

Evaluating Washington State's Immunization Information System as a Research Tool

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ABSTRACT

OBJECTIVE: Immunization information systems (IISs) are powerful public health tools for vaccination activities. To date, however, their use for public health research has been limited, in part as a result of insufficient understanding on accuracy and quality of IIS data. We evaluated the completeness and accuracy of Washington State IIS (WAIIS) data, with particular attention to data elements of research interest.

METHODS: We analyzed all WAIIS records on all children born between 2006 and 2010 with at least 1 vaccination recorded in WAIIS between 2006 and 2010. We assessed all variables for completeness and tested selected variables for internal validity. To assess external validity, we matched WAIIS data to records from Group Health, a large integrated health care organization in Washington State. On these children, we compared vaccination data in WAIIS with vaccination data from Group Health's immunization registry.

RESULTS: The WAIIS data included 486,265 children and 8,670,234 unique vaccinations. Variables required by WAIIS

(such as date of vaccination) were highly complete, but optional variables were often missing. For example, most records were missing data on route (80.7%) and anatomic site (81.7%) of vaccination. WAIIS data, when complete, were highly accurate relative to the Group Health immunization registry, with 96% to 99% agreement between fields such as vaccination code and anatomic site.

CONCLUSIONS: Required data elements in WAIIS are highly complete and have both internal and external validity, suggesting that these variables are useful for research. Research requiring nonrequired variables should use additional validity checks before proceeding.

KEYWORDS: immunization; immunization programs/statistics and numerical data; information systems

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WHAT'S NEW

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IMMUNIZATION INFORMATION SYSTEMS (IISs) are state-managed, computerized registries that house immunization data submitted by vaccine providers on patients in a defined geographic area.¹ The National Vaccine Advisory Committee has recommended implementation of state IISs as a public health imperative,² and one of the United States Healthy People 2020 goals is for 95% or more of children under 6 years of age to have immunization records recorded in a fully operational IIS.³ IISs can be used for public health activities such as identifying under-vaccinated children in various health care settings,⁴ assessing population-level immunization coverage,^{5,6} and facilitating vaccine recalls.^{7,8}

In addition to their uses for public health practice, IISs are also potentially powerful tools for public health research. A fully implemented IIS can allow researchers to create unbiased samples of the population who have received 1 or more vaccines and to identify vaccination history for sampled individuals, at a fraction of the cost of manual medical record review. To date, however, the use of IISs for research has been limited. IISs have been used to estimate the effectiveness of various vaccines (including rotavirus, hepatitis A, and influenza vaccines^{9–13}) and have been explored as tools for monitoring vaccine safety.¹⁴ One barrier to wider use of IISs for research purposes is the paucity of data on the accuracy and completeness of IIS data. Thus, assessments of data quality and accuracy are high priority subjects for evaluating IISs.¹⁵ Here we present results from an evaluation of data in the Washington State Immunization Information System (WAIIS) from a research perspective. This evaluation aimed to 1) assess the completeness and internal validity of data available in the WAIIS and 2) assess the accuracy of a sample of WAIIS data using a large health system's vaccine records as the gold standard.

METHODS

WAIIS

WAIIS is a statewide IIS covering persons of all ages in Washington State.¹⁶ WAIIS serves as a clinical decision support tool for providers to identify children in need of specific vaccines. It also provides required reports for child care and school entry immunization requirements, provides geographic immunization coverage information, and supports case investigation during vaccine preventable disease outbreaks. Although providers are not mandated to contribute data to WAIIS, as of 2011, WAIIS covers more than 95% of children in the state.¹⁷ Providers contribute data by manual entry into the WAIIS Web interface, by submission of batch files, or by direct HL7 linkage.¹⁸ WAIIS also uses Washington State birth certificate data to identify children and to acquire data on vaccinations given during the birth hospitalization.

For this evaluation, we first identified the study population as all children in WAIIS who (a) were born between January 1, 2006, and December 31, 2010 (the study period); (b) had at least 1 vaccine recorded in WAIIS during the study period; and (c) were not known to have died or moved out of state based on WAIIS data. Children born in other states who moved to WA and were vaccinated during the study period were included, and the frequency of known immigrants was calculated on the basis of state of birth. For children in the study population, we compiled all WAIIS vaccination records for vaccines administered during the study period. WAIIS data on children, vaccinations, and providers were collected on July 25, 2011.

COMPLETENESS AND INTERNAL VALIDITY OF WAIIS DATA

The first set of analyses measured the completeness and internal validity of WAIIS data. Internal validity refers to the agreement between different data elements within the WAIIS. We characterized missing data as the percentage of observations with missing values for each variable in the patient table (which contains patient-level data including unique identifier, date and state of birth, and current zip code) and the vaccines table (which contains vaccination-level data including date, route, and anatomic site of vaccination). We also stratified missing data by year of vaccination and by method of upload, to explore trends in missing data over time and by upload method.

We used several measures of internal validity. We calculated the proportion of observations that had a known date error (eg, where vaccination date preceded birth date) and the proportion of vaccines for which the route of administration was inconsistent with the vaccine type. For example, a rotavirus vaccine given intramuscularly would represent an inconsistency between vaccine route and type. We also calculated the proportion of records with contradictory vaccine type based on CPT and CVX codes.

ACCURACY OF WAIIS COMPARED TO EXTERNAL DATA

In the second set of analyses, we identified the subset of children in our WAIIS analysis who had been members of Group Health (GH) any time after January 1, 2006. GH is

an integrated health care organization with approximately 424,000 group practice members in Washington State. GH has maintained an electronic immunization registry since 1991. Before 2005, GH staff completed an Injection Order Form for all vaccines administered at GH, which included data on the patient; the date and anatomic site of vaccination; the name of the individual administering the vaccine; and the vaccine type, manufacturer, and lot number. Data from Injection Order Forms were then entered into the electronic immunization registry. Since 2005, when GH fully implemented its electronic medical record (EMR) system, the GH immunization registry is updated by HL7 messaging from the EMR system.

The GH immunization registry exchanges data with WAIIS. During the dates covered by this evaluation, GH transferred data on all vaccination records for GH members (including vaccinations received outside of GH) to WAIIS by means of monthly batch electronic files. WAIIS transferred data only on vaccinations received outside of GH to GH by monthly batch files. GH data transferred both to and from WAIIS included all required and optional WAIIS data elements.

We identified GH children in the WAIIS data on the basis of the presence of a GH consumer number (GH's unique person-level identifier) in the health plan ID field of the patient table. Using GH's enrollment databases, we then identified all GH enrollees who were born during the study period and had at least 1 vaccination recorded in the GH immunization registry during the study period. For this cohort, we identified all recorded vaccinations during the study period. We merged the GH cohort with the WAIIS cohort on the basis of the GH consumer number. For GH children who could not be matched to a child in WAIIS we determined the proportion who died or disenrolled from GH to approximate the exclusion from the WAIIS data of children who died or moved out of state. In this analysis, disenrollment from GH is a proxy for moving out of state, as children moving out of state would necessarily disenroll from GH, although children may disenroll without moving out of state.

Among children matched between the 2 systems, we attempted to match all vaccine records to assess the accuracy of WAIIS data compared to GH's immunization registry. In the first matching step, vaccines were matched that had an identical date of administration and either CVX or CPT code. For vaccinations without a match in the first step, vaccines were then matched on the basis of identical date of vaccination and similar CVX or CPT codes. Similar codes were defined as codes for the same vaccine antigens but with different levels of specificity, for example, having a code in one system that simply specifies *Haemophilus influenzae* type b (Hib) vaccine, compared with a code in the other system that specifies the Hib vaccine as PRP-D, PRP-T, PRP-OMP, or HbOC.¹⁹ In the third matching step, for vaccines unmatched in either of the first 2 steps, vaccine records were matched on the basis of identical date of vaccination and an apparent coding error in the CPT or CVX code, defined as vaccines against the same pathogen but with incompatible specific vaccine

information. For example, live attenuated influenza vaccine in one system and inactivated influenza vaccine in the other were considered a match in the third step. We calculated the number and percentage of vaccines in each system that could not be matched to the other. To test whether agreement results may be biased by WAIS data uploaded to GH for vaccines not given at GH, we repeated the matching process using only vaccines given at GH.

Among vaccines with an exact match on date of vaccination and either CVX or CPT coded, we identified discrepancies between the WAIS data and the GH immunization registry for variables, including the anatomic site of administration and the CPT code.

This study was approved by both the GH and State of Washington institutional review boards. Analyses were conducted in 2011 and 2012 by SAS software, version 9.2 (SAS Institute, Cary, NC).

RESULTS

WAIS POPULATION AND DATA COMPLETENESS

The WAIS data included 486,265 eligible children. Data elements required by WAIS (Table 1) were highly complete: all children had a date of birth and unique identifier, and only 2841 (0.6%) children were missing home zip code. For the 272,208 (56.0%) children with a state of birth listed, 269,476 (99.0%) were born in WA. Completeness of patient-level data from fields not required by WAIS was highly variable. For example, 423,017 (87.0%) children were linked to a primary care facility, but only 99,388 (20.4%) were linked to a specific primary care provider. State of birth was missing for 214,057 (44.0%) children as a result of an error in uploading birth state from Washington State birth certificate records to WAIS over several years.

The 486,265 children in the study were linked to 8,670,234 unique vaccinations administered during the study period. Unsurprisingly, data on vaccinations were highly complete for WAIS-required fields or fields generated by the WAIS (Table 2), but were often missing for nonrequired fields. For example, the vaccine provider is required to submit either a CVX code or CPT code for each vaccination; only 1348 (<0.1%) records are missing a CVX code and only 6334 (0.1%) are missing a CPT code. In contrast, 7,002,213 (80.7%) records were missing

data on route of administration and 7,092,456 (81.7%) were missing data on anatomic site of administration.

Of potential research interest is the ability to link vaccines to specific facilities or providers through WAIS. This would allow ecologic studies or facility-level intervention studies of interventions to improve vaccination rates. The WAIS assigns a unique organization code to each record at the time of upload. However, the specific facility at which the vaccine is administered is entered by the user and was missing for 1,243,278 (14.3%) vaccination records. Furthermore, the optional physician identifier field was missing for 5,898,979 (68.0%) records. Among the 6,903,297 vaccines not listed as historical and thus was presumably recorded by the administering site, facility was missing for 4.6% of records and physician identifier was missing for 59.9% (Table 2).

Completeness of optional WAIS vaccination data elements varied on the basis of method of upload to WAIS (Table 3). Vaccine manufacturer and route and site of administration were nearly always missing for vaccine records uploaded as batch files. These fields were also missing from birth certificates, as they are not part of the Washington State birth certificate data. Physician identifier and route and site of administration were most commonly completed for records entered into WAIS manually. Records uploaded by HL7 messaging had less missing data than batch files, but sometimes more missing data than manual entry. The proportion of records uploaded by HL7 messaging and by electronic batch file increased over the study time period (Table 4).

INTERNAL VALIDITY OF WAIS DATA

The WAIS data had a high degree of internal validity. Only 31 vaccinations (<0.001%) had a date of administration that preceded the date of birth, and only 18 vaccinations (<0.001%) had a date of administration that was later than the date of upload to WAIS. Of the 1,668,021 records with a route of administration listed, only 17,823 records (1.1%) had a route of administration that was inconsistent with the vaccine type. No records had contradictions between CPT and CVX codes.

EXTERNAL VALIDITY OF WAIS DATA

A total of 26,054 children from the WAIS sample had a GH consumer number, while 28,299 GH enrollees were born and had at least 1 vaccination during the study period, according to the GH immunization registry. All but 3 (>99.9%) of the children in the WAIS sample could be matched to a child in the GH sample (Figure). However, 2248 (7.9%) of the children in the GH sample were not found in the WAIS sample. Of the 2248 GH children without a match in WAIS, 1188 (52.8%) had died or disenrolled from GH before acquisition of the WAIS data for this study and thus may not have been included in the WAIS data set created for this study.

The 26,051 children who were matched between the 2 data systems had received 478,709 vaccines during the study period according to the GH immunization registry,

Table 1. Missing Values in Data Elements for Patients Table (N = 486,265 Children) in the WAIS

Variable	No. Missing	Percentage Missing
WAIS ID*	0	0.0%
Date of birth	0	0.0%
State of birth†	214,057	44.0%
Patient zip code	2841	0.6%
Primary care physician ID†	386,877	79.6%
Facility ID†	63,248	13.0%

WAIS indicates Washington State Immunization Information System.

*Used to link records between patient and vaccine tables.

†Optional field.

Table 2. Missing Values in Data Elements for Vaccines Table (N = 8,670,234 Records) in the WAIS

Variable	All Vaccines		Restricted to 6,903,297 Vaccines Not Reported as Historical	
	No. Missing	Percentage Missing	No. Missing	Percentage Missing
WAIS ID*	0	0.0%	0	0.0%
Organization ID†	0	0.0%	0	0.0%
Date of vaccination	0	0.0%	0	0.0%
CVX code	1348	0.0%	893	0.0%
CPT code	6334	0.1%	1599	0.0%
Physician ID‡	5,898,979	68.0%	4,138,460	59.9%
Facility ID‡	1,243,278	14.3%	314,563	4.6%
Manufacturer ID‡	6,172,672	71.1%	4,570,368	66.2%
Lot number‡	5,698,929	65.7%	4,098,510	59.4%
Route of administration‡	7,002,213	80.7%	5,242,749	75.9%
Site of administration‡	7,092,456	81.7%	5,329,718	77.2%

WAIS indicates Washington State Immunization Information System.

*Used to link records between patient and vaccine tables.

†Indicates the organization of record; may or may not indicate the location where vaccine was administered.

‡Optional field.

and 475,963 vaccines according to the WAIS (Figure). Overall, 4922 (1.0%) vaccines in the GH registry could not be matched to a vaccine in the WAIS, and 2176 (0.5%) vaccines in WAIS could not be matched to a vaccine in the GH registry. Nearly all of the 473,787 vaccines that could be matched between the 2 systems (457,744, 96.6%) were matched exactly on date and either CVX or CPT code. An additional 11,446 (2.4%) were matched exactly on date and had a similar CVX or CPT code between the 2 systems. Only 4597 (1.0%) matched exactly on date with an apparent code error in 1 of the 2 systems. Matching was similar when restricting to the 307,229 vaccines given at GH, with 291,417 (94.9%) matching exactly on CVX or CPT code, 7097 (2.3%) having a similar CPT code, and 869 (0.3%) having apparent code errors.

Agreement was high between the 2 data systems among the 457,744 records matched exactly on child, vaccination date, and CVX/CPT code. For example, 247,856 records had a lot number listed in both systems, and only 2370 (0.9%) had a different lot number in the 2 systems. Similarly, 457,682 records had a CPT code listed in both systems, and only 11,127 (2.4%) had a different CPT code in the 2 systems. These 11,127 would have matched exactly on CVX code, and the mismatched CPT codes were probably errors in the systems used by WAIS or GH to map CVX codes to CPT codes. For example, 7315 (65.7%) of the mismatched CPT codes were for Hib vaccines, which differed only in the vaccine formulation be-

tween the 2 systems (PRP-T vs HbOC). Only 7077 records listed anatomic site of vaccination in both systems (with 241,122 having an anatomic site in GH but not WAIS data, and 21,162 having an anatomic site in WAIS but not GH data). Of these 7077 records, only 30 (0.4%) listed a different anatomic site in the 2 systems.

DISCUSSION

Our study findings have several implications for the use of WAIS as a research tool. First, several elements of WAIS could be useful for public health research. Child-level data on birth date and current zip code of residence (as of July 25, 2011) are highly complete, as are vaccine-level data on date of vaccination and type of vaccination, by CPT code or CVX code. Vaccination data also had a high degree of internal validity as well as accuracy relative to the GH immunization registry. These data elements could be used for public health research on topics such as vaccine effectiveness, including possibly variations by county, over time, or by age group.

Second, our study suggests that several elements of WAIS are not suitable for use in public health research without further validation. Optional fields such as the specific provider who gave the vaccine, or the facility where the vaccine was given, are often missing. This was true even when excluding vaccines recorded as historical, for which the provider entering the data may not know the

Table 3. Missing Values in Data Elements in the WAIS, Stratified by Method of Upload, 2006–2010

Variable	Percentage of Records (N = 8,670,234) Missing By:			
	Electronic Batch File	State Birth Certificates	HL7	Manual Entry
CVX code	0.0%	0.0%	0.0%	0.0%
CPT code	0.0%	0.0%	0.1%	0.1%
Physician ID	78.2%	100.0%	77.6%	48.5%
Facility ID	18.6%	99.6%	4.6%	5.6%
Manufacturer ID	95.2%	100.0%	44.4%	47.2%
Lot number	87.9%	99.9%	34.7%	45.4%
Route of administration	99.8%	99.9%	68.0%	58.9%
Site of administration	99.5%	99.9%	79.3%	57.9%

WAIS indicates Washington State Immunization Information System.

Table 4. Proportion of Records (N = 8,670,234) Uploaded to the WAIS by Method, 2006–2010

Year	Electronic Batch File	State Birth Certificates	HL7	Manual Entry
2006	37.3%	6.2%	7.2%	49.3%
2007	36.7%	3.5%	9.5%	50.4%
2008	54.5%	3.0%	10.3%	32.2%
2009	54.4%	2.8%	12.4%	30.4%
2010	49.5%	2.2%	19.1%	29.3%

WAIS indicates Washington State Immunization Information System.

provider or facility where the vaccine was administered. Thus, WAIS is not suited for research comparing the effects of interventions across different providers or facilities, for example, without knowing the extent and completeness of reporting to WAIS by different facilities. State of birth was also missing on 44% of children, and is probably differentially missing for children born out of state because 99% of children with a nonmissing state of birth were born in Washington.

Third, data completeness is changing over time as data uploading shifts away from manual entry. Moving toward electronic batch uploading decreased the completeness of optional data elements relative to manual entry, particularly for vaccine manufacturer and lot number. In contrast, HL7 transfer was roughly comparable to manual upload in terms of completeness, with the exception of physician ID and site of administration. As the relative proportion of sites entering data manually decreases, completeness of these data elements may decline over time unless specific efforts are made to include these data elements in batch and HL7 files.

In addition, our study results have implications for the use of WAIS as a tool for public health practice. Public health applications of IIS data include monitoring population vaccine coverage, issuing patient reminders or vaccine

recalls, and providing feedback to vaccine providers, among others. Our study found that data in optional fields were frequently missing. These missing data include provider-level data such as physician or facility ID, which may limit the utility of the IIS for provider feedback. Vaccine-level data such as manufacturer and lot number were also often missing, which restricts the usefulness of the IIS for vaccine recalls. The Washington State Department of Health may wish to reconsider whether these optional data elements should be collected, and consider making data elements of interest required. Alternatively, some optional elements such as anatomic site of vaccination may be of low utility for either research or public health practice and perhaps should not continue to be collected.

This study had several strengths. First, it is the first published study to use integrated care system immunization records to evaluate the accuracy of data in a state immunization registry. Previous validations of state IIS data have relied on review of providers' medical records,^{4,20,21} which may not contain data from vaccines given at other providers' offices or public health clinics. This is illustrated by the finding in prior evaluations of IISs that 10% to 24% of vaccinations identified in the IIS were not found in the medical record review.^{4,20,21} In contrast, the GH immunization registry contains data on vaccinations given at any GH facility, as well as claims for payment for vaccinations given at non-GH facilities. Using records from an integrated care system is thus equivalent to combining review of providers' medical records with review of insurance claims for vaccinations provided. In this study, only 0.5% of vaccinations for GH children in WAIS could not be matched to a vaccination in the GH registry. A second strength of this study is the depth to which WAIS was evaluated. Prior IIS evaluations have typically^{5,20–22} only assessed whether vaccines identified in the IIS could also be found in the

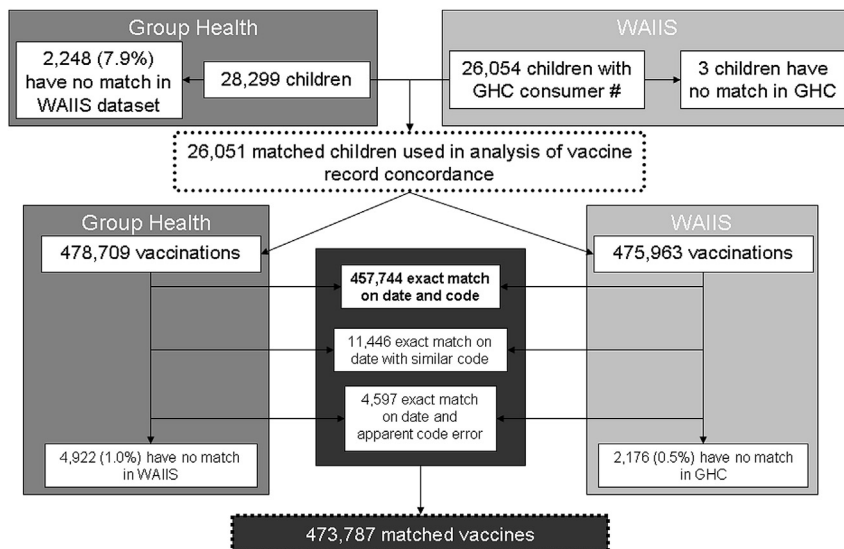


Figure. Matching children and vaccination records from the Group Health immunization registry to the Washington State Immunization Information System (WAIS).

medical record, and vice versa. In contrast, this study assessed both the internal and external validity of the WAIS data, providing a more complete picture of the WAIS data.

Our study also had several limitations. First, this analysis was limited to a single IIS and may not be fully generalizable to other state IISs. Second, the GH immunization registry and the WAIS are not fully independent data systems. GH submits data to and receives data from WAIS. For vaccinations given to children before they enrolled in GH, the GH record only contains data that was originally transmitted to GH by WAIS, inflating the apparent agreement between the 2 systems on data shared by batch upload used between GH and WAIS during the study period. However, restricting to data on vaccines given at GH did not meaningfully change the degree to which records could be matched between the 2 systems. Third, although every effort was made to create data sets from both WAIS and GH that would be highly compatible, there were still 2248 children (7.9%) receiving care at GH in the time period of interest that we were not able to include in our analysis of accuracy. This discrepancy is likely due in part to enrollment criteria in how the data sets were designed. It is not likely due to reporting lags (as study data were compiled 18 months after the end of follow-up) or by in-migration (as GH would share the same data with WAIS regardless of birth state). The unexplained discrepancy creates potential for bias in our findings. Finally, our estimates of IIS errors in fields such as date of vaccination was limited to obvious internal discrepancies in the data; other types of date errors could not be detected with the available data.

We have demonstrated a novel method for evaluating the validity of state IISs through the use of vaccination data from integrated health care organizations. Applying this approach found the WAIS to have high internal validity, completeness, and accuracy compared to medical records. However, analyses for research purposes should be limited to fields required for registry participation, or should involve additional validity checks on optional fields. For example, a study with a research design requiring vaccinations to be attributed to a specific provider or practice location should examine the quality of the data uploaded to the WAIS by the practices of interest before proceeding. State immunization systems interested in maximizing the use of registry data for public health studies of vaccine safety may want to reconsider the use of required fields.

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