

Immunization Information Systems to Increase Vaccination Rates: A Community Guide Systematic Review

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Context: Immunizations are the most effective way to reduce incidence of vaccine-preventable diseases. Immunization information systems (IISs) are confidential, population-based, computerized databases that record all vaccination doses administered by participating providers to people residing within a given geopolitical area. They facilitate consolidation of vaccination histories for use by health care providers in determining appropriate client vaccinations. Immunization information systems also provide aggregate data on immunizations for use in monitoring coverage and program operations and to guide public health action. Evidence **Acquisition:** Methods for conducting systematic reviews for the Guide to Community Preventive Services were used to assess the effectiveness of IISs. Reviewed evidence examined changes in vaccination rates in client populations or described expanded IIS capabilities related to improving vaccinations. The literature search identified 108 published articles and 132 conference abstracts describing or evaluating the use of IISs in different assessment categories. Evidence Synthesis: Studies described or evaluated IIS capabilities to (1) create or support effective interventions to increase vaccination rates, such as client reminder and recall, provider assessment and feedback, and provider reminders; (2) determine client vaccination status to inform decisions by clinicians, health care systems, and schools; (3) guide public health responses to outbreaks of vaccine-preventable disease; (4) inform assessments of vaccination coverage, missed vaccination opportunities, invalid dose administration, and disparities; and (5) facilitate vaccine

J Public Health Management Practice, 2014, 00(00), 1−22 Copyright © 2014 Wolters Kluwer Health | Lippincott Williams & Wilkins management and accountability. **Conclusions:** Findings from 240 articles and abstracts demonstrate IIS capabilities and

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Names and affiliations of Task Force members are available at www .thecommunityguide.org/about/task-force-members.html.

We gratefully acknowledge the team of consultants, referred to as the "team," who helped us form the framework and research questions, and establish criteria for included studies for this review. We are also grateful to the CDC Immunization Information System Support Branch for the subject matter expertise they provided, and to Gary Edgar for his support throughout the review process. In addition, the authors thank Dr Robert Menzies, from the National Centre for Immunisation Research and Surveillance of Vaccine Preventable Diseases (NCIRS) at the University of Sydney, for his input on the sections pertaining to the Australian Childhood Immunisation Register.

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention

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The authors declare no conflicts of interest.

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DOI: 10.1097/PHH.00000000000000069

actions in increasing vaccination rates with the goal of reducing vaccine-preventable disease.

KEY WORDS: immunization registry, immunization information systems, systematic review, vaccination

Context

Immunizations are among the top 10 great public health achievements of the 20th century for their success in realizing substantial declines in cases, hospitalizations, deaths, and health care costs associated with vaccine-preventable diseases. In the United States, population-based vaccine delivery requires collaboration of public and private health care providers with local, state, and federal governments and public health agencies. Efforts to achieve and maintain high levels of vaccine coverage in the population require implementation and coordination of a wide range of public policy, health system, and community-based interventions.

Ensuring well-coordinated activities to foster high immunization coverage levels is dependent on the availability of timely, accurate, and complete information pertaining to vaccinations received by members of a population.4 Immunization information systems (IISs) provide a potentially powerful tool to allow collaboration between vaccination providers and public health agencies and for coordination of populationbased interventions. They are confidential, populationbased, computerized databases that record all vaccination doses administered by participating providers to people residing within a given geopolitical area.5 At the point of clinical care, an IIS can provide consolidated immunization histories to assist vaccination providers in determining appropriate client vaccinations. At the population level, an IIS provides aggregate data on vaccinations for use in assessments of coverage and program operations and in guiding public health action to improve vaccination rates.

The development of IISs in the United States, which began in the 1970s, has been spurred by funding from federal, state, and private institutions and aided by policy recommendations and program standards disseminated by the National Vaccine Advisory Committee since 1999.⁶ The Centers for Disease Control and Prevention (CDC) makes annual revisions to the IIS Functional Standards based on input from a variety of technical experts, which are disseminated to IIS partners, nationally (http://www.cdc.gov/vaccines/programs/iis/func-stds.html). In 2011, 55 of 56 US state and city immunization grantees used an IIS.⁵

Since 2001 in the United States, a subset of IISs with higher levels of child participation and provider site reporting has participated in a collaboration with the CDC as part of the "IIS Sen-

tinel Site Project" both to conduct populationbased vaccination studies using IIS data and to implement systematic data quality improvement activities (http://www.cdc.gov/vaccines/programs/ iis/activities/sentinel-sites.html). From 2001 to 2003, 8 IISs (Arizona, District of Columbia, Michigan, New York City, Oklahoma, Oregon, San Antonio, and Utah) participated in a pilot project. Sentinel Site grant funds were awarded to 6 sites (Arizona, District of Columbia, Michigan, Minnesota, Montana, and Oregon) for the 2004-2007 project period, 7 states (Arizona, Colorado, Michigan, Minnesota, North Dakota, Oregon, and Wisconsin) and 1 city (New York City) for the 2008-2012 project period, and 6 sites (Michigan, Minnesota, North Dakota, New York City, Oregon, and Wisconsin) for the 2013-2017 project period. Sentinel Site grant funds were awarded on the basis of established data quality measures including:

- 85% or more of children younger than 19 years have 2 or more immunization records in the IIS;
- 85% or more of vaccine provider sites are enrolled in the IIS; and
- 70% or more of vaccine doses administered in the Sentinel Site area are submitted to and processed by the IIS within 30 days of administration.

A number of countries, including Australia, Canada, Denmark, Italy, the Netherlands, New Zealand, Norway, Scotland, Sweden, and the United Kingdom, in addition to the United States, have implemented stand-alone IISs or incorporated vaccination data into a more comprehensive medical record system. One stand-alone IIS with capabilities and activities similar to US systems is the Australian Childhood Immunisation Register (ACIR) (http://www.humanservices.gov.au/customer/services/medicare/australian-childhood-immunisation-register). The ACIR is a national register administered by Medicare Australia that covers children younger than 7 years, with participation rates at 99%.⁷

Considerable costs are associated with IISs, because the systems require time and effort of participating vaccination providers, as well as ongoing staffing and financial support from state and federal partners. As both programs and providers work to balance the utility and value of IIS with these infrastructure and participation costs, an assessment of IIS capabilities and effectiveness in improving immunization rates and preventing vaccine-preventable disease is especially important.

Evidence Acquisition

Community Guide methods (http://www.thecommunityguide.org/about/methods.html) were used to

conduct this systematic review to determine the effectiveness of IIS in increasing vaccination rates, reducing vaccine-preventable disease, or enhancing vaccination program capabilities.8 Briefly, a coordination team* ("the team") was constituted, including subject matter experts from various agencies, organizations, and academic institutions, together with qualified systematic reviewers. For this review, the team included CDC staff from Immunization Information Systems Support Branch in the National Center for Immunization and Respiratory Diseases, CDC field staff, immunization staff working at state health departments, and individuals within academic institutions and health care systems. The team worked under the oversight of the Community Preventive Services Task Force (Task Force), an independent, nonfederal, unpaid panel of public health experts.

For each Community Guide systematic review, the team (i) establishes a conceptual approach to assess the evidence of effectiveness of a given intervention in improving health at the population level; (ii) develops an analytic framework depicting interrelationships among interventions, populations, and outcomes; (iii) systematically searches for and retrieves evidence; (iv) evaluates the strengths and limitations of the body of evidence; (v) summarizes the evidence on effectiveness and calculates summary measures, if possible, for health-related outcomes; (vi) concludes on public health benefits from the intervention of interest; (vii) summarizes information on applicability (ie, the extent to which conclusions are generalizable to diverse population segments and settings in the US context), economic impact, additional benefits, potential harms, and considerations for implementation; and (viii) identifies important evidence gaps.

The Task Force considers results from the review process taking into account the population-level importance of the overall body of evidence, effect estimates, and supporting information to reach consensus conclusions on recommendations for public health practice and policy. Task Force options include recommending the use of an intervention (practice or policy), recommending against use, or finding that evidence available is insufficient to determine effectiveness.

Conceptual approach and analytic framework

The analytic framework (Figure) postulates the impact of IIS on a wide range of vaccination provider and public health outcomes. Based on timely and complete reporting from vaccination providers, IISs maintain consolidated immunization histories, which can be retrieved in clinical settings to determine appropriate vaccinations for clients. IISs have the ability to support providers through provider reminder functions (also referred to as clinical decision support systems for *immunizations*, or CDSi), generation of reminder/recall notices for clients, and provision of data to support assessment and feedback interventions efficiently. School systems can use IIS records to determine whether students meet entry requirements. At the population level, IISs can be used to assess local vaccination coverage levels or to assist during disease outbreaks, public health emergencies, or vaccine shortage situations to identify individuals in need of vaccination. In addition, IISs can be used in vaccine management and accountability, in tracking of vaccine safety issues, and in the evaluation of vaccine effectiveness.

In this review, IISs were also considered for their ability to support additional vaccination-related interventions and to enhance or expand vaccination program capabilities. These included 3 interventions previously reviewed and recommended by the Task Force on the basis of evidence of effectiveness in increasing vaccination rates:

- Client reminder and recall notices, disseminated either through mail or by phone, used to remind members of a target population that vaccinations are due (reminders) or late (recall).
- Provider assessment and feedback, which involves, retrospectively, evaluating the performance of providers in delivering 1 or more vaccinations to a client population and giving providers feedback on their performance.
- Provider reminder systems (or CDSi), used to prompt providers about due or past due vaccinations for a client being seen.

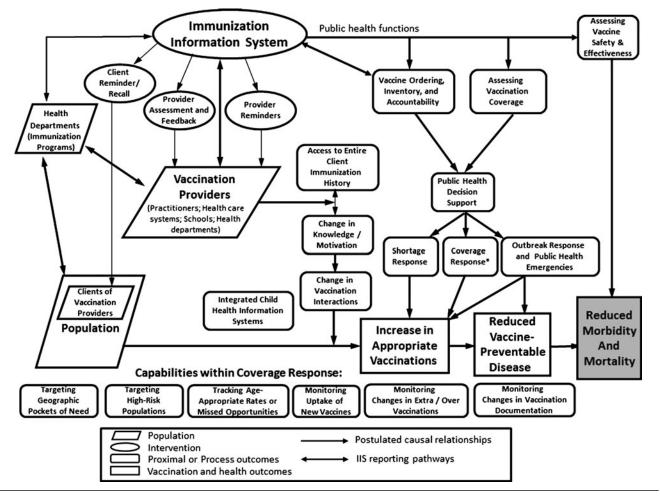
Each of these interventions was found to be effective as a stand-alone intervention (http://www. thecommunityguide.org/vaccines/index.html); review, however, assessed effectiveness of implementing each intervention through the use of an IIS or a population-based vaccination database.

Research questions

The review team generated the following research questions for this review:

^{*}Members of the review team were Diana Bartlett, CDC; Ned Calonge, The Colorado Trust; Rebecca Coyle, American Immunization Registry Association (AIRA); Kevin Dombkowski, University of Michigan; Amy Groom, CDC field staff assigned to Indian Health Services; Joe Hagan, Pediatrician; Mary Beth Kurilo, Oregon Immunization Program; Bobby Rasulnia, CDC; Sue Scholz, Aurora Health Care; Timothy Van Wave, CDC; Pascale Wortley, CDC; Jane Zucker, CDC field staff assigned to New York City's Department of Health and Mental Hygiene.

FIGURE Analytic Framework for Review of IISs, Which Postulates the Impact of IIS on a Wide Range of Vaccination **Provider and Public Health Outcomes**



IIS indicates immunization information system.

- 1. How effective are IISs in creating or supporting interventions to increase vaccination rates or reduce vaccine-preventable disease?
- 2. Do IISs effectively support public health efforts to determine client vaccination status to inform decisions by clinicians, health care systems, and schools?
- 3. Do IISs effectively support public health responses to outbreaks of vaccine-preventable disease?
- 4. Do IISs inform assessments of vaccination coverage, missed vaccination opportunities, invalid dose administration, and disparities?
- 5. Do IISs facilitate vaccine management accountability?

Search for evidence

The following databases were searched for this review: The Cochrane Library; MEDLINE; CINAHL; PsycINFO; ERIC; Sociological Abstracts; Web of Knowledge; EMBASE; and CAB International. The search period was January 1994 to April 2011. Details of the search strategy are available (see the Appendix). Reference lists of retrieved articles and reviews were also searched, and subject matter experts were consulted to identify studies that might have been missed.

The team also decided to include an assessment of unpublished US literature, in the form of conference abstracts, in order to capture more recent information about how IISs are being used to support vaccination-related interventions and expand vaccination program capabilities in the United States. Abstracts presented at 4 selected conferences (Immunization Registry Conference; National Immunization Conference; Pediatric Academic Society; Vaccine University) in the United States in the period from January 2002 to April 2011 were screened and relevant evidence was included in this review. Because abstracts, in general, provided only summaries of

information typically evaluated as part of the Community Guide assessment of study quality of execution, the team decided not to conduct quality assessments of included studies in this review in favor of an overall assessment of limitations in the included evidence.

Inclusion criteria

To qualify as a candidate for inclusion in this review, a study had to:

- Evaluate the effectiveness of an IIS or populationbased vaccination database, or the effectiveness of an intervention generated from an IIS, or describe an IIS capability linked to increasing vaccination rates or reducing vaccine-preventable disease.
- Be conducted in a high-income country,* be a primary research publication or US conference abstract, and be published in English.
- Report 1 or more quantitative outcomes (changes in vaccination rates, coverage, or uptake; reductions in missed opportunities) or describe system capabilities linked to increasing vaccinations or reducing vaccine-preventable disease.

Included studies focused on IISs or other population-based vaccination databases intended to consolidate immunization data from all participating providers in a geographic area. This review did not include studies evaluating encounter-based data systems and electronic health records (EHRs) as primary data sources based on team and Task Force concerns about applicability of that evidence to current IISs.

Assessing and summarizing evidence on effectiveness

Each study that met the inclusion criteria was read by 2 reviewers who used standardized criteria to abstract study details and assess the suitability of study design.8 Uncertainties and disagreements between reviewers were reconciled by consensus among review

team members. Studies that collected data on exposed and comparison populations prospectively were classified as having the greatest design suitability. Those that collected data retrospectively or lacked a comparison group, but conducted multiple pre- and postmeasurements on their study population(s), were rated as having moderate design suitability. Studies with least suitable designs were cross-sectional studies and those that involved only a single pre- or postmeasurement in the intervention population, as well as studies providing descriptions of program capabilities or the use of an IIS for vaccination-related decisions by clinicians, health systems, schools, and public health agencies.

Studies meeting inclusion criteria were categorized into appropriate evidence categories, described later, for abstraction and assessment. Articles providing unique effect estimates or descriptions of program capabilities were considered as distinct studies within this review, even when the information came from an evaluation of the same immunization information system or vaccination database. Most study findings were organized and summarized in a narrative format. In a few categories, studies provided quantitative measurements of change in vaccination rates, and for this evidence, effect estimates were calculated as absolute percentage point change and summary estimates included the median effect estimate and the interquartile interval.

Economic Evaluation

An independent Community Guide review of the economic evidence regarding IISs was carried out. Findings are described elsewhere (Patel et al, in press, 2014).

Evidence Synthesis

Body of evidence of included studies

The review included 108 published articles and 132 conference abstracts for a total of 240 studies in 9 assessment categories:

- 1. Overall effects on vaccination rates;
- 2. Assessments of IIS-supported interventions to increase vaccination rates;
- 3. Use of IIS in vaccination-related decisions by clinicians, schools, and health care systems;
- 4. IIS-supported outbreak and public health emergency responses;
- 5. IIS for vaccine ordering, inventory, and accountabil-
- 6. IIS to assess vaccine safety and effectiveness;
- 7. IIS as a tool for public health decision support;

^{*}Countries with high-income economies as defined by the World Bank are Andorra, Antigua & Barbuda, Aruba, Australia, Austria, The Bahamas, Bahrain, Barbados, Belgium, Bermuda, Brunei Darussalam, Canada, Cayman Islands, Channel Islands, Cyprus, Denmark, Estonia, Faeroe Islands, Finland, France, French Polynesia, Germany, Greece, Greenland, Guam, Hong Kong (China), Iceland, Ireland, Isle of Man, Israel, Italy, Japan, Republic of Korea, Kuwait, Liechtenstein, Luxembourg, Macao (China), Malta, Monaco, the Netherlands, Netherlands Antilles, New Caledonia, New Zealand, Norway, Portugal, Puerto Rico, Qatar, San Marino, Saudi Arabia, Singapore, Slovenia, Spain, Sweden, Switzerland, Trinidad and Tobago, United Arab Emirates, United Kingdom, United States, and Virgin Islands (United States).

- 8. IIS integrated with other child health information systems; and
- 9. IIS as contributing to change in documentation.

Sixteen articles had study designs of greatest suitability, and the remaining 224 studies had moderate (n=36) and least (n=188) suitable designs. Most studies (n=209) evaluated systems in the United States, 26 studies examined the national system in Australia, and 5 studies evaluated other national systems. Of the US studies, 108 articles (52%) described actions and capabilities of systems within the IIS Sentinel Site program (http://www.cdc.gov/vaccines/programs/iis/activities/sentinel-sites.html).

Effectiveness

Overall effects on vaccination rates

Two studies, both of least suitable designs, evaluated the association of IISs with changes in vaccination rates.^{9,10} The first study documented changes in vaccination rates among children following implementation of the ACIR in 1996.9 Following the linkage of ACIR participation with parental and provider financial incentives in 1998 and inclusion of immunizations administered overseas in 2001, reported rates for full immunization among children aged 24 months in Australia increased from 64% in 1997 to 92.7% in 2007. The second article, a cross-sectional study conducted in the United States, evaluated the association between practice use of an IIS and likelihood of children being up-to-date. Practices using an IIS between 2004 and 2006 did not have significantly higher coverage levels than those practices not using an IIS.¹⁰

Assessments of IIS-supported interventions to increase vaccination rates

The search identified 47 studies evaluating or describing at least 1 of 3 specific interventions to increase vaccinations supported directly by an IIS or population-based vaccination database: (1) client reminder and recall notices; (2) provider assessment and feedback activities; and (3) provider reminder systems.

Client reminder and recall—Thirty studies evaluated effectiveness of client reminder and recall notices generated from an IIS or vaccination database. All but one study were conducted in the United States. Thirteen studies, 9 of greatest suitability of design, were published in peer-reviewed journals¹¹⁻²³ and 17 studies, 5 studies²⁴⁻²⁸ of greatest suitability and 12 studies²⁹⁻⁴⁰ of moderate or least suitable design, were presented as conference abstracts.

Thirteen studies^{12-19,24,25,27-29} with 16 study arms provided measurements of change in vaccination rates

with a median absolute percentage point improvement of 6 percentage points (pct pts; interquartile interval, 4-7 pct pts). The remaining 17 studies^{11,20-23,26,30-40} provided descriptive information about the use of IIS data to generate reminder/recall notices; 2 studies^{38,40} described using the IIS to recall children during a measles outbreak, and 3 studies^{21,35,37} recalled children who had received doses of a subpotent or recalled vaccine.

Provider assessment and feedback—A total of 15 studies, 14 US and 1 Australian, evaluated the use of IIS data to assess provider vaccination performance within an assessment and feedback intervention. Three studies, one of greatest suitability of design, were published in peer-reviewed journals, 15,41,42 and 12 studies, 11 of least suitable design, were presented as conference abstracts. 43-54

Five included studies^{15,44,46,49,53} provided measurements of change in vaccination rates and observed a median absolute percentage point increase of 9 pct pts (range, 5-15 pct pts). The 10 remaining studies^{41,43,45,47,48,50-52,54} provided descriptions of IIS-generated assessments, with 3 studies^{48,51,54} using IIS data to identify invalid doses administered to clients and 2 studies^{45,52} describing time saved by using an IIS compared with the previous practice of pulling and reviewing charts within the provider practice.

Provider reminders—Three US studies,⁵⁵⁻⁵⁷ all conference abstracts of least suitable design, described or evaluated the use of IIS-generated reminders to vaccination providers. One study⁵⁶ evaluated effectiveness of a provider reminder system in increasing vaccination rates in a provider practice and found an absolute percentage point increase of 14.2 pct pts. Two studies^{55,56} described the use of Web-based IIS features as reminders to providers on vaccine availability and updated recommendations for administration of a pandemic influenza vaccine.

Use of IIS in vaccination-related decisions by clinicians, schools, and health care systems

The search identified 14 US studies⁵⁸⁻⁷¹ evaluating or describing the use of IIS by vaccination providers, schools and day cares, or health care systems. All 14 studies were conference abstracts of least suitable design.

Use of IIS by vaccination providers—No studies identified in this review specifically evaluated or described the use of IIS by individual vaccination providers in making clinical decisions about client vaccinations. No evidence was identified in this review to inform an assessment of IIS access and frequency of use in clinical settings and to examine IIS use and clinical outcomes such as coverage rates and timeliness.

Use of IIS by schools and child care centers (day cares)—Ten US studies, 58-60,63,64,66,68-71 all conference abstracts of least suitable design, described IIS interactions with schools and day cares. One abstract⁶³ quantified school use of an IIS to print out certificates of immunization status. Eight abstracts^{58-60,64,66,68,69,71} described how inclusion of school and day care data in the IIS helped improve data completeness and accuracy, thereby becoming a more useful tool for assessing student immunization status. The remaining abstract⁷⁰ described the use of the state IIS to determine whether the IIS included records of children with school-documented vaccine exemptions receiving the exempted vaccine.

Use of IIS by health care systems—Four studies, 61,62,65,67 all of least suitable design, described the use of a state IIS by a health care system. One published study⁶⁵ and 2 abstracts^{62,67} described the use of IIS data for quality measurements including HEDIS (Healthcare Effectiveness Data and Information Set) reporting; one of these studies adopted the IIS as the vaccination database. One abstract⁶¹ described the use of an IIS to screen and vaccinate health care workers on-site.

IIS-supported outbreak and public health emergency responses

Eighteen US studies, 4 of moderate suitability of design⁷²⁻⁷⁵ and 14 of least suitable design,^{38,40,55,76-86} evaluated or described the use of IIS in responses to outbreaks of vaccine-preventable disease or other public health emergencies. Three abstracts examined the use of IIS data to identify residents for targeted recall notices during outbreaks of measles^{38,40} and hepatitis A.⁷⁹ For example, the New York City IIS was used to recall more than 7000 children younger than 5 years who were not fully vaccinated with the measles vaccine. Four conference abstracts^{72-74,80} and 1 published study⁷⁵ described the use of IIS data in retrospective assessments of vaccination status or uptake following outbreaks of pertussis to determine whether providers complied with recommendations to use the accelerated vaccination schedule of the Advisory Committee on Immunization Practices. Seven conference abstracts^{56,77,78,81,82,84,86} described provider participation, client management, vaccine distribution, or reporting outcomes related to the use of IIS for vaccine allocation during the 2009 H1N1 influenza pandemic. Finally, 2 published studies76,85 and 1 abstract83 described the use of IIS data in vaccination decisions for clients displaced by Hurricane Katrina, quantifying substantial benefits attributable to reductions in unnecessary vaccinations. One assessment⁸⁵ projected a total savings of \$13.1 million in vaccine and administration fees by using IIS to retrieve vaccination histories and avoid overimmunization of individuals in areas affected by Hurricane

IIS for vaccine ordering, inventory, and accountability

Fourteen studies, 86-99 all of least suitable design, provided descriptions of the use of IIS in facilitating vaccine ordering, inventory monitoring, and vaccinerelated accountability. In 10 studies, the focus was on inventory management of vaccines available through the federally funded Vaccines for Children (VFC) program (http://www.cdc.gov/vaccines/programs/vfc/ index.html). One published study⁹⁴ and 2 conference abstracts86,92 described the application of VFC vaccine tracking requirements for vaccination providers for H1N1 monovalent influenza vaccine doses during the 2009 H1N1 influenza pandemic. Six abstracts^{87,89,90,93,95,99} described modules for vaccine ordering within their IISs to improve vaccination provider accountability for VFC vaccine doses received. Four pilot studies described challenges96 and successes88,91,98 with the integration of the VFC-required Vaccine Tracking System (VTrckS) within existing IIS. Finally, 1 conference abstract97 described the use of IIS to facilitate billing for non-VFC doses to private insurers.

IIS to assess vaccine safety and effectiveness

Seventeen studies¹⁰⁰⁻¹¹⁶ of least suitable design (12 in the United States) described the use of IIS in assessment of, or response to, vaccine safety issues or in evaluation of vaccine effectiveness. Four published studies 103,111,113,115 and 1 conference abstract 116 described activities related to vaccine safety. The abstract described implementation of a targeted recall of potentially contaminated vaccine in a large metropolitan area, where IIS data were used to identify both affected vaccination providers and patients. 116 Three published studies described tracking of adverse events related to administration of the H1N1 monovalent influenza vaccine, 113 the inadvertent administration of anthrax vaccine to pregnant women,¹¹¹ the association between MMR (measles-mumps-rubella) and DTP (diphtheria and tetanus toxoids and pertussis) vaccines and adverse events, 103 and the introduction of a new meningococcal vaccine in New Zealand.115

Vaccine effectiveness assessments, typically involving comparison of IIS immunization records with disease or illness case reports, were described in 12 studies. 100-102,104-110,112,114 Two published studies examined general feasibility issues for US systems, 106,110 but the remaining studies described evaluations of specific vaccines, including rotavirus vaccine (4 published studies and 1 abstract), 101,102,104,112,114 pneumococcal conjugate vaccine (1 abstract),108 influenza vaccine in children (2 published studies), 100,105 Haemophilus

influenzae type b (Hib) vaccine (1 published study), ¹⁰⁷ and meningococcal vaccine (1 published study). 109

IIS as a tool for public health decision support

The studies categorized in this section described IIS capabilities to provide information, such as vaccination rates or coverage trends, which might prompt additional public health intervention.

A total of 110 studies, 2 of greatest suitability^{14,117} and 108 of moderate or least suitable design,* were identified; 83 were conducted in the United States. Evidence included 57 published articles 11,14,107,109,117-169 and 53 conference abstracts,† which examined the use of IIS data in assessments of vaccination coverage for a wide range of vaccines and target populations. Within this body of evidence, most reports described IIS-based assessments of vaccination coverage in specific populations, including 32 published studies ‡ and 19 abstracts.§ Four studies¹⁵⁴⁻¹⁵⁷ published in the MMWR Morbidity and Mortality Weekly Report provided influenza vaccination coverage estimates using data from participating IIS Sentinel Sites within 3 months of the end of the influenza season. Prior to 2010, estimates of influenza vaccination coverage, assessed using data from the National Immunization Survey (NIS) or the National Health Interview Survey, were not published until the year after the most recent influenza season. Thirty-two studies (13 published, 19 abstracts) described IIS assessments in higher-risk individuals and populations. In 9 studies (1 published 141), IIS records were used to assess potential disparities in vaccination coverage rates by neighborhood ("pockets of need") or population characteristic. IIS records informed assessment of the uptake of a new vaccine recommendation in 10 published studies# and 6 abstracts.114,171,176,178,182,198 IIS-based assessments of age-appropriate and series completion rates were reported in 4 published studies^{127,130,144,162} and 5 abstracts.^{51,54,176,189,193} Missed opportunities were estimated, typically by comparing rates of simultaneous receipt of recommended vaccinations, in 4 studies. 134,135,158,208 Four published studies11,120,168,169 evaluated vaccination coverage and provider compliance with interim recommendations during vaccine shortages. Finally, 1 abstract²¹⁶ evaluated the extent of overimmunization among US children, as documented in 6 Sentinel Site IISs.

IIS integrated with other child health information systems

Eight US studies, 217-224 all of least suitable design, discussed integration of additional child health data into an existing IIS. Two published articles^{220,221} described Michigan's experience with determining which systems were appropriate to integrate with the Michigan IIS, as well as steps taken to move legislation in support of allowing data to be used for public health purposes beyond immunizations. One published article and 2 abstracts describe the successful integration of immunization data with other data sources in New York City,²²³ New Jersey,²²² and San Diego.²¹⁷ The linkages described include blood lead levels, Early Hearing Detection and Intervention screening, and a body mass index calculation chart. Three other articles218,219,224 describe the importance of moving toward integrated child health information systems from the perspective of how it can improve health care providers' abilities to be more fully informed and effective in client management.

IIS as contributing to change in documentation

IIS data quality issues were evaluated in 15 published studies^{106,190,225-237} and 9 abstracts.²³⁸⁻²⁴⁶ Twentyone studies compared the completeness of individual IIS vaccination records with medical records,* the NIS, 232, 239, 246 or parental report. 227, 236, 243 Thirteen of these studies† were published between 2000 and 2006, and 2 abstracts^{239,245} were published between 2010 and 2011. In 8 studies, 228-232, 234, 237, 245 individual immunization assessments were more complete when the IIS or registry record was combined with medical record data; however, this statement was often paired with the conclusion that IIS data were incomplete and not adequate as stand-alone data sources for assessments of coverage in studies conducted prior to 2007. Three studies^{230,231,234} examined the impact on vaccination rates of aggregating private and public health department immunization data into a regional registry with a demonstration project that resulted in a registry comprising a vast network of practices in the Denver metropolitan area. In 3 studies, 232,239,246 IIS coverage estimates were compared with estimates from the NIS. One study²⁴⁶ found that IIS provided comparable coverage to the NIS for birth-dose hepatitis B coverage. Two other studies^{232,239} found individual vaccination coverage to be higher in the NIS than in the IIS, and rates were highest when data sources were pooled.

^{*}References 11, 33, 34, 36, 51, 54, 107, 109, 114, 118-216.

[†]References 33, 34, 36, 51, 54, 114, 158, 170-216.

[‡]References 117, 118, 121, 122, 124, 125, 131-133, 138-140, 143, 145-149, 151-161, 163, 166, 167.

[§]References 170, 172-175, 183-185, 187, 188, 191, 197, 199, 201, 203, 205, 212-214.

[¶]References 11, 14, 33, 34, 107, 109, 119, 126, 130, 134, 136, 137, 142, 144, 153, 164, 177, 179-181, 183, 186, 190, 193, 198, 202, 206, 207,

^{||}References 32, 36, 141, 192, 194-196, 200, 204.

[#]References 109, 123, 128, 129, 134, 135, 137, 144, 150, 165.

^{*}References 106, 190, 225, 226, 228, 229, 233, 235, 237, 238, 240-242, 244, 245.

[†]References 225-229, 232, 233, 235, 237, 241-244.

Applicability of findings

Findings from the included evidence were considered for applicability to IIS as implemented in the United States. Most included studies (n = 209) described or evaluated US systems, with 166 reporting vaccination outcomes. Published studies included 1 or more assessments from 32 of 53 US systems (60%). Sentinel Site programs (IISs with higher levels of data completeness, provider participation, and system capabilities) contributed 108 (52%) of the US studies. Most US studies examined IIS activities regarding children and vaccinations within the childhood series, whereas only 33 of 166 articles (20%) reporting vaccination outcomes described the use of IIS for adolescents and 12 (7%) described the use of IIS for adult populations, with most studies focused on influenza vaccination. Few studies provided any information on demographic characteristics of the study population such as race/ethnicity, income, education, or insurance status.

Overall, the included studies provide evidence on capabilities that should be applicable to most US IISs, especially as systems achieve levels of provider and client participation demonstrated by Sentinel Site programs. Evidence is broadly applicable to IIS activities regarding vaccinations as part of the childhood series.

Many studies highlighted the benefits of an IIS for tracking vaccine delivery to children eligible for the VFC program; VFC offers no-cost vaccines to children and adolescents through 18 years of age who are uninsured, underinsured, or Medicaid-enrolled or are American Indian or Alaskan Native. Providers participating in the VFC program are required to document the eligibility of participants and track all administered VFC doses, a requirement that is often fulfilled by using an IIS. IISs are also being used to track vaccine inventory, a benefit that can be realized among VFC and non-VFC participating providers, as described in several included studies. As more providers make improvements in vaccine accountability and inventory management, the applicability of IIS to fully represent all children, regardless of eligibility status, is also improved.

Other benefits and harms

In addition to the benefits realized through integration of IIS with other child health information systems (eg, newborn screening, body mass index assessments), described earlier, there are benefits that may come with the ongoing expansion of IIS to life span systems. As more IISs incorporate vaccine administration data for adults, either through enrolling vaccination providers that serve adults or as individuals already enrolled in the IIS age into adulthood, the capabilities of IIS will become more universally applicable to individuals of all ages. Incomplete or delayed reporting of vaccination records might result in overvaccination of some clients with fragmented care, although this potential outcome is not unique to IIS and is likely to be even more common in the absence of a centralized data source.²⁴⁷

Considerations for implementation

As summarized earlier, the studies and outcomes included in this review describe program actions and capabilities that could be adopted or enhanced by other US IISs.

Included studies also describe a number of barriers to the implementation and operation of IISs. Many systems rely on voluntary participation of vaccination providers, with IIS data completeness (and subsequent utility) dependent on the extent and timeliness of provider reporting. In the United States, 31 IIS programs mandate participation by some or all providers by law and only 21 reported a mechanism in place to enforce the mandate.²⁴⁸ In addition, there is variability about which types of providers (ie, public providers, private providers, or VFC providers) and what ages fall under the mandate. 248 Vaccination providers have expressed concerns over technological constraints, as well as time and staffing demands required to enter complete and timely reports into the system.²⁴⁹

Client participation and confidentiality requirements may limit the ways in which IIS data can be entered, retrieved, or used for clinical and public health purposes. State policies differ, with 3 IIS programs (Texas, Montana, and South Carolina) requiring written consent to participate in the IIS for all ages (through adulthood) and 8 IIS programs (Arizona, Arkansas, Kansas, Montana, New Jersey, New York City, New York State, and Texas) requiring consent for individuals 19 years and older.248 The requirements of the federal Family Educational and Rights to Privacy Act (FERPA) (http://www.ed.gov/ policy/gen/guid/fpco/ferpa/index.html) also restrict opportunities to update IIS records using information provided to schools because of requirements for parental or adult client consent for such use. Confidentiality requirements can limit provider access to client records across IIS jurisdictions (although different city and state programs do have data exchange agreements or provide clients access to hard copies of vaccination records), thereby limiting the potential benefits of IIS.

Integration of IIS with other child health information systems (eg, newborn screening) can provide additional benefits by consolidating health information within a single system. Integrated child health information systems reduce duplication of data collected and improve the coordination of services provided, ensuring that all children receive needed preventive care services and case management.²⁵⁰

Conclusion

The studies included in this review provide evidence that IISs are effective in improving vaccination-related activities linked to increased vaccination rates and reduced risk for vaccine-preventable disease. Evidence from 240 published articles and conference abstracts demonstrate IIS capabilities to (1) create or support effective interventions such as client reminder and recall, provider assessment and feedback, and provider reminders (47 studies); (2) determine client vaccination status for decisions made by clinicians, health care systems, and schools (14 studies); (3) generate and evaluate public health responses to outbreaks of vaccinepreventable disease (18 studies); (4) inform assessments of vaccination coverage, missed vaccination opportunities, invalid dose administration, disparities in vaccination rates (110 studies), and vaccine safety and effectiveness (17 studies); and (5) facilitate vaccine management and accountability (14 studies).

Evidence gaps

Only one of the included studies, from Australia, documented the association of improvements in vaccination coverage with the implementation and enhancement of an IIS. Additional studies are needed, especially in US settings, that examine the overall impact of IIS (or IIS activities) either on vaccination coverage in the general population or on important target populations with gaps in coverage.

Few studies provided information relevant to an assessment of the utility of IIS for vaccination providers in clinical settings. Descriptions, assessments, and evaluations focused on the utility of, or barriers to, the use of IIS in day-to-day operations of vaccination providers in a range of clinical settings would provide important information to help determine the overall value of these interventions and identify tools, interactions, and reporting policies in need of adjustment or modification.

As a population-based resource, IIS should capture data and provide services to all members of the population, including groups with lower rates of vaccination coverage. Future studies could examine participation rates and record capture based on demographic characteristics such as race/ethnicity, household income, and insurance status. If IIS records included all data elements specified in the IIS Functional Standards, these analyses could be conducted using solely IIS data. (http://www.cdc.gov/vaccines/programs/iis/ func-stds.html). Until IIS consistently capture complete demographic data, this would likely require merging with data from other sources.

Although annual program surveys identify a wide range of IIS-supported actions, such as generation of client reminders, the extent of these activities within the covered population remains unclear. A survey of pediatricians conducted in 2013 by the AAP found that over 70% of respondents reported using their state IIS. Among IIS users, 70% reported using it to recall patients for needed vaccines, and nearly all (97%) said that it reduces unnecessary vaccination. 251 Future studies should attempt to quantify the frequency and reach of various IIS activities within the population.

Limitations of this review

The findings of this review are subject to a number of limitations. This project, unlike previous Community Guide reviews, included reports of program descriptions, actions, and experiences and considered this information as evidence contributing to a determination of effectiveness. In most cases, these reports do not provide a formal comparison, although a change in system capability or impact is implied. Of the evidence that included a formal comparison, the most common evaluation was a simple before-after format, a study design that is subject to the influences of potential biases, trends, or other explanatory factors.

Although the search of published evidence was systematic, screening by the team of abstracts from selected US conferences with a known focus on immunization research might have introduced or reinforced a selection bias in the inclusion of evidence. In addition, half of the studies included in this review came from IISs within the US Sentinel Site program, which has requirements to present and submit for publication as a condition of funding. Although Sentinel Sites provide a good understanding of the potential of all IISs, once they have achieved the required levels of participation, these capabilities and findings might not be universally applicable to IIS. However, as more IISs achieve the levels of reporting and timeliness required of Sentinel Sites, the findings from these studies may become more universally applicable.

Discussion

This review provides a systematic and organized synthesis of a large body of evidence on capabilities and effectiveness of IIS. The 240 included studies describe and evaluate a wide range of public health and clinical activities to support public health efforts to conduct assessments of vaccination rates and disparities in coverage, to identify individuals and populations for additional immunization-related intervention, to

improve vaccination-related decisions and actions in routine and public health emergency situations, and to support studies assessing vaccine uptake, effectiveness, and safety. Together, the evidence documents utility of IIS for vaccination providers and public health decision makers at the local, state, and national levels and provides a wide range of options for activities to examine and address patient status and local concerns and emergencies.

One primary goal of efforts to implement, populate, and maintain IIS is to support vaccination providers by facilitating (1) vaccination decisions with patients, (2) common immunization-related activities such as generation of vaccination record forms, (3) access to additional interventions to increase vaccination rates and reduce missed opportunities, and (4) interactions with public health and public sector immunization services. Most US state and city IISs include capabilities to generate or support effective interventions to increase vaccination rates, specifically client reminder/recall notices, assessment and feedback activities, and reminder systems for vaccination providers, as suggested by IIS annual report data (see Table 1). However, few studies included in this review provided information about vaccine providers' use of IIS. Some studies have examined effectiveness and use of IIS for generating reminders for pediatric²⁵ and adolescent populations,²² but no formal evaluations examined the frequency of consultation of IIS for clinical decision making within a population of vaccination providers. Without a better understanding of the relationships between providers and these systems in clinical settings, it will remain difficult to (1) assess the utility of IIS for vaccination providers, (2) identify barriers to regular use, and (3) determine how each of the different IIS capabilities contributes to improvements in vaccination rates. The lack of information on the use of IIS in clinical settings is, therefore, especially unfortunate because, if fully used by vaccination providers (or within a participating health care system), these IIS capabilities alone could translate into improved patient follow-up and fewer missed vaccination opportunities.

Studies identified in this review provide some information on the use of IIS by schools and health care organizations. For schools, IIS access provides an efficient mechanism for determining and documenting student vaccination requirements. For health care systems, adoption of IIS as the vaccination database, or incorporation of IIS data into existing EHRs through automated data exchange, can reduce duplication of record keeping, support assessment and feedback initiatives for providers, and facilitate reporting of relevant coverage rates associated with participation in HEDIS. In both settings, participation by an entire system (eg, school district, health care organization) also provides the opportunity to expand enrollment and documentation substantially, further enhancing the completeness and utility of the IIS for the community.

Annual IIS program surveys conducted by the CDC indicate general trends of improved and expanded capabilities of US systems. Table 1 describes the number of immunization programs in the United States that are supported by an IIS that serves their entire state/city jurisdiction and the expanding IIS functionalities that support immunization programs and other immunization stakeholders. These data suggest that programs and partners are increasingly using IIS to facilitate a wide range of interventions, assessments, and response efforts. Table 2 describes population and provider site participation in IIS over time and documents noted improvements in data capture across the life span. In 2002, 64% of IISs were including immunization data for populations of all ages, whereas in 2011, reported inclusion of life span data had increased to 93%. From 2002 to 2011, a 65% increase in the percentage of children participating in IIS and 4-fold increase in provider site participation were observed. It is important to recognize that the definition of child participation in an IIS requires that a child younger than 6 years have a minimum of 2 routinely recommended vaccines entered into an IIS, far fewer vaccines than a child needs to achieve up-to-date status even during infancy. While national trends indicate enhanced IIS functionality and improved data quality, IISs exist at varying levels of maturity, which impacts their ability to support vaccination providers and other immunization stakeholders.

Currently, most IISs in the United States rely on voluntary participation and reporting from vaccination providers to achieve functional levels of data completeness. Without reporting mandates, it is difficult to improve provider participation and timeliness of immunization reporting—issues that directly affect the utility of the system—both for individual clinical care decisions and for population-based assessments and actions. Evidence from Australia's ACIR indicates that IIS can achieve very high levels of participation and data completeness through coordination of system entry and reporting. In Australia, incentives have been offered both to parents whose children were up-to-date with immunizations (or who had filed an exemption) and to vaccination providers based on up-to-date coverage rates within their client population.⁷ Although coordinated incentives may not be feasible universally at the IIS program level in the United States, elements could be considered for application in some US settings, such as incentives offered by participating health care systems to vaccination providers based on vaccination and reporting performance. In addition, there are substantial barriers to developing a national IIS in the United States, because each immunization

TABLE 1 🕟 IIS Data Use and System Functionality Reported by 56 US City- or State-Based Immunization Programs Receiving Grant Funding From CDC in 2002, 2006, and 2011^a

IIS Data Use and System Functionality	2002 (n = 42 ^b)	2006 (n = 52 ^b)	2011 (n = 55 ^b)
Reminder/recall for clients ^c	34	43	52
AFIX (provider assessment and feedback) ^c	26	43	46
Forecasting algorithm (provider reminders) ^c	36	48	51
Up-to-date assessments (individual)/coverage (population)	N/A	41/44	48/49
Routine surveillance (look-up vaccine history)	N/A	38	36
Outbreak management	N/A	32	42
New vaccine uptake	N/A	37	38
Track doses administered	17	41	47
Pockets of need	24	34	38
Emergency preparedness	N/A	26	38
Track adverse events	14	22	22

Abbreviations: CDC, Centers for Disease Control and Prevention; IIS, immunization information system; N/A, not available; AFIX, Assessment, Feedback, Incentives, and eXchange. ^aFrom Annual immunization progress report for CY (calendar year) 2002, 2006, 2011, CDC (http://www.cdc.gov/vaccines/programs/iis/annual-report-IISAR).

program must incorporate unique state or city immunization laws and policies into its IIS functionality, which sometimes create barriers for the exchange of data across state lines.252

While child and provider site participation in IIS is currently high, completeness and timeliness of reporting in US systems may further improve in coming years for a variety of reasons. First, several states have adopted mandatory reporting requirements for some vaccinations, especially for vaccines provided through the VFC program. Second, national, state, and local IIS stakeholders have engaged to develop and publish additional standards to support common IIS functions CDSi (http://www.cdc.gov/vaccines/ programs/iis/interop-proj/cds.html), operational IIS practice guidelines (http://www.cdc.gov/ vaccines/programs/iis/activities/mirow.html), electronic messaging and transport layer standards (http: //www.cdc.gov/vaccines/programs/iis/interop-proj /ehr.html), and patient-level deduplication guidelines. The publication and implementation of these standards allow IIS to consolidate knowledge from diverse systems, support consistent best practices across the IIS community, more effectively and efficiently exchange data with other electronic data systems, and reduce costs required for each IIS to address tasks individually. Third, several initiatives have provided federal support for enhanced IIS data use and system functionality. Immunization programs that receive funds under section 317 of the Public Health Service Act are encouraged to use their IIS to assess vaccination coverage for subpopulations (eg, geographic and provider-based populations) to identify pockets of need that might benefit from intervention. To further support enhanced IIS functionality, the CDC has awarded \$18.7 million to 37 IISs since

TABLE 2 Population and Provider Site Participation in IIS in 2002, 2006, and 2011

Capability of Reporting IIS Programs	2002 (n = 42 ^b)	2006 (n = 52 ^b)	2011 (n = 55 ^b)
Number of life span IIS	27	39	51
Percentage of children participating (aged <6 y; 2+ immunizations) ^c	51	63	84
Percentage of adolescents participating (aged 11-17 y; 2+ immunization during adolescence) ^c	N/A	N/A	53
Percentage of adults participating (aged ≥19 y: 1+ immunization during adulthood) ^c	N/A	N/A	24
Number of public provider sites active in the IIS ^d	4 432	7 184	12 688
Number of private provider sites active in the IIS ^d	7 548	29 348	41 647
Percentage of doses reported within 30 d of administration	68	70	72

Abbreviations: CDC, Centers for Disease Control and Prevention; IIS, immunization information system.

^bNumber of immunization programs supported by an IIS that serves the entire state/city .

^cInterventions recommended by the Community Preventive Services Task Force.

^aFrom Annual immunization progress report for CY (calendar year) 2002, 2006, 2011, CDC (http://www.cdc.gov/vaccines/programs/iis/annual-report-IISAR).

^bNumber of immunization programs supported by an IIS that serves the entire state/city.

clmmunizations do not include travel vaccine or 2009 H1N1 influenza pandemic vaccine.

^dProvider reported data to the IIS in the previous 6 months.

2011 to establish and/or enhance interfaces between IIS and VTrckS, CDC's national vaccine ordering and inventory management system for publicly purchased vaccine. Four additional programs have committed to using their IISs to interface with VTrckS. In these states and cities, vaccination providers who wish to participate in the VFC program order and manage publicly purchased vaccine through the IIS.²⁵³ Finally, the modernization of health care in the United States through the electronic exchange of data to support clinical care is anticipated to positively impact IIS. The use of 2-dimensional barcode technology to record and electronically report vaccine information, including product and manufacturer, lot expiration date, and lot number, to EHRs and IIS is expected to further improve IIS data quality.6

Several initiatives have been established to support interoperability in the United States. The ARRA investment in the Section 317 Immunization Program was provided to expand access to vaccines and vaccination services by making more vaccines available, increase national public awareness and knowledge about the benefits and risks of vaccines and vaccinepreventable diseases, and strengthen the evidence base for vaccination policies and programs. The Health Information Technology for Clinical and Economic Health (HITECH) Act includes provisions intended to "accelerate adoption of nationally certified EHR systems, standardize EHR products, support growth in the health information technology workforce, and facilitate secure exchange of health data between disparate partners."254(p11) The Prevention and Public Health Fund (PPHF),²⁵⁵ created by the Affordable Care Act, was established to invest in prevention and public health programs to improve health and help limit the growth in health care costs. And, the Centers for Medicare & Medicaid Services established an initiative that provides financial incentives to eligible health care providers that acquire certified EHR products and demonstrate meaningful use of these products, defined in part as the exchange of data with IIS (https://www. cms.gov/Regulations-and-Guidance/Legislation/ EHRIncentivePrograms/Meaningful_Use.html). From 2010 to July 2013, the CDC awarded \$46.2 million of American Recovery Reinvestment Act/HITECH and PPHF funds to 37 IISs to enhance interoperability between EHRs and IIS and support the meaningful use initiative. It is anticipated that these activities will result in more complete immunization histories in IIS and improve the timeliness of data submissions to IIS.

With all US jurisdictions, excluding 1 state, supported by an IIS, the findings of this review provide information on the use of programs on efforts to support, expand, enhance, evaluate, or revise their own operations and to improve interactions with vaccination providers and patients.

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Appendix

Search for Evidence

This Task Force finding is based on studies identified in the search period (1994-2011). Reference lists of articles reviewed as well as lists in review articles were also searched, and members of our coordination team were consulted for additional references.

Search Strategy

Details of the search (1994-2011)

The team conducted a broad literature search to identify studies evaluating the effectiveness of an IIS or populationbased vaccination database, or the effectiveness of an intervention generated from an IIS, or describe an IIS capability linked to increasing vaccination rates or reducing vaccine-preventable disease. The following 9 databases were searched during the period of January 1994 up to April 2011: CABI, CINAHL, The Cochrane Library, EMBASE, ERIC, MEDLINE, PsycINFO, Sociological Abstracts, and Web of Science. Reference lists of articles reviewed as well as lists in review articles were also searched, and subject matter experts were consulted for additional references. The team also included an assessment of unpublished US literature in the form of conference abstracts. Abstracts presented at 4 selected conferences (Immunization Registry Conference; National Immunization Conference, Pediatric Academic Society, Vaccine University) in the United States were searched during the period January 2002 to April 2011. To be included in the review, a study had to

- have a publication date of 1994-2011;
- evaluate vaccinations recommended for children, adolescents, and/or adults;
- meet the evidence review and Guide chapter development team's definition of the interventions;
- be a primary research publication or US conference abstract with 1 or more outcomes related to the analytic frameworks;
- take place in a high-income country or countries;
- be written in English'
- report 1 or more quantitative outcomes (changes in vaccination rates, coverage, or uptake; reductions in missed opportunities) or describe system capabilities linked to increasing vaccinations or reducing vaccine-preventable disease.

Search Terms

MeSH (Medical Subject Headings) were exploded to include all related subject headings. British spelling variations, plurals, title, abstract, and keywords were searched in the non-MEDLINE databases as well.

- 1. Immunization
- 2. Vaccination
- 3. Immunization information system
- 4. Immunization registry
- 5. Vaccination registry



Economic Review of Immunization Information Systems to Increase Vaccination Rates: A Community Guide Systematic Review

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Context: A recent systematic review found that use of an immunization information system (IIS) is an effective intervention to increase vaccination rates. The purpose of this review was to evaluate costs and benefits associated with implementing, operating, and participating with an IIS. The speed of technology change has had an effect on costs and benefits of IIS and is considered in this review. Evidence Acquisition: An economic evaluation for IIS was conducted using methods developed for Community Guide systematic reviews. The literature search covered the period from January 1994 to March 2012 and identified 12 published articles and 2 government reports. **Evidence Synthesis:** Most studies involving cost data evaluated (1) system costs of building an IIS and (2) cost of exchanging immunization data; most economic benefits focused on administrative efficiency. Conclusions: A major challenge to evaluating a technology-based intervention is the evolution that comes with technology improvements and advancements. Although the cost and benefit data may be less applicable today due to changes in system technology, data exchange methods, availability of vendor support, system functionalities, and scope of IIS, it is likely that more up-to-date estimates and comprehensive estimates of benefits would support the findings of cost savings in this review. More research is needed to update

KEY WORDS: benefit, Community Guide, Community Preventive Services Task Force, cost, cost-effectiveness, economics,

and address limitations in the available evidence and to enable

assessment of economic costs and benefits of present-day IIS.

J Public Health Management Practice, 2014, 00(00), 1–10 Copyright © 2014 Wolters Kluwer Health | Lippincott Williams & Wilkins immunization, immunization information system, systematic review

Context

Vaccines are considered one of the most effective prevention tools used within public health to prevent vaccine-preventable diseases (VPD) among children, adolescents, and adults. Through vaccinations, the United States has experienced declines in incidence of morbidity, disability, and mortality from VPD.^{1,2} Recommended childhood vaccinations that protect against diphtheria, tetanus, pertussis, *Haemophilus influenza* type b (Hib), poliovirus, measles, mumps, rubella, hepatitis B, varicella, hepatitis A, pneumococcal, and rotavirus prevent approximately 20 million disease episodes and 42 000 premature deaths, resulting in

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This review would not have been possible without the subject matter expertise and contributions of Daniel Martin and Gary Urquhart from the Immunization Information Systems Surveillance Branch at Centers for Disease Control and Prevention. The authors also thank Kate W. Harris, Kristen Folsom, and Onnalee Gomez for their assistance throughout the review process.

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The authors declare no conflicts of interest.

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DOI: 10.1097/PHH.00000000000000100

estimated net savings of \$68.8 billion (2009 dollar) from averted medical costs and reduced absenteeism from work.³

Although the success of childhood vaccination programs has led to more than 95% decline in these infectious diseases, cases of illness and death by VPD still occur, as evidenced by the measles outbreak during 1989-1991 attributable to unvaccinated or undervaccinated persons. ⁴⁶ Immunization programs and vaccination providers remain challenged to identify unvaccinated and undervaccinated subpopulations and individuals, ensure that individuals are appropriately vaccinated, and conduct outreach and interventions to maintain high vaccination coverage levels.

Use of an immunization information system (IIS) is one strategy that can be adopted to increase and improve vaccination delivery in the United States. Immunization information systems are confidential, population-based, computerized databases that record all vaccination doses administered by participating providers to people residing within a given geopolitical area. These information systems have multiple clinical and public health functions, all of which assist in ensuring appropriate vaccination to reduce risk for VPD.

Based on the results of a systematic review, the Community Preventive Services Task Force (Task Force) recently recommended use of IIS as an effective intervention to increase vaccination rates.⁸ Subsequently, this systematic economic review was conducted to evaluate costs and benefits associated with implementing, operating, and participating with an IIS.

Economic evaluations of technologically based interventions are challenging because of the speed and complexity of technology change. This challenge is particularly applicable to IIS, as systems have undergone major advancements since inception in the 1970s. This review identified the following 5 factors in the dynamic nature of IIS that complicate economic evaluation: (1) evolution of system technology; (2) evolution of data exchange methodologies; (3) emergence of software vendors that support IIS; (4) continued enhancements to system functionality; and (5) shift in the scope of IIS. With these factors in mind, this economic evaluation was conducted and assessed, and the results

were compared with criteria of modern systems and capabilities.

Costs and benefits of IIS

Historically, in the United States, funding for IIS development has been provided by federal, state, local governments, private foundations, and managed care organizations (MCOs).^{9,10} Implementing IIS requires upfront investment from these payers, whereas the benefits—both financial and nonfinancial—accrue to the payers, providers, patients, and the general population. For example, using an IIS to prevent a duplicative vaccination reduces costs to the patient (eg, money, time, and pain of vaccination) and also reduces costs to providers, public health officials, and the general population by allocating fewer public and private resources to administer vaccines.

Expected costs of implementing an IIS include system costs (costs to develop and operate the IIS, to populate data at the central IIS, hardware and software costs, and/or licensing fees) and the cost of exchanging immunization data. Tables 1 and 2, respectively, provide an overview of system costs for 2 types of IIS and data exchange costs. Data exchange costs accrue to both the provider and the IIS. Data exchange costs to the provider include labor costs to enter data manually into IIS or costs associated with linking an existing software system (eg, an electronic health record) to IIS. Data exchange costs to IIS include identifying, enrolling, and training providers on use of IIS and establishing electronic linkages with other information systems, which incurs both operational and technical costs.

Economic benefits of IIS may include improved clinical service for vaccine administration and reduced administrative burdens associated with a vaccine delivery system. The ability of IIS to produce consolidated vaccination histories and to forecast (typically algorithm-based) which vaccinations are due and when those doses are due for each individual served by the system can support immunization providers in improving vaccination coverage and reducing overimmunization. Administrative support functions for vaccine delivery provided by IIS include increased efficiency of provider

TABLE 1 • System Cost: Cost of Implementing and Operating an IIS

	Costs Specific to Type of IIS	Costs Applicable to All IIS
Custom-built IIS	Development (design system architecture, software and security features)	Operation (personnel cost to maintain the IIS) Hardware
Vendor-supported IIS	Licensing fee customization (features and applications)	Populate IIS (manual entry or electronically) Capability and function upgrades Software/hardware upgrades Servers

Abbreviation: IIS, immunization information system.

TABLE 2 Data Exchange Cost: Cost of Exchanging Data With an IIS

Potential Types of Cost	Perspective
Hardware	Provider
Software configuration	
Labor cost to manually enter vaccination data	
Operational and/or technical costs to link existing software system (eg, electronic health records) to IIS	
Identifying new providers Training providers	IIS implementer
Operational and/or technical costs to link IIS with other information systems (eg, birth records, electronic health records)	

Abbreviation: IIS, immunization information system.

reminder functions, generation of reminder/recall notices for patients, and assessment and feedback interventions for providers.7 Immunization information systems may also be used to track vaccine stock and assess immunization activity for a provider practice. Improved vaccine supply and management should result in less waste and more accurate vaccine inventory and less time required to create vaccination coverage and assessment reports for the provider practice and the population. Ultimately, IIS can lead to an increase in appropriate vaccinations, which results in reduced VPD, an associated reduction in morbidity and mortality, and an improvement in quality-adjusted life-years. A reduction in morbidity and mortality is quantified as an economic outcome by measuring averted health care costs and productivity loss averted.

Evidence Acquisition

A systematic review of economic evaluation studies is typically conducted for community-based interventions recommended by the Task Force. Methods used by the Guide to Community Preventive Services (Community Guide) in conducting systematic reviews of economic evaluations are described elsewhere. 11,12 To be eligible for inclusion in this economic review, studies had to satisfy the intervention definition stipulated in the effectiveness review—confidential, populationbased, computerized databases that record all vaccination doses administered by participating providers to people residing within a given geopolitical area. Immunization systems that include multiple providers in a geographic area and represent a majority of a population are considered population-based for the purposes of this assessment. Search of the economic

literature also mirrored the effectiveness search period of January 1994 to March 20127 and combined economic-specific key words such as cost, cost-benefit, cost-effectiveness, and cost utility with the effectiveness search terms. In addition to the databases searched in the effectiveness review (ie, The Cochrane Library; MEDLINE; CINAHL; PsycINFO; ERIC; Sociological Abstracts; Web of Knowledge; EMBASE; and CAB International), EconLit, Social Sciences Citations Index, JSTOR, and Google were used. All monetary values were adjusted to 2011 US dollars, using the general Consumer Price Index from the Bureau of Labor Statistics (www.bls.gov/).

To take into account the scale of IIS and increase comparability between studies, the Community Guide Economics Team (the Team) calculated cost per child vaccinated by using other measures provided in each study if this average cost information was not provided.

Evidence Synthesis

The economic search resulted in 71 potentially relevant studies after title and abstract screening. After a review of the full text of these studies, 12 published articles^{9,13-23} and 2 government reports^{24,25} were included as the final body of evidence. All studies assessed IIS in a US setting and focused on pediatric immunizations. Nine of these studies provided information related to either system costs or data exchange costs, and 9 provided information on benefits; 4 studies provided an assessment of both benefits and costs.

System cost

Seven studies^{9,14,16,18,21,22,25} evaluated IIS system cost (see Table 3), which includes costs of developing the system architecture, software, hardware, hardware configuration, populating the database, and training. Operation costs are the costs of maintaining the system and managing records. Three9,14,21 studies combined the cost of bringing providers online—equipment, data entry costs of the provider, and/or training costs—with development cost. Unfortunately, the studies did not stratify costs to distinguish systems cost from data exchange cost. Total costs ranged from \$205 077 to \$108 million, annual cost per child ranged from \$5.40 to \$60.82, and cost per vaccination record ranged from \$0.11 to \$12.88. Variability in costs might be attributable to the scale of the IIS and the target population size. Three studies16,18,21 evaluated a city IIS, whereas 2 studies^{14,22} evaluated a combination of city/state (or county) IIS. One study²⁵ solely evaluated a state IIS, whereas an additional study focused on a national projection.

TABLE 3 System Costs Reported in the Included Studies

Study (Author, yr)	Sample Size	Time Period, yr	System Technology	Year of Evaluation	Total Costs (2011 Dollar)	Cost/Child or Cost/Record (2011 Dollar)
Rask et al (2000) ^{21 a}	1 City IIS (Atlanta)	3	NR	1997	\$61 ,580	\$5.80/child/yr ^b (n = 35 550)
Slifkin et al (1999) ²²	4 State/city/county IIS	5	NR	1997	\$4.4 million (mean)	\$15.70 to \$60.82/child/yr ^b (n = 11 124-66 071)
Fontanesi et al (2002) ¹⁶	3 City IIS (CA-HMO; health departments)	3	Client-Server Architecture, Mainframe Architecture, Off-the-shelf software	1998	\$352 036 (mean)	NR
Horne et al (2000) ^{9a}	Modeled nationwide registry	1	NR	1998	\$108 million	\$5.40/child/yr
McKenna et al (2002) ¹⁸	1 City IIS (Boston)	1	NR	1998	\$205 077	Overall: $$7.50/\text{child/yr}$ (n = 63 420)
	23 Provider IIS				\$271 790 (mean)	
Bartlett et al (2006) ^{14a}	24 State/city IIS	5	NR	2002	\$1.15 million to \$1.9 million	\$0.11/record (n = 2.9-3.2 M records) to \$12.88/record (<250 000 records)
Virginia Department of Planning and Budget 2010 (VA State Report) ²⁵	1 State IIS (VA)	1	NR	2010	\$2.4 million	NR

Abbreviations: CA-HMO, California Health Maintenance Organization; IIS, immunization information system; NR, not reported; yr, year.

Data exchange costs

Two^{19,20} studies reported data exchange costs associated with IIS (see Table 4). One study²⁰ reported operational costs from the provider perspective of reporting vaccination information to a central registry, and another study¹⁹ estimated costs for a MCO to link to an existing IIS to improve reporting for the Healthcare Effectiveness and Data Information Set, quality measurement, and the physician incentive program. Data

exchange costs ranged from \$8395 to \$33 459. No evaluated studies reported explicit data exchange costs accrued by IIS. As mentioned previously, these costs were included in the development costs from 3 studies.^{9,14,21}

Benefits

Nine studies^{9,13,15,17-19,23-25} focused on savings that could accrue from using an IIS. Most studies focused on administrative efficiency of an IIS in contrast to manually

TABLE 4 • Data Exchange Costs Reported in the Included Studies

Study (Author, Yr)	Sample Size	Time Period, yr	Data Exchange Method	Year of Evaluation	Total Costs (2011 Dollar)	Cost/Child (2011 Dollar)
Rask et al (2000) ²⁰	4 Provider sites (Atlanta)	1	Electronic Linkage Manual Entry	1998 1998	\$16 650 \$8395 to \$33 459	\$0.91/child ^a \$5.14 to \$11/child ^a
O'Connor et al (2010) ¹⁹	Managed Care Organization (Michigan)	1	Electronic Linkage	2007	\$15 533	N/A

Abbreviation: N/A, not applicable; yr, year.

^aIIS systems included resources to provide computers and/or data entry costs of providers to populate IIS.

^bAverage cost measure calculated by the Community Guide Economics Team.

^aAverage cost measure calculated by the Community Guide Economics Team.

performed vaccination-related activities (eg, pulling records [health care and education system], contacting previous providers for vaccination histories, and generating immunization-related reports). Four studies^{9,15,23,25} considered reduction in costs that would result from decreased overvaccination. Of these studies, 2^{15,23} estimated benefits of IIS during a public health emergency, a rare but critical event. To estimate potential savings from reduced vaccination duplication, both studies assumed that every record identified retrospectively through the Louisiana IIS, LINKS (Louisiana Immunization Network for Kids Statewide), represented savings from avoiding revaccination of children displaced during Hurricane Katrina. This assumption that every child with a record in the LINKS would have been revaccinated in the absence of the system—likely leads to an overestimate of administrative savings; however, the estimate does not account for unnecessary pain and the inconvenience of reimmunization, nor for the costs associated with lost work time and school absenteeism because of vaccination appointments.¹⁵ The other studies^{9,25} modeled all potential benefits from reduced overvaccination (in addition to other benefits) on the basis of assumptions designated by the authors.

Benefits evaluated in these studies were mostly specific to savings associated with administrative efficiency and decreased overvaccination and thus provide a limited picture of benefits that might be realized with IIS. No studies evaluated economic benefits that result from reduced morbidity and mortality from VPD. Benefit outcomes evaluated in the included studies are presented in Table 5.

Cost-benefit

Four studies^{9,18,19,25} provided an assessment of benefits and program costs, each focusing on a different perspective (national, local city/state, or health care system). One study⁹ modeled cost and benefits of a nationwide IIS and indicated a benefit-cost ratio of 3.5:1. A state-level study²⁵ modeled anticipated yearly benefits; compared with annual IIS costs to the state, the benefitcost ratio was 1.59:1. At the city level,¹⁸ one evaluation found that using an IIS compared with manually performing immunization activities resulted in net savings of \$36 815. Among health care systems, a MCO¹⁹ estimated a return of \$8 for every \$1 spent after linking to a state IIS for electronic data reporting versus manually retrieving claims data.

Conclusions

Cost studies in this review provide information on costs to implement and operate the system and associated costs to participate and exchange information with an IIS. Studies with benefit information focused on administrative efficiency of clinical vaccination activities and savings resulting from decreased overvaccination. A major challenge to evaluating a technologybased intervention is the evolution that comes with technology improvements and advancements. To determine whether cost and benefit estimates from the evaluation provide insight into the economic efficiency of present-day IIS, the IISs evaluated in the included body of evidence are compared with standards of more recent systems (discussed in the next section). To assess whether the evidence reflects mechanisms, capabilities, and scale of present-day IIS, the Team considered system technology, use of vendor support, data exchange methods, system functionality, and scope of IIS.

Relevance of findings

Six of the studies that assessed IIS systems cost date from 1997 to 2002 and thus reflect an IIS created at least 10 years before the evidence was gathered in 2012. As would be expected with a technology-based intervention, IIS system technology has evolved over time. When IISs were first developed in the United States, these systems primarily used mainframe technology with limited or no network connectivity. As the technology infrastructure improved, most IISs transitioned to client-server computer systems that enabled more automated data exchange by using a networked approach. Costs associated at this stage involved purchasing servers to support the IIS and information technology staff to maintain server functionality. Although many IISs continue to use client-server technologies, some are exploring use of cloud-based technology, which distributes computing infrastructure outside the organization, with more advanced networking. Costs associated with cloud-based technology are expected to be less than those associated with client-server technologies because of economies of scale and efficiency improvements and requirement of lower up-front costs.^{26,27} Unfortunately, only 1 study¹⁶ discussed details of the technological setup of the IIS. Two types of system technology were represented in the single studymainframe architecture and client-server architecture. No studies reported costs associated with cloud-based technology.

Another evolution in IIS development has been the emergence of software vendors that support IIS. Most IISs were originally developed, coded, quality tested, and maintained by in-house information technology staff. Several major vendors now support IIS implementers. In 2013, 77% (43/56) of immunization programs in the United States were supported by IIS vendors (L. P., unpublished data, 2014). Because no studies

TABLE 5 • Benefits of IIS Considered in the Included Studies

Study (Author, Yr)	Sample Size	Modeled (Y/N/Partially)	Improved Vaccine Supply/Management	Decreased Overvaccination	Decreased Reporting Burden	Decreased Time Retrieving Vaccination Records	Cost Offset (Savings)
Societal perspective Horne et al (2000) ⁹	Modeled Nationwide	>-		×	×	×	\$376 million/yr
	Registry—4 million annual birth cohort						
Public health emergency							
<i>response</i> Boom et al (2007) ¹⁵	18 966 evacuee records	Partially		×			\$3.4 million ^a
	identified	: :		:			() () () () () () () () () ()
Urquhart et al $(2007)^{23}$	21 295 evacuee records identified	Partially		×			\$5.3 million ^a
Public health department							
VA State Report 2010 ²⁵	1 State IIS—5 million	>	×	×	×		\$3.8 million/yr
	enrollees	i			;		
Bartlett (2007)	1 State health department	Z			×		\$14 352/yr
Providers							
Bartlett (2007) ¹³	Mean for 23 "vaccine for	Z			×		\$545/yr
	children" providers						
Glazner et al (2004) ¹⁷	2 Private practices /2 community health	Z				×	Not monetized
	centers						
Florida SHOTS Report	2 Provider sites	Z				×	\$111 to \$259 per 1000
(200 <i>3)</i> McKenna et al (2002) ¹⁸	23 Provider sites and 1	Z			×	×	Not monetized
	city IIS						
Managed care organization							
0'Connor et al (2010) ¹⁹	State-based MCO with 480 000 members	Z				×	\$128 096/yr

Abbreviations: IIS, immunization information system; MCO, managed care organization; N, no; Y, yes; yr, year. ^aStudy reported total savings.

included in this review evaluated costs of vendorsupported IIS, expenses associated with use of this technology compared with original in-house systems were not clear. However, it can be postulated that vendor-supported systems incur lower development and maintenance costs, particularly for IIS that are less customized. Vendor-supported software allows implementers to take advantage of investments already made in software development by the vendor, as well as predecessors who customized components of the system, rather than developing a system in-house. Correspondingly, some states have also shared costs in developing and implementing an IIS. In this review, many IISs in the studies represent the early adopters of IIS and thus are expected to have higher costs for using a new technology with no precedent system.

Third, methods for immunization data exchange have also changed over time. When IISs were first developed, immunization information was sent from the IIS on diskettes to vaccination providers who then loaded that information onto locally supported computer systems, updated that information with new vaccinations, and returned diskettes to the IIS. Other users relied primarily on paper reporting, which required that vaccination providers record immunization information on standard forms and mail or fax that information to the IIS. As the Internet became widely used, IIS transitioned to Web-based reporting systems so that providers could log on to a secure IIS Web site, then retrieve and submit immunization information in real time. As computers and electronic systems became commonplace in provider practices (eg, electronic billing systems and electronic health records), many providers and IIS developed capacity to exchange immunization information electronically between these systems. Electronic data exchange originally relied on batch reporting, in which data were queued up and sent to receiving systems at scheduled times. However, advances in system technologies, combined with use of Health Level 7 (HL7) standards, a nationally recognized standard for electronic data exchange between systems storing health data, have further supported the ability of IIS and provider-based systems to exchange data bidirectionally in real time. Costs associated with electronic data exchange include cost of information technology staff to maintain and support electronic data exchange for both the provider and the IIS. Only 2 studies provided information on data exchange costs. 19,20 Of these studies, 1 measured costs associated with manual data entry performed by clinic personnel versus a billing or patient management system.²⁰ However, it is unclear whether that study accounted for the technician costs to link the system to the IIS; the study reported only time and equipment costs. The other study is from the perspective of an MCO and

included cost of linking existing internal electronic systems to IIS.¹⁹ The MCO did not directly input data into the IIS; consequently, the estimate might be applicable to a provider with an electronic health record system.

Fourth, rapid advances in computing and technology have produced numerous benefits by enabling new functions and improving existing functions. Generally speaking, IISs were originally developed to primarily consolidate vaccination histories across multiple providers to provide clinical decision support, conduct reminder/recall, and monitor vaccination coverage. However, in recent years, the functions and features of IIS have expanded to support the diverse needs of multiple immunization stakeholders, such as vaccine ordering and inventory management functions and emergency preparedness support, and have improved reporting functions to better address geographic pockets of needs (L. P., unpublished data, 2014). Most benefits in this body of evidence focused on reduction of labor and time costs that accrued from using computerized versus manual systems. Although 4 studies evaluated potential savings that would result from reduced duplicative immunizations because of better tracking and consolidated access of patient immunization records, the modeled/partially modeled findings have limitations because of their assumptions and hypothetical projections.

The addition and expansion of IIS functionality is associated both with costs, which are unclear, and benefits. This review provides only a small glimpse into the economic benefits that result from implementation of IIS. The absence of reporting many of the expected benefits does result in an underestimation; however, it is important to note that the benefits evaluated in this review are relevant to current IIS systems and can be viewed as the minimum benefits that can be expected.

Finally, IIS economies of scale have changed. Many of the IISs in this review focused on citywide systems. Today, most of these city-based systems have been consolidated into a state-based IIS that serves a larger population, helping to reduce costs associated with developing, maintaining, and connecting multiple smaller-scale systems. Immunization information systems have also expanded their original focus of childhood vaccinations to include adolescents and adults. As more IISs incorporate vaccine administration data for adults, either through adding adult patients to the system or as individuals already enrolled in the IIS age into adulthood, the capabilities of IIS will become more universally applicable to individuals of all ages. Ninety percent (53/56) of immunization programs are supported by an IIS that serves the life span and have become universally applicable to individuals of all ages (L. P., unpublished survey, 2014). The expansion of populations served increases the volume of data received, processed, and reported. Unfortunately, costs associated with enhancing IIS to be able to support this increase in volume were not available. With these limitations in mind, Table 6 provides a summary of why the evidence provided in the included studies might be less relevant in determining costs of a present-day IIS.

Summary of findings

Based on the limitations discussed in this article, evidence in this review might not accurately represent present-day IIS; however, it is unlikely that the ratio of economic benefits to costs is any less favorable. As IIS functionality has improved, benefits are expected to be greater than what is captured in this review. With multiple factors influencing cost—potentially lowering costs through advancements in technology, introduction of vendor-supported IIS, and increase in scale, and potentially raising costs through improved functionality—it is unclear how present-day costs would compare with costs reflected in the studies. However, it is unlikely that costs increased at the same magnitude as benefits, which were underestimated in this review; costs might also potentially be lower. Therefore, it is likely that more up-to-date estimates of costs and benefits would support the findings of cost savings in this review. In addition, more research is needed to update and address the limitations in available evidence and

enable an assessment of economic costs and benefits of a present-day IIS.

Evidence Gaps

More economic data are needed on the costs of implementing present-day IIS, with information detailing whether the system is developed in-house or vendor supported. Details of system technology would be helpful in comparing each type of technology with its associated costs. This body of evidence primarily captured the economic benefit of reducing reporting burden and time spent locating records. Additional benefits (improved efficiencies and decreased time associated with conducting provider reminder/recall functions, provider assessment and feedback efforts, improved vaccine supply and management, and reduced morbidity and mortality) need to be monetized to fully capture the economic returns that accrue from using an IIS.

Lastly, the number of direct linkages between IIS and electronic health records (EHRs) are increasing in part due to the Centers for Medicare & Medicaid Services Meaningful Use initiative that provides financial incentives to eligible health care providers that acquire and demonstrate meaningful use of certified EHR products, which includes the exchange of data with IIS.²⁸ As more providers create direct linkage from EHRs to the central IIS, more information and details are needed about the costs of this type of connection.

TABLE 6 • Relevance and Limitations of Evidence Findings

Obj. J. (A. Albert Ve)				
Study (Author, Yr)	Year of Evaluation	Limitations in IIS Evaluated		
Slifkin et al (1999) ²²	1997	1. System technology likely to be out-of-date		
Rask et al (2000) ²¹	1997	2. Focus on developing an in-house system, versus a		
Fontanesi et al (2002) ¹⁶	1998	vendor-supported system		
Horne et al (2000) ⁹	1998	3. Only 1 study mentioned off-the-shelf software option		
McKenna et al (2002) ¹⁸	1998	but did not provide cost details		
Bartlett et al (2006) ¹⁴	2002			
VA State Report (2010) ²⁵	2010	 Study provided only operating costs Method (in-house or vendor-supported) of implementing IIS not clear due to limited cost details 		
		Limitations in Data Acquisition Methods Evaluated		
Rask et al (2000) ²⁰	1998	 Not clear whether study included costs of linking patient/billing system to central IIS (study focused on time and equipment costs) Manual data entry may be used less frequently 		
O'Connor et al (2010) ¹⁹	2007	 Managed care organization used IIS as a unidirectional data source; did not involve input of information into internal system or the IIS 		

Abbreviation: IIS, immunization information system; yr, year.

Discussion

This review provides an initial assessment of costs and benefits of implementing an IIS. As systems have evolved over time through technological innovation, in coordination with implementer input, competition, and experience, new approaches have been developed to build IISs that are more streamlined, operate faster, and have more capabilities. All included studies provide insight into the types of costs that might be incurred for implementers interested in building an IIS; however, dollar figures are less relevant because the systems evaluated are outdated.

The primary difficulty in assessing economic evidence was the rapid change in technology costs. As health information systems are increasingly adopted across public health settings, understanding upfront and ongoing costs, alternative costs of software, and associated benefits is key to determining the value of interventions. However, with continued rapid advancement of technology, challenges faced in this review will likely be a problem for other technologybased reviews. One approach might be to restrict the search inclusion criteria to exclude older technology or categorize the relevance of studies by comparing with more recent technology.

Reporting costs faced by vaccine providers who participate in IIS were also reviewed. Advancements in technology now allow providers to share immunization data through a direct link to the central IIS. However, cost barriers exist for providers to create the direct linkage, and significant administrative efforts and trainings might be required to re-engineer and align the providers' immunization practices to take full advantages of functionality efficiencies of IIS.¹⁶

Another public health goal is to integrate a vaccineordering module within an IIS that interfaces with the Centers for Disease Control and Prevention's Vaccine Tracking System for ordering and managing vaccine distribution.²⁹ Linking systems would streamline the process and potentially save money by reducing errors and waste and ensure that appropriate supplies of vaccines are distributed to providers.

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Practice Brief Report

Recommendation for Use of Immunization Information Systems to Increase Vaccination Rates

Community Preventive Services Task Force

ased on findings of a systematic review, the Community Preventive Services Task Force recommends immunization information systems on the basis of strong evidence of effectiveness in increasing vaccination rates. Evidence is considered strong, based on the findings from 108 published articles and 132 conference abstracts showing that immunization information systems are effective in increasing vaccination rates and reducing vaccine-preventable disease through their capabilities to (1) create or support effective interventions such as client reminder and recall systems, provider assessment and feedback, and provider reminders; (2) generate and evaluate public health responses to outbreaks of vaccine-preventable disease; (3) facilitate vaccine management and accountability; (4) determine client vaccination status for decisions made by clinicians, health departments, and schools; and (5) aid surveillance and investigations on vaccination rates, missed vaccination opportunities, invalid dose administration, and disparities in vaccination coverage.

KEY WORDS: immunization information systems, immunization registries, vaccination coverage

About the Task Force and This Recommendation

This article provides the recommendation of the Community Preventive Services Task Force (Task Force) for the use of immunization information systems (IISs). The Task Force makes recommendations about community- and system-based interventions, determined by the Task Force, to be of public health impor-

J Public Health Management Practice, 2014, 00(00), 1–4 Copyright © 2014 Wolters Kluwer Health | Lippincott Williams & Wilkins tance in preventing illness, injury, or premature death. Recommendations are based on a systematic review of the evidence on effectiveness, as well as on benefits and harms and applicability to populations other than those studied. Gaps in the available evidence are also noted during the review.

The Task Force recognizes that a decision to implement an evidence-based intervention involves more consideration than evidence alone. Potential implementers should understand the evidence but individualize decision making to the specific population(s) and setting(s) in which the intervention will be implemented, as well as the relevant constraints (eg, resources).

Task Force Finding

The Task Force recommends IIS on the basis of strong evidence of effectiveness in increasing vaccination rates. Evidence is considered strong, based on the findings from 108 published articles and 132 conference abstracts showing that IISs are effective in increasing vaccination rates and reducing vaccine-preventable disease through their capabilities to:

 create or support effective interventions such as client reminder and recall systems, provider assessment and feedback, and provider reminders;

Author Affiliation: Names and affiliations of Task Force members can be found at http://www.thecommunityguide.org/about/task-force-members.html.

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The authors declare no conflicts of interest.

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DOI: 10.1097/PHH.0000000000000092

- generate and evaluate public health responses to outbreaks of vaccine-preventable disease;
- facilitate vaccine management and accountability;
- determine client vaccination status for decisions made by clinicians, health departments, and schools; and
- aid surveillance and investigations on vaccination rates, missed vaccination opportunities, invalid dose administration, and disparities in vaccination coverage.

The full Task Force Finding and Rationale Statement are available at www.thecommunityguide.org/vaccines/RRimminfosystems.html.

Definition

Immunization information systems are confidential, population-based, computerized databases that record all immunization doses administered by participating providers to people living in a given geopolitical area.¹ At the point of clinical care, an IIS can provide consolidated immunization histories and forecasts for immunizations due or past due for use by a vaccination provider in determining appropriate client vaccinations. At the population level, an IIS provides aggregate data on vaccinations for use in surveillance and program operations and in guiding public health action with the goals of improving vaccination rates and reducing vaccine-preventable disease. In the United States, minimum functional standards for the operation of IISs were developed in 1997 by the Centers for Disease Control and Prevention, the National Vaccination Advisory Committee, and immunization program grantees. These standards are updated periodically.2

Basis of Finding

The Task Force considered a wide range of information relevant to program effectiveness. The Community Guide systematic review on which the Task Force finding is based³ included articles published in the peerreviewed literature from January 1994 to April 2011, as well as abstracts presented at conferences in the United States between January 2002 and April 2011, with specific focus on 4 conferences (National Immunization Conference; Pediatric Academic Society; Vaccine University; Immunization Registry Conference). In addition to studies providing a comparative assessment of program impact, the Task Force considered articles providing descriptions of IIS program activities and capabilities. The Task Force finding represents the first effort within a systematic review for

the Guide to Community Preventive Services (Community Guide) to incorporate quantitative assessments of change with qualitative assessments of program activities.

The systematic review included a number of studies demonstrating the capabilities and effectiveness of IIS to generate or directly support interventions known to increase vaccination rates: (1) client reminder and recall systems; (2) provider assessment and feedback; and (3) provider reminders. In 2009, the Task Force determined that each of these interventions had strong evidence of effectiveness in increasing vaccination rates (http://www.thecommunityguide.org/vaccines/index.html).

The role of IIS in generating and evaluating public health responses to outbreaks of vaccine-preventable disease and other public health emergencies was also well described in the included evidence. Several studies characterized the use of IIS records and system capabilities to target reminder and recall notices during outbreaks of measles and hepatitis A, to evaluate provider responses during pertussis outbreaks, and to inform vaccine allocation during the 2009 H1N1 influenza pandemic.

Included studies also demonstrated the utility of IIS in facilitating vaccine ordering, inventory monitoring, and vaccine-related accountability, especially the use of IIS for vaccines available through the US Vaccines for Children (VFC) program. Studies also described efforts to integrate the VFC-required Vaccine Tracking System (VTrcks) within the existing IIS.

Interactions between IISs and health care systems and between IISs and schools and daycares were described in the available evidence. Several included studies described how IIS data were used by health care systems for quality measurements including HEDIS (Healthcare Effectiveness Data and Information Set) reporting. Many studies highlighted how inclusion of school and daycare data in the IIS helped improve data completeness and accuracy, thereby becoming a more useful tool for assessing student immunization status.

The Task Force found limited evidence to evaluate the use of IIS by vaccination providers in clinical settings. Although several studies described IIS utility in vaccine management, few studies provided information on whether and how vaccination providers used IIS data or capabilities during clinical encounters or in the management of client vaccinations.

Most of the identified studies described the use of IISs to provide surveillance information or to support specific investigations of changes, trends, or gaps in vaccination coverage in the population. In these cases, the IIS provided information for decision makers to use in planning and implementing additional interventions to address the identified issue. The included studies described a wide range of IIS surveillance capabilities

including coverage assessments for specific vaccinations, investigations of coverage in high-risk subsets of the population, and an ability to monitor the uptake of new vaccines.

Applicability

Most of the included studies described activities in the United States and findings are likely applicable to US settings, systems of care, and client populations. Available evidence may reflect the capabilities and accomplishments of more mature IISs, and effectiveness my not directly translate to IISs with lower rates of client, provider, or practice participation.

Economic Evaluation

A review of the economic evidence found 12 studies and 2 government reports that met Community Guide criteria for a systematic review of economic evidence. Most studies involving cost data evaluated (1) system costs of building an IIS and (2) cost of exchanging immunization data; most economic benefits focused on administrative efficiency. Four studies compared the benefits with costs and found net savings. A major challenge to evaluating a technology-based intervention is the change that comes with technological improvement and advancement. Although the cost and benefit data may be less applicable today owing to changes in system technology, data exchange methods, availability of vendor support, and system functionalities, it is likely that more up-to-date estimates would support the findings of cost savings in this review.

Considerations for Implementation

The Task Force found benefit of IISs in efficient implementation of common vaccination-related activities, such as the rapid generation of official vaccination records for use by schools, health departments, and vaccination providers, and the ability to use IIS data to assess coverage and develop activities to improve on it. Furthermore, the Task Force identified no specific harms of IISs. Vaccination provider concerns that may impede IIS implementation include the time and effort required to participate, as well as concerns about data quality of vaccination records (timeliness, completeness, and accuracy). Increasingly, providers are using electronic transfer of data, thereby reducing barriers to provider participation. However, remaining challenges include increasing IIS and electronic health record system capability to exchange data using Health Level Seven messaging standards. There is also a need to continue supporting implementation of standards for data

exchange and interoperability among IISs, health plans, Health Information Exchanges, and other health information systems. Finally, issues related to client participation and confidentiality requirements may limit the ways that IIS data can be entered, retrieved, or used for clinical and public health purposes. For example, in US schools, IIS utilization must adhere to the requirements of the Family Education Rights and Privacy Act (available at www.ed.gov/policy/gen/guid/fpco/ferpa/index.html), which may impede the exchange of information.

Information From Other Advisory Groups

The National Vaccine Advisory Committee has published a series of reports on the progress of IIS over time and has stated that "IIS have demonstrated their effectiveness in improving immunization services and immunization coverage," while also highlighting barriers and challenges to their use.^{4,5} A number of associations and advisory groups have issued letters of support for IIS, including the American Academy of Pediatrics, the American Medical Association, the American Public Health Association, the National Medical Association, and the US Department of Education (www.cdc.gov/vaccines/programs/iis/resources-refs/partner-org-support.html).

Healthy People 2020

Broader implementation of IIS capabilities described in this review may be useful in meeting *Healthy People 2020* objectives to increase vaccination coverage and reduce vaccine-preventable disease. *Healthy People 2020* has established 2 IIS-related objectives: (1) to increase from 75% to 95% the proportion of children younger than 6 years whose immunization records are in fully operational, population-based IIS (IID-18) and (2) to increase the number of states that have 80% of adolescents aged 11 to 18 years with 2 or more age-appropriate immunization recorded in an IIS (IID-20) (http://healthypeople.gov/2020/topicsobjectives 2020/objectiveslist.aspx?topicid=23).

Evidence Gaps

The Task Force noted a critical gap in the body of evidence reviewed: information about the daily use and utility of IISs to vaccination providers, especially in clinical settings, is lacking. As this is one of the major applications of IISs, gaining additional insight in this area is particularly important. Intervention research

should attempt to quantify the use and effectiveness of IISs as a clinical decision support tool and investigate the effective practices and requirements involved in incorporating IISs into clinical practice.

Additional studies are needed to examine the relationship between IIS and IIS-related activities on overall vaccination coverage in the general population, or on important target populations with gaps in coverage. In terms of the economic efficiency of IISs, additional research is needed to address gaps in information and enable a more up-to-date and comprehensive economic assessment of IISs.

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Immunization Information Systems: A Decade of Progress in Law and Policy

Daniel W. Martin, MSPH; N. Elaine Lowery, JD, MSPH; Bill Brand, MPH; Rebecca Gold, JD; Gail Horlick, MSW, JD

his article reports on a study of laws, regulations, and policies governing Immunization Information Systems (IIS, also known as "immunization registries") in states and selected urban areas of the United States. The study included a search of relevant statutes, administrative codes and published attorney general opinions/findings, an online questionnaire completed by immunization program managers and/or their staff, and follow-up telephone interviews.

The legal/regulatory framework for IIS has changed considerably since 2000, largely in ways that improve IIS' ability to perform their public health functions while continuing to maintain strict confidentiality and privacy controls. Nevertheless, the exchange of immunization data and other health information between care providers and public health and between entities in different jurisdictions remains difficult due in part to ongoing regulatory diversity.

To continue to be leaders in health information exchange and facilitate immunization of children and adults, IIS will need to address the challenges presented by the interplay of federal and state legislation, regulations, and policies and continue to move toward standardized data collection and sharing necessary for interoperable systems.

KEY WORDS: electronic data interchange, health information exchange, immunization information system, informatics

Electronic exchange of patient health information is a major component of the United States national strategy to improve health care quality, improve population health outcomes, and reduce costs. Making health information on a patient available to clinicians when and where needed allows both the clinician and the

J Public Health Management Practice, 2013, 00(00), 1–8 Copyright © 2013 Wolters Kluwer Health | Lippincott Williams & Wilkins patient to be supported in making the right decision.² Consolidating information from multiple sources enables public health authorities to better monitor, assess, and respond to changing needs in the population.

Immunization Information Systems (IIS), also known as "Immunization Registries," have made patients' health information available to growing numbers of immunization providers for more than 20 years.^{3,4} Using secure database technology, IIS consolidate the fragmented immunization records of patients who seek care from multiple providers⁵⁻⁷ and

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The authors thank the Immunization Information System managers, immunization program managers, and other staff of the immunization programs in the state and urban health departments who responded to their surveys to provide the raw data for this study. In addition, the authors thank Janet Kelly, MPH, RN, for her participation in the planning phase of this project.

The findings and conclusions in this report are those of the authors and do not necessarily represent the views of the Centers for Disease Control and Prevention.

Data gathering and analysis were conducted by the Public Health Informatics Institute, Decatur, Georgia, under cooperative agreement no. HM08-080502C0NT12 from the Centers for Disease Control and Prevention.

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All authors report they have no financial or other conflicts of interest to disclose.

Supplemental digital content is available for this article. Direct URL citations appear in the printed text and are provided in the HTML and PDF versions of this article on the journal's Web site (www.JPHMP.com).

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DOI: 10.1097/PHH.00000000000000040

provide clear clinical guidance in the context of increasingly complex immunization recommendations.^{8,9} Many IIS now receive a growing proportion of their data through interfaces with Electronic Health Record (EHR) systems rather than through direct-entry or paper record submission. Both the Medicare and Medicaid EHR Incentive Programs (which incentivize the adoption and "Meaningful Use" of EHR systems in clinical practice)¹⁰ and Centers for Disease Control and Prevention (CDC) assistance of more than \$40 million nationwide (CDC, unpublished data, 2012) have supported this trend.

Since the early 1990s, states have enhanced legal and policy support for IIS. A survey of states that examined state laws, regulations, and policies in 2000 found that 36% of states had laws or rules specifically addressing IIS for children.¹¹ A more recent study in 2010/2011 found an increased number of states (66%) with laws specifically authorizing the operation of an IIS.¹²

The legal framework goes beyond simply authorization of registry operations. A variety of laws and regulations define the balance between public health authority and individuals' rights to privacy and consent with regard to their own data. These include not only state and local law but also the federal Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule. 13-15 This complex patchwork of federal, state, and local laws and policies presents challenges for both intra- and interstate exchange of immunization information.

Complicating this patchwork of laws even more are new entities created to facilitate health information exchange, alternatively called Health Information Organizations, Health Information Exchanges (HIE), or Health Information Service Providers (collectively referred to in this paper as "HIEs"). HIEs often have specific statutory authorities and duties, including requirements for patient consent, which may or may not be consistent with those governing IIS. For example, a state may have a law that mandates provider reporting of pediatric immunizations to an IIS without need for parental consent, but the laws for HIE require written patient consent for participation. Such a situation effectively means that the provider cannot fulfill a mandate to report immunizations without either violating the HIE consent requirement or bypassing the HIE for nonconsented patients.

Objective

The objective of this study was to obtain information relating to legislation, regulations, rules, and policies (collectively referred to as "laws") that enable, support, or constrain the ability of an IIS to receive or disclose immunization information for both children and adults and to assess trends with regard to these laws.

Participants

The initial target population included all domestic recipients of federal Section 317 immunization grant funding administered by the CDC: 50 states, 5 municipalities, and the District of Columbia. Houston discontinued operation of its IIS in 2010 and Chicago does not operate an IIS. Both municipalities were excluded from this study. At the time of this study, New Hampshire did not operate an IIS and was excluded. The final study population was 49 states, 3 municipalities (New York City, Philadelphia, and San Antonio, each of which operates an IIS independent of its respective state), and the District of Columbia, for a total of 53 participants.

Design

Online survey

A self-reported, online survey was pilot tested by 3 state immunization program manager volunteers. Prior to administration, this survey was reviewed by the CDC National Center for Immunization and Respiratory Diseases Human Subjects Advisor and determined not to involve human subjects and, therefore, exempt from institutional review board monitoring. After the pilot, all participant programs were asked to complete the final 36-question survey on SurveyMonkey during February and March 2012. Respondents were directed to refer to state statutes and laws, municipal ordinances if applicable, state and local rules and regulations, state and local written policies, and written findings/opinions of attorney general or general counsel. The immunization program manager was asked to provide answers in consultation with other appropriate individuals, including IIS managers or other program/IT staff. The response rate was 100%.

Legal research

In October and November 2011, the study team conducted a WestLaw search of relevant statutes, administrative codes, and published attorney general opinions/findings. ¹⁶ Results of the legal research were examined by members of the study team who are attorneys to restrict the scope to citations addressing IIS, as opposed to laws regulating non-IIS issues such as clinical practice, outbreak control, health officer emergency powers, and school attendance.

Follow-up telephone interviews

In March and April 2012, 1 member of the study team conducted a 30-minute telephone follow-up interview

with every program in the study. Interviews addressed any inconsistent or unclear answers and allowed participants to elaborate on any of their responses to the online survey, including any apparent discrepancies between survey responses and the study team's legal research. Participants on the follow-up calls varied and included immunization program managers, IIS managers, CDC Public Health Advisors, legal counsel, and IIS vendors.

Validation

Modifications of the original online responses were made as a result of the follow-up telephone interviews; the modified responses and the study team's reclassification of "Other" responses were validated with the respondents through a second round of e-mail and telephone communication in February 2013.

Comparative data for trends

When possible, data gathered in this study were compared with Horlick's¹¹ review of IIS-related legislation. The data in Horlick were gathered in 2000, so this is the year used for reference in any comparisons made. The study by Horlick in 2000 did not address the details of adult versus childhood records in IIS, nor did it include municipal IIS, so not all data were comparable.

Results

A complete line-listing of data is summarized in Supplemental Digital Content Survey Data, available at http://links.lww.com/JPHMP/A72.

Lifelong or childhood IIS

Fifty-one (96.2%) of the 53 IIS programs were authorized to collect immunization records for all age groups (also known as a lifelong IIS). For 2 (3.8%) programs, the IIS was limited to immunization records for children only.

Type of authority to operate an IIS for children

Thirty-six (68%) of the IIS programs studied collected immunization data for children (age ranges vary by state) on the basis of laws specifically authorizing IIS, another 6 (11%) on the basis of immunization information-sharing laws (which did not mention an IIS), and 1 (2%) on the basis of laws allowing the sharing of general health information. The remaining 10 (18.9%) programs relied on general public health authority rather than explicit authorization to operate an IIS for children (Figure 1).

Taken together, these findings represent a total of 43 of 53 (81%) jurisdictions that directly provided legal authority for public health to operate an IIS. These numbers contrast with the legal authority for IIS reported in 2000: 24 (47%) IIS-specific, 9 (18%) immunization-information, and 3 (6%) general public health authority¹¹ (see Supplemental Digital Content Figure 1A, available at http://links.lww.com/JPHMP/ A69), or the only 9 (18%) states with any IIS authorization reported in 1995.3

Type of authority to operate an IIS for adults

Of the 51 IIS programs that were authorized to operate an IIS for adults, 27 (52.9%) had laws that specifically authorized operation of IIS, 8 (15.7%) had laws that authorized sharing of immunization information, but did not specifically authorize the operation of IIS, 3 (5.9%) had laws allowing the sharing of health care information, but did not refer to immunization information explicitly, and 13 (25.5%) relied on general public health statutes or regulations to operate IIS for adults.

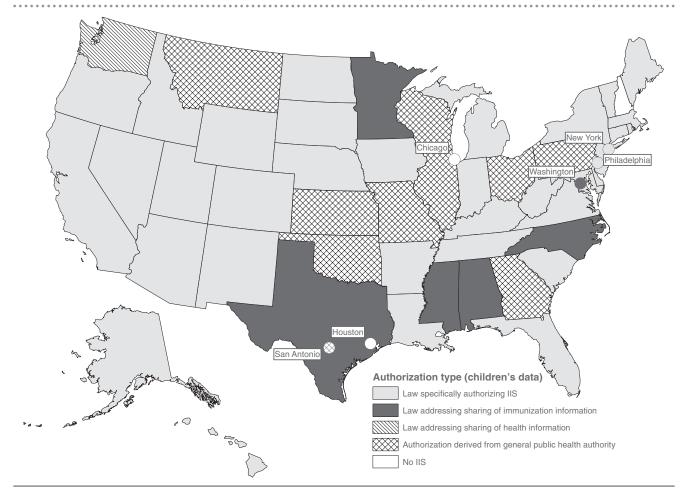
Mandate to report immunizations

Thirty-one (58.5%) jurisdictions mandated at least 1 type of provider or entity to report immunizations and 22 (41.5%) had no mandate to report immunizations (Figure 2). By contrast, in 2000¹¹ only 12 states had mandated reporting (see Supplemental Digital Content Figure 2A, available at http://links.lww.com/JPHMP/ A70).

A mandate to report may be limited to certain age groups or certain vaccines (eg, publicly funded vaccines). Of the 31 IIS programs with some type of mandate to report immunizations, 21 (67.7%) mandated all immunization providers to report, 27 (87.1%) mandated public health providers to report, 23 (74.2%) mandated Vaccines for Children (a federal vaccine-purchase program) providers to report, 21 (67.7%) mandated private providers to report, and 22 (71%) mandated pharmacies/pharmacists to report.

Among the 31 IIS programs with some type of mandate to report immunizations, 12 (38.7%) mandated that immunizations for all age groups be reported and 17 (54.8%) mandated that immunizations for children/adolescents/young adults (with upper age limits ranging from 18 to 26 years of age) be reported but not immunizations for adults. Only 2 (6.3%) programs mandated reporting of immunizations for only young children (with upper age limits of 6 or 7 years of age). Among the 31 programs with some type of mandate to report immunizations, 26 (83.9%) mandated

FIGURE 1 • Legal Basis for IIS Operation, United States, 2012



that the report be to the IIS, 3 (9.7%) mandated that the report be to local public health, and 2 (6.3%) mandated that the report be to both local public health and the IIS. For San Antonio, the mandate was to report to either the San Antonio IIS or the state of Texas IIS.

Of the 31 IIS programs with some type of mandate to report immunizations, 21 (67.7%; 39.6% of total participants) had a mechanism to enforce the mandate. The authorized enforcement mechanism was a penalty or fine in 4 (12.9%) locations. Fourteen (45.2%) programs had authority to enforce a mandate by limiting the amount of public vaccine a provider can order if that provider fails to report immunizations. Four (12.9%) programs were authorized to enforce a mandate to report immunizations both through a penalty/fine and by restricting orders of public vaccine.

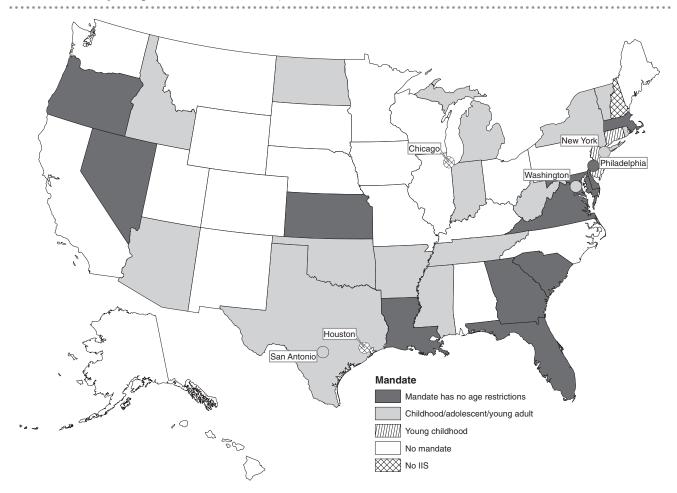
Of the 21 IIS programs with a mechanism to enforce the reporting mandate, 4 (19%) reported that they enforced it through feedback to the noncompliant provider and did not use penalties, fines, or limitation

of vaccine orders. Eleven (52.3%) enforced reporting by limiting the amount of public vaccine a nonreporting provider could order. One (4.8%) program used both limitation on the amount of public vaccine and feedback to noncompliant providers. Five (23.8%) did not enforce the mechanism.

Consent for vital records

Forty-six IIS (86.8%) received information on births in their jurisdiction from vital records or from birthing hospitals. Of those 46, 21 (45.7%) imported the birth record into the IIS on the basis of implied consent; 5 (10.9%) had no consent requirement, but the parent or guardian had the right to opt out of having his or her child's information in the IIS; 15 (32.6%) imported the birth record without consent and there was no right to opt out; and in the remaining 5 (10.9%), written consent was required to share birth record information with the IIS.

FIGURE 2 IIS Reporting Mandate, United States, 2012



Consent to share childhood immunization information

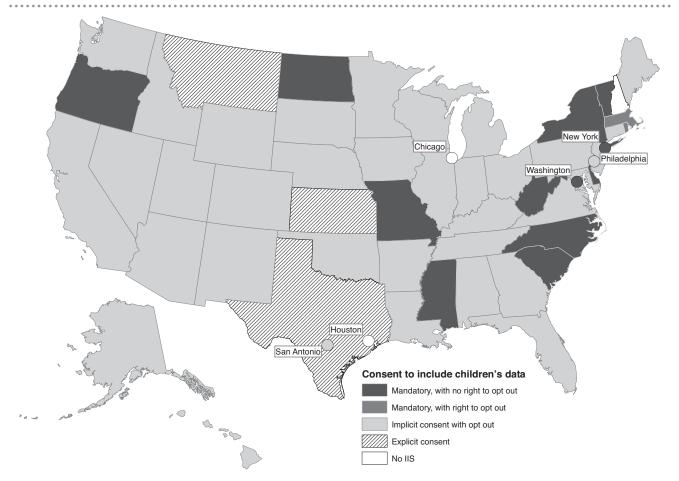
For 36 (67.9%) IIS programs, childhood immunization information could be included in and shared by the IIS on the basis of implied consent, with a right to exclude or remove immunization information from the IIS ("opt out"). In 14 (26.4%) programs, childhood immunization information could be shared with the IIS without any consent, with no right to opt out in 12 jurisdictions and with a right to opt out in 2 (Figure 3). In Oregon and Florida, the right to opt out was very restricted. In Oregon, the parent had to prove that disclosure of immunizations would disclose a medical condition or provide an affidavit that disclosure would present a potential safety issue such as domestic abuse. (Because of the restriction, Oregon was classified as "no right to opt out" in this study). In Florida, the parent could restrict the sharing of information by the IIS but could not prevent inclusion in the IIS. Explicit consent was required to share childhood immunization information with the IIS in 3 (7.5%) IIS programs (written consent was required in 2 of these 3).

As shown in Supplemental Digital Content Figure 3A, available at http://links.lww.com/JPHMP/A71, there has been a notable reduction in jurisdictions requiring explicit consent since 2000.

Consent to share adult immunization information

Of the 51 programs with authority to operate an IIS for adults, 34 (66.6%) relied upon implied consent to share adult immunization information with the IIS, with a right to opt out. For 9 (17.6%) programs, adult immunization information could be shared without any consent, with no right to opt out in 8 of these programs and with a right to opt out in 1. Explicit consent was required to share adult immunization information in 8 (15.9%) jurisdictions (written consent was required in 5). In the District of Columbia, no consent was required to share information for adults immunized with publicly purchased vaccine, but consent was implied with a right to opt out for adults (older than 26 years) immunized with privately purchased vaccine. In Arizona,

FIGURE 3 IIS Consent Requirements, United States, 2012



explicit consent was required before sharing adult vaccination information, except for immunizations administered by pharmacists for which there was implicit consent with right to opt out.

Withdrawal of consent

Consent to retain information in the IIS could not be withdrawn in 7 (13.2%) jurisdictions. In the remaining 46 (86.8%) jurisdictions, if consent to retain information in the IIS was withdrawn: all data were retained and access was limited or prohibited in 32 (69.6%), all data were removed in 7 (14.6%), and limited identifying demographic information was retained in 6 (12.5%). One program was in the process of upgrading its IIS and reported that its existing system could not adequately address withdrawal of consent.

Health Insurance Portability and Accountability Act

Twenty-four (45.3%) IIS were considered by their programs to be covered entities under HIPAA, 25 (47.2%) were considered to not be covered entities under HIPAA, and 4 (7.5%) respondents did not know whether the IIS was considered to be a covered entity under HIPAA.

Interaction with HIEs

Fifty (94.3%) IIS programs reported that sharing of immunization data between their IIS and HIEs was implemented or contemplated. Thirty-six (67.9%) programs already had authority to exchange data with HIEs in their jurisdiction. Of the 36 with authority to exchange data, in 15 (41.7%) the authority was derived from a data exchange agreement only, in 13 (36%) the authority was derived from general public health laws, and in 9 (25%) the authority was derived from a specific statute or regulation. Seven (19.4%) programs reported that they did not know whether they had authority to share immunization information with HIEs in their jurisdiction and 1 program responded that the question was not applicable because the HIE was merely a conduit for data transmission.

Authority to transmit or allow access to data across state borders

Thirty-six (67.9%) IIS programs had authority to transmit or allow access to immunization data across state borders. Of the 36 with authority to transmit or allow access across state borders, in 15 (41.7%) the authority was derived from a data exchange agreement only, in 11 (30.6%) the authority was derived from general public health laws, and in 10 (27.8%) the authority was derived from a specific statute or regulation. Two (3.8%) IIS programs responded that they did not know whether they had authority to transmit or allow access to data across state borders. New York State had legislative authority to transmit or allow access to data across state borders and also required a data-sharing agreement. Twenty-nine (54.7%) programs responded that they currently transmit or allow access to data in the IIS across state borders and 24 (45.3%) did not conduct such transmission or access.

Discussion

There is a long-standing recognition of the need for appropriate legal/regulatory support for IIS. Linkins and Feikema⁸ proposed several categories of "registryfriendly" legislation addressing authorization, mandate to report, privacy/confidentiality, and the sharing of health information. Although national IIS-like systems have been discussed, 12,17 the states remain the locus of such legislation.

Notwithstanding the variability documented in this study, there is much progress to report. The fact that 43 jurisdictions have directly addressed IIS authorization through some form of law or regulation versus 36 in 2000 suggests that legislative bodies have been increasingly supportive of IIS activities.

There is a similar trend with regard to a mandate to report to IIS. The finding that 31 jurisdictions report some form of mandate today versus only 12 jurisdictions in 2000 may indicate increased recognition among legislative bodies of the utility of IIS to public health. Although another recent study¹² reported only 46% of states with a reporting mandate, the difference may be due to methodology. Hedden's text analysis approach included only published laws and regulations. Our interview methodology included written policies, which Hedden did not analyze.

Privacy and consent

Privacy, confidentiality, and consent have been consistent themes in IIS policy from the inception of electronic immunization reporting.^{3,8,11,18-20} All states report having such policies in place.²¹

There is considerable variability regarding whether inclusion of an individual's record in IIS, and the sharing of that record with authorized users, requires the consent of the individual or his/her parent/ guardian. State IIS policies and laws range from highly restrictive—that is, the record is only included on an opt-in basis—to mandatory inclusion with no opportunity to opt out of the IIS. The majority of jurisdictions either mandated reporting or used implied consent, in which the patient or parent/guardian is notified of the provider's requirement to report and offered the opportunity to opt out. In the case of IIS with a provision to opt out, there is further variation as to whether the record of an individual who opts out is completely deleted from the system, or whether access to that individual's record is restricted (eg, to public health and the original reporting health provider).

National public health experts recommend opt out consent policies when feasible in order to lower the barrier to comprehensive reporting to IIS.8,18 Such policies respect an individual's right to privacy, including the right to exclude information from public health databases, while maximizing the availability of needed data for quality care and public health. It has been suggested that switching from opt in to opt out could save more than \$1 million per year in 1 state,²² and at least 1 study has suggested that opt out policies may correlate with improved immunization coverage.23

Health Information Exchange

There remain important barriers to successful interoperation of HIE systems with IIS. Although the overwhelming majority (50/53, 94%) of IIS programs reported intent to exchange immunization information with HIEs, differences in consent requirements could present an impediment to successful exchange, for example, between an opt in HIE and an opt out IIS. Interstate information exchange is particularly hampered by the variation in consent laws.9

Immunization Information Systems have in many ways blazed the trail for HIEs, addressing issues of data quality, interoperability, and even interstate data exchange.²² Immunization Information Systems by definition are intended to facilitate the exchange of immunization information between authorized entities such as health care providers. Such exchange can fully be realized only when other information systems, such as EHRs and other health databases, can interoperate with IIS¹⁰ in a standardized manner.²⁴

Limitations

The study is based on self-reported data and is not a comprehensive review of the law. Biases inherent in self-reported information were minimized through the collection and review of laws, regulations, and published attorney general opinions.

Conclusions

Immunization Information Systems have been in the forefront of electronic health information exchange efforts and can serve as "building blocks" to a more mature national health information exchange.24 Over the past decade, legislation, regulation, and policies concerning immunization data have become more conducive to full participation in IIS and to sharing and using the information outside the IIS, for example, with HIEs. To continue to be leaders in health information exchange and facilitate immunization of children and adults, IIS will need to address the challenges presented by the interplay of federal, state, and local legislation, regulations, and policies and continue to move toward standardized data collection and sharing necessary for interoperable systems. While the expanded use of EHRs and HIEs will continue to facilitate the exchange of immunization information, this expansion may challenge IIS' continuing efforts to protect privacy and confidentiality and to enhance system security in order to maintain the trust of individuals, providers, and the public.

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Editorial

Immunization Information Systems

Lloyd F. Novick, MD, MPH

Four articles on immunization information systems are being published ahead of print by the *Journal of Public Health Management and Practice*. Three of these articles are related to findings of a recent systematic review by the Community Preventive Services Task Force. A fourth article, from the Centers of Disease Control and Prevention, by Daniel Martin "Immunization Information Systems: A Decade of Progress in Law and Policy" is a study of laws, regulations, and policies governing Immunization Information Systems (IIS), also known as immunization registries.

A Community Guide systematic review, "Immunization Information Systems to Increase Vaccination Rates," synthesized evidence from studies that evaluated IIS capabilities to (1) create or support interventions to increase vaccination rates; (2) identify patient vaccination status to inform health care decisions; (3) aid population-based responses to vaccine-preventable disease; and (4) provide other information relevant to vaccine administration and aid vaccine management. Review of 240 papers and abstracts demonstrated a positive association between IIS activities and improvements in vaccination coverage.

A companion article from the Community Preventive Services Task Force, "Recommendations for Use of Immunization Information Systems to Increase Vaccination Rates," concluded that there was strong evidence that immunization information systems are "effective in increasing vaccination rates and reducing vaccine preventable disease" based on the findings from 108 published articles and 132 conference abstracts.

Another Community Guide systematic review, "Economic Review of Immunization Information Systems to Increase Vaccination Rates," evaluated the costs and benefits associated with using these systems. IIS require funding for implementing and operating the system and providers and the IIS incur costs for data exchange. The benefits include reduced duplicative vacci-

J Public Health Management Practice, 2014, 00(00), 1–2 Copyright © 2014 Wolters Kluwer Health | Lippincott Williams & Wilkins nation, improved vaccination coverage, fewer administrative burdens, and allocation of less public and private resources to administer vaccines. Economic evaluations, including those published in this study, are complex because of the speed of technology change, including growing use of electronic health records. Although IIS functions and features and available technologies continue to expand, it is anticipated that benefits to providers, public health and the general population will outweigh costs associated with these advancements.

In addition to traditional immunization partners such as vaccination providers and schools, the rise in electronic data exchange and other technologies has expanded the number and type of entities interfacing with IIS (eg, health information exchanges, pharmacy networks, etc). In addition, federal agencies such as Centers for Medicare and Medicaid Services and Office of the National Coordinator, which support the management and execution of Meaningful Use initiatives, are interested in IIS capacity to support clinical and public health data exchange. Expanded stakeholder involvement in IIS has increased the need for standardization of both IIS operations and technical capacities. Publication of HL7 implementation guides for immunization messaging, Clinical Decision Support for immunization guidelines, and the adoption of 2-dimensional barcode technology for recording vaccination information in electronic health records and IIS are examples of standardization movements. The adoption and implementation of such standards only serves to further increase the number of IIS stakeholders and the ability of these partners to use IIS information to benefit the health of the public.

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DOI: 10.1097/PHH.0000000000000111

Begun in the 1970s, IIS now operate in all but one US state and most serve children, adolescents, and adults. The articles now being published demonstrate substantial progress in participation of patient and immunization provider in IIS and enhanced system functionalities that serve a broad set of immunization

stakeholders. As new technology develops, standards for data exchange and data use are established and implemented, and IIS stakeholders expand, the effectiveness of IIS to serve the immunization needs of clinicians, public health, the general population of all ages will also increase.