The Role of the Centers for Disease Control in Developing Immunization Information Systems in the United States

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December 7, 2010
Discussion Points

• What is an immunization information system (IIS)?
• The Need for Immunization Information Systems in the U. S.
• Developing U. S. Immunization Information Systems
• CDC Monitoring of IIS Performance
What are Immunization Information Systems?

Immunization Information Systems are computerized systems that:

• Record all shots on all children given by all providers in a geopolitical catchment area.

• Have functions and features needed by an immunization program (e.g. vaccine inventory management, adverse event reporting etc.);

• Have interoperability with other health information systems including Electronic Health Records (EHR).
The Need for Immunization Information Systems in the U. S.
Births in the U. S. - 2009: 4.23 million live births (11,579 births every day).\(^1\)

The U.S. Census Bureau reports that between 2008 and 2009, 37.1 million (12\%) people moved in the United States – 11.0 million (30\%) are < 19 years of age.\(^2\)

\(^1\) U.S. National Center for Health Statistics, Vital Statistics of the United States, annual; and National Vital Statistics Reports (NVSR)
\(^2\) U.S. Census Bureau
Consolidation of Immunization Histories

Patients with at least 1 immunization from Dane County Health Department, Wisconsin
Extra-Immunization

• A 2000 study published in JAMA found that 1 in 5 US children had received at least 1 extra vaccine dose by age 19 to 35 months.¹

• Annual costs associated with extra-immunization were conservatively estimated to be $26.5 million.

CDC Funding to Immunization Programs
1990 - 2009

Section 317 grant funding
Vaccines for Children funding
Reminder and Recall

• In 2000, the Task Force on Community Preventive Services\(^1\) made evidence-based recommendations that included client and provider reminder/recall interventions to improve vaccination coverage.

• In spite of these recommendations, a recent study found that reminder and recall messages remain underused by both pediatric and public health clinics.\(^2\)

• A randomized, controlled trial of immunization registry reminder/recall for influenza vaccination in children found vaccination rates for recalled high-risk children to be 42% versus 25% for the control group.\(^3\)

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## Vaccine-Preventable Diseases Morbidity – United States, 2009

<table>
<thead>
<tr>
<th>Disease</th>
<th>20th Century Annual Morbidity†</th>
<th>2009 Reported Cases † †</th>
<th>Percent Decrease</th>
</tr>
</thead>
<tbody>
<tr>
<td>Smallpox</td>
<td>29,005</td>
<td>0</td>
<td>100%</td>
</tr>
<tr>
<td>Diphtheria</td>
<td>21,053</td>
<td>0</td>
<td>100%</td>
</tr>
<tr>
<td>Measles</td>
<td>530,217</td>
<td>71</td>
<td>&gt; 99%</td>
</tr>
<tr>
<td>Mumps</td>
<td>162,344</td>
<td>1,991</td>
<td>99%</td>
</tr>
<tr>
<td>Pertussis</td>
<td>200,752</td>
<td>16,858</td>
<td>92%</td>
</tr>
<tr>
<td>Polio (paralytic)</td>
<td>16,316</td>
<td>1</td>
<td>&gt; 99%</td>
</tr>
<tr>
<td>Rubella</td>
<td>47,745</td>
<td>3</td>
<td>&gt; 99%</td>
</tr>
<tr>
<td>Congenital Rubella Syndrome</td>
<td>152</td>
<td>2</td>
<td>99%</td>
</tr>
<tr>
<td>Tetanus</td>
<td>580</td>
<td>18</td>
<td>97%</td>
</tr>
<tr>
<td><strong>Haemophilus influenzae</strong></td>
<td>20,000</td>
<td>213*</td>
<td>99%</td>
</tr>
</tbody>
</table>

† JAMA. 2007;298(18):2155-2163
† † CDC. MMWR August 20, 2010;59(32):1025-1039 (Final 2009 NNDSS data)
* 35 type b and 178 unknown serotype (< 5 years of age)
Coverage Assessment

- Disease levels are at record lows and do not serve as a constant reminder to patients/practitioners of the need for timely immunization.

- Studies have consistently shown that both parents and providers over-estimate coverage.\textsuperscript{1, 2}

\textsuperscript{1} Goldstein KP, Kviz FL, Daum RS. Accuracy of immunization histories provided by adults accompanying preschool children to a pediatric emergency department. JAMA 270:2190-2194, 1993.

Immunization Information Systems
Clinical Decision Support

### Recommended Immunization Schedule for Persons Aged 0 Through 6 Years—United States • 2010

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>
</tr>
</thead>
<tbody>
<tr>
<td>Hepatitis B&lt;sup&gt;1&lt;/sup&gt;</td>
<td></td>
<td>HepB</td>
<td>HepB</td>
<td></td>
<td></td>
<td></td>
<td>HepB</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rotavirus&lt;sup&gt;2&lt;/sup&gt;</td>
<td></td>
<td>RV</td>
<td>RV</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diphtheria, Tetanus, Pertussis&lt;sup&gt;3&lt;/sup&gt;</td>
<td>DTaP</td>
<td></td>
<td>DTaP</td>
<td></td>
<td></td>
<td></td>
<td>DTaP</td>
<td></td>
<td></td>
<td></td>
<td>DTaP</td>
<td></td>
</tr>
<tr>
<td>Haemophilus influenzae type b&lt;sup&gt;4&lt;/sup&gt;</td>
<td>Hib</td>
<td></td>
<td>Hib</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>HLayout</td>
<td></td>
</tr>
<tr>
<td>Pneumococcal&lt;sup&gt;5&lt;/sup&gt;</td>
<td></td>
<td>PCV</td>
<td>PCV</td>
<td></td>
<td></td>
<td></td>
<td>PCV</td>
<td></td>
<td></td>
<td></td>
<td>PPSV</td>
<td></td>
</tr>
<tr>
<td>Inactivated Poliovirus&lt;sup&gt;6&lt;/sup&gt;</td>
<td>IPV</td>
<td></td>
<td>IPV</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>IPV</td>
<td></td>
</tr>
<tr>
<td>Influenza&lt;sup&gt;7&lt;/sup&gt;</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>influenza</td>
<td></td>
<td>Influenza (Yearly)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Measles, Mumps, Rubella&lt;sup&gt;8&lt;/sup&gt;</td>
<td>MMR</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>see footnote&lt;sup&gt;9&lt;/sup&gt;</td>
<td>MMR</td>
<td></td>
</tr>
<tr>
<td>Varicella&lt;sup&gt;9&lt;/sup&gt;</td>
<td></td>
<td></td>
<td>Varicella</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>see footnote&lt;sup&gt;9&lt;/sup&gt;</td>
<td>Varicella</td>
<td></td>
</tr>
<tr>
<td>Hepatitis A&lt;sup&gt;10&lt;/sup&gt;</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>HepA (2 doses)</td>
<td></td>
<td>HepA Series</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Meningococcal&lt;sup&gt;11&lt;/sup&gt;</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>MCV</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

This schedule includes recommendations in effect as of December 15, 2009. Any dose not administered at the recommended age should be administered at a subsequent visit, when indicated and feasible. The use of a combination vaccine generally is preferred over separate injections of its equivalent component vaccines. Considerations should include provider assessment, patient preference, and the potential for adverse events. Providers should consult the relevant Advisory Committee on Immunization Practices statement for detailed recommendations: http://www.cdc.gov/vaccines/pubs/acip-list.htm. Clinically significant adverse events that follow immunization should be reported to the Vaccine Adverse Event Reporting System (VAERS) at http://www.vaers.hhs.gov or by telephone, 800-822-7967.
In August 2005, Hurricane Katrina caused massive destruction in Louisiana, Mississippi and Alabama but an IIS offered some assistance to the victims.

After Hurricane Katrina, the Louisiana Immunization Network for Kids Statewide (LINKS) remained operational via a backup server in Baton Rouge.

Several studies found that the availability of IIS data saved millions of dollars for vaccines that would have been needed to re-vaccinate displaced school children.¹,²


The Need for Immunization Information Systems - Summary

Immunization information systems provide operational support to immunization programs, providers, patients, and parents by:

- automating evidence-based strategies
- producing real-time data to ensure that the 4 million U.S. children born every year, plus adolescents, and adults are protected, and by
- assisting programs to deploy their resources efficiently and effectively
Developing U. S. Immunization Information Systems
“...perhaps in the rather distant future, the capabilities of electronic computers for storing and retrieving information could greatly facilitate our immunization programs...A nationwide computer system could put us well on the road to efficient national follow-up of births for maintenance of immunization levels.”

2nd National Immunization Conference, 1965

James L. Goddard, M.D., M.P.H., 8th CDC Director, 1962 – 1966

CDC Public Health Image Library (PHIL)
“Almost a million children under the age of two are missing one or more of their recommended shots still....We have to make sure that every child now is safe from every vaccine-preventable disease....As parents move from place to place, they often leave their children’s immunization records behind. Their new doctors often cannot get access to these records. So I’m directing Secretary Shalala to start working with the states on an integrated immunization registry system....”

The White House, July 23, 1997
In Response to President Clinton….

- The *Initiative on Immunization Registries* -- led by National Vaccine Advisory Committee (NVAC) with support from CDC formed a *Workgroup on Immunization Registries*.

- March 1998: the NVAC Workgroup began a collaborative project to develop a plan to facilitate and coordinate a nationwide network of community- and state-based immunization registries.
CDC’s Role – Planning IIS

• The NVAC Workgroup convened four community meetings in New Orleans, Washington, D.C., San Francisco, and Atlanta as forums for expert testimony and discussion among immunization program stakeholders.

• Based upon the community meetings, the NVAC Workgroup developed recommendations, a goal to outline the policy directions, and major steps to establish a nationwide network of community and state population-based registries that are capable of sharing information while maintaining privacy and confidentiality.
CDC’s Role – Planning IIS

The NVAC Workgroup recommendations included:

• Ensuring appropriate protections of privacy and confidentiality for individuals and security for information included in the registry.

• Ensuring participation of all immunization providers and recipients.

• Ensuring appropriate functioning of registries.

• Ensuring sustainable funding for registries.
IIS Privacy and Confidentiality

CDC led a Privacy and Confidentiality Implementation Team with representatives from other stakeholders to develop minimum specifications:

- Confidentiality policies in writing that comply with laws and apply to all users with access.
- Agreements to protect confidentiality signed by users.
- Notification for parents and guardians.
- Choice for parents of whether to participate.
- Use of immunization registry information for only specific purposes.
- Access to and disclosure of immunization registry information.
- Penalties for unauthorized disclosures.
- Data retention and disposal.
Participation in an IIS

• CDC funded research projects to:
  • Identify strategies to encourage provider participation;
  • Improve registry data quality by developing generalizable algorithms that ensure only one record per child in a database; and
  • Assess the feasibility of avoiding duplicate data entry in provider offices by enabling pre-existing billing or patient management systems to report vaccinations directly to an immunization registry.

• CDC established a Provider Participation Team and Work Group to identify concerns and implement solutions to ensure participation of vaccination providers and recipients.
IIS Functionality

• CDC, in collaboration with immunization program managers, identified the following 12 functional standards for immunization registries to be fully operational.

• CDC established a technical working group (TWG), which included external registry stakeholders and information technology specialists to:
  • reach agreement on standard vocabularies and protocols for data transfer;
  • recommend registry functional standards;
  • assist in determining a registry certification method and provide ongoing quality assurance monitoring;
  • Identify ways to facilitate the integration of registry functions into existing information systems.
Funding Immunization Information Systems

- CDC provides annual funding to 56 Immunization Program Grantees (50 states, Washington DC, and 5 large cities)
- IIS development and implementation are a required component for immunization programs
- All grantee IIS must use the same technology-neutral functional standards
**IIS Evaluation and Research**

**IIS Sentinel Sites:** 8 high functionality IIS sites partner with CDC to track patterns in immunization practices and assess vaccination coverage among children less than 19 years of age in their sentinel site geographic regions.

**Systematic Evidence-based Review on Effectiveness of IIS:** Conducted by Task Force (*Guide to Community Preventive Services*) in collaboration with CDC to identify and review ~70 studies published 1980–2009 (also included grey literature of >100 abstracts). The main outcome in an immunization-related Task Force review focuses on effectiveness of intervention in increasing vaccination coverage.
IIS Operational Assistance

• **Enhanced Technical Assistance Project:** CDC provides Enhanced Technical Assistance to grantees with a Cooperative Agreement with the Public Health Informatics Institute to provide targeted technical assistance intervention to 317 Immunization Program grantees.

• **Operational Guidelines Production and Implementation:** CDC and the American Immunization Registry Association (AIRA) collaborate to produce operations practice guidelines for registry topics.

• **Training:** Development of a 60-minute IIS training module (IIS 101: What Every Program Manager Should Know) for new IIS managers, immunization program managers, other immunization program staff, and stakeholder groups.
Electronic Health Records Initiative

• On April 27, 2004, in his State of the Union address, President Bush called for “…the majority of Americans to have interoperable electronic health records within 10 years.”
  o Establishes the position of National Coordinator for Health Information Technology.
  o Develops a strategic plans with goals that include:
    o *Introduction of information tools into clinical practice*;
    o *Electronically connecting clinicians to other clinicians*;
    o *Using information tools to personalize care delivery*; and
    o *Advancing surveillance and reporting for population health improvement*. 
Electronic Health Record Status, 2007

- DesRoches et al published “Electronic Health Records in Ambulatory Care – A National Survey of Physicians” in NEJM in July 2008 and concluded that of about 1,800 physicians surveyed:
  - EHRs were more prevalent with younger physicians; larger practices; and in the western United States.
  - < 20% of the physicians responding to the survey had a fully functional or basic EHR.
  - **Barriers to adoption of EHRs included:** cost; ability to meet practice needs; ROI; and application life cycle.
  - **Facilitators to adoption of EHRs included:** incentives for purchase; payment for use; and liability protection.
President Obama’s administration introduced the HITECH Act which was passed by Congress in 2009 to support the adoption and use of Electronic Health Records (EHRs)

The purpose of HITECH is to achieve significant improvements in care through **meaningful use** of EHRs by health care providers.

Established incentive payments to eligible professionals and hospitals to promote the adoption and meaningful use of interoperable HIT and qualified electronic health records (EHRs)
Meaningful Use Goals

“Meaningful Use” has 5 health outcome policy priorities:

- Improve quality, safety, efficiency, and reducing health disparities
- Engage patients and families in their personal health development
- Improve care coordination
- Improve population and public health
- Ensure adequate privacy and security protection for personal health information
Public Health Meaningful Use Criteria

Three Public Health objectives, which involves EHR capacity to send electronic data using HL7 messaging standards to an:

- Immunization Registries (IR)/ Immunization Information Systems (IIS)
- Syndromic Surveillance systems
- Reportable Lab results
IISSB HITECH Initiatives
EHR – IIS Enhanced Interoperability Cooperative Agreement
funding for 20 CDC Immunization Program grantees --- $21.4 M

• **Purpose:** To provide support for the enhanced interoperability of EHR with IIS with a specific focus on the exchange of vaccination records and reducing the duplicate data entry burden on providers.

• **Measureable Outcomes:**
  1. Increase the number of enhanced EHR–IIS practice-based electronic interfaces available by 45%;
  2. Increase the number of practice-based electronic immunization transactions reported/timeframe (week, month) to the IIS by 10% and
  3. Increase the number/proportion of practice-based immunization data received and recorded in an IIS within 30 days or less by 25%.
CDC Immunization Program grantees selected to receive funding for the EHR-IIS Enhanced Interoperability cooperative agreement
September 2009

SAFER · HEALTHIER · PEOPLE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
IISSB HITECH Initiatives
EHR – IIS Enhanced Interoperability support contract --- $599 K

• Purpose: To obtain administrative, operational and evaluation support for HITECH Act grantees to enhance EHR-IIS interoperability.

• Key Activities:
  1. Serve as the main liaison to each grantee to provide program expertise, budget guidance, financial tracking, program performance monitoring functions.
  2. Monitor project planning, implementation, budget, coordination, evaluation, and close out of grantee project milestones and tasks
  3. Collect project status reports from grantees.
  4. Assist with report preparation and other substantive program.
IISSB HITECH Initiatives
EHR – IIS Enhanced Interoperability Expert Panel contract --- $2.2 M

• **Purpose**: To obtain technical, operational and product support to HITECH Act grantees for the IISSB with a final project report containing references to the products, best practices, & guidance documents developed. Sustain grantee interoperability and support efforts on an ongoing basis.

• **Key Activities**:
  1. Support transport layer technical assistance to stakeholders
  2. Support HL7 2.5.1 Implementation Guide technical assistance
  3. Verify IIS and EHR communication interface
  4. Prepare and maintain documents including design documents, operations & user manuals, data quality validations, business rules and project profiles.
  5. Provide ongoing technical assistance.
  6. Bring client de-duplication and identification up to a best practice standard
EHR- IIS Interoperability Outcomes

• Up to 2,000 practice EHRs in 17 states and 3 cities will receive enhanced interoperability to enable real-time exchange of immunization data.

• HL7 enhancement best practices will be developed to sustain activities in practices and IISs.
EHR- IIS Interoperability Outcomes

• Enhancements may assist practices in receiving Meaningful Use incentives.

• Enhancing EHR-IIS interoperability will improve data quality challenges by addressing:
  • Accuracy
  • Timeliness
  • Completeness
Assessing Variability Among IIS Vaccine Forecasting Algorithms

• Ambiguity in interpretations of ACIP recommendations can lead to invalid doses and extra-immunizations
  – Of the 36 IIS forecasting algorithm tools testing the nine case, 19 (53%) IIS forecasted the next dose due ≥ 5 days before the minimum age for at least one test case or more.

• Need for harmonization of ACIP recommendations
  – Clearly defined language, technology-neutral, and ACIP-approved

Source: 2010 NIC presentation by Amanda Bryant, Janet Kelly, and Laura Pabst
IISSB HITECH Initiatives
Clinical Decision Support Expert Panel contract --- $1.97 M

• Purpose: To promote vaccine registry transparency among clinicians to create the meaningful interchange and use of vaccination registries.

• Key Activities:
  1. Produce a foundation for the specification (blueprint/model) & develop specifications and.
  2. Develop evaluation test cases and procedures.
  3. Support a minimum of five (5) CDC-selected IIS in implementing the vaccination forecasting specification (blueprint), providing technical assistance, as needed.
  4. Conduct (2) training sessions for up to 15 individuals per session.
  5. Document lessons learned, change management activities, and provide a final Specification document to CDC.
  6. Provide an approach and products to provide a quick and easy update of vaccination forecasting.
CDC Monitoring of IIS Performance
Immunization Information Systems
State Legislation

IIS State Legislation (including Washington DC):

• Authorizes an IIS: 27 states (53%)
• Mandates reporting: 14 states (27%)
• Requires participation (Opt-Out): 44 states and Washington D.C. (86%)

Source: Survey of State Registry Legislation (updated 11-9-2005)
# Immunization Information Systems

## Age Groups Participating in an IIS

<table>
<thead>
<tr>
<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td>Participation of U.S. children &lt; 6 years in an IIS with 2 or more immunizations.</td>
<td>21%</td>
<td>77% (18.4 million children &lt; 6 years)</td>
</tr>
<tr>
<td>Participation of U.S. adolescents 11-18 years in an IIS with 1 or more immunizations.</td>
<td>-</td>
<td>46% (15.1 million adolescents 11-18 years)</td>
</tr>
<tr>
<td>Participation of U.S. adults &gt;19 years in an IIS with 1 or more immunizations.</td>
<td>-</td>
<td>13% (30.8 million adults &gt;19 years)</td>
</tr>
<tr>
<td>U.S. participation – all ages.</td>
<td>-</td>
<td>33% (88.5 million persons of all ages)</td>
</tr>
</tbody>
</table>

Source: 2009 Immunization Information System Annual Report
Percentage of children aged < 6 years participating in a grantee immunization information system – United States, and six cities, 2009

National Participation: 77% (excluding Territories)
Source: CY 2009 IISAR
Immunization Information Systems
Provider Site Participation in an IIS

<table>
<thead>
<tr>
<th></th>
<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td>Public provider sites</td>
<td>38%</td>
<td>80% (11,191 public provider sites)</td>
</tr>
<tr>
<td>Private provider sites</td>
<td>19%</td>
<td>38% (34,990 private provider sites)</td>
</tr>
<tr>
<td>All U.S. provider sites</td>
<td></td>
<td>44% (46,181 of all U.S. provider sites)</td>
</tr>
</tbody>
</table>

Source: 2009 Immunization Information System Annual Report
Immunization Information System Capacity to Track Adolescent and Adult Vaccinations

Data from the 2009 Immunization Information System Annual Report indicate that:

• About 82% (46 of 56 grantees) report that they include all ages in their IISs.

Source: 2009 Immunization Information System Annual Report
Immunization Information System Selected Data Quality Measures - December 31, 2009

Of those grantees with an IIS reporting:

- On average, 76% of newborn records are recorded in a grantee IIS within 6 weeks of birth
- 93% of grantees receive and process vaccine and other immunization data from their IIS within a 30 days of vaccine administration and 53% in < 7 days

Source: 2009 Immunization Information System Annual Report
Compliance with HL 7 Messaging Standards in a grantee Immunization Information System – United States, and six cities, 2009

Source: 2009 Immunization Information System Annual Report
Contact Information

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