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## State-Level Immunization Information Systems: Potential for Childhood Immunization Data Linkages

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### Abstract

**Objectives**—Sources of immunization data include state registries or immunization information systems (IIS), medical records, and surveys. Little is known about the quality of these data sources or the feasibility of using IIS data for research. We assessed the feasibility of collecting immunization information for a national children's health study by accessing existing IIS data and comparing the completeness of these data against medical record abstractions (MRA) and parent report. Staff time needed to obtain IIS and MRA data was assessed.

**Methods**—We administered a questionnaire to state-level IIS representatives to ascertain availability and completeness of their data for research and gather information about data formats. We evaluated quality of data from IIS, medical records, and reports from parents of 119 National Children's Study participants at three locations.

**Results**—IIS data were comparable to MRA data and both were more complete than parental report. Agreement between IIS and MRA data was greater than between parental report and MRA, suggesting IIS and MRA are better sources than parental report. Obtaining IIS data took less staff time than chart review, making IIS data linkage for research a preferred choice.

**Conclusions**—IIS survey results indicate data can be obtained by researchers using data linkages. IIS are an accessible and feasible child immunization information source and these registries reduce reliance on parental report or medical record abstraction. Researchers seeking to

link IIS data with large multi-site studies should consider acquiring IIS data, but may need strategies to overcome barriers to data completeness and linkage.

## Keywords

Data linkages; Immunizations; Immunization information system; Children

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## Introduction

Receipt of evidence-based clinical preventive immunization services is among 24 objectives highlighted by the Institute of Medicine's Healthy People 2020 (National Research Council 2011). Researchers and policy makers need to monitor this preventive measure (Hagan et al. 2008) using high-quality validated immunization data. At least three potential sources of these data exist including: self or parental report, medical records, and state-level immunization information systems (IIS). Known issues of faulty recall in self report and access and effort required to obtain medical records or IIS data led to this evaluation of access, availability, and quality of these three sources.

Information about most childhood immunizations provided by parental recall or record-keeping—influenza excepted—has validity and reliability problems (Poehling et al. 2012; Bolton et al. 1998; Luman et al. 2009); immunization information reported by parents can be inaccurate and inconsistent, depending on literacy, education level, level of familiarity with child vaccinations, and record-keeping capability. While medical record abstraction (MRA) is labor-intensive, expansion of electronic health record systems (EHRS) under the Patient Protection and Affordable Care Act (PPACA) may transform researchers' access to this information. However, validity and reliability of pediatric immunization information from MRA range in quality (Kosala et al. 2005; Mahon et al. 2008). Over the last few decades prior to EHRS expansion, the U.S. Public Health Service has supported development of IIS (Bartlett 2004). Getting immunization data from existing electronic databases, such as an IIS, appeals to researchers who want to maximize cost-efficiency and minimize participant burden. For example, IIS data have successfully been used to assess vaccine effectiveness; however, information about the quality of IIS data for use in research is limited (Placzek and Madoff 2011). CDC-funded IIS do currently allow opting-out, which poses a potential roadblock to data reliability. To date, no national cohort studies have systematically linked IIS data because states vary in their administrative and technological infrastructure for research access. It could be cost-effective to link IIS data to research cohorts if data access and linkages are feasible.

Exploratory work conducted for the National Children's Study (NCS) (Landrigan et al. 2006) provided an opportunity to assess child immunization data sources. Our study sought to learn more about IIS data and its availability to researchers for data linkages and to compare the access, availability, and quality of the three data sources. To accomplish the first goal, we surveyed state-level IIS administrators to evaluate the practicality of using these data for a national cohort study. For the second goal, we compared immunization data from parental recall in surveys, medical records, and IIS from three NCS study locations in North Carolina, Wisconsin, and South Dakota/Minnesota. We compared completeness and

agreement across the sources and determined the feasibility, acceptability and effort of obtaining IIS data from multiple locations.

## Methods

This research was reviewed and approved by the Institutional Review Boards of all participating institutions. All participants about whom we collected data provided consent prior to study inclusion.

### Survey of Immunization Information Systems

We systematically gathered administrative data about IIS to evaluate whether these systems could be used as data sources for a national, population-based child health study. The frame of registries came from CDC's National Immunization Program website ([www.cdc.gov/vaccines/programs/IIS/contact-state.htm](http://www.cdc.gov/vaccines/programs/IIS/contact-state.htm)). A questionnaire to collect IIS characteristics, availability, and data architecture was developed by our teams and pretested with IIS contacts in our own states. A fixed-question instrument facilitated data aggregation of these administrative-level, non-confidential data (given that three teams shared data collection responsibility). Half of the questionnaires were administered by staff over the phone (our preferred method), and the remaining ones were e-mailed to registry contacts, self-administered, and electronically submitted (for their convenience). The IIS survey was conducted from November 2010 through January 2011 with a target of 31 IISs—27 contacted by our teams and four corresponding to our own Vanguard locations, for which our investigators served as IIS informants (Minnesota, North Carolina, South Dakota, Wisconsin). Three registry contacts did not provide information, resulting in a final sample size of 28. IIS contacts for registries covered more than two-thirds of the states that had NCS Vanguard primary sampling units. Univariate statistics were produced to describe IIS features, relationships with health care providers, availability of IIS data for research, and data architecture.

### Comparison of Childhood Immunization Data

The original sample of 269 eligible children for whom we collected and compared sources of immunization information (parental recall, MRA, and IIS) consisted of NCS enrollees born in three Vanguard locations (representing four states) between August 2009 and August 31, 2010; 115 children were enrolled in the South Dakota/Minnesota location, 82 in North Carolina, and 72 in Wisconsin. Standardized surveys that included immunization information were administered to parents in all locations when the children were 3 and 6 months of age.

Immunizations of interest were either required or recommended by the four states during the first 4 months of life: Hepatitis B (Hep B) #1 and #2; Diphtheria, Tetanus, and acellular Pertussis (DTaP) #1 and #2; inactivated polio vaccine (IPV) #1 and #2; Haemophilus influenzae type B (Hib) #1 and #2; Pneumococcal conjugate vaccine (PCV) #1 and #2; and Rotavirus (RV) #1 and #2. Hep B can be administered starting at birth with a second dose administered at either 1 or 2 months of age, while the other vaccines of interest are administered at 2 and 4 months of age. State immunization requirements for enrolling in

early childhood care and kindergarten varied across the states. For example, DTaP and polio vaccinations were required by all four states for early childhood care, while Hep B, PCV, and Hib requirements varied by state; rotavirus vaccine was not required to enroll in early childhood care in any of the four states.

Immunization data were obtained from three sources: (1) interview data from parents of NCS children at 3 and 6 months of age captured in the NCS information management system (allowing enough time lapse for assessing immunization dose #2 administered around four months of age), (2) pediatric medical records from 50 clinics, and (3) four state IIS. Only first-dose information for each vaccine antigen was evaluated and reported in this research; because of NCS protocol changes, both three- and six-month interview data in which parents were asked about their child's immunizations were available for only 19 participants. We calculated percent agreement between all pairs of data sources as well as Cohen's kappa coefficients to quantify agreement beyond what is expected by chance. Our interest was the extent to which NCS parental reports agreed with medical record and IIS data. We report prevalence of immunizations from parental report, medical records, and IIS systems and measure agreement between sources using Cohen's kappa (Cohen 1960; Fleiss 1971), presenting results for magnitude of agreement along with tests of statistical significance that agreement between sources is greater than that expected by chance alone (Cohen 1960).

An additional data quality assessment evaluated consistency in the date of immunization administration across the three sources.

Data collectors at the three NCS study locations tracked time spent obtaining medical record and IIS information so that effort associated with accessing, reviewing, abstracting, entering, and cleaning data per child could be determined and labor estimated. Staff noted start and end times and the number of records extracted per session when collecting data from these two sources (e.g., pre-testing the recording form, training, getting data access); waiting in doctor's offices; traveling to doctor's offices; and entering data. The average time to extract a child's immunization record was calculated by dividing the total number of minutes required for data collection activities by the total number of records extracted for that data source. Staff at one of our study locations entered data into an Access database directly from the source (e.g., IIS screen or during phone calls with pediatricians' offices). Level of effort to collect each of these data sources was compared.

## Results

### Immunization Information Systems Characteristics

Most of the 28 IIS in our sample had been operational for several years. The systems were established between 1980 and 2007, with the majority (57 %) initiated in the mid-1990s or later. At the time of questionnaire completion, the average system had been operating for 11.7 years, and half had existed for 12.5 years or longer. All systems in our sample collected immunization data for young children.

IIS sponsorship and support has come largely through federal funding. In our sample, 74.1 % identified federal funds as their primary funding source, and when asked about all sources (federal, state, and local), 37.5 % indicated exclusive support by federal agencies. Among the IIS with combined funding, all included federal sources, 50.0 % identified federal and state sponsorship, while only 4.2 % indicated local support as well as federal and state funds.

Immunization reporting to the IIS—statewide (or city-wide for municipal IISs)—was not exhaustive. Whereas 82.1 % of IIS contacts responded that three-quarters or more of the public health departments in their geographic scope were IIS participants, a lower proportion (57.1 %) responded that three-quarters or more of the medical provider practices participated in their IIS. Technologies for data cataloging and transfer were not standard across states, complicating linking IIS data to research data. Although most systems (70.4 %) were capable of linking to EHRS, 29.6 % could not. Of those IIS responding that their systems could handle data from EHRS, 59.1 % reported that they were able to export IIS data to populate EHRS and import EHRS data to the IIS. Only 30 % of the IIS contacts knew their systems were not bi-directional; of these, 38.5 % reported that information from EHRS could be imported to the IIS, rather than the other way around, and the remaining did not know. A few IIS contacts commented that technological improvements were under development.

Data access may pose challenges. For 13.8 % of the IISs reporting, researchers were not allowed to access their data. Some IIS contacts indicated it was possible for researchers to request access, although it was “unlikely” that it would be granted based on research requests never having been approved; one IIS contact stated that research access is allowed only to providers, school nurses, and state research institutions. Of 27 IIS registries that allow access by researchers, 55.6 % allow it to individual records while 29.6 % do not. Furthermore, 48.1 % of the IIS registries that allow research access allowed it for identified data, while 37.0 % did not. Two-thirds (66.7 %) of the IIS registries could provide a complete dataset upon request, while 11.1 % reported that their agency did not provide complete datasets; 22.2 % lacked sufficient information to respond.

Registries may impose other requirements, such as applications for data access or data access fees, with 72.4 % of IIS requiring a data use agreement (DUA) before releasing data to researchers. Content analysis of the few DUAs obtained as part of our inquiry included a requirement to submit study protocols. A description of how data are to be used is also generally required, as is a data security plan and statement of intended data destruction. Data use agreements indicated data users could not contact any individual identified from the data, and data users needed to present credentials (ranging from a user name to requiring a *curriculum vitae*). Some DUAs indicated that findings derived from the data must be reviewed by the IIS agency before publication or release, and statements citing the IIS agency as the data source must be included with research reports.

Although the DUAs indicated costs or fees associated with obtaining the data, 67.9 % of the IIS contacts reported no fees. Two IIS contacts were aware of a fee while 25.0 % were unclear whether a fee would be charged. Data costs were not fixed by all IIS; rather, the fees

depend on level of effort required of IIS staff and technical resources. Fees may not be specified until a formal request for data is made; therefore, it may be difficult for researchers to budget these costs.

For most IIS, the child's immunization record is initiated at birth, with 78.6 % of systems structured for, and automatically populated with, birth certificate information. Among those, 64.0 % include the neonatal dose of hepatitis B as the debut immunization. At the time of our data collection, 25.0 % of the IIS reporters stated that parents could not opt-out. (All CDC-funded IIS currently allow for opt-out, although doing so requires some effort from parents.)

### Comparison of Childhood Immunization Data

For the 119 eligible children for whom we had either 3 or 6 months visit parent interview data, we were able to review the corresponding medical records for 99.2 % and IIS records for 98.3 %.

To assess data completeness, analysis of the initial dose for each immunization and the complete set of initial doses reveals that parental recall as obtained from NCS interviews was the least-complete source of information and medical records were the most complete source (Table 1). For each type of immunization included in the comparison, percentage of first immunization doses received was lowest when based on parental report (ranging from 61.3 to 80.7 %). The highest reports were from medical record abstraction (from 77.1 to 95.8 %), with IIS reports falling in-between (from 72.6 to 91.4 %) and similar to medical record abstraction. Examination of total coverage with all six first-dose immunizations being received (Table 1) revealed parental recall yielded the lowest count of coverage (41.2 %) and medical records reported the best coverage (73.7 %), with the IIS in between at 70.9 %. Data sources regarding children receiving none of the six immunizations (Table 1) indicated parental recalls were most likely to report that none of the first immunizations was administered (16.0 %), compared with 6.8 % for the IIS and 4.2 % for the medical record.

To assess reliability, we analyzed agreement about whether an immunization was administered across each pair of data sources (Cohen 1960; Fleiss 1971). For each of the six immunizations, IIS data and medical record data had the highest agreement (ranging from 86.2 to 91.4 %) (Table 2). Parental report data agreed best with the medical record and IIS data for Rotavirus ( $\kappa = .48$  and  $.56$ , respectively, indicating moderate agreement with a statistical significance level  $p < 0.001$ ) and Hepatitis B ( $\kappa = .21$  and  $.28$ , respectively, indicating fair agreement with statistical significance of  $p < 0.01$  and  $p < 0.001$ , respectively) (Table 2). We note that parents had poorest recall of IPV, PCV, Hib, and DTaP doses. Medical records and IIS do a notably better job of completely documenting these four immunizations and are more reliable data sources than parental report. Results from these four tests of statistical significance indicate that we would not expect to find differences in medical record and IIS immunization data quality in the larger population.

We further examined agreement about date of administration of the immunization. Table 3 shows that IIS data and medical record again agree best (ranging from 93.6 to 96.9 % agreement except for Hepatitis B) with regard to date of administration. Parental recall has

the lowest percent agreement with medical records or IIS with regard to date of immunization.

Our methods for collecting medical record and IIS data were tracked, and we compared staff effort. Study location staff who used an Access database to collect the records took about half as much time as staff who recorded onto a paper instrument and later double-entered (e.g., 25 min per participant for IIS direct entry v. 51 min per participant hard-copy recording then double-entering; 39 min per participant for medical report direct entry v. 77 min per child hard-copy recording then double-entering). Regardless of collection technology, IIS data recording took almost 40 % less staff time than medical record abstraction.

## Discussion

We successfully obtained data from four state IIS registries representing three National Children's Study locations, demonstrating that IIS can be a source of immunization data from diverse locations and disparate populations and have potential for use in national children's health studies. The medical record was the most complete source of immunization information, and immunization data obtained from the IIS were a closer approximation of medical record data than parental report. Furthermore, staff spent substantially less time obtaining IIS data than medical record abstraction. Although IIS data may be somewhat less complete than medical record data, a possible strategy for future national health studies is supplementing incomplete IIS data with medical record data.

Based on findings from our survey of IIS and our experience obtaining IIS data, researchers pursuing IIS linkages can expect to have good geographic coverage with considerable IIS experience registering immunization data. Most states have federally funded IIS registries that should allow health researchers to leverage or enhance access if they are also federally funded. Although technologies for data cataloging and transfer were not standard at the time of inquiry, escalating interest in data sharing since then— especially among federal agencies—is likely to impose isomorphism across systems. Extensive inclusion of children's (v. adult) immunizations in the IIS registries minimizes the biases introduced by disparities in health data (Specker et al. 2013); excluding annual influenza immunizations, up to 29 immunizations are routinely recommended for children through age 6 years, and six immunizations are routinely recommended for children and adolescents between ages 11 through 18 years. The IIS is likely to do a better job capturing these records than parental report. We found fairly consistent data structures across the IIS registries, suggesting fewer challenges when aggregating data for research with a national scope in the future due to anticipated improvements and technological advancements for recording, reporting and data linkages. IIS record initiation at the time of birth via birth certificate data should enhance data linkage.

Researchers pursuing IIS data linkages may encounter barriers, including lack of access to individuals' records, identified records or datasets. Researchers may need to negotiate this access because data linkage requires unique identifiers to confidently match records across datasets. Researchers may need to supplement with ancillary medical record data

abstraction. Data reliability issues must be monitored because IIS registries allow parents to opt out and some IIS are designed to import data better than export. Obtaining IIS data may come with fees and some IIS do not have transparent cost structures, complicating planning and budgeting.

Advantages of IIS data include high agreement with and potential for reduced effort relative to medical record abstracted data; disadvantages include inconsistencies across systems and the need for researchers to work with the individual IIS to standardize the data for linkages and minimize costs for doing so that will allow them to affordably conduct population-level studies. In the absence of increased IIS data reliability, researchers would be next best served to draw data from (expanding) EHRS.

### **Limitations of This Study and Recommendations for Future Research**

Our primary challenge in conducting the child immunizations comparison was having fewer parental reports from the NCS survey than anticipated for analysis, particularly six-month parental interview data reporting second immunization dose. An additional complication was that NCS protocols changed during our research window from a protocol that asked about immunizations to a protocol that did not, thereby resulting in a smaller sample size than originally designed. Because our analysis of childhood immunization data included only three study centers across four states, our experience may not be generalizable to all locales in a national study. In each of our study locations, investigators developed agreements for data sharing with their respective IIS that might be difficult to operationalize on a nationwide basis.

Moving forward we recommend a replication of this exploratory analysis to include: a comparison of more immunizations over a longer time and at the population level to assess the cost-benefits specifically of IIS and EHR child immunization data—to determine which is more cost-effective. We also strongly suggest that researchers pursuing data linkages for studies on a national scale establish agreements with IIS guardians during the research design and planning phase. The PPACA is changing the landscape around how we think about population-based data sources, and ultimately, collect data around preventative healthcare measures like vaccines.

### **Conclusions for Practice and Policy**

Linkages to IIS data for national health studies will require coordination by researchers and IIS administrators. Operationally, linkages to IIS data may vary by state but would need to include several unique identifiers to match records and link the datasets. IIS data may be inaccessible in some areas or accessible but unsuitable in some settings. Some of these barriers to access may be overcome if federal sponsors seek cooperative agreements with the CDC, which sponsors many IIS registries. IIS present another data source for researchers to understand children's health at the population level, aiding policy-makers in understanding that not all children get immunized and that the distribution of children without immunizations is not uniform according to socioeconomic status.



IIS data were shown to be an acceptable and feasible source of child immunization data. Acquisition of IIS data is likely to incur some costs, and those costs are difficult to estimate. We expect that these costs will mostly be nominal, one-time costs for data access, but that depends on the state agencies overseeing the IIS. IIS data extraction for linkages with child health studies should result in fairly comprehensive, high-quality datasets at low cost to researchers. Without complete and generalizable IIS systems, we are unable to understand vaccine coverage and effectiveness at the population level.

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**Significance Statement**

This study informs the challenges and processes for using existing ‘big data’ sources to supplement data collected and analyzed by government-funded researchers.

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**Table 1**

Percent of child participants receiving first dose of each immunization, all six immunizations, or none of the six immunizations by 6 months of age, as documented by medical records abstraction (MRA), Immunization Information System (IIS), or parental survey (Parent) for three study locations of the National Children's Study, 2009–2010 (n = 119)

	MRA%	IIS%	Parent%
Child participant received first dose of each vaccine			
Diphtheria, Tetanus, and acellular Pertussis (DTaP)	95.8	91.4	80.7
Hepatitis B (HepB)	91.5	91.4	75.6
Haemophilus influenza type B (Hib)	94.9	91.4	65.5
Pneumococcal conjugate vaccine (PCV)	92.4	90.6	66.4
Inactivated polio vaccine (IPV)	93.2	90.6	64.7
Rotavirus (RV)	77.1	72.6	61.3
Child participant received all six immunizations	73.7	70.9	41.2
Child participant received none of the six immunizations	4.2	6.8	16.0

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**Table 2**  
**Percentage agreement and Kappa coefficients comparing immunization data sources from parental survey (Parent), medical record abstraction (MRA), and immunization information systems (IIS), for three study locations of the National Children's Study, 2009–2010**

Sample size for the respective data source	IIS v. MRA			Parent v. MRA			Parent v. IIS		
	117	118	119	118	119	118	119	118	119
	% Agreement	$\kappa$	% Agreement	% Agreement	$\kappa$	% Agreement	$\kappa$	% Agreement	$\kappa$
Diphtheria, Tetanus, and acellular Pertussis (DTaP)	88.8	.08	81.3	.16 <sup>**</sup>	80.3	.21 <sup>**</sup>			
Hepatitis B (HepB)	91.4	.45 <sup>*****</sup>	77.1	.21 <sup>**</sup>	79.5	.28 <sup>*****</sup>			
Haemophilus influenzae type B (Hib)	87.9	.06	65.2	.04	66.7	.11 <sup>*</sup>			
Pneumococcal conjugate vaccine (PCV)	86.2	.13	69.5	.14 <sup>*</sup>	69.2	.16 <sup>*</sup>			
Inactivated polio vaccine (IPV)	87.1	.14	66.9	.10 <sup>*</sup>	68.4	.18 <sup>**</sup>			
Rotavirus (RV)	88.8	.71 <sup>*****</sup>	77.1	.48 <sup>*****</sup>	80.3	.56 <sup>*****</sup>			

\*  $p < 0.05$

\*\*  $p < 0.01$

\*\*\*  $p < 0.001$

\*\*\*\*\*  $p < 0.0001$

**Table 3**  
**Percent agreement comparing administration date of first immunization dose from Parental Report (Parent), Medical Record Abstraction (MRA) and Immunization Information Systems (IIS) for three study locations of the National Children's Study, 2009–2010**

	Parent v. IIS	Parent v. MRA	IIS v. MRA	Parent vs MRA vs IIS
<b>Sample size for the respective data source</b>	<b>119, 117</b>	<b>119, 118</b>	<b>117, 118</b>	<b>119, 118, 117</b>
	<b>% Agreement</b>	<b>% Agreement</b>	<b>% Agreement</b>	<b>% Agreement</b>
Diphtheria, Tetanus, and acellular Pertussis (DTaP)	80.9	81.5	96.0	81.2
Hepatitis B (HepB)	11.6	14.5	64.3	7.5
Haemophilus influenzae type B (Hib)	77.8	79.5	94.9	79.1
Pneumococcal conjugate vaccine (PCV)	74.3	80.0	93.7	75.7
Inactivated polio vaccine (IPV)	79.2	82.2	96.9	81.2
Rotavirus (RV)	79.1	80.6	93.6	79.4