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Childhood immunization reporting laws in the United States: Current status

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ABSTRACT

Context: Immunization Information Systems (IIS), or registries, were developed to improve effectiveness and efficiency in immunization services. Complex laws that govern IIS and immunization records are developed at the state-level, interact with each other, and may impact utility for all immunization stakeholders. As states develop Health Information Exchange laws they may also interact with IIS laws.
Objectives: To provide immunization stakeholders an overview of the laws applicable to healthcare providers and health departments. Comparisons are provided to illustrate the trends since the previous studies.
Methods: IIS relevant statutes, regulations and ordinances of jurisdictions (states, large cities) of 56 "Grantees" receiving funding under the 317b Public Health Service Act were identified via legal databases then systematically reviewed for authorization, reporting and consent requirements. Key provisions were coded and mapped according to 131 variables.
Results: Including subsections, 984 laws across Grantees relate to immunization records, falling under many administrative sections of state and city government. Most Grantees have more than one law that addresses immunization records reporting, exchange and privacy protections. Not all of these laws are in alignment, but there is a trend toward increased Grantee IIS authorizing laws, mandated reporting and implied consent provisions. Of the 56 Grantees, 37 (66%) had IIS authorizing laws, and 46 (82%) had laws addressing healthcare provider and vital statistics reporting. However, much variation remains, even within the provisions of these laws. The coding instrument received 93.7% agreement and a K-α of 0.791.
Conclusions: The trend toward laws that encourage participation should continue to improve functionality and value, but inconsistencies among laws should be addressed, both across jurisdictions within states and between different states. They may impair the value of the information that is collected. Greater uniformity could improve the overall usefulness of IIS.

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1. Introduction

The 87–99% reduction in most vaccine-preventable infections in U.S. children demonstrates the dramatic success of immunizations on public health [1–4]. A supportive, but complex, immunization infrastructure including public health laws is associated with the high vaccination levels responsible for much of this success [5,6]. Ongoing challenges to this success include: complexity of the immunization schedule, expense, privacy and safety concerns, and family mobility and recordkeeping requirements [7]. In recognition, the Institute of Medicine National Vaccine Plan included the following directive: "[m]aintain and enhance the capacity to monitor immunization coverage for vaccines..." [8] Efficiency, accessibility and accuracy of recordkeeping requires the cooperation of multiple stakeholders: parents, public and private healthcare providers, school officials, public health officials, and insurance companies [9,10].

Immunization Information Systems (IIS) were devised to help meet complex immunization and recordkeeping challenges. IIS, or immunization registries, are "confidential, computerized information systems that collect and consolidate vaccination data from multiple health-care providers..." [11] including schools, hospitals and other institutions that provide immunizations and existing immunization histories [12]. Health departments and other state and local agencies typically implement IIS [13], which may include vital records information (e.g., births). IIS can improve the accuracy of records and timeliness of care [14–16]. State and local public health departments can use IIS for surveillance, program evaluation, and targeted reduction of vaccine-preventable diseases [17]. Parents can request copies of their child's immunization records

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for medical or school purposes. IIS can improve efficiency and care delivery through clinical decision support and save administrative effort, generating patient reminders and health department or insurance plan reports [18–21], and facilitate the examination of trends and program needs.

National efforts to develop IIS increased in 1993 with federal funding for IIS development [22,23]. *Healthy People 2010* and *2020* goals included >95% participation in IIS of children aged 0–6 years [24,25]. Additionally, the Centers for Medicare & Medicaid Services provide financial incentive for IIS use.

While need for national-level records has been suggested [26], in the United States the power to protect public health and safety is reserved primarily for the states [27]. This means each state's legislature or regulatory body passes its own statutes or regulations, respectively, governing IIS creation, implementation, and maintenance. Local governments may also pass ordinances governing health practices. The result is a patchwork of IIS-related statutes, regulations and ordinances (henceforth "laws") [28,29] with wide variation across states and localities each shaped by unique political and ideological characteristics [30–34].

IIS authorizing laws are not required for creation of an IIS. However, laws that guide IIS creation and use could result in improved IIS utility; authorizing or requiring reporting, facilitating exchange among defined groups, and providing safeguards for patient privacy, while protecting physicians from liability for reporting.

In practice, healthcare providers have expressed confusion about their legal IIS obligations and liability, which has served as a barrier to IIS participation [22,35–37]. The growth in Health Information Exchanges (HIEs) which offer the means to share health data more broadly may increase confusion as new HIE laws interact with existing IIS/immunization records laws.

Examinations of immunization record laws conducted in 1995 and 2000 show growth in the number of states (from 7 to 24) with laws related to IIS, but with wide variation among the laws, particularly provisions for consent, data reporting, access and use [35,38]. More than a decade has passed since the previous two studies. The 1995 study conducted research of any law pertaining to immunization records. The 2000 study used a different methodology, a survey of state IIS managers. It also focused specifically on IIS laws. Neither study included city-level localities operating federally supported immunization programs. The present study used a methodology similar to the 1995 study, but with a few differences including use of a codebook and the Delphi method to inform it. The objectives of the present study were to provide stakeholders a foundational overview of their current applicable laws and to identify some of the changes in provisions over time, as available and appropriate.

2. Materials and methods

The unit of analysis, the Grantee, is a geopolitical unit receiving federal funding for vaccines under section 317b of the Public Health Service Act [39]. Fifty-six Grantees are included in this study (50 states, five cities, and the District of Columbia). IIS-related "laws" for the purposes of this study included statutes and regulations in the jurisdictions of Grantees. These laws were obtained in 2010 and 2011 through systematic searches of legal databases and library holdings. The initial search included IIS and immunization records. If no law within the locality referenced IIS or immunization records, health records laws were used and noted as such. Otherwise, only laws that specified IIS or immunization records were collected. The only HIE laws that were collected include: (1) those that referenced immunization records or IIS or (2) when HIE was the only appropriate law. Otherwise, HIE is not examined. This study captured immunization records laws that pertain to both health and education records. However, those that apply to schools and school nurses, were not included in this analysis.

Grantee constitution and case laws were excluded given that constitutions were unlikely to be modified for IIS, and no legal cases, based on a claim related to an IIS, were found. Laws exclusive to adult IIS were excluded. This empirical study followed the manifest content analysis method, analysing for visible and obvious components in a text [40–45].

Content analysis was conducted using a codebook developed for this study. Previous studies of IIS and public health law [35,38,46,47] and the Alcohol Policy Information System database criteria [48] informed codebook categories. Experts in IIS, including authors of the previous two IIS laws studies, IIS managers, and representatives from the American Immunization Registry Association, were consulted in developing the categories and definitions. It was finalized via the Delphi method [49,50]. The categories included: (1) authorization of IIS creation, (2) adoption of the Model Interstate Immunization Information Sharing Statute [51], (3) immunization reporting and health department access, (4) penalties and enforcement, and (5) notification and consent. Three independent coders assessed the reliability of the resultant 131 variable coding instrument (agreement percentage = 93.7% and K-α = 0.791).

3. Results

A sizeable number of laws (396 combined for coding purposes or 984 including all laws and subsections) across Grantees related to immunization records [52]. As many as 38 provisions (17 if collapsed for coding purposes) of statutory and regulatory law per Grantee, some well over 100 pages in length, were identified. These were categorized under many government departments and topic headings: administration, children and family, civil, criminal, education, environment, health, insurance, licensing, Medicaid, professions, records, and workforce. Laws specific to IIS are primarily known as "authorizing laws," which establish and define the use of IIS. Other types of laws had IIS or immunization records provisions. Results presented here focus on healthcare providers and health departments.

No Grantee had adopted the Model Interstate Immunization Information Sharing Statute developed by Every Child By Two and Department of Health Policy at George Washington University [51], to assist the states in sharing information across state lines. Four Grantees (Alaska, Minnesota, Oklahoma and Texas) had medical records laws mentioning HIEs. Of the Grantees with HIE laws, Washington's HIE law referenced IIS specifically.

3.1. IIS authorization

Authorizing laws can *permit* (using words offering a choice, such as "may") or *require* (using words implying no choice, such as "must") a health department to create an IIS. Fig. 1 shows Grantee adoption of IIS authorizing laws in 1995, 2000 and 2010. The percentage of Grantees with authorizing laws increased over time from 25% (13 of 52) in 1995 [38] to 47% (24 of 51) in 2000 [35] and to 66% (37 of 56) in 2010.

Health departments (e.g., Kansas or Ohio) may develop an IIS without an authorizing law [53]. In such cases, legal status is based on other public health laws governing immunization records and reporting (if available) and federal privacy laws.

3.2. Reporting and access

Laws can also authorize or require immunization providers to report immunizations to their health department or IIS, as well as allow health department access to these records. As Fig. 2

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