
A Review of State Legislation Related to Immunization Registries

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Background: Since the early 1990s, a concerted effort has been made to develop community- and state-based immunization registries. A 1995 survey showed that nine states had laws specifically authorizing immunization registries. This survey was conducted to describe the current status of legislation and policies addressing immunization registries and the sharing of immunization information.

Methods: A telephone survey was administered from September 1997 to February 1998 to immunization program managers and/or their designees within the state health department of each of the 50 states and the District of Columbia. Some of the survey items were later updated through follow-up interviews and informal communications. Copies of legislation, administrative rules and regulations, and immunization registry policies were collected for review.

Results: As of October 2000, 24 of 51 states (47%) had laws (21) or rules (3) specifically authorizing an immunization registry. Nine additional states (18%) have laws specifically addressing the sharing of immunization information.

Conclusions: Over half of the states have enacted legislation or rules addressing registries or the sharing of immunization information. Further research should be conducted to assess the impact of this legislation on immunization registries.

Medical Subject Headings (MeSH): confidentiality, information systems, immunization, legislation, privacy, registries (Am J Prev Med 2001;20(3):208–213)

Introduction

Community- and state-based immunization registries are an important tool for ensuring that our nation's preschool children are adequately immunized to prevent disease.^{1,2} These computerized information systems consolidate immunization histories on a given population of children, thus making it possible to implement several proven strategies for increasing immunization rates.³ Such strategies include assessment of needed immunizations, measurement of immunization coverage levels, and provision of reminder and recall notices regarding children who are due or overdue for immunizations.⁴

A concerted effort to develop immunization registries in states and local communities has been underway since 1993.^{3,5} Although immunization registries are currently operating or planned in every state, few contain complete immunization histories on all chil-

dren for the targeted population or have the active participation of all providers.³

In 1998, the National Vaccine Advisory Committee (NVAC) work group identified the protection of privacy and confidentiality as critical to the successful development of community- and state-based immunization registries. Public testimony and findings from 21 parent focus groups indicate that parents and providers are concerned about the confidentiality of information in immunization registries. Despite these concerns, parents generally view registries as helpful in ensuring that their children are appropriately immunized.

In January 1999, the NVAC recommended the development of minimum specifications necessary for protecting the privacy of immunization registry participants and the confidentiality of the information contained in registries.⁶ These specifications, developed by an implementation team led by the Centers for Disease Control and Prevention (CDC), were approved by NVAC in February 2000.⁷

In 1995, nine states had laws specifically authorizing immunization registries.⁸ States are now using a variety of legislative approaches to protect privacy and confidentiality and increase provider participation in immunization registries. This article describes results from a

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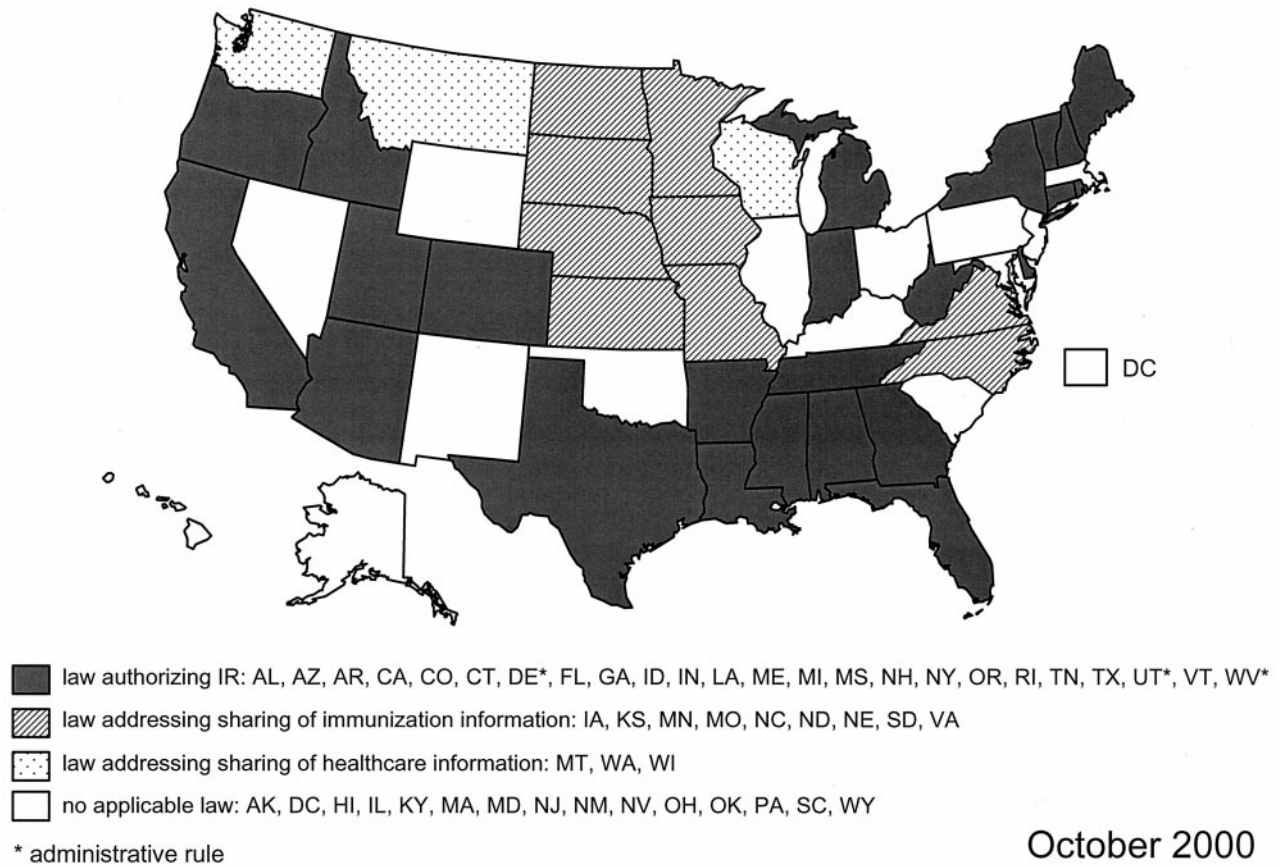


Figure 1. Status of state immunization registry legislation

survey conducted to update knowledge about state legislative strategies undertaken to address these concerns.

Methods

A survey designed to collect information on state legislation and policies addressing immunization registries and the sharing of immunization information was pilot tested in four states and New York City during the summer of 1997 and revised based on the responses to the pilot test. (For copies of the survey questionnaire, contact the corresponding author.)

One of the authors (GH), an attorney, conducted telephone interviews with immunization program managers, their designees, or both from state health departments in the remaining 46 states and the District of Columbia from September 1997 through February 1998. The survey was sent in advance for respondents to review. In this article, the District of Columbia is referred to as a state. New York City was not included in the analysis because the survey does not address city laws, ordinances, and health codes.

Copies of legislation, administrative rules, and immunization registry policies were collected for review. In September 2000, follow-up was done with the states that previously reported plans to introduce or amend registry-related legislation or administrative rules and with states that had not addressed certain questions asked at the time of the original survey. Those updated findings are incorporated here, as well as any additional changes of which we were aware at the time

of publication. (A table of survey results by state is available at www.cdc.gov/nip/registry.)

Results

Status of Immunization Registry–Related Legislation

As of October 2000, 24 of the 51 states (47%) have laws (21) or rules (3) that specifically authorize the establishment of an immunization registry (authorizing laws) and nine states (18%) have laws that address the sharing of immunization information (immunization information-sharing laws), but do not specifically authorize the establishment of an immunization registry. Three states (6%) have laws that allow the sharing of health care information without consent between providers involved in a patient's care (health care information-sharing laws); these laws do not refer to immunization information explicitly. The remaining 15 states (29%) currently do not have authorizing laws or rules, immunization information-sharing laws, or health care information-sharing laws (Figure 1). However, as of October 2000, at least three of these 15 states (20%) plan to introduce registry-related legislation. In addition, one state with an authorizing law and two states with immunization information-sharing laws plan to

amend existing legislation or introduce legislation specifically authorizing a registry. Note that the immunization registry–related legislation considered here is distinct from state laws governing the confidentiality of medical records.

Legislation Authorizing Immunization Registries

Of the 24 state authorizing laws and rules, 13 (54%) require the department of health to establish a registry (Arizona, Arkansas, Florida, Georgia, Idaho, Maine, Michigan, Mississippi, New Hampshire, Tennessee, Texas, Utah [rule], and West Virginia [rule]). The remaining 11 authorizing laws (46%) permit the establishment of a registry (Alabama, California, Colorado, Connecticut, Delaware [rule], Indiana, Louisiana, New York, Oregon, Rhode Island, and Vermont).

Mandated Reporting and Penalties for Failure to Report

Twelve (50%) of the 24 state authorizing laws or rules also mandate provider reporting to the registry. Providers are required by law to report immunizations to the registry in Arizona, Arkansas, Connecticut, Georgia, Maine, Michigan, Mississippi, Tennessee, Texas, Vermont, and by rule in Delaware and West Virginia. In Tennessee, reporting is mandatory only for public providers, and in Vermont, providers are required to report to the department of health. In eight of the 12 states with mandatory provider reporting (67%), parents or guardians may opt out of the registry or limit access to the information contained in the registry.

Reports indicate that even in states with mandatory reporting, not all providers are reporting to the registry. Only four of the 12 states (33%) with laws or rules that mandate reporting (Arizona, Arkansas, Michigan, and West Virginia [rule]) have laws or rules that contain penalties for failure to report to the immunization registry. There were no reports of sanctions being utilized.

Immunity Provisions

Eleven of the 24 states (46%) with authorizing laws or rules provide some type of immunity from civil and/or criminal liability for providers and other health care professionals who report information to (and in some cases, obtain information from) the registry in good faith. Some of these laws also provide immunity from liability for authorized persons in schools, child care facilities, and other entities.

Penalties for the Improper Disclosure of Information

Eight of the 24 state authorizing laws or rules (33%) contain penalties for the improper disclosure of infor-

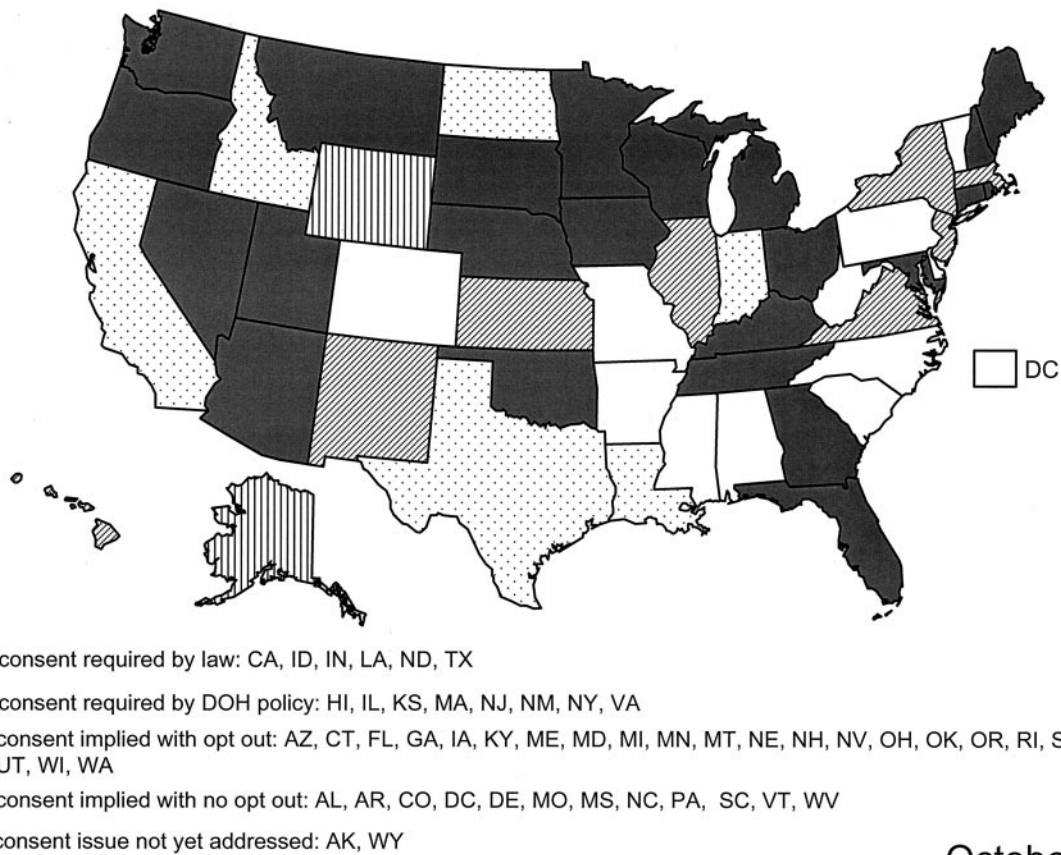
mation (Arizona, Delaware [rule], Idaho, Indiana, Michigan, Texas, Utah [rule], and West Virginia [rule]). Two of the nine state immunization information–sharing laws (22%) contain penalties for the improper disclosure of information (Nebraska and South Dakota). The improper disclosure of immunization registry information is frequently a misdemeanor; there may be civil and professional sanctions as well. Other state laws also contain penalties for the improper disclosure of confidential medical information (e.g., Rhode Island), and in states such as Georgia, computer fraud laws contain penalties for the improper use and disclosure of confidential information.

Consent

Parental or guardian consent for a child to be in an immunization registry or for their immunization information to be shared can be required by law or by immunization registry policy. The type of consent required varies. Of the 51 states surveyed, 14 states (27%) require explicit consent, and 35 states (69%) have implied consent to share information with registries. Two states (4%) are in such an early stage of development that they have not decided whether to use explicit or implied consent (Figure 2).

Required Written or Verbal Consent

Fourteen (27%) of the 51 states have laws or state health department policies that require childrens' parents or guardians to give explicit consent to participate in the registry. In some states, consent to share immunization information may include sharing with the department of health, schools, and daycare providers, in addition to health care providers. In six of the 14 states that require explicit consent (43%) (California, Idaho, Indiana, Louisiana, North Dakota, and Texas), consent is required by law, and in the remaining eight states (57%) the state health department policy requires consent (Hawaii, Illinois, Kansas, Massachusetts, New Jersey, New Mexico, New York, and Virginia). In all but two of the 14 states that require consent, written consent must be obtained. North Dakota law requires either verbal or written consent to share immunization information. California law requires verbal consent, and that the health care provider must first disclose to the parent or guardian certain information including what information would be shared, with whom, and under what circumstances, should the parent or guardian give consent for this information to be shared with the registry. In many states, even when consent is obtained, access to demographic data is controlled, and only immunization data are released.



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Figure 2. Overview of consent requirements

Implied Consent

In 35 (69%) of the 51 states, consent to be in the registry or to share immunization information is implied, i.e., that is, a child's immunization information is included in the registry and/or shared without explicit authorization by a parent or guardian. In 23 of these 35 states (66%), there are provisions that allow parents to either opt out of the registry or to limit access to the information contained in the registry. In 12 of these 35 states (34%), there are currently no provisions to opt out or to limit access to the information contained in the registry; thus, participation is mandatory. However, at least three of these 12 states are considering implementing an opt-out mechanism.

The means of opting out varies; the process may entail a verbal request, a telephone call, or a signature on a vaccine administration form. In some states, if a parent chooses to opt out of the immunization registry, the information stays in the provider's office, and no immunization information is shared with the department of health or any community, regional, or state-wide database. In other states, if a parent chooses to opt out of the registry, the immunization data remain in the centralized registry, but access to the information is limited or not allowed.

Notification

States that inform parents that their child's immunization information will be in the registry, or that it will be shared, or both, are said to provide notification. As of October 2000, 35 of the 51 states (69%) provide notification or are planning to provide it when their registries are operational. Thirteen of the 51 states surveyed (25%) do not currently provide notification, and the remaining three states (6%) have not yet addressed the issue of notification.

Notification about the registry may be required by law or policy. The form and type of notification differ by state. In 14 of the 35 states (40%) that provide or plan to provide notification, required written or verbal consent serves as notification. In the remaining 21 states (60%) that provide or plan to provide notification, consent is implied and the form of notification varies. Only five of the 35 states (14%) explicitly require notification by law (California, Idaho, Tennessee, Texas, and Utah [rule]). In all of these cases except Utah, consent serves as notification. Other types of notification include verbal notice by a health care provider, a sign posted in the provider's office, a statement on the vaccine administration form, or a letter or brochure provided to parents.

Discussion

Health care providers have traditionally shared immunization information among themselves on a need-to-know basis. Changes in the health care delivery system and the widespread use of electronic information systems have increased patients' concerns about confidentiality and providers' concerns about liability for the improper disclosure of confidential information. Whether they have been operating registries for many years or are just beginning registry development, states reported the need for laws or administrative rules to provide clear legal authority to operate an immunization registry, ensure provider participation in the registry, protect confidentiality, and address providers' liability concerns.

Not all states perceive a need for registry-related legislation. Several states reported that broad public health disease reporting and prevention laws provide sufficient legal authority for registry operation. Several other states reported that they prefer to avoid legislation, particularly legislation mandating reporting to the registry, until it is clear that funding is secure and that voluntary provider participation is insufficient.

Some limitations in legislation may not be apparent until after the legislation has been enacted and interpreted. For example, legislation allowing providers to exchange immunization information may be interpreted to exclude schools; Women, Infant, and Children (WIC) nutrition programs; managed care organizations; or the health department because these entities may not be considered providers under the law if they do not provide direct service. At least three states that had authorizing laws at the time of the original survey have since amended these laws. Colorado amended legislation to enable schools, managed care organizations, and other entities to report information to the registry. Tennessee amended its law governing the release of medical records to give providers immunity from liability for good faith reporting to the registry and to require notice of inclusion in the registry and an opt-out mechanism. California amended legislation twice, to allow for two-way communication among sharing partners including schools, child care centers, WIC, health plans, and the county welfare department. In addition, North Carolina amended rules for its immunization information-sharing law to allow health maintenance organizations and other state and local health departments to get access to information.

State legislation and policies addressing notification about the registry and choice about participation in the registry should be consistent with the principles of "fair information practice" that were developed in 1973 and continue to be important today.⁹ In California, the prototype language required by law for health care providers' disclosure to patients, parents, or guardians

on immunization record sharing incorporates these principles.

Notification is an important aspect of fair information practice. The 1999 NVAC recommendations state that patients and parents should be notified of the existence of the registry and the information contained in it, and of the purpose and potential uses of the registry.⁶ In light of the increasing emphasis on the right of individuals to be informed, it is noteworthy that as of October 2000, only 35 states (69%) provide or plan to provide notification of inclusion in the registry or of the sharing of immunization information. Three additional states have not yet addressed the issue of notification.

The NVAC report also recommends that parents be given the option to decide whether their children will participate in a registry. States provide the opportunity to exercise choice through explicit consent, or implied consent with opt-out mechanisms, or the right to limit access to information contained in the registry. As of October 2000, 12 states with implied consent do not currently provide such options and thus mandate participation.

Several state immunization registry program managers reported that the ability to make an informed choice about participation in an immunization registry is particularly important to members of certain religious groups and others who are concerned about tracking systems, or outreach efforts, or both, to ensure widespread immunization against disease. Anecdotal information suggests that only a small proportion of people (e.g., "less than 1%," "none in 4 years") actually exercise options to opt out of immunization registries or do not consent to participate.

At this date, the impact of the proposed federal privacy regulations (published in November 1999 pursuant to the Health Insurance Portability and Accountability Act of 1996) on immunization registries is uncertain as the final regulations have not been published.¹⁰ Furthermore, Congress can still enact legislation to protect the privacy of health care information at any time. If Congress enacts legislation based on Secretary Shalala's 1997 recommendations to Congress, such legislation will not pre-empt stricter state laws.¹¹ The interstate exchange of immunization information would continue to be a problem, as states with strict statutory protections may not be able to share immunization data with states with less stringent safeguards.

This survey, with anecdotal updates, is not a comprehensive review of the law. It applies only to state laws and registries operated at the state level, and reflects self-reported information. Biases inherent in self-reported information were minimized through the collection and review of state legislation, rules, and policies. Some community-based registries are also governed by local laws, rules, ordinances, and policies not addressed here.

Since 1995, states have participated in extensive

legislative and policy-making activity around the authorization of immunization registries and the sharing of the information contained therein. Almost three times as many states now have immunization registry authorizing laws as did in 1995. The variety of legislative and policy-based approaches mirrors the variation in the development of immunization registries themselves. It will be important to continue to monitor registry-related legislation and policies to determine the impact of such legislation and policies on immunization registry development and the protection of confidentiality.

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