Immunization information systems: a clinical review

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2009
Acknowledgement

I would like to thank my project advisor April Gardner, MSBS, PA-C, for her contributions, guidance, and support in the development of my project. I would also like to thank reference librarian Jolene Miller for her assistance with research and development of the project.
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Tables and Figures

Table 1- Recommended Immunization Schedule for Persons Aged 0-6 years of age

Figure 1 - Percentage of children aged < 6 years participating in a grantee immunization information system 2007
**Introduction**

Vaccines are a key component in the foundation of preventive medicine. Since the introduction of safe vaccines, the United States and the majority of other developed countries have experienced over 95% reductions in cases of childhood vaccine-preventable diseases, compared with pre-vaccine era levels (Orenstein, Hinman, & Rodewald, 1999). Vaccinations improve the quality of life by decreasing the incidence and preventing the spread of infectious disease. It is estimated that every $1 spent on vaccinations decreases future medical costs by $6.30 (Zavolinsky, 2004). Although there are currently high levels of vaccination coverage in the U.S., underimmunization continues to occur. One study suggested that low vaccination rates may be due to scattered medical records; missed opportunities; and lack of tracking, reminder, or recall systems (Santoli, Szilagyi, & Rodewald, 1998).

In addition, there are arising challenges making it difficult to vaccinate children according to the recommended schedule and keeping their records up-to-date (UTD). In particular, vaccine recommendations are increasing in both number and complexity. It is currently recommended that children receive a total of 15-19 vaccine doses by 18 months of age, compared with only 8 doses 20 years ago (Stokley, Rodewald, & Maes, 2001). Table 1 shows the current Centers for Disease Control and Prevention (CDC) recommended vaccination schedule for persons 0-6 yrs of age including high risk groups. (Table 1) (Centers for Disease Control, 2009). Furthermore, the development of new and combination vaccines contribute to the difficulties of maintaining accurate vaccination records for practitioners and parents.

In addition to these complications of the immunization system, populations are becoming more mobile, making it difficult for providers to establish complete immunization records. One study of 1352 children reported that 304 (22%) visited more than one provider for immunizations.
by 19-35 months of age (Stokley et al., 2001). Of particular concern, higher rates of children with multiple providers have been reported in populations with traditionally low immunization rates, such as inner city and rural populations. A study in rural Colorado found that nearly 33% of children were receiving vaccines from multiple providers (Kempe et al., 2001). This transfer between providers can lead to misclassifying a patient’s immunization status and ultimately missing or re-administering vaccinations (Stokley et al., 2001). For these reasons, it is increasingly important that providers keep their records current and accurate in order to ensure that children are receiving the correct vaccinations on schedule to prevent disease outbreaks.

One tool that has been developed to assist practitioners in immunization record maintenance is the Immunization Information System (IIS). IISs are confidential, population-based, computerized systems that contain information regarding children’s vaccinations. Children from a defined region are entered into the system at birth. If the registry contains the majority of children, it has the ability to provide data for all vaccine providers serving a geographic region. IISs allow providers to use the information contained in the IIS to develop immunization strategies, decrease resources, and maintain high vaccination levels (Centers for Disease Control, 2001a). IISs increase immunization levels and up-to-date records by consolidating records from multiple providers, generating reminder and recall systems for patients, and providing official vaccination coverage assessments (Centers for Disease Control, 2001b). IISs give providers the ability to quickly access vaccination records, monitor office immunization rates, and use data for statistical research. The current gold standard for estimating immunization rates is using parent reported and provider validated immunization records, however, this is labor intensive and requires multiple phone contacts for each child (Santoli et al., 1998).
Currently, the American Academy of Pediatrics, the American Medical Association, the National Association of Pediatric Nurses, and the National Medical Association have developed policy statements or written letters of endorsements for IISs (Centers for Disease Control, 2008b). Despite recommendations and potential benefits of IISs, and 15 years of development, national participation stands at 71% with considerable variation of participation levels between states, with four states (Kentucky, Kansas, Massachusetts, and New Hampshire) not even having an active IIS. (Figure 1)(Centers for Disease Control, 2007).

In Healthy People 2010, a goal was established to increase the proportion of children under the age of 6 years who participate in a fully operational population-based IIS to 95% (U.S. Department of Health and Human Services, 1999). However, the development of IISs has been slowed by lack of political support, lack of financial support, and operational obstacles hindering progress toward this goal (Fontanesi, Flesher, De Guire, Lieberthal, & Holcomb, 2002). This study assessed the advantages and disadvantages of IISs and summarized the perceptions and challenges that prevent providers from participating in their local IIS as described by the literature.
Background

In 1974, Delaware became the first state to develop a population based IIS (Ortega, Andrews, Katz, Dowshen, & Curtice, 1997). Through the 1980s, IISs were developed and used mainly by large health management organizations rather than on a population based level (Wood, Saarlas, Inkelas, & Matyas, 1999). From 1988 to 1991, the United States experienced one of the longest continuous measles epidemics since the development of the measles mumps and rubella vaccine (MMR). It was found that only 50% of children were receiving correct vaccination doses by their second birthday, partly due to the unavailability of vaccination records to providers (Iowa Department of Public Health, 2008). The measles outbreaks lead to the significant political and financial support for the development of IISs that occurred in the early 1990s.

A leader in the support and development of IISs was the Robert Wood Johnson Foundation (RWJF). In 1991, the RWJF became one of the first organizations to define, describe, and financially support IISs by starting the All Kids Count Program (Freeman & DeFriese, 2003). The program consisted of three phases. During phase I in 1992, 26 grants were awarded to applicants to provide financial support for the development of IISs. Phase II followed in 1998, awarding another 16 applicants with grants for the development of IISs. The two phases combined awarded nearly $20 million to applicants for the development of their systems (Saarlas, Edwards, Wild, & Richmond, 2003). By the end of the first two phases, the All Kids Count Program reported success in the public sector with nearly 100% of public providers participating in the IISs developed with RWJF grant funds. The development in the
private sector was not as successful, with only 59% of private providers participating in an IIS (Freeman & DeFriese, 2003). 5 million dollars was awarded during the third and final stage of the All Kids Count Program. Phase three differed from the initial two phases in that funds were allocated for technical assistance and user education with the goal to further increase knowledge of existing IISs rather than to promote the development of new IISs (Saarlas et al., 2004).

In 1993, U.S. President Bill Clinton included IISs in his initiative on immunizations. Section 317 of the immunization grant program allowed funds to be used for the development of IISs (Freeman & DeFriese, 2003). Additionally, in 1993 the CDC began awarding grants for the development of IISs. The National Vaccine Advisory Committee (NVAC) agreed with the CDC in 1994, and supported the development of IISs and recommended increased funding. In 1997, an initiative on immunization registries was started by the NVAC with support from the National Vaccine Program (NVP) and the CDC with the goals to develop a long term policy and to ensure that IISs were implemented nationwide with adequate funding (Saarlas et al., 2004). During this time, the CDC funded research projects to encourage provider participation, improve registry data, and evaluate the likelihood of avoiding duplicate data entry (Centers for Disease Control, 2001a). As of 1997, there was $142 million in funds from Section 317 grants and an additional $200 million from private, public, and foundation funds put toward the development of IISs (Centers for Disease Control 2001c). With continued financial development and growth of IISs, functional standards were needed to ensure IISs were working efficiently. In 1997, the National Immunization Program (NIP) surveyed IIS managers in an effort to define and describe the role of an IIS (Freeman & DeFriese, 2003). As a result, NIP developed 13 standards which have since been modified to 12 minimum functional standards of IISs. The modified 12 functional
standards were approved by NIP in 2001 (N. I. P. Centers for Disease Control, 2006). The 12 minimum functional standards of IISs are as follows:

1. Electronically store data on all NVAC-approved core data elements.
2. Establish a registry record within six weeks of birth for each newborn child born in the catchment area.
3. Enable access to and retrieval of immunization information in the IIS at the time of the encounter.
4. Retrieve and process immunization information within one month of vaccine administration.
5. Protect the confidentiality of health care information.
6. Ensure the security of health care information.
7. Exchange immunization records using Health Level Seven (HL-7) Standards.
8. Automatically determine the routine childhood immunization(s) needed, in compliance with current Advisory Committee on Immunization Practices (ACIP) recommendations, when an individual presents for a scheduled immunization.
9. Automatically identify individuals due/late for immunization(s) to enable the production of reminder/recall notifications.
10. Automatically produce immunization coverage reports by providers, age groups, and geographic areas.
11. Produce official immunization records.
12. Promote accuracy and completeness of registry data.

With the minimal functional standards defined, IISs have continued to grow over the past two decades. Currently, 22 out of 56 (40%) of the state and city IISs receiving national funding
report having child participation levels of 80% or higher (Alan R Hinman, Urquhart, Strikas, & Committee, 2007). Although there have been advances in the development of IISs, vaccine preventable outbreaks continue to occur. In 2003, there was a limited measles outbreak in a highly vaccinated school after a student was exposed to measles in Lebanon. In a school of 600 students, 9 cases were identified. Among the 9 cases identified, 6 of the students either had not received both doses of the vaccine or had received their vaccine outside the of United States (Yeung et al., 2005). Proper vaccine administration and management is vital to preventing the spread of vaccine preventable diseases
Overcoming Provider Perceptions

One challenge to the development of IISs is overcoming poor provider perceptions of IISs and motivating providers to participate in the system. The IIS National Evaluation and Agenda, a 2005 survey of 26 IIS participants in multiple fields of IIS, found that the most important issue addressing IISs was the provider perspective and needs (Kelly, Zimmerman, Reed, & Enger, 2007). Many providers see IISs as an unnecessary hassle and do not want to invest time and finances to replace their current system of immunization tracking (Christakis et al., 1999; Clark, Cowan, & Bartlett, 2006).

Lack of communication with providers is the first obstacle when motivating immunization providers to participate in an IIS. When non-participating immunization providers were surveyed, 51% reported that they had not been contacted about participating in an IIS (Clark et al., 2006). Once immunization providers have knowledge of the IIS, they must then take the initiative to implement the system in their office. A survey conducted in 1998 indicated that even though almost 40% of physicians had heard of the IISs, only 6.3% of them actually used the system in practice (Gaudino et al., 2002). Even though immunization providers believe that IISs are the best chance to maintain accurate documentation, they may still avoid participating in the IIS due to the high start up costs and perceived lack of benefits of the system.

In 1999, a survey of 344 immunization providers using Washington’s CHILD IIS found 77% of RN/NPs, 47% of family physicians, and 60% of pediatricians thought that IISs represented the best chance to solve documentation problems. Despite optimism about IISs, these providers stated the most common reasons for not participating in an IIS were inaccuracy of data
(53%), lack of training (29%), and cost and time demands on the practice (31%) (Christakis et al., 1999). Physicians did not see the benefit of participating in an IIS because they viewed their own systems of immunization maintenance as more complete and accurate than the existing IIS records. In 2006, a similar survey of 756 private providers, using one of 15 IISs, found that non-participating providers chose not to participate because of cost, staff time allocated to performing registry activities, or the office already had an office based method of immunization information maintenance, not because of incompleteness of the IIS (Clark et al., 2006). Similarly in 2007, only 18% of immunization providers using Michigan’s Care Improvement Registry (MCIR) expressed minor concerns with overall IIS data accuracy when asked to identify issues associated with using the IIS (Dombkowski, Leung, & Clark, 2007). The foremost reason of inaccuracy and incompleteness of data, as indicated from earlier studies, is no longer a main obstacle in preventing participation. The growth, development and increased participation of IISs have lessened the perception among providers that IISs are incomplete. Still, there remains a perception that reporting and retrieving information from an IIS will cost the office precious time and resources (Bartlett, Washington, Bryant, Thurston, & Perfili, 2007). This has shown to inhibit the participation of providers. Thirty-three percent of IIS non-participants stated that it was unlikely that they would participate in an IIS in the next two years and 22% said that it was unlikely that they would ever participate in an IIS (Clark et al., 2006). These perceptions of an expensive, unnecessary system prevent provider participation in a system that is dependent on maximum provider participation.

Once an office has decided to participate in an IIS, provider satisfaction with the IIS is essential to the continued use of an IIS. There can be variation in satisfaction with an IIS that is subject to individual experiences with the IIS. In particular, one study found that immunization
providers familiar with the IIS were less likely to think that IISs were the solution to the documentation problem and more likely to believe that it would be a long time before they become effective. (Christakis et al., 1999). Conversely in 2002, 96% of the members of the Metro Atlanta Team for Child Health IIS thought that registry data was useful and 92% thought that the registry was helpful in exchanging information with other providers. (Gaudino et al., 2002). Dissatisfaction with the system can lead to decreased use, creating a perception of an unnecessary, expensive immunization tracking system.

IIS interface time also affects provider perception of IIS. Clinicians do not feel that it is their job to enter demographic and immunization data into the IIS. They believe their job is to diagnose and treat patients. Offices with clinical staff responsible for performing duties associated with the IIS, such as routine data entry, have been shown to produce errors in data entry. In addition, clinical staff perceive the IIS as an obstacle to performing their clinical tasks (Bartlett et al., 2007). This is of concern as presumably clinical staff will be less likely to participate in the IIS if they become frustrated with it, potentially resulting in delays in reporting and decreased use of the IIS.

The challenge of influencing positive provider perceptions can be overcome in the design of an IIS. It is important that the IIS has an easy-to-use web-based system with practitioner requested components (Alan R Hinman et al., 2007). IIS developers must communicate with all participants in IISs and pay attention to concerns and needs. Many grant guidelines, including those from the All Kids Count Program, support a planning phase that recommends addressing providers’ concerns and expectations prior to the implementation of the IIS (Saarlas et al., 2004). Active feedback after program implementation is vital to meeting provider expectations and ensuring provider participation (A. R. Hinman, Eichwald, Linzer, & Saarlas, 2005). Poor
provider perceptions can also be overcome by providing data on the proportion of children that receive vaccines at multiples sites so that providers understand the benefits of IISs (Clark et al., 2006). Providers must be aware of all benefits that IISs have to offer their practices and the risks of improperly immunizing children not enrolled in the IIS. If they do not use the IIS for all potential benefits such as reminder/recalls and office vaccination assessment, they are more likely to perceive the IIS as unnecessary.
National Cost and Savings

Determining the cost benefits of IISs is a complex task. Past evaluations of IISs have shown that it is very difficult to compare total costs of different IISs due to differences in the number of children enrolled, efficiency, location of population, number of participating providers, and type of outreach functions (Rask, Wells, Kohler, Rust, & Cangialose, 2000b). Initial research of IISs found costs ranging from $0.65 per child per year to $217 per child per year. This created discrepancies in the actual cost effectiveness of IISs. In order to compare IISs, systems were developed to evaluate IISs based on their specific applications. The cost benefits ratio of an IIS can now be compared to the available functions of the system (Rask et al., 2000b).

IISs have been shown to be very expensive to develop and maintain. According to estimates by the National Immunization Program (NIP), reaching the national 2010 goal will cost as much as $124.3 million annually (Linkins, 2001). Funding for the development and maintenance of IISs comes from a variety of sources. In general, as IISs increase in size, they tend to gain more funding from CDC immunization grants and state funds. Of the IISs with greater than 3.44 million immunization records, 95% of their funding came from CDC immunization grants. The remainder came from in-kind and state government contributions (Bartlett, Molinari, Ortega-Sanchez, & Urquhart, 2006). Additionally, states have attempted alternative means to providing funds, such as creating a private non-profit cooperation to underwrite costs, using tobacco tax revenues to supplement costs, and charging providers for use of the registry (Linkins, 2001).
Proper development of IISs has the ability to increase efficiency and offset these expenses (Glazner, Beaty, Pearson, Elaine Lowery, & Berman, 2004; Horne, Saarlas, & Hinman, 2000; McKenna, Sager, Gunn, Tormey, & Barry, 2002). IISs decrease spending first by reducing the number of duplicate immunizations. Approximately 22% of the nation attends more than one provider by the time they receive their preschool immunizations. When reviewing records for 3 doses of the diphtheria, tetanus, pertussis (DTaP) vaccine at 6 months of age, the most recent provider underestimated the vaccination coverage by 9.8%. Larger percentages of vaccine underestimation were noted when reviewing vaccines administered in the second year of life (Stokley et al., 2001). These underestimations led providers to administer additional, unnecessary vaccines. Similarly, a study found that 21% of children received duplicate immunizations. Children who received immunizations from more than one provider were twice as likely to receive duplicate immunizations resulting in increased costs and additional office visits. Inadequate records for children with multiple providers resulted in approximately 1.8 million extra vaccine doses administered and an additional 412,569 unnecessary office visits, costing the U.S. national system approximately $26.5 million (Feikema, Klevens, Washington, & Barker, 2000). IISs provide a method of immunization record maintenance that would eliminate these costs.

Another way which IISs can save money is by decreasing the cost associated with manually pulling paper files. The costs associated with staff manually pulling paper files can be as high as $14.70 per chart compared to $0.49 when records are retrieved using an IIS (Glazner et al., 2004). Based on these estimates, nationally it costs as much as $16.2 million to manually pull the immunization records of children that see more than one provider, $58 million to manually pull charts for proof of immunization for children entering kindergarten, and $2 million
to manually pull charts to review immunization records as part of health plan employer data information set reports (Horne et al., 2000). These costs could be obsolete if IISs allowed providers to quickly and efficiently identify patient records. In particular, some IISs allow schools to have lookup-only access to the IIS (Alan R Hinman et al., 2007). This potentially eliminates the entire costs encountered by the providers when charts must be manually pulled.

One final way in which IISs could greatly reduce the costs of the current immunization system is by providing instant information for immunization assessment and surveys. This could result in $168 million in savings from activities for entry in school and childcare (Yasuda, 2006). The National Immunization Survey (NIS), a CDC conducted survey to assess immunization coverage levels, annually costs $13.5 million (Horne et al., 2000). Cost can also be decreased at the state and city level as well. One study found that the Utah State Vaccine for Children Office took a median time of 87.5 minutes per assessment when performing the assessments manually. Use of the Utah State IIS resulted in a decrease in time to 1.52 minutes. If all providers used the Utah State ISS, the Utah Department of Health could expect an annual savings of up to $11,740 (Bartlett et al., 2007). This shows that assessment costs can be significantly reduced if IISs are used to rapidly provide UTD immunization coverage assessments pertaining to certain populations.

IISs could save $168 million in immunization assessment activities, $84.2 million by reducing the need to manually pull charts, $26.5 million by reducing duplicate immunizations, and $2 million in health plan employer data and information sets. This would result in a savings of $180 million a year if an efficient nationwide system were in place and run effectively (Horne et al., 2000).
Provider Cost and Savings

On a national level, IISs have shown that if run efficiently, they have the potential to substantially reduce costs. Determining the initial costs and savings of an IIS to an individual provider is difficult. Everything from the computer system used to the person who enters the data affects the savings associated with participating in an IIS. Costs are defined as either developing costs which include software, hardware, personnel, technical support and training or maintenance costs which include technical support and personnel costs (McKenna et al., 2002). With each variable individually affecting the cost of an IIS, the IIS can have a wide range of cost effectiveness to a provider.

The developing costs for an IIS have been shown to be fixed at $250,000 (in 1998 dollars) regardless of the size of the cohort covered. This already creates cost variation in the cost of an IIS (Fontanesi et al., 2002) because higher patient volumes can lower the price per patient cost for participating in an IIS (Rask, Wells, Kohler, Rust, & Cangialose, 2000a). The $250,000 is based on an office with no computer or electronic medical records system participating in a distributive system. A distributive system is an IIS which requires offices set up and use of specific software to communicate with a specific IIS. Currently, systems are switching from distributive to web based applications. With new web based applications, offices only need a computer with internet access (Centers for Disease Control, 2008b). Even though there were initial costs upon participation, these costs were offset by increased efficiency as well as the functions that the IIS could perform that were not possible when charts were manually retrieved and reviewed (Bartlett et al., 2007).
The telecommunication infrastructure comprised of telecommunications and hardware, affects the cost of developing and maintaining the IIS. Despite different IIS hardware, costs remained fixed at approximately $6,400 no matter which type is used. Approximately $5,000 of this is allocated to computation storage and $1,400 is allocated for computers, printers, software, and telecommunication devices. There are variations in cost for specific telecommunication devices. Although initial costs were less expensive for dial up modems, higher capacity frame-relay and T-1 lines were found to be more cost effective for high volume practices despite higher initial cost (Fontanesi et al., 2002). The ability for providers to quickly obtain data electronically from health records, managed care organizations, and other vaccination sources increases cost effectiveness of IISs (Bartlett et al., 2006). One study found that when comparing costs of offices which manually entered data and offices that used an automated interface, the costs were lowest at sites that used automated interface and did not require any manual data entry by clinic personnel. This resulted in reduced personnel costs and increased IIS cost effectiveness.

Personnel expenses have shown to be the largest aspect in IIS costs. Personnel expenses account for 75-86% of yearly expenses (Rask et al., 2000b) and have shown to be a much better indicator than cost-per-child-per-year when analyzing cost relationships (Fontanesi et al., 2002). In order to reduce costs, a lower salaried worker should be responsible for routine data entry opposed to a highly paid clinician in order to reduce costs (Glazner et al., 2004). When employees are hired specifically for data entry, the costs become relatively insignificant. An office that used a dedicated employee, rather than doctors and nurses, experienced costs of only $0.11 per chart (Fontanesi et al., 2002). Despite these studies, the person responsible for entering data is a clinical nurse and less often clerical or billing staff 92% of the time (Clark et al., 2006).
The training that personnel receive can decrease the overall cost of the IIS. An office that has a specialized employee who is well trained and has good knowledge of the IIS will experience the most cost effective IIS due to decreased interface time and errors (Rask et al., 2000a). Additionally, offices that report immunizations through electronic billing can experience financial losses if not billed correctly. In particular, one study found that 62,213 injections were omitted, either by the clerical staff or the immunization provider, resulting in estimated losses as high as $980,477 (Kolas, Cherry, Chilkatowsky, Reyes, & Lutz, 2005). A properly trained employee who is familiar with the system can increase IIS cost effectiveness by ensuring appropriate immunization billing.
Time Demands Associated with IISs

Time demands often inhibit provider participation as 41% of private providers surveyed report time demands as a major barrier to participation in an IIS (Clark et al., 2006). The personnel time needed to install an IIS can be as much as 56 hours and training can take as long as 8 months for an office to effectively implement an IIS (Rask et al., 2000b). Even though there are substantial time commitments to developing and maintaining an IIS, once the system is in place it has shown the potential to reduce time spent on vaccine management, and as a result, reduced practice costs. One study found that the amount of time spent on obtaining vaccination information and demographic data was reduced by 4.8 minutes per vaccination administered when compared to the pre-IIS period (Glazner et al., 2004). A similar time decrease of 3 minutes and 17 seconds per vaccination administered was reported in a study of the webKIDS IIS in 2003 (Zavolinsky, 2004). IISs not only reduce time demands for maintaining individual vaccination records, but can also reduce time demands of reporting vaccination status. One study found that the time required to manually develop quarterly dose administered reports was 360 minutes compared to 80 minutes when an IIS was used (Bartlett et al., 2007). One study did find an overall increase in the amount of time required when using an IIS. In this particular study, they reviewed the use of the IIS at a public health office. After the installation of the IIS, time spent on vaccine maintenance increased by 6 minutes (a 68% increase). However, this particular public health office was using the IIS in addition to using paper records for each visit. This proved to be an inefficient use of an IIS. (Glazner et al., 2004).
If properly implemented, IISs can greatly reduce the overall practice time spent on vaccination record management. Forty-one percent of respondents stated that they spent less than 2 hours per week interacting with the IIS to manage immunization information for an entire office (Clark et al., 2006). In comparison, studies have found that offices that do not have IIS can take as much as 30 minutes to manually pull a single patient’s chart to obtain immunization information (McKenna et al., 2002).

IISs can decrease the time spent on immunization tracking if used correctly, and conversely, they can increase time if used incorrectly. For this reason, it is important that the staff is adequately trained to quickly and accurately enter data into the IIS in order to reduce the amount of IIS interface time. One study found that offices with an automated data interface required, on average, 57 seconds to enter a shot and 1.47 minutes to enter demographic data. Offices that manually entered data took 2.47 minutes to enter a new vaccine and 5.10 minutes to enter demographic information (Rask et al., 2000a). Having a small staff that is properly trained to work with the IIS can greatly decrease time spent on data entry. Offices that had fewer individuals interact with the IIS spent less time interacting with the system (Rask et al., 2000a). High turnover may inhibit an office’s ability to have properly trained designated staff, but it is important to consider that trained staff are an integral component in decreasing interface time and reducing costs for immunization maintenance.
Accuracy and Completeness of IISs

The cost effectiveness of an IIS is dependent on the ability of the IIS to increase the efficiency of immunization documentation. An effective IIS must have the ability to ensure accurate and complete data entry and record maintenance. If there is inaccurate or missing data in the IIS, the risk of over or underimmunization still remains, and many of the benefits associated with maintaining appropriate immunization levels are lost. A study performed in 1998 simulated the function of an IIS by compiling immunization records from all immunization providers in Olmsted County, Minnesota. The simulation results showed a 6.9-27.0% increase in UTD immunization coverage, showing that IISs have the potential to be more complete than paper charts alone (Yawn et al., 1998). The effects observed when IISs were put into practice have had varied results. Similarly, a 1998 study examining the San Antonio Immunization Registry System (SAIRS) agreed that registry data are more complete than clinic records (Boyd, Linkins, Mason, Bulim, & Lemke, 2002). Similar findings were reported in a study of Denver’s Automated Data Integration Operation System (ADIOS) that was developed in 1996. IIS completeness and UTD status were compared for two cohorts, the first cohort before the implementation of ADIOS and the second cohort two years after implementation of ADIOS. IIS completeness increased from 71% to 98% of immunizations administered being recorded in the IIS in the second cohort. In addition, registry defined UTD status increased from 44% to 100% of children being UTD with immunizations in the second cohort (Davidson et al., 2003). During this time period of increased recording and immunization levels, the number of children enrolled in ADIOS increased nearly four times. The greater the number of providers and children participating in the IIS, the more complete and accurate it becomes, due to an increased ability to
link records and assess immunization levels. Similar results were found in an assessment six months after the implementation of the Colorado Rural Immunization Services Project (CRISP). Immunization levels increased as much as 25% for one practice involved with the study (Kempe et al., 2001). However, some studies of IISs have found conflicting results and show that IISs are not as accurate and complete as chart review. A study performed in 2003, reviewed children’s records at 30 private provider offices that participated in Philadelphia’s KIDS IIS. Results indicated that 94 of the 567 children (24%) were found in the registry but were missing information on at least one vaccination. This indicated that children were previously entered into the IIS for vaccinations, but their provider failed to enter all vaccines administered into the IIS (Kolasa, Chilkatowsky, Clarke, & Lutz, 2006). Another study was performed that also evaluated Philadelphia’s KIDS IIS. This study evaluated the proportion of immunizations reported to the registry. Researchers found that of the 256,969 immunizations administered by providers, 62,213 (24%) were not recorded in the registry (Kolasa et al., 2005). There were similar findings in a study that evaluated the effectiveness of Arizona’s State Immunization Information System (ASIIS) to determine the immunization rates in the emergency department. The study found that the IIS was as complete as the PCP records 59% of the time while parent records were as complete as the PCP records 62% of the time (Stecher, Adelman, Brinkman, & Bulloch, 2008). Similarly, a study examining City of New York Immunization Registry (CNY) found that 95% of patients were UTD, while only 61% were documented to be so in the CNY (Callahan, Reed, Meguid, Wojcik, & Reed, 2004). The above studies have identified incidences when the IISs were not as complete as the immunization provider’s records. It is difficult to generalize these findings to all IISs, but evaluations at a national level have had similar results. A study examining IIS data completeness and provider record completeness in comparison to the
National Immunization Survey had similar findings. This study assessed four sites distributed across the U.S., three of the sites were state IISs and one was an urban IIS. Results from each site showed that 7.7 to 39.8% of children that were considered UTD on their diphtheria, tetanus, and pertussis vaccine (DTaP) by the provider’s charts had 1-3 doses of the three doses of the DTaP missing from the registry. In addition, 9.9% to 39.6% of children could not be found in the registry and therefore had any or all doses missing from the registry (Khare, Piccinino, Barker, & Linkins, 2006).

Vaccine administration is the first step to an IIS contributing to high immunization levels. Once the vaccine has been administered, it is necessary that the vaccine information entered into the system is correct as well. An important benefit of an IIS is it can be used as a tool for assessing vaccine effectiveness by tracking key immunization data. Information included for complete immunization data consists of 14 standardized core elements including name, birth date, sex, birth state/country, mother’s name, vaccine type, vaccine manufacturer, vaccination date, and vaccine lot number (2008a). Despite these information requirements, data were often incorrectly entered into the system. One study found that even if vaccination administration was entered, key vaccination information such as formulation manufacturer and lot number were often inaccurate in the registry (Mahon, Shea, Dougherty, & Loughlin, 2008). This inaccuracy of vaccination information greatly negates the benefit of using IISs in vaccination assessments. Accurate vaccine information in IISs can be a powerful tool in assessing vaccine failure and efforts need to be made to improve accurate entry.

Accuracy can be improved by increasing the number of providers in the service area participating in the IIS. As more providers participate in an IIS, the more complete the records become, and the greater the ability to link records throughout the system. Through this linkage,
providers are able to track immunizations given at other offices and reduce the chances of
duplicate vaccinations being administered. Providers choosing not to participate in a registry
create an incomplete system and perpetuate non-user perceptions of data incompleteness, further
inhibiting participation (Christakis et al., 1999). Accuracy can also be increased if immunization
providers are aware of the factors associated with inaccurate data reporting. Practice size affects
reporting accuracy as offices that administer large numbers of immunizations are more likely to
correctly report immunization data to the IIS. Providers that serve less than 150 children are less
likely to report administered vaccines to the IIS (Kolasa et al., 2005). Practice type also has an
effect on reporting accuracy. When compared to hospital-based clinics, family practice and
pediatric offices have more difficulty reporting immunizations to the IIS immediately after
administering them (Kolasa et al., 2006). This could be attributed to time constraints, personnel
shortages in busy practices, and a higher quantity of vaccines administered at these sites. The
development of new vaccines can also contribute to registry incompleteness. When the
pneumococcal conjugate vaccine was recommended in 2000, it created provider confusion on
billing codes. As a result, the pneumococcal vaccine was administered but not reported to the IIS
33% of the time (Kolasa et al., 2005). Finally, the variations in the time from immunization to
reporting to the IIS can have a large affect on accuracy. There are wide variations in the time to
reporting vaccines with some offices reporting immediately, and others delayed by weeks to
months. In 2006, a self-administered internet-based survey was taken by IIS users. The results
showed that 69% of immunization providers report immunizations given within 30 days, 11%
between 31-60 days, and 20% take more than 60 days to report to the IIS (2008a). This creates a
lag time which can result in incompleteness in the registry. The best way to avoid these
inaccuracies is to declare the IIS the official office record of immunizations. This requires
clinics to immediately document vaccinations when they are given (Davidson et al., 2003). It has been shown that the best method to immediately report immunizations is to use electronic entry or direct transfer from electronic medical records. Offices that used direct electronic entry or electronic medical records had statistically significant lower rates of incorrect entry when compared to offices reporting to the IIS through electronic billing forms, paper billing, or paper logs (Kolasa et al., 2006).
Reminder/Recall Systems

IISs have the ability to produce reminder/recalls that have been associated with increasing immunization coverage. A review of reminder/recall studies indicated that reminder/recalls increase vaccination rates 80% of the time with rates increasing from 5%-20% (Szilagyi et al., 2000). The recommended vaccination schedule is one that is constantly evolving. The addition of new vaccines such as pneumococcal and haemophilus influenza B create a complex schedule. The task of remembering scheduled immunizations is difficult even for a trained provider. A study reviewing parents’ perceptions of their child’s vaccination status showed that only 66% of children who were reported as UTD by parents were actually UTD upon chart review. Additionally, personalized vaccination cards were carried by 24% of parents, and of the cards present, 34% were found to be incorrect (Williams, Meza, Salazar, Dominici, & Fasano, 2007). This creates a problem, as parents are often responsible for scheduling vaccination appointments. This indicates a need for both an improvement of parental records and more accountability for the providers to provide accurate immunization reminders to their patients.

Some studies of reminder/recall systems have found that they are not effective in increasing UTD immunization status. In particular, this seems to be a problem in inner city populations. In general, inner city populations are associated with having low vaccination rates. One study found that 47% of children seven months of age were delayed on their immunizations and only 10% were actually UTD (Stille & Christison-Lagay, 2000). The difficulties in maintaining vaccination levels have been attributed to financial obstacles, low patient education
of vaccines, and high patient relocation rates. In order to develop an efficient reminder/recall system, the provider must first have current contact information for the patient. A study examining the effectiveness of reminder/recall systems in an inner city population found that 13.6% of the children never received the vaccination reminder postcard sent to them (Irigoyen et al., 2006). Likewise, a study examining the use of IIS based recall for the new pneumococcal vaccine found it difficult to reach targets by phone or by letter. Forty percent of the subjects never received a phone call due to wrong numbers, disconnected numbers, or unanswered calls (Daley et al., 2002). Various forms of notification such as autodialer, personal calls, and outreach programs have been examined. One review of notification systems showed that the autodialer system was the most cost effective method of reaching patients (LeBaron, Starnes, & Rask, 2004), however, additional studies showed no difference in outcome when comparing various reminder/recall methods (Rask, LeBaron, & Starnes, 2001). A review of all reminder/recall studies of all populations found that telephone reminders appear to be more effective than letters, but letters and postcards still have been shown to increase immunization rates as well (Szilagyi et al., 2000).

The second obstacle in maintaining an effective reminder/recall system is that the provider must have the correct vaccination status of the patient. This again is complicated by delays in vaccination reporting to the IIS. A study found that 25% of children were misclassified as due or late on a vaccine and as a result were sent false reminders. Some of these false reminders were sent to children who had been vaccinated within the practice sending the reminder, but their immunization entry into the IIS was delayed. In order for these reminder recall systems to work, it is essential that patient contact information and immunization status be up-to-date at the reminder date (Irigoyen et al., 2006).
The final obstacle of maintaining an efficient reminder/recall system is having a high immunization capture rate at the time of the visit. Immunization capture rates are the ability of the provider first to know that their patient is in need of a vaccine and second to administer the vaccine at the appropriate visit. A study evaluating missed vaccination opportunities found that healthcare providers missed 58% of opportunities to immunize children in need of a vaccine. Nearly 40% of these missed opportunities occurred during well child visits (Prislin et al., 2002). This is a concerning issue as a key component of the well child visit is to ensure that the child’s vaccination status is UTD. If used effectively, IISs can alert a physician using clinical prompts to indicate that a child is due for an immunization during an office visit. Clinical alerts are associated with an 81.7% to 90.1% increase in vaccination rates at both well child and sick child visits (Fiks, Grundmeier, Biggs, Localio, & Alessandrini, 2007). Although clinical prompts have been shown to be effective in combination with reminder/recall interventions, reminder/recall interventions with clinical prompts were insignificantly better than reminder/recall alone (Szilagyi et al., 2000).

Despite recommendations to use IISs to create reminder/recall systems for immunization providers on the use of reminder/recall systems, only 16% were using practice-based reminder messages, recall messages, or both. The most common reason for the lack of adoption of reminder/recall systems was lack of time and money, and not having a simple way of identifying children due for vaccines (Tierney et al., 2003). The potential of reminder/recall systems to increase the number of UTD immunizations should be emphasized to immunization providers. In addition, the risks involved with incorrectly identifying a patient and the ability to reduce the number of missed vaccination opportunities warrant the consideration of investing the time and money into reminder/recall systems on the part of providers.
**Uses of IISs**

Positive provider perceptions of IISs are dependent on the knowledge of the advantages created by the IIS. IISs have been developed with 12 minimum functional standards. In addition to the current 12 functional standards, IISs are now being developed with additional features such as vaccine management, adverse event reporting, and lifespan vaccination histories (Bartlett et al., 2006). Cost effectiveness and provider perceptions depend on both the knowledge and use of IIS applications. A study of private provider participation in IISs, found that 81% of users did use the IIS to review immunization records of individual patients. However, only 29% used the IIS to assess immunization coverage for the practice, and 19% used the IIS to generate reminder recall notices (Clark et al., 2006). Many IISs now have the ability to receive information from persons of all age ranges but 25% of IISs do not have any information on persons over 50 years of age and the IISs that do contain information on older age groups only contain 23% of the population (Alan R Hinman et al., 2007).

IISs also have the ability to identify high risk patients, such as children with asthma, and allow the provider to assess the need of additional vaccinations such as the influenza vaccine. Twenty-one percent of providers have electronic medical records in their offices but they are rarely linked to an IIS to identify high risk populations in need of additional immunizations (Dombkowski et al., 2007). To ensure the maximum effectiveness and satisfaction of an IIS, providers should be using all applicable functions of the IIS. The benefit of identifying high risk individuals is obsolete if they are not used by immunization providers.
IISs are also being used for rapid assessment of immunization supply. One example of this was the use of the Michigan Childhood Immunization Registry (MCIR) to assess the pneumococcal vaccine shortage. In 2004, during the pneumococcal vaccine shortage, the MCIR was used to rapidly track provider cooperation with the recommendations to limit vaccine use. The MCIR allowed for simultaneous analysis of not only the pneumococcal vaccine administration, but enabled comparison to two vaccines that are usually given at the same age as the pneumococcal vaccine, MMR and DTaP. Using the IIS, public health officials were able to see that there had been a decrease in the level of pneumococcal vaccine administration but not MMR or DTaP, indicating that physicians were following guidelines regarding the pneumococcal vaccine shortage (Allred et al., 2006). Without the coinciding assessment of the MMR and DTaP vaccination levels along with the pneumococcal vaccine by the MCIR, the drop in pneumococcal vaccine administration could have been interpreted as a decrease in all vaccinations or a decrease in healthcare provided.

IISs have also been used in disaster preparedness and response. One way they are useful is by allowing providers to access medical records of displaced patients. Several states are beginning to share immunization data across state lines (Zavolinsky, 2004). This proved to be extremely helpful in the wake of Hurricane Katrina. After Hurricane Katrina, nearly 200,000 evacuees left New Orleans for Houston Texas, many of them without their vaccination records. Since both the Louisiana and Houston systems used HL-7 standards for electronic exchange, this allowed a connection to be made between Houston-Harris County Immunization Registry (HHCIR) and the Louisiana Immunization Network (LINKS). The HHCIR-LINKS connection was developed 10 days after Katrina made land fall and a total of 18,966 records were recovered using the registry connection within 1 year. The recovery of records prevented the unnecessary
re-administration of vaccines. This was estimated to have saved $3.04 million in administrative fees and vaccine costs (Boom, Dragsbaek, & Nelson, 2007). IISs are also being used in preparation of natural disasters as 83% of IIS managers said that their IIS will be used for collecting individual vaccine doses administered for pandemic flu (Rask et al., 2000a).

IISs are also being integrated with existing child information systems in an effort to reduce costs by eliminating time, money, and resources needed from multiple information systems. Examples of systems that have the potential to be integrated with IISs are newborn dried blood spot screening, and early hearing detection and intervention (A. R. Hinman et al., 2005). One study examined the integration of the New York Citywide Immunization Registry and the Childhood Blood Lead Registry. Upon integration of the systems, 37% of the children in the IIS had additional information linked to their existing files through the blood lead registry. This represents an opportunity to reduce excess money being spent maintaining an unnecessary second information system (Papadouka et al., 2004). Similar actions are being pursued in Utah as they develop the Child Health Advanced Records Management program (CHARM). CHARM provides real-time access to information such as screening results, immunization status, referrals, follow-ups, assessment, and outcomes for children. The CHARM system is not meant to replace existing databases, but to act as a manager that allows registries to share information (A. R. Hinman et al., 2005). The combination of systems could greatly reduce national health care costs associated with maintaining health care records.
Parent knowledge and Support

High immunization levels are dependent on parents’ knowledge of their child’s vaccination status. Parents cannot place sole responsibility on their health care providers to inform them of when their child’s next immunization is due. Parents must know how a child’s records are maintained and where the records are located (in an IIS, a provider’s chart, and/or a home calendar). The readily available source of personalized information regarding a child’s immunization status in an IIS is only useful to parents if they have knowledge of the system and how to access the information. Despite signing a release form to enroll their child in the IIS and receiving written information and education about the system, only 29% of parents were aware that their child was entered into the IIS (Callahan et al., 2004). This information was gathered on children 11 years and under, so rates may be higher in children under 2 years who are receiving immunizations more frequently. Results from a study of school-aged children (kindergarten through 5th grade) in 4 state IISs (Colorado, Massachusetts, Missouri, and Washington) found even lower results with less than 10% of parents being aware that their child was enrolled in an IIS (Linkins et al., 2006).

Personal immunization cards and home calendars are methods of promoting parental awareness of children’s vaccination records. Vaccination cards can be a key source of reminders of vaccination status but are often not current, if available. One study showed that only 15% of vaccination cards were available and correct when reviewed at a local emergency department (Williams et al., 2007). IISs can offer a solution to provide updated vaccination information to parents at each visit. The use of home calendars did show some improvement in UTD
vaccination levels. Personally tailored calendars provided to parents contained the child’s next immunization date along with other pertinent information such as home safety, child development, and the child’s height and weight. Children who received these calendars were more likely to be UTD on immunizations than children who did not receive these calendars (Kreuter, Caburnay, Chen, & Donlin, 2004). The use of these calendars combined with the powerful record keeping of IISs could be a useful tool in ensuring up-to-date records and increasing vaccination levels.

Despite the many different efforts used to educate parents, parents are not adequately educated about vaccination record locations. A combination of these methods may be the best to maintain UTD status. The greater the number of people aware of a child’s immunization status, the less likely the provider will be to miss an immunization opportunity. Continuous patient education throughout a child’s care is necessary to ensure parental knowledge of their child’s vaccination records and maintain high UTD vaccination levels. IISs can be an integral component of patient education by allowing physicians to rapidly provide personalized and up-to-date immunization information.
Conclusion

Vaccinations remain a vital component of public health and disease prevention. Although vaccination levels are currently high in the U.S., constant effort is necessary to sustain high immunization levels. An increasingly mobile patient population increases the need for high vaccination coverage. Diseases that are no longer of concern in the United States, due to proper sanitation and high vaccination levels, are still present in other countries. Travel to various parts of the world may place people at risk of contracting a disease and becoming a carrier upon returning home. Although most vaccine preventable diseases are rare in the U.S., under-vaccinated children remain at risk and outbreaks of these diseases still occur today (Yeung et al., 2005). Total eradication of these diseases may not be possible, but prevention, even in a mobile population, is possible by maintaining high vaccination levels with the assistance of IISs.

High vaccination levels are dependent on proper tracking and record maintenance of immunizations administered. Current vaccination records are vital to maintaining high immunization levels, as well as in the evaluation of an ill child. A febrile child that is UTD with vaccinations will be evaluated differently than a child who has not received vaccines (Callahan et al., 2004). In this mobile population, maintaining UTD records, which are available to all of the child’s immunization providers at the time of immunization, is a necessity. IISs provide a viable solution to maintaining current records that are available to all providers which can result in increased UTD levels.

IISs have the potential to decrease costs at the national level as well as decreasing the cost to the individual provider. IISs decrease cost by eliminating costs associated with manually
pulling charts when immunization information is requested by employers, schools, or researchers. IISs must be used to their maximum to ensure cost effectiveness. This includes consolidation of immunization records, the use of reminder/recall systems, and immunization level assessments. IISs have been adapted for integration with pre-existing registries and have been shown to be useful in unforeseen situations such as natural disasters (Boom et al., 2007). IISs should continue to be used for basic immunization tracking systems while being developed for new, additional uses that will increase provider benefits and ultimately lead to an increased use of IISs.

In order for IISs to be effective, there must be an agreement between immunization providers, political advocates, and the families of children being vaccinated. All parties must be aware of their involvement in and the benefits of the systems. Studies have shown that as more immunization providers participate in IISs, the less expensive (Horne et al., 2000) and more complete (Davidson et al., 2003) they become. All immunization providers in a geographic area should participate to create the most effective IIS. This includes tracking all immunizations administered and promptly entering them into the IIS. Because it is not feasible for all offices to adopt an electronic medical record, or another form of direct information transfer, more research needs to be done to improve the process of submitting immunizations from offices that submit immunizations via paper or electronic log forms (Kolasa et al., 2006). This could lead to an increase in provider participation and a more complete IIS. Regardless of the method in which the physician reports the information, it is vital to the effectiveness of the IIS that it be current, complete, and without delay. Currently, there can be as much as a 6-month lag time between the time when vaccines are administered and the availability of information for review (Allred et al., 2006). Physicians must declare IISs as their main source of immunization record maintenance
and develop methods of promptly reporting information. Continued provider education and feedback are necessary to ensure provider satisfaction with the system and continued use.

In order to ensure maximum effectiveness of an IIS, it is important that all children in a geographic area are registered. Children missing from the system are at risk of being misclassified and over or underimmunized. The more children enrolled in the IIS, the more effective it will become.

The studies reviewed for the purpose of this paper were focused on state or city IISs. Nationally, different IISs have a variety of functional standards, a wide range of participating populations, and different laws and regulations governing providers and their use of IISs. This study attempted to generalize the outcomes of these focused studies to all IISs. Future studies are needed which evaluate the use of IISs nationally rather than focusing on individual state IISs.

The technology associated with the development and use of IISs is constantly evolving. During the era of major development of IISs, there was a substantial amount of research published on IISs. As a result, some of the studies were performed years ago and provide the only information pertaining to certain topics. This information could have changed in recent developments of technology, resources, and funding in IISs. These studies should be repeated to evaluate IISs with the most current information.

IISs provide an excellent resource for rapid assessment of a child’s vaccination levels without the hassles associated with manually reviewing information from paper charts. By using IISs, providers no longer have to question patients on their vaccination status, the location of the vaccination, and the date of vaccination. IISs give immunization providers the ability to quickly access immunization information and determine a patient’s immunization status.
Providers will not have to contact other offices in order to locate records or pay fees to release medical records for new patients. This greatly decreases the time investment associated with record verification. IISs provide an immunization record maintenance solution by providing rapid assessments of immunization levels and helping to identify population pockets of low immunization levels, all while reducing provider costs and time.
References


Table 1

Recommended Immunization Schedule for Persons Aged 0 Through 6 Years—United States • 2009

For those who fall behind or start late, see the catch-up schedule

<table>
<thead>
<tr>
<th>Vaccine ▼</th>
<th>Age ▶</th>
<th>Birth</th>
<th>1 month</th>
<th>2 months</th>
<th>4 months</th>
<th>6 months</th>
<th>12 months</th>
<th>15 months</th>
<th>18 months</th>
<th>19-23 months</th>
<th>2-3 years</th>
<th>4-6 years</th>
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<tr>
<td>Hepatitis B&lt;sup&gt;1&lt;/sup&gt;</td>
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<td></td>
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<tr>
<td>Rotavirus&lt;sup&gt;2&lt;/sup&gt;</td>
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<td>RV</td>
<td>RV</td>
<td>RV&lt;sup&gt;2&lt;/sup&gt;</td>
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<tr>
<td>Diphtheria, Tetanus, Pertussis&lt;sup&gt;3&lt;/sup&gt;</td>
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<td>DTap</td>
<td>DTap</td>
<td>DTap</td>
<td>see footnote 7</td>
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<tr>
<td>Haemophilus influenzae type b&lt;sup&gt;4&lt;/sup&gt;</td>
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<td>Hib</td>
<td>Hib</td>
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<td>Measles, Mumps, Rubella&lt;sup&gt;7&lt;/sup&gt;</td>
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<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>HepA (2 doses)</td>
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<td>HepA Series</td>
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<tr>
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<td>MCV</td>
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Figure 1
FIGURE 1. Percentage of children aged <6 years participating in a grantees immunization information system -- United States, six cities, and eight Territories, 2007

National Participation: 1%e (excluding Territories)
Source: *"2007" IRISW

Legend:
- No Report
- 0-33%e
- 34-66%e
- 67-94%e
- 95-100%e

States and Cities: Chicago, Illinois (60%e-65%), District of Columbia (93%e-100%), Houston (93%e-98%), Miami (93%e-99%), New York (96%e-100%), Philadelphia (97%e-100%), San Antonio, Texas (87%e-90%), and 2 areas of Memphis (99%e-100%), Owasso, Oklahoma (95%e-100%), and 2 areas of Montgomery (99%e-100%), and 2 areas of Oklahoma (99%e-100%).
Abstract

Objective: This study evaluates the advantages and disadvantages of Immunization Information Systems (IISs) and the perceptions and challenges that prevent providers from participating in an IIS.

Methods: Sources were located by searching PubMed and the Centers for Disease Control for Immunization Information Systems, Immunization Registries and current immunization recommendations.

Results: There were 69 references obtained and reviewed including original research, IIS progress reports and immunization provider information.

Conclusions: IISs give immunization providers the ability to quickly access immunization information. IISs increase immunization levels and up-to-date records by consolidating records, generating reminder and recall systems, and providing vaccination coverage assessments. IISs provide an immunization record maintenance solution by providing rapid assessments of immunization levels and helping to identify population pockets of low immunization levels, all while reducing provider costs and saving time. IISs provide a viable solution to immunization documentation and should be adopted into practice by providers administering immunizations.