation should be sought to support the further development and initial implementation of registries, with evaluation of costs and benefits an integral part of these efforts. This funding would provide time to establish a mechanism for long-term funding.

   Action steps

   4.1 CDC should complete reviews of selected registries to develop estimates of start-up and maintenance costs as well as estimates of costs that will be off-set by having functional registries in place. This should be accomplished within 30 days.

   4.2 Based on these estimates, CDC should work with DHHS to develop and introduce a legislative proposal for a 5-year grant program to assist communities/states in the development and initial implementation of registries.

   4.3 NVPO should convene a meeting of representatives of state/local health departments, vaccine manufacturers, health insurers, managed-care organizations, HCFA, professional organizations, etc., to deliberate the pros and cons of different funding mechanisms and to recommend approaches for long-term support.

   4.4 CDC should continue to monitor the costs and benefits of immunization registries.

BACKGROUND

Vaccines are among the nation's most important public health tools: they save lives and money, protect people (particularly infants and young children) from unnecessary suffering caused by vaccine-preventable diseases, and improve the quality of life for infants, children, adolescents, and adults. Since the introduction of safe and effective vaccines, the United States and most developed countries have experienced at least a 97% reduction in the number of cases of vaccine-preventable diseases of childhood compared to pre-vaccine-era levels. Reported cases of vaccine-preventable diseases in children are currently at record low levels (Table 1). However, these diseases can readily return if immunization levels decline as a result of complacency or other factors.[1]

Table 1. Maximum and current morbidity from childhood vaccine-preventable diseases, United States

Condition	Maximum	1997	% change
Diphtheria	206,939	4	-99.99
Hib	20,000*	165	-99.18
Measles	894,134	138	-99.98
Mumps	152,209	683	-99.55
Pertussis	265,269	6,564	-97.52
Polio (paralytic)	21,269	0	-100.00
Rubella	57,686	181	-99.69
CRS	20,000*	5	-99.98
Tetanus	1,560**	50	-96.79

*Estimated
**Deaths

Source: Centers for Disease Control and Prevention (CDC)

Immunization Delivery in the United States

In the United States immunizations are delivered through both the public and the private sectors. Historically, the public sector has provided immunization services to low-income families, commonly through local health department clinics that might or might not provide other preventive or curative services. These activities have been supported by local, state, and federal funds (through the Public Health Service Act 317d categorical grant program, the Maternal and Child Health Block Grant, Medicaid, and other programs). The private sector has traditionally provided immunizations to the more affluent as part of comprehensive child health care. Although virtually all Health

Maintenance Organizations and Preferred Provider Organizations cover childhood immunizations, traditional indemnity fee-for-service insurance plans have lagged in provision of immunization coverage. A recent survey of Employee Retirement Income Security Act of 1974 (ERISA) plans, which provide 40% of the commercial insurance in the United States (and are not subject to state laws) revealed only approximately 50% cover childhood and adult vaccines. This has forced some children, who have received most of their well- and sick-child care from private practitioners, to go to public health departments to receive (free) vaccine.

Until recently, it was estimated that about half of the nation's children received immunizations in the public sector. With the enactment of the Vaccines For Children (VFC) program in 1994 and the advent of Medicaid Managed Care, however, free vaccines are now provided to uninsured and underinsured children in both public and private settings. As a result, the balance has shifted, and current estimates are that approximately 70% of childhood immunizations are administered in the private sector sites where children receive other health-care services (their "medical home").

Reaching High Immunization Levels: the 1993 Childhood Immunization Initiative

In the late 1970s-early 1980s, the nation undertook a major effort to increase disturbingly low immunization levels in children (particularly school children). One component was to enact and enforce laws requiring children to be immunized before school entry. Implementation of these laws led to immunization levels of over 95% in 5- to 6-year-old children beginning in the early 1980s. In preschool children, however, Immunization levels remained chronically low, particularly in the inner cities (as low as 20% in 2-year-old children in some urban areas) and led to outbreaks of disease. An epidemic resurgence of measles in 1989-1991 affected mainly preschool children in low-income inner-city neighborhoods. The resurgence was attributed to low immunization rates in preschoolers as well as inadequate access to care, missed opportunities for administering vaccines, and inaccurate (high) estimates of protection on the part of both parents and providers.[2]

To address the barriers that prevented infants and young children in the United States from receiving needed immunizations, the federal government launched the Childhood Immunization Initiative (CII) in 1993. This national initiative set goals to improve the delivery of immunizations to infants and young children and to ensure that children completed the primary immunization series by their second birthday, as recommended by the American Academy of Pediatrics (AAP) and the U. S. Public Health Service (PHS) Advisory Committee on Immunization Practices (ACIP). Supported by unprecedented levels of federal resources with activities spearheaded by community-wide coalitions, CII efforts at national, state, and local levels managed to increase coverage in preschool children (19-35 months) to record high levels. In July 1997, President Clinton announced that the nation had exceeded its childhood vaccination

goals for 1996, with 90% or more of U.S. toddlers receiving the critical doses of most of the routinely recommended vaccines by age 2 (Table 2).[3]

Table 2. Immunization coverage levels in children aged 19-35 months, 1997, National Immunization Survey

Vaccine (doses)	% immunized
DTP (≥3)	95
OPV (≥3)	91
Hib (≥3)	93
Measles (≥1)	91
Hepatitis B (≥3)	84
Varicella	26
4 DTP, 3 OPV, MMR	76

Source: CDC

Although protection against individual conditions is high nationwide, there is significant variation around the nation and among different socioeconomic groups. The low coverage with varicella vaccine, recently added to the schedule, demonstrates the difficulties in implementing new vaccines. It is likely similar problems will be noted with the recently licensed (and recommended) rotavirus vaccine and others in the future. In addition, completion of the whole series of vaccines (a measure of how well the system works) is suboptimal, as shown above.

Three successful community-based strategies that were widely implemented nationwide beginning in 1993 played a major role in boosting immunization coverage:

- Reminder/recall systems maintained by providers to notify parents of pre-school children about needed immunizations
- The "AFIX" evaluation system implemented by public health departments to Assess providers' immunization coverage, provide Feedback on results, provide Incentives, and eXchange information to boost coverage and avert missed immunization opportunities
- Linkages between immunization programs and WIC (Women, Infants, and Children) services to ensure that a child's immunization status is assessed at every WIC visit

These strategies have been extensively studied and demonstrated to be effective.[4] The independent Task Force on Community Preventive Services (TFCPS), reviewed the literature on these and other interventions and found strong scientific evidence for improved immunization coverage through reminder/recall, provider feedback, and WIC linkages. Despite the need for reminders for parents, few physicians operate reminder

or recall systems. A national survey of pediatricians and family physicians in 1992 reported that only 13% of pediatricians and 10% of family physicians operated routine reminder systems.[5] By 1995 those figures had increased to 35% and 23%, respectively (L. Rodewald, personal communication). The ACIP, AAP, and the American Academy of Family Physicians (AAFP) have recently recommended "the regular use of [reminder/recall] systems by public and private health-care providers in settings that have not achieved high documented levels of age-appropriate vaccinations."[6]

IMMUNIZATION REGISTRIES: THE NEED AND THE RESPONSE

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

- New vaccines continue to be added to the already complex immunization schedule. Today, 20-21 total doses of 11 different antigens (including the recently licensed rotavirus vaccine) are recommended for each child by age 6 years. In addition, a variety of new vaccines that are expected to provide substantial public health benefit will likely become available in the near future.
- In our increasingly mobile society, families relocate and change medical providers or health insurance coverage with growing frequency, leaving medical and immunization records scattered among different care givers, clinics, and offices, and resulting in missed opportunities to immunize.
- Few providers operate reminder or recall systems.
- Both parents and providers **over**estimate coverage.
- Federal funds in support of immunization activities are declining.
- Maintaining resource-intensive, paper-based reminder/recall systems, AFIX activities, and WIC linkages is becoming increasingly difficult for funding-constrained communities.
- Disease levels are at record lows and do not serve as a constant reminder to patients and practitioners of the need for immunization.

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

<u>What are immunization registries?</u>

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

The concept of immunization registries is not new.[7] Many individual practices and health plans have developed information systems to keep track of immunizations given to their patients. Often these are based on computerized information systems designed for other purposes such as billing. There is also a growing movement toward development of totally computerized patient medical records. These site- or plan-specific registries cover only immunizations administered by participating providers to covered patients. Only **population-based immunization registries** (which include all children in a defined area) can provide information on all children and all doses of vaccines administered by all providers.

Benefits of Immunization Registries

Immunization registries can be extremely helpful, if not essential, to maintaining the progress made to date in the Childhood Immunization Initiative, particularly since disease levels are at record lows and do not serve as a constant reminder to patients/practitioners of the need for timely immunization. Studies have consistently shown that both parents and providers **over**estimate coverage, which can lead to complacency.[8,9] A detailed listing of the benefits of registries to parents, providers, communities, and public health officials is included in the box on the next page. Not all registries will necessarily provide all these services.

Benefits of Immunization Registries
(depending on system attributes)

For **parents**, immunization registries:

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

For **providers, plans, and purchasers**, immunization registries:

- Consolidate immunizations from all providers into one record
- Provide a reliable immunization history for any child, whether a new or continuing patient
- Provide definitive information on immunizations due or overdue
- Provide current recommendations and information on new vaccines
- Produce reminders and recalls for immunizations due or overdue
- Complete required school, camp, and day-care immunization records
- May reduce a practice's paperwork
- Facilitate introduction of new vaccines or changes in the vaccine schedule
- Help manage vaccine inventories
- Generate coverage reports for managed-care (e.g., HEDIS) and other organizations
- Reinforce the concept of the medical home

For **communities**, immunization registries:

- Help control vaccine-preventable diseases
- Help identify high-risk and under-immunized populations
- Help prevent disease outbreaks
- Link (where supported by legislation) with other health databases, such as newborn and lead screening, or other state registries
- Provide information on community and state coverage rates
- Streamline vaccine management

For **public health officials**, immunization registries:

- Provide information to identify pockets of need, target interventions and resources, and evaluate programs
- Promote reminder and recall of children who need immunizations
- Ensure that providers follow the most up-to-date recommendations for immunization practice
- Facilitate introduction of new vaccines or changes in the vaccine schedule
- Integrate immunization services with other public health functions
- Can help monitor adverse events

In summary, immunization registries can serve as a source of complete and accurate immunization histories; assess immunization status of individuals; assess immunization status of groups to identify pockets of need; remind patients/parents when immunizations are due; remind providers when immunizations are due, thereby reducing missed opportunities; recall patients when immunizations are overdue; provide immunization decision support; facilitate introduction of new vaccines; produce reports summarizing immunization status (e.g., for the Health Plan Employer Data Information Set [HEDIS]); generate immunization records for individuals for use with schools, camps, etc.; and exchange data with other registries when appropriate (e.g., when families move).

In addition, they can be used to note contraindications, monitor/report adverse events following immunization, manage vaccine inventories, and generate VFC reports. By consolidating all immunization information on each child in a single record, fully operational immunization registries can identify and characterize groups of under-immunized children ("pockets of need") so that special efforts can be targeted to protect children and avert outbreaks of disease. By consolidating all immunization information in a single record, registries can also prevent unnecessary (duplicative) immunization.[10] They can facilitate rapid and accurate implementation of changes in the recommended childhood immunization schedule, including introduction of new vaccines. Registries can also strengthen the concept of a "medical home" by facilitating accurate assessment of a child's immunization history, followed by vaccination or referral back to the medical home.[11,12]

Immunization registries are of such recent development that there is little published literature about their effectiveness. However, it is very clear that they can facilitate implementation of the proven effective strategies of patient reminder/recall, provider reminder/recall, and assessment/feedback. In addition, Yawn and colleagues showed that by consolidating immunization records from different providers, a simulated registry resulted in immunization coverage improvements of 5-9% compared to on-site records in the different facilities. They also demonstrated that 5% of the county's 2-year-olds had received at least one immunization that was not needed.[13] Another study showed that individual provider record systems underestimated true coverage by 9.6 - 34.6% because of the scattering of records (Stokley S, personal communication).

Experience with Immunization Registries

In 1994, the National Vaccine Advisory Committee (NVAC) Subcommittee on Vaccination Registries recommended expanded funding and new federal policies for a system of immunization registries to support national immunization goals. The members determined that:

- "Immunization registries are essential to reaching and sustaining coverage levels at the national goal."

- "Immunization registries can be used to inform families of needed vaccines, help providers in vaccinating children, and monitor immunization coverage."
- "Families, providers, and public health agencies share the responsibility for keeping immunizations and immunization records up to date."
- "The barriers to creating a national system of state-based registries are mainly political and financial rather than technical."
- "State and local areas are moving ahead with immunization registry, recall, and reminder projects, and a federal framework is needed."[14]

The U.S. Centers for Disease Control and Prevention (CDC) has provided limited funding to support immunization information and registry development projects for several years. With federal support, community- and state-based registries are proliferating across the country. As of September 1997, 60 of 64 (94%) federal immunization grantees (states, territories, cities) were developing or implementing registries. At least 255 other areas are developing registries independently. An estimated $142 million in 317d categorical immunization grant funds were awarded in support of immunization registries in the period 1993-1998.

The private sector is also funding registry development. In 1991, the Robert Wood Johnson Foundation (RWJF) launched the All Kids Count (AKC) project to develop vaccine tracking and monitoring systems for preschool children. Other private foundations joined this effort, resulting in 24 funded projects, each of which worked to develop an automated immunization registry to monitor immunization status, identify service gaps and barriers, and establish follow-up and referral mechanisms. These efforts were meant to be complementary, not duplicative or competitive, with other immunization initiatives, and the results were shared so that successes can be replicated and sustained. The experiences of the AKC projects are summarized in a supplement to the American Journal of Preventive Medicine.[15]

RWJF is currently funding All Kids Count II, in which 16 of the most fully developed registries in the country are receiving additional support to become fully operational by January 1, 2000. "Fully operational" registries will include all children in a given geographic area, with information about all doses of all vaccines delivered by all providers. In total, RWJF has provided approximately $20 million in support of registry development.

Experience gained from these projects demonstrated that registries must be tailored to local needs; a **national** immunization registry is not the solution. Instead, the goal has become to establish **a nationwide network of community/state population-based registries that are capable of sharing information while maintaining privacy and confidentiality**.

Many of the currently operational registries are capturing and distributing large amounts of immunization data on a daily basis, but most still concentrate primarily on

public sector providers. Limited headway has been made in many areas in recruiting private providers or establishing links to exchange information with other registries. As a result, few, if any, sites have state-of-the-art registries that include complete records from all providers on all targeted children in the geographic area. Nonetheless, several states now have registries covering their entire area and including information on a large number of children and providers. For example, Oklahoma's registry contains immunization histories on 95% of the 0 to 2 year-old population; Arizona includes 87% and Oregon 81% of the 0 to 2 year-olds. In New York City, more than 60% of private physicians are now reporting immunizations to the local registry.[16]

Working together, CDC and AKC developed a *Community Immunization Registries Manual* which was completed in September 1996. This widely used document included four sections: Planning, Confidentiality, Technology, and Operations. NVAC formally endorsed the section on Confidentiality and, in January 1998, released the report *Strategies to Sustain Success in Childhood Immunizations*, which included these recommendations (among others):

- "All immunization providers, public and private, should assess the immunization coverage levels of their patients annually..."
- "All immunization providers, public and private, should operate recall and reminder systems…"
- "Immunization registries involving both public and private providers should be developed in each State."[17]

The proposed Healthy People 2010 objectives also include an objective to "Increase to 95% percent the number of children enrolled in a fully functional population-based immunization registry (birth through age 5)."[18]

The concept of immunization registries is not unique to the United States. Australia has developed a national registry system and the 1996 Canadian National Immunization Conference concluded that "an immunization tracking system is urgently needed in Canada." Participants at a Consensus Conference on a National Immunization Records System was held in Ottawa in March 1998 agreed that Canada should establish comprehensive immunization registries in all provinces and territories within 5 years.[19]

1997 INITIATIVE ON IMMUNIZATION REGISTRIES

Creation and Framework

On July 23, 1997, President Clinton celebrated the successful attainment of the 1996 immunization goals established by the national Childhood Immunization Initiative (CII). An important additional goal was to build a sustainable system to maintain high immunization coverage in young children. The President said:

> "Almost a million children under the age of two are missing one or more of their recommended shots still.…We have to make sure that every child now is safe from every vaccine-preventable disease....As parents move from place to place, they often leave their children's immunization records behind. Their new doctors often cannot get access to these records. So I'm directing Secretary Shalala to start working with the states on an integrated immunization registry system...it may have something to do with whether their children live or die. And we have to do it and do it right."[20]

Soon after the July 1997 ceremony, CDC was asked to begin discussions on how to respond to the President's directive. CDC's National Immunization Program (NIP) assembled a planning task force of staff from CDC, AKC, and the National Vaccine Program Office (NVPO) to review ongoing immunization registry development efforts and to consider various alternatives to address the President's challenge.

The result of these deliberations was the formation of a new effort -- the *Initiative on Immunization Registries* -- led by NVAC, with support from NIP and NVPO. Four NVAC members were selected to form a *Workgroup on Immunization Registries* to guide the Initiative. Representatives from provider organizations, managed care plans, state and local health departments, parent and consumer groups, and the health information system community were invited to participate as consultant members. The Workgroup launched the Initiative at a meeting on March 13, 1998, in Houston, Texas. A roster of Workgroup members is included in Appendix A.

As an outgrowth of that initial meeting, the Workgroup began a collaborative project to develop a plan to facilitate and coordinate a nationwide network of community- and state-based immunization registries. The Workgroup identified four issues that would provide the conceptual framework for the initiative:

> *Protecting the privacy of individuals and the confidentiality of information* -- Most areas of public health practice involve issues of individual autonomy, including privacy, confidentiality, and consent. In developing immunization registries, these issues become particularly complex, sensitive, and problematic. One of the greatest challenges in registry development is balancing the need to gather and share health information with the need to protect the privacy of patients and families.

Ensuring provider participation -- Registries will be most successful if they have active participation from all public and private immunization providers. Linking private providers to current systems has been a slow and time-consuming process. Currently, 30 of 64 U.S. immunization projects have 50% or higher participation from their public clinics, but only 6 have active participation from a significant proportion of private providers. With the shift in immunization delivery from the public to the private sector, registry projects are enhancing efforts to recruit private providers.

Overcoming technical and operational challenges -- Since 1993, CDC has encouraged the local development of immunization registries to meet the needs of states and communities. CDC has been working with the Program Managers Immunization Registry Working Group and a technical committee of state representatives to coordinate registry activities and to provide leadership in integrating the variations in different systems. The result is a wide variety of systems that cover different jurisdictions, operate on different computer platforms, use different software packages, and vary in functionality. Enabling these systems to collect complete immunization information on children and exchange this information with other registries (when appropriate) is a challenge. Currently available technology will need to be put in place to ensure that registry systems are secure, so that unauthorized persons cannot gain access to their information.

Determining resources needed to develop and maintain immunization registries -- Information is lacking on the initial and long-term costs of developing and implementing registries, their cost-effectiveness, and the consequences and costs of not developing registries. State and local governments, federal agencies, private foundations, the medical community, and other private partners have already made significant investments in registry development and implementation. Although sustained funding is imperative, all assistance need not be financial. Registries also require support in the form of human resources, software and hardware purchase, telecommunication services and training, and marketing.

Workgroup Activities

To identify challenges and solutions related to each of these issues and to ensure input from stakeholder groups and the general public, the Workgroup convened four public meetings, which were held in New Orleans, Louisiana (April 6, 1998), Washington, D.C. (May 13-14, 1998), San Francisco, California (June 18-19, 1998), and Atlanta, Georgia (July 16-17, 1998). The meetings provided a forum for expert testimony by, and discussion among, health-care providers, parents, and representatives from universities, research institutes, health plans, school nurses, community-based organizations, professional organizations, public health agencies, the information technology industry, vaccine manufacturers, private foundations, and federal agencies.

Each meeting also included opportunities for public comments and questions. In Washington, San Francisco, and Atlanta, all four issues were addressed in separate sessions; discussions in New Orleans centered only on privacy and confidentiality. To assist in the preparation of testimony, several questions were posed to all invited speakers (Appendix B).

More than 400 persons attended the meetings to present or hear expert testimony from 104 persons (Appendix C). Of these, 12 persons provided public comment on their own behalf or as representatives of special-interest groups or agencies. At each meeting, time was scheduled for the public to comment on the Initiative and to question the invited speakers. All meetings were advertised in the *Federal Register* and complete transcripts, testimonies, and public comments are available on NIP's Immunization Registry Clearinghouse web site (www.cdc.gov/nip/registry).

To ensure input from a cross-section of parents, the Workgroup subsequently asked NIP to sponsor a series of parent focus groups. After a pilot focus group in Rockville, Maryland, 20 focus groups were conducted between September 9, 1998, and October 27, 1998, in Baltimore, Maryland; Miami, Florida; Portland, Oregon; Ankeny, Iowa; Tucson, Arizona; Tulsa, Oklahoma; and Los Angeles, California. These locations were selected based on the racial make-up and socio-economic and urban/rural characteristics of the communities. Details on the purposes and processes of the focus groups are included in Appendix D. Findings from the focus group meetings are summarized below in the section on Privacy and Confidentiality and summarized in Appendix D.

Workgroup Findings

The establishment of immunization registries is a complex endeavor that has been most successful at the local and state levels. Much of the current variation in registries is a result of varying state laws. Speakers at the public meetings generally concurred that, because registries must be tailored to local needs, a "national immunization registry" is not the solution. Rather, the most workable approach to universal coverage of U.S. children by immunization registries is to establish a **nationwide network of community/state population-based registries that are capable of sharing information while maintaining privacy and confidentiality.** Many independent activities currently underway (e.g., implementation of the Health Insurance Portability and Accountability Act of 1996 [HIPAA]) could influence the development of such a network. The challenge is to maintain appropriate coordination with these activities while working to resolve registry-specific issues and continuing to move forward expeditiously.

Several new federal initiatives also offer opportunities related to immunization registries. For example, in addition to the ongoing support from 317d categorical grant funds, NIP has awarded cooperative agreements to nine state health agencies to promote the integration of information systems, with a focus on immunization registries.

The projects are a joint effort of NIP and CDC's Information Network for Public Health Officials (INPHO), which was initiated in 1992 to strengthen state/local public health infrastructure via use of state-of-the-art telecommunications and computer-networking technologies.

Also, to respond to the need to demonstrate improved health outcomes for Medicaid populations, many state Medicaid agencies are establishing new contracts for their massive Medicaid Management Information Systems (MMIS). Immunization is a critical Medicaid service and Medicaid typically serves as much as 25-50% of the childhood population in a state. This is a timely opportunity for states to closely integrate their pubic health information systems to both serve their Medicaid recipients and simultaneously develop immunization registries.

Finally, the Health Resources and Services Administration (HRSA) has provided Maternal and Child Health (MCH) block grant (Title V) funds to state health agencies since 1981. These funds have been used to support programs that improve the health infrastructure for women and children. In May 1996, HRSA released a strategy statement on data utilization and enhancement that recommends developing a Maternal and Child Health Information System to meet the programs' functional needs. State, local, and federal agencies could incorporate immunization registry activities into this larger effort.

Issue-specific findings from the public meetings and focus groups are detailed below.

Privacy and Confidentiality

Privacy is the legal right of an individual to limit access by others to some aspect of the person (e.g., information). *Confidentiality* is the treatment of information that an individual has disclosed in a relationship of trust and with the expectation that it will not be divulged to others in ways that are inconsistent with the understanding of the original disclosure. *Security* encompasses a set of technical and administrative procedures designed to protect data systems against unwarranted disclosure, modification, or destruction. Resolution of privacy and confidentiality issues, which vary from community to community, is critical to the acceptance and success of immunization registries. As noted at the public meetings, experience to date indicates that registries in general, and privacy and confidentiality policies in particular, are most successful when developed in collaboration with the communities they will serve.

A 1997 survey of states that was recently informally updated found that 18 states have laws authorizing registries; 10 of these require providers to report immunizations to the registries. Approaches to ensuring confidentiality vary. In 33 states, consent to be in the registry is implied and, in 24 of these states, children are included unless their parents decline to participate (“opt out”). In 12 states, laws or policies limit inclusion to children whose parents specifically consent to enrollment (“opt in”). The other states have not specifically addressed this issue.

Many current events on the national scene will likely affect privacy and confidentiality issues. Key among these are implementation of HIPAA and congressional action on pending privacy legislation. HIPAA charges Congress with enacting, by August 1999, privacy legislation that would ensure the confidentiality of medical records. If Congress does not enact legislation by this date, the Secretary of Health and Human Services is charged with promulgating regulations to ensure the confidentiality of data. HIPAA also requires the adoption of information security standards for certain electronic health-care transactions and the development of a unique medical identifier for every individual, employer, provider, and health care plan. Some believe that such identifiers could help to ensure the confidentiality of medical records by removing personally identifiable information from records that are transmitted electronically. Because of opposition, however, the development of the unique identifier for individuals has been halted pending further Congressional action.

Testimony from representatives of advocacy and parent groups reflected concerns about the privacy and confidentiality of immunization registries, centering on the potential for:

- Government use of demographic data to track families for purposes other than immunization (e.g., Immigration and Naturalization Service [INS] use to track undocumented immigrants; use of data to deny other government services)
- Unauthorized use of data that might jeopardize the safety of the child or a parent, such as in cases of domestic violence
- Use of data to link to other health information that would lead to denial of health insurance or services
- Government intrusion into family decisions about health care
- Use of data in a way that is harassing or punitive to parents who choose not to immunize

Findings from the focus groups across the nation also indicated that parents have concerns about privacy and confidentiality (Appendix D). Key findings from the focus groups included the following:

- "Most people had a generally positive initial reaction to the idea of an immunization registry, but some people voiced their concerns about issues such as the accuracy and privacy of the data."
- "Initial reactions to the content of the registry were generally positive, although some people questioned the need for some of the information or wondered if the information could be misused."
- "The idea of linking the registry to other health care databases, such as those kept by WIC and Medicaid, received mixed reactions."
- "Many participants immediately noted several drawbacks to a law or policy that allows parents to opt out, but very few indicated they would actually opt out if given the choice."

- "Most participants favored a law or policy that requires explicit consent of parents before information enters the registry."
- "The majority of participants were least comfortable with a law or policy that requires automatic inclusion of children in a registry."
- "Participants consistently named the convenience of having immunization information in one place as the main benefit of a registry."
- "Participants most commonly named the possibility of a breach in confidentiality and privacy as the issue about which they were most concerned."[21]

Privacy and confidentiality concerns of the immigrant community deserve special consideration. Because children in immigrant families account for 10% of all U.S. children and one in six children in low-income families, their inclusion is key to the success of registries. Recent changes in immigration and welfare law have put the immigrant community in a particularly vulnerable position. As a result, the use of Social Security numbers or demographic information (including a parent's place of birth or address) is extremely sensitive. In addition, immigrants from less technologically developed countries may not be familiar with how information systems work.

Some leaders of the Hispanic health advocacy community (the National Coalition of Hispanic Health and Human Services Organizations [COSSMHO]) expressed reservations about registry development because of the potential to further marginalize underserved populations including immigrants, migrants, and Hispanic families. Concern that registries could be misused to track families could lead some immigrants and migrants to avoid participation in immunization registries. In contrast, the focus group research found that "Hispanic groups were more open [than other race/ethnic groups] to allowing a wider variety of individuals and organizations to have access to the information in the registry."

There was a strong, consistent message from those testifying that narrowing and focusing the scope and use of registry data would best protect patient privacy and confidentiality. Participants agreed that information in immunization registries should **not** be used for law enforcement purposes. They also agreed that the federal government should develop national models or standards for privacy/confidentiality in immunization registries. They did not agree as to whether federal legislation should be pre-emptive or should set a minimum floor of protection. Participants felt that the federal government could play a useful role in reviewing confidentiality legislation and policies, highlighting best practices and providing model policies and legislation for registry developers. Vital records model legislation and model birth/death certificates were suggested as potentially useful models for a federal role: although there is no national vital records registry, data collection is relatively consistent across states and there is a great capacity to share data across state lines.

Ensuring Provider Participation

The usefulness of registries is directly proportional to the level of participation by providers and patients. To be fully successful, all health care providers,[d] both public and private, must participate actively. Testimony at the hearings was consistent in stating that, to ensure that providers will participate in immunization registries, they must be involved as partners in registry development and implementation from the earliest stages. Registries offer several potential benefits to providers as listed in the Box on page 14.

Providers favor registries that are user friendly, flexible, and compatible with existing office systems. To support these goals, providers recommended initially keeping the registry data as simple as possible (to help ensure accuracy) and using third-party-payer information when possible (to decrease the administrative burden of dual data entry). Data entry must be quick and easy, and extracted data must be accurate. Providers also desire easy access to technical and non-technical support 24 hours a day, seven days a week. They must be educated about the benefits of registries and given initial training and ongoing technical assistance.

Registries provide ongoing monitoring and self-assessment of immunization coverage at a practice site and in segments of the population. Self-assessment leads to improved quality of care and higher immunization rates. Participants at the public meetings agreed that registry information should not be used to punish providers with low rates and that punitive measures should not be used to increase provider participation.

Barriers to provider participation in registries include a lack of knowledge about the benefits of registries and competition with other priorities. Also, since disease levels are very low and immunization coverage is currently at an all-time high, providers may not be motivated to participate, particularly given concerns about costs, staff time and staffing associated with registries. Providers may also be concerned about confidentiality, privacy, security, informed consent, and liability issues. Providers favor parental notification and choice on inclusion in registries and generally feel that “opt out” approaches would pose less of an administrative burden than “opt in” approaches.

Technical and Operational Issues

Meeting participants agreed that the barriers to creating a nationwide system of community- and state-based registries are mainly political and fiscal, rather than technical. Nonetheless, they did identify several technical and operational issues that need to be addressed in registry development.

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[d]Providers include physicians, nurses, and others authorized by law to provide immunization services, including systems of care.

Registry developers have taken several different approaches, from complete development in-house to minor adaptation of existing software programs. Data-entry mechanisms are similarly varied and include on-line entry, batch entry, bar coding, and voice or fax entry. One consequence of these diverse approaches has been difficulty in developing effective sharing of information from one registry to another, thus impeding overall utility.

Communication standards are essential to allow registries to exchange information when needed (e.g., a family moves to another town). The HL7 organization has made considerable progress in standardizing the format and vocabulary of messages used to transmit queries for immunization data and responses to such queries. Standard message formats in HL7 version 2.3 define a query for a patient's immunization history, a response to that query when a unique patient is found in a database, a response when multiple potential matches are found, and an unsolicited update to an immunization history. This standard also defines the vocabulary for manufacturers and vaccine names. The existence of such an international standard allows multiple software vendors and registry developers to create uniform interfaces for their software, allowing disparate systems to "talk" to one another.

Additional standardization could be done to help improve the uniform representation and transfer of immunization data in electronic format. This work includes improved standard vocabularies that can be used to store and represent immunization data. Such work should be promoted to further the important goal of integrating immunization registries with other software used by practitioners.

Certification that a registry correctly performs a minimum set of functions is also important. CDC has established a set of core functions, and NVAC has previously approved core data elements for immunization registries. These lists should be reviewed in light of information obtained during this initiative and in light of their potential use during a certification process. Although self-certification by registry developers would reduce the cost of certification, stakeholders will probably have more confidence in the outcome if the process is conducted by an independent organization (e.g., CDC or a standards organization). Restricting the types of data available in a registry should promote its use by allaying concerns about patient privacy and confidentiality.

Another component of certification involves the clinical decision-support function. Although participants felt that CDC should not develop decision-support software, they thought it could assist the process. CDC is working with the ACIP on a template for each recommended vaccine that will ensure specificity for decision-support algorithm developers and is working on benchmark test cases that can be used to evaluate the output of different decision-support systems. CDC might also endorse algorithms encoded in a standard format (e.g., Arden Syntax, a standard of Health Level Seven [HL7]) that could then be distributed to registries.

Maintaining the security of patient data is a core function of a registry. Security includes preventing unauthorized or inappropriate access, maintaining data integrity, and detecting inappropriate access through techniques such as audit logs. Technical capacity currently exists to ensure security. Participants advocated establishment of clear policies on access to patient data with appropriate enforcement and penalties for transgressions, as well as the adoption of fair information practices to govern entry to a system and viewing/correction of patient data. Registries should rely on standards promulgated by authoritative bodies (e.g., DHHS under HIPAA; the National Research Council in *For the Record*).

Participants agreed that involvement of all relevant stakeholders, including practitioners, parents, community organizations, professional organizations, standards organizations, and government, is important in ensuring that desired registry functions are incorporated into systems being developed. Maintaining flexibility to meet the goals of all groups is key.

Data contained in a registry should be readily available for review and, if necessary, correction by the patient/parent/guardian.

Another issue is consolidation of patient records. Duplication of records in an electronic record system can be as high as 20%-50%. The need to search through multiple records to review all of a patient's data can increase the workload in a practitioner's office. Inappropriate recall or over-immunization can result if documentation of previous vaccinations cannot be located because records are stored under several identifiers. Poor data quality can decrease reliance on, and participation in, registries. Although a single, unique national health identifier would help overcome these problems, discussion of this topic yielded considerable controversy. Some people were concerned about the potential threat to patient privacy posed by such an identifier. Some contend that individuals may be uniquely identified by use of a collection of values (rather than a unique identifier) without posing a privacy risk. Because of uncertainty in this area, NVAC deferred this issue to appropriate national authorities under the auspices of HIPAA and other regulatory systems.

An immunization registry must have the technical capacity to correctly link records from all sources with existing records in the registry, while simultaneously correctly identifying new records. False matches and false unique records each create a different problem in assembling immunization histories. Automated matching and "deduplication" processes can handle 80-90% of a registry's records, but manual resolution of the remainder is required. All registries need to build in this technical capacity in order to ensure data integrity and instill confidence in the contents.

Resource Issues

Preventing disease through immunization is a priority public health issue. Leadership and (at least partial) funding for registries should come from government (local, state, federal). The federal government has taken the lead in coordinating the development of Healthy People Goals for 2000 and 2010 and has responsibility for the lead in developing approaches to registry funding. Such leadership carries with it the ability to set standards and ensure that registries are able to exchange information. It also carries the responsibility to assess the costs and benefits of registries compared to other approaches for achieving and maintaining high immunization rates.

Testimony during the hearings showed that several sources (e.g., private foundations, local, state, and federal governments, managed-care organizations, Medicaid) are currently supporting registry development and implementation. Participants generally agreed that those who benefit from registries (including patients, providers, and insurers) should also participate in their support. It is not currently possible to recommend a definitive approach for funding registries. Information is lacking on the initial and long-term costs of registry development and implementation, cost-effectiveness, and the consequences and costs of not developing registries. Participants advocated immediate data collection and continued deliberation on the optimum approach to registry funding. Additional investigation is also needed to determine if/how state and local health agencies can secure other sources of funding to partially or fully support their immunization registries.

Options to support the long-term operational costs of a nationwide network of registries include: continuing federal appropriations; imposing a vaccine surcharge on each antigen; or incorporating funding into the health-care financing system, with specific attention to evolving opportunities in the Children's Health Insurance Program (CHIP), the re-procurement of Medicaid Management Information Systems in many states, and the potential development of a Maternal and Child Health Information System. Preliminary consideration suggests that a surcharge on childhood vaccines might be the most equitable and stable source of support. It seems likely a combination of funding sources may turn out to be the long-term solution. Involvement of all stakeholders in considering funding sources will be critical.

The limited information available on registry costs includes a recent study of the 16 AKC II immunization registry projects. Findings indicate that the cost of maintaining immunization registries would be approximately $3.91/child/year, or approximately $78 million/year nationally to enroll all children and keep them in the registry through the first five years of life.[22] CDC has developed other estimates based on recent visits to three immunization projects (Florida, Oregon, San Antonio). Preliminary analysis indicates an average annual cost per child of $3.38-$6.15/year, translating to national costs of $67.6-$123.0 million/year. These studies also identified a range of funding sources for current registry efforts, including local and state governments, federal 317d funds, RWJF, Medicaid, and managed-care organizations.

Any analysis of registry costs should also include savings derived from registry use. In addition to savings related to prevention of vaccine preventable diseases, fully functional immunization registries can offset many costs presently being borne by patients, providers, and carriers, such as the costs of manual review of individual records. The AKC study queried five private-sector providers, who administer more than 100,000 immunizations each month, about the cost to manually retrieve and review an immunization record, provide the information to a nurse or physician, update the record, and refile it. The average cost per review was $14.50. This cost is equivalent to more than three times the average annual cost of maintaining a child in a registry. Since each child must have a record pulled and reviewed at least once for school entry, automatic generation of the records by registries would save approximately $58 million/year ($14.50 X 4 million children). In addition, 22% of American children see two immunization providers in their first two years of life and an additional 3% see three or more (S. Stokley, personal communication). Each change in provider necessitates a manual record pull and review (total annual cost approximately $16 million); these costs would also be offset by use of a fully functional immunization registry.

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

NVAC Recommendations

Vision

The **Vision** guiding these recommendations is **a nation with all children appropriately protected against vaccine-preventable diseases**.

Goal

The **Goal** of the recommendations is to outline the **policy directions and major steps needed to establish a nationwide network of community/state population-based registries that are capable of sharing information while maintaining privacy and confidentiality** that will provide the information necessary to achieve the vision and the Healthy People 2010 objective. Achieving this goal will require a series of actions to meet four primary objectives, which are closely related to the four issue areas addressed by the Workgroup on Immunization Registries. These recommendations address the major policy issues and action steps needed to carry out NVAC's recommendations and achieve the goal. Specific implementation plans with time lines will need to be developed for individual components. These implementation plans should be developed as soon as NVAC approves this report and be completed by the time the report is formally released. For each objective there are research needs and opportunities as well as need for evaluation and communications strategies. Some of these are mentioned.

Objectives, recommendations, and action steps

1. Ensure appropriate protections of privacy and confidentiality for individuals and security for information included in the registry.

NVAC Recommendations

1. Protection of privacy and maintenance of confidentiality are essential to the successful development of immunization registries. Registry developers must give careful consideration to privacy and confidentiality issues to reflect the values and special needs of the communities they serve.

2. Registry developers must give special consideration to the privacy and confidentiality needs of immigrant communities.

3. Federal legislation to establish a minimum set of privacy/confidentiality standards would be very helpful. To assist in the development of registries that can exchange data while also ensuring privacy and confidentiality, the federal

government should work with key stakeholders to develop and disseminate model privacy and confidentiality policies and legislation for registries.

4. At a minimum, immunization registries should:
   - Ensure that patients/parents are notified of the existence of the registry and of the information contained in the registry
   - Inform patients/parents of the purpose and potential uses of the registry
   - Permit patients/parents to review and amend information in the registry
   - Accept responsibility for reliability and protection of registry information

5. Parents must be given the option to decide whether or not their children will participate in a registry. In some communities, parents are informed of the registry and its purposes and potential uses during routine educational sessions offered at the birth hospital. At this time, or at any later time, parents should be allowed to opt out of a registry. In communities where the "opt in"/informed consent approach is most consistent with community values, this is the option that should be offered. Parents should not be penalized for choosing not to participate in a registry for religious, philosophical, privacy, or other reasons.

6. Registry developers should limit access to registry information and maintain audit trails to monitor access to records. Individuals should have access to their own records and to these audit trails.

7. Strong penalties for the unauthorized use of registry data should be in place and consistently enforced.

8. Use of registry data in a manner that is punitive to parents/patients (e.g., denial of health insurance/coverage, INS tracking of immigrants, other law enforcement purposes) must be prohibited.

9. If registries are to be integrated with larger health information systems, protection of privacy and confidentiality must be ensured.

10. The federal government should support an ongoing independent assessment of the benefits, risks, and costs of registry development and implementation with regard to issues including privacy and confidentiality.

Action steps

1.1 Develop specifications for minimum protections needed with specific guidelines on notification, parental choice, access, audit trails, law enforcement, etc. This should be completed within 90 days and should also address assuring legal authorization for state-to-state exchange of information.

- Convene a workgroup of representatives from NVAC, CDC, and the National Committee on Vital and Health Statistics (NCVHS) Subcommittee on Privacy and Confidentiality to design specifications. The NVAC-approved document on Confidentiality in Community Immunization Registries contains many of these specifications.

- Charge the workgroup to review new legislative proposals and determine if any fill the need (DHHS has already developed positions on existing legislative proposals). If so, develop a DHHS position paper to support that legislation. If not, propose changes that would make proposal(s) adequate, and convey these to congressional staff. The workgroup should also review and comment on any proposed regulations developed pursuant to HIPAA requirements.

1.2 Develop and disseminate a DHHS-approved policy statement on needed protections to guide states and communities until legislation is enacted. The statement could be based on the recent agreement between the Health Care Financing Agency (HCFA), HRSA, and CDC regarding exchange of information.

1.3 Each immunization registry should have a written policy and protocols on privacy and confidentiality consistent with the specifications in 1.1, and each user of the registry should sign an agreement to abide by the policy. Enforcement mechanisms should be in place and used.

1.4 CDC should continue to monitor privacy and confidentiality developments (including legislation) at state and local levels to identify new issues and to resolve existing issues.

2. Ensure participation of all immunization providers and recipients.

NVAC recommendations

1. Providers and interested community groups should be involved throughout registry development and implementation, beginning at the initial planning stages.

2. Registries should be simple to use and should be designed to minimize the administrative burden on providers. When possible, registries should capitalize on data already being collected and used in providers' practices for billing or other purposes thereby avoiding duplicate data entry. This could be done using billing or encounter information systems, although some modifications might be necessary to ensure data completeness and quality. Initial and subsequent

training should be provided; technical and non-technical support should be readily available.

3. Registries should include reminder/recall functions to improve adherence to recommended immunization schedules. Whether both reminders and recalls will be used will depend on local circumstances.

4. Data in immunization registries should be used to improve immunization services and immunization coverage; they should not be used to "punish" providers whose immunization coverage is low.

Action steps

2.1 CDC should take the lead in meeting with major professional organizations (including AMA, NMA, AOA, AAP, AAFP, ACP, ACPM, ATPM, ANA, AMIA, etc.)[e] and health agencies (including ASTHO, NACCHO, CSTE, ASTMCHD, NACHC, APHA, etc.)[f] to assess their needs and develop organizational/institutional support. Special attention should be paid to meeting with managed-care providers and purchasers of care (AAHP, HIAA, WBGH, PBGH, etc.).[g] This should be accomplished within 90 days.

2.2 State and local health agencies and CDC should work with parent, community, and professional organizations to develop educational materials for parents and patients.

2.3 State and local health agencies and CDC should work with professional organizations, health agencies, and managed-care representatives to develop educational materials for providers.

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[e]American Medical Association, National Medical Association, American Osteopathic Association, American Academy of Pediatrics, American Academy of Family Physicians, American College of Physicians, American College of Preventive Medicine, Association of Teachers of Preventive Medicine, American Nurses Association, American Medical Informatics Association, respectively.

[f]Association of State and Territorial Health Officials, National Association of County and City Health Officials, Council of State and Territorial Epidemiologists, Association of State and Territorial Maternal and Child Health Directors, National Association of Community Health Centers, American Public Health Association, respectively.

[g]American Association of Health Plans, Health Insurance Association of America, Washington Business Group on Health, Pacific Business Group on Health, respectively.

2.4 The Technical Working Group (see 3.1 and 3.2 below) should work with practice management vendors, third party payers, and other information system vendors to make registry use as simple as possible and to facilitate integration of registry functions into existing information systems.

2.5 CDC should monitor the level of provider and recipient participation, conduct research on effective means of ensuring participation, and share this information with registry partners.

3. Ensure appropriate functioning of registries.

NVAC Recommendations

1. CDC, in cooperation with state and local health agencies, provider groups, software/hardware vendors, and national standard-setting organizations, should take the lead in developing, implementing, and maintaining 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 on the same individual
- Enabling intra- and inter-registry record exchange with standard (e.g., HL7) messages
- Adopting system security standards to address both technical and administrative issues and to ensure that access is limited to authorized persons
- Certifying registry functions

2. The initial target group for inclusion in immunization registries should be children from birth through 5 years, although many registries will want to continue the registry beyond school entry and/or include other age groups (e.g., adolescents, older adults).

Action steps

3.1 CDC and other stakeholders, including state/local health departments, representatives of managed care, the NCVHS Subcommittee on Standards and Security, informatics associations, etc., should form a Technical Working Group to reach agreement on standard vocabularies and protocols for data transfer as well as other areas listed in recommendation 3.1. This should use information from current efforts and be accomplished within 90 days.

3.2 The Technical Working Group should develop benchmarks and protocols for accreditation or certification and provide ongoing quality assurance monitoring.

3.3 CDC should monitor the implementation of registries and provide technical assistance.

4. Ensure sustainable funding for registries.

NVAC Recommendations

1. CDC should immediately pursue further study to characterize start-up and maintenance costs of registries and compare these to costs of alternative systems. Information about the prospects for state and local health agencies to secure funding to partially or fully support their immunization registries should also be gathered and evaluated.

2. NVPO should coordinate discussions leading to a recommendation about appropriate mechanisms for long-term funding of registries.

3. A short-term (3-5 year) federal appropriation should be sought to support the further development and initial implementation of registries, with evaluation of costs and benefits an integral part of these efforts. This funding would provide time to establish a mechanism for long-term funding.

Action steps

4.1 CDC should complete reviews of selected registries to develop estimates of start-up and maintenance costs as well as estimates of costs that will be off-set by having functional registries in place. This should be accomplished within 30 days.

4.2 Based on these estimates, CDC should work with DHHS to develop and introduce a legislative proposal for a 5-year grant program to assist communities/states in the development and initial implementation of registries.

4.3 NVPO should convene a meeting of representatives of state/local health departments, vaccine manufacturers, health insurers, managed-care organizations, HCFA, professional organizations, etc., to deliberate the pros and cons of different funding mechanisms and to recommend approaches for long-term support.

4.4 CDC should continue to monitor the costs and benefits of immunization registries.

Glossary

AAFP - American Academy of Family Physicians
AAHP - American Association of Health Plans
AAP - American Academy of Pediatrics
ACIP - Advisory Committee on Immunization Practices
ACP - American College of Physicians
ACPM - American College of Preventive Medicine
AFIX - Assessment, Feedback, Incentive, eXchange
AKC - All Kids Count
AMA - American Medical Association
AMIA - American Medical Informatics Association
ANA - American Nurses Association
AOA - American Osteopathic Association
APHA - American Public Health Association
ATPM - Association of Teachers of Preventive Medicine
CDC - Centers for Disease Control and Prevention
CHIP - Child Health Insurance Program
CII - Childhood Immunization Initiative
COSSMHO - National Coalition of Hispanic Health and Human Service Organizations
DHHS - Department of Health and Human Services
ERISA - Employee Retirement Income Security Act of 1974
HCFA - Health Care Financing Administration
HEDIS - Health Plan Employers Data Information Set
HIAA - Hospital Insurance Association of America
HIPAA - Health Insurance Portability and Accountability Act of 1996
HL7 - Health Level 7
HRSA - Health Resources and Services Administration
MCH - Maternal and Child Health
MMIS - Medicaid Management Information System
NACHC - National Association of Community Health Centers
NCVHS - National Committee on Vital and Health Statistics
NIP - National Immunization Program
NMA - National Medical Association
NVAC - National Vaccine Advisory Committee
NVPO - National Vaccine Program Office
PBGH - Pacific Business Group on Health
PHS - Public Health Service
RWJF - Robert Wood Johnson Foundation
TFCPS - Task Force on Community Preventive Services
VFC - Vaccines for Children
WBGH - Washington Business Group on Health
WIC - Special Supplemental Nutrition Program for Women, Infants, and Children

References

1. Gangarosa EJ, Galazka AM, Wolfe CR, Phillips LM, Gangarosa RE, Miller E, Chen RT. Impact of anti-vaccine movements on pertussis control: the untold story. Lancet 351:356-361, 1998.

2. National Vaccine Advisory Committee. The measles epidemic. The problems, barriers, and recommendations. JAMA 266:1547-1552, 1991.

3. Centers for Disease Control and Prevention. National, State, and Urban Area Vaccination Coverage Levels Among Children Aged 19-35 Months--United States, 1997. Morbid Mortal Wkly Rep 47:547-554, 1998.

4. Shefer A, Briss P, Rodewald L, Bernier R, Strikas R, Yusuf H, Ndiaye S, Williams S, Hinman AR. Improving immunization coverage rates: An evidence-based review of the literature. Epidemiol Rev. In press.

5. Szilagyi PG, Rodewald LE, Humiston SG, et al. Immunization practices of pediatricians and family physicians in the United States. Pediatrics 84:517-523, 1994.

6. Anonymous. Recommendations of the Advisory Committee on Immunization Practices, the American Academy of Pediatrics, and the American Academy of Family Physicians: Use of reminder and recall by vaccination providers to increase vaccination rates. Morbid Mortal Wkly Rep 47:715-717, 1998.

7. Loeser H, Zvagulis I, Hercz L, Pless IB. The organization and evaluation of a computer-assisted, centralized immunization registry. Amer J Public Health 73:1298-1301, 1983.

8. Goldstein KP, Kviz FL, Daum RS. Accuracy of immunization histories provided by adults accompanying preschool children to a pediatric emergency department. JAMA 270:2190-2194, 1993.

9. Bushnell CJ. The ABC's of practice-based immunization assessments. Proceedings of the 28th National Immunization Conference. U.S. Dept. Health and Human Services, Washington DC, 1994, pp 207-209.

10. Yawn BP, Edmonson L, Huber L, et al. The impact of a simulated immunization registry on perceived childhood immunization status. Amer J Man Care 4:185-192, 1998.

11. Sinn JS, Kronenburg MA, Morrow AL. The purpose and functions of immunization information systems withing health care organizations. Arch Pediatr Adolesc Med 151:615-620, 1997.

12. Linkins RW, Feikema SM. Immunization Registries: The cornerstone of childhood immunization in the 21st century. Pediatr Annals 27:349-354, 1998.

13. Yawn BP, Edmonson L, Humber L, Poland G, Jacobson RM, Jacobaea SJ. The impact of a simulated immunization registry on perceived childhood immunization status. Am J Man Care 4;185-192, 1998.

14. National Vaccine Advisory Committee Subcommittee on Vaccination Registries. Developing a National Childhood Immunization Information System: Registries, Reminders, and Recall. Dept. Health and Human Services, Washington DC, 1994.

15. Cordero JE, Guerra FA, Saarlas KN, eds. Developing Immunization Registries: Experiences from the All Kids Count Program. Amer J Prev Med 13(suppl):1-128, 1997.

16. All Kids Count. Project Descriptions; All Kids Count II, September 1998. All Kids Count, Decatur GA, 1998.

17. National Vaccine Advisory Committee. Strategies to Sustain Success in Childhood Immunizations. Dept. Health and Human Services, Washington DC, 1998.

18. Dept. Health and Human Services. Healthy People 2010 Objectives: Draft for Public Comment. Washington DC, 1998.

19. Anonymous. Canadian Consensus Conference on a National Immunization Records System. Canada Commun Dis Rep 24(17), 1998.

20. Remarks by the President in announcement on immunization-child care, July 23, 1997. Available on the World Wide Web at: www.cdc.gov/nip/announce/clinton.htm

21. Sharp K, Edgar T, Fowler K. Findings of Focus Group Research on Immunization Registries (draft). Westat, Rockville MD, December 1998.

22. Horne, PR. Testimony on resource issues relevant to immunization registries. Presented at the National Immunization Registry Initiative public meeting, Atlanta GA, July 17, 1998.