

Immunization Information Systems Current Status

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National Vaccine Advisory Committee

Washington, D. C.

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Discussion Points

- Background**
- NVAC involvement with Immunization Information Systems (IIS)**
- The need for IIS in the U. S.**
- The Current Status of Immunization Information Systems**
- Selected IIS initiatives**
- Proposed IIS Functional Standards for 2013-2017**

Background

- ❑ **Immunization Information Systems (IIS) are confidential, computerized, population-based systems that collect and consolidate vaccination data from vaccination provider sites and provide important tools for designing and sustaining effective immunization strategies at the provider and immunization program levels**
- ❑ **55 of 56 grantees are supported by an IIS**
 - ❑ **Varying levels of maturity, unique state environment, etc.**
- ❑ **Breadth of evaluation and functionality to support the Immunization Program and the clinical setting**

NVAC IIS Studies and Progress Reports

- ❑ “Developing A National Childhood Immunization Information System: Registries, Reminders, and Recall” National Vaccine Advisory Committee, Subcommittee on Vaccination Registries, 1994**
- ❑ “Development of Community- and State-Based Immunization Registries - Report of the National Vaccine Advisory Committee (NVAC)”, Approved January 12, 1999**
- ❑ “Immunization Information Systems - NVAC Progress Report”, Approved February 5, 2007**

1997 NVAC Registry Initiative

- ❑ **Charged with identifying barriers to developing and implementing immunization registries**
- ❑ **Defining milestones for development and implementation of a comprehensive plan for implementation of universal state-based and community-based immunization registries**

1997 NVAC Registry Initiative

- ❑ 4 public meetings attended by >400 persons
- ❑ Testimony from 104 persons
- ❑ 20 focus group interviews by CDC
- ❑ “Development of Community- and State-Based Immunization Registries” approved by NVAC January 1999

Immunization Information Systems Goals

- ❑ Ensure appropriate protections of privacy and confidentiality for individuals and security for information included in the registry**
- ❑ Ensure participation of all immunization providers and recipients**
- ❑ Ensure appropriate functioning of registries**
- ❑ Ensure sustainable funding for registries**

Healthy People 2010 Goal

- ❑ Increase to 95% to proportion of children <6 years of age who participate in fully operational population-based immunization registries

The Need for Immunization Information Systems in the U. S.

Increasing Populations – Population Mobility

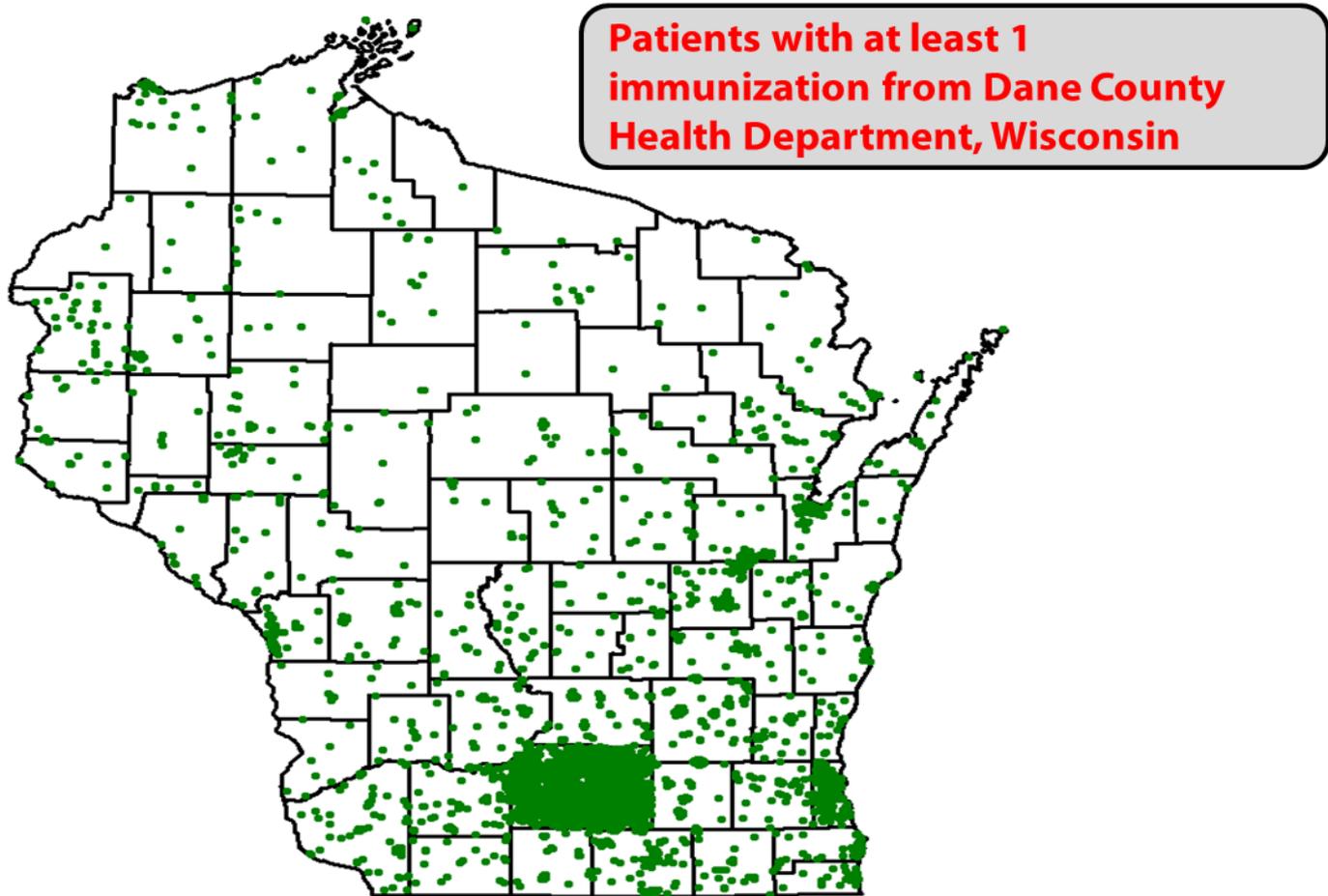


- ❑ Births in the U. S. - 2010:
- ❑ 3.99 million live births (10,957 births every day).¹
- ❑ The U.S. Census Bureau reports that between 2010 and 2011, 35.1 million (12%) people moved in the United States – 10.6 million (30%) are < 19 years of age.²

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



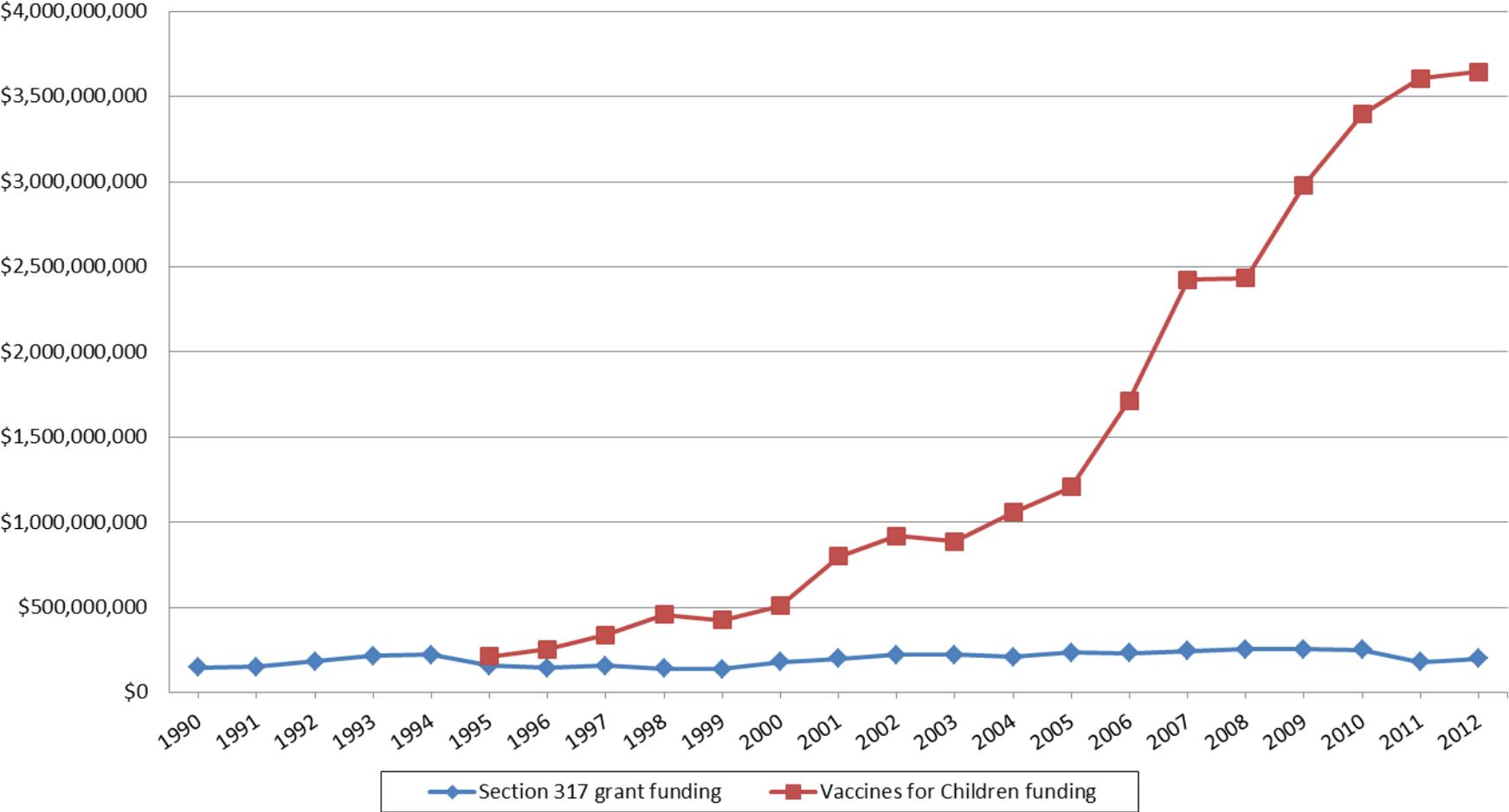
Extra-Immunization



- ❑ 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.

¹ Feikema, SM, Klevens, RM, Washington, ML, Barker, L. Extra-immunization Among US Children. JAMA 2000;283:1311-1317.

CDC Funding to Immunization Programs 1990 – 2012



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.^{1, 2}**

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.

² Bushnell CJ. The ABC's of practice-based immunization assessments. Proceedings of the 28th National Immunization Conference. U.S. Dept. Health and Human Services, Washington DC, 1994, pp 207-209.

Immunization Information Systems Clinical Decision Support

FIGURE 1: Recommended immunization schedule for persons aged 0 through 6 years—United States, 2012 (for those who fall behind or start late, see the catch-up schedule [Figure 3])

| Vaccine ▼ | Age ► | Birth | 1 month | 2 months | 4 months | 6 months | 9 months | 12 months | 15 months | 18 months | 19–23 months | 2–3 years | 4–6 years | |
|---|-------|-------|---------|----------|----------|--------------------|---------------------------|-----------------------------------|-----------|---------------------------|--------------|-------------|-----------|---|
| Hepatitis B ¹ | | Hep B | HepB | | | HepB | | | | | | | | Range of recommended ages for all children |
| Rotavirus ² | | | | RV | RV | RV ² | | | | | | | | |
| Diphtheria, tetanus, pertussis ³ | | | | DTaP | DTaP | DTaP | see footnote ⁷ | | DTaP | | | | DTaP | Range of recommended ages for certain high-risk groups |
| <i>Haemophilus influenzae</i> type b ⁴ | | | | Hib | Hib | Hib ⁴ | | Hib | | | | | | |
| Pneumococcal ⁵ | | | | PCV | PCV | PCV | | PCV | | | | PPSV | | |
| Inactivated poliovirus ⁶ | | | | IPV | IPV | IPV | | | | | | IPV | | |
| Influenza ⁷ | | | | | | Influenza (Yearly) | | | | | | | | |
| Measles, mumps, rubella ⁸ | | | | | | | | MMR | | see footnote ⁹ | | | MMR | Range of recommended ages for all children and certain high-risk groups |
| Varicella ⁹ | | | | | | | | Varicella | | see footnote ⁹ | | | Varicella | |
| Hepatitis A ¹⁰ | | | | | | | | Dose 1 ¹⁰ | | | | HepA Series | | |
| Meningococcal ¹¹ | | | | | | | | MCV4 — see footnote ¹¹ | | | | | | |

This schedule includes recommendations in effect as of December 23, 2011. 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. Vaccination providers should consult the relevant Advisory Committee on Immunization Practices (ACIP) statement for detailed recommendations, available online at <http://www.cdc.gov/vaccines/pubs/acip-list.htm>. Clinically significant adverse events that follow vaccination should be reported to the Vaccine Adverse Event Reporting System (VAERS) online (<http://www.vaers.hhs.gov>) or by telephone (800-822-7967).

Public Health Emergencies

- ❑ 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}

¹ Boom, JA, Dragsbaek, AC, Nelson, CS. The Success of an Immunization Information Systems in the Wake of Hurricane Katrina. Pediatrics. 2007; 119:1213-1217.

² Urquhart GA, Williams W, Tobias J, Welch FJ. Immunization Information Systems Use During a Public Health Emergency in the United States. J Public Health Management Practice; September/October 2007.

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**

The Current Status of Immunization Information Systems:

- ❑ Ensure appropriate protections of privacy and confidentiality for individuals and security for information included in the registry**
- ❑ Ensure participation of all immunization providers and recipients**
- ❑ Ensure sustainable funding for registries**
- ❑ Ensure appropriate functioning of registries**

Immunization Information Systems Privacy and Confidentiality - 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%)**

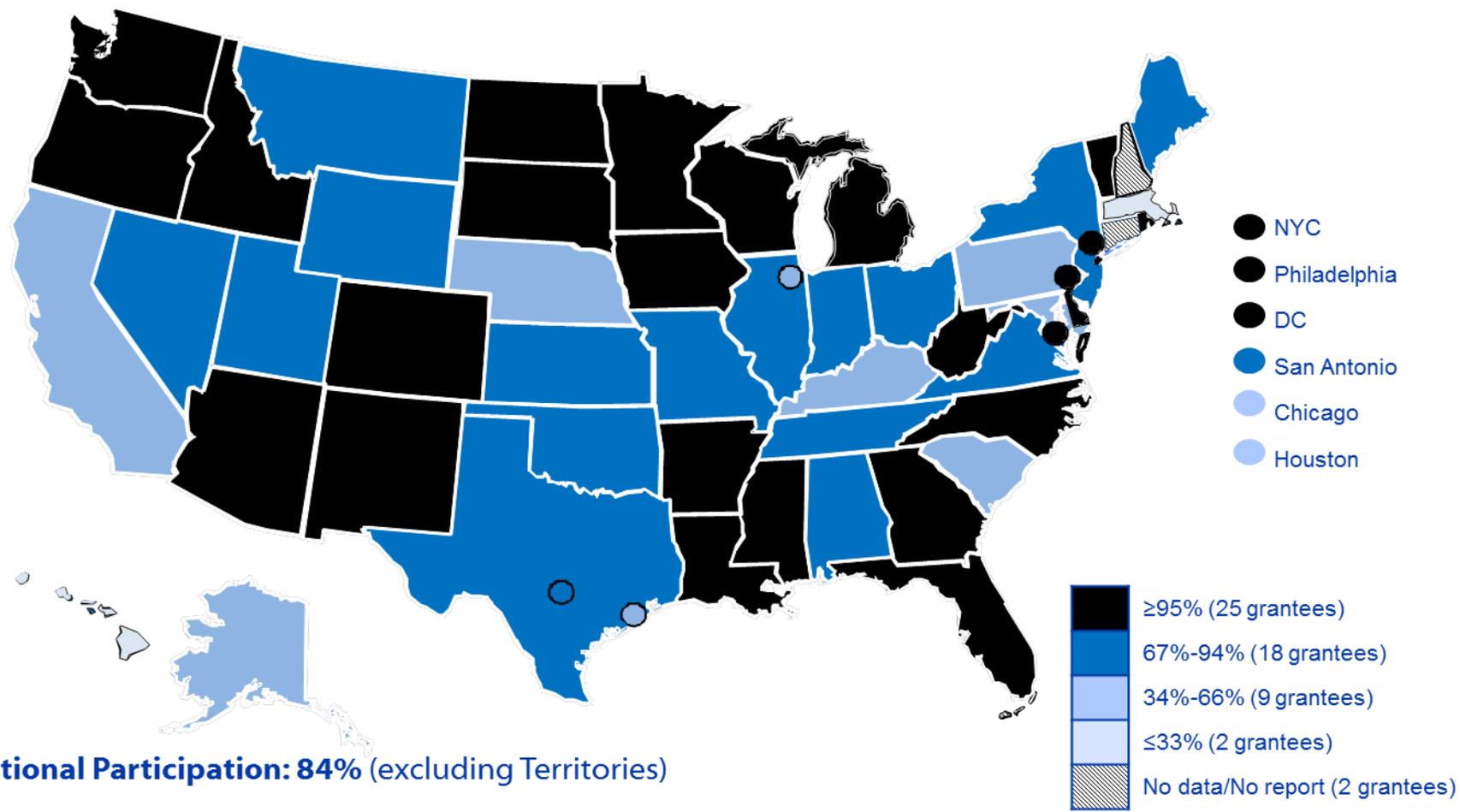
Source: Survey of State Registry Legislation (updated 11-9-2005)

IIS Progress to Improve Participation

| | U.S. - 2000 | U.S. - 2011 |
|--|-------------|--|
| Participation of U.S. children < 6 years in an IIS with 2 or more immunizations. | 21% | 84% (19.2 million children < 6 years) |
| Participation of U.S. adolescents 11-17 years in an IIS with 2 or more adolescent immunizations. | - | 53% (15.4 million adolescents 11-17 years) |
| Participation of U.S. adults ≥19 years in an IIS with 1 or more adult immunizations. | - | 24% (56.7 million adults ≥19 years) |

Children < 6 Years Participation in IIS, 2011

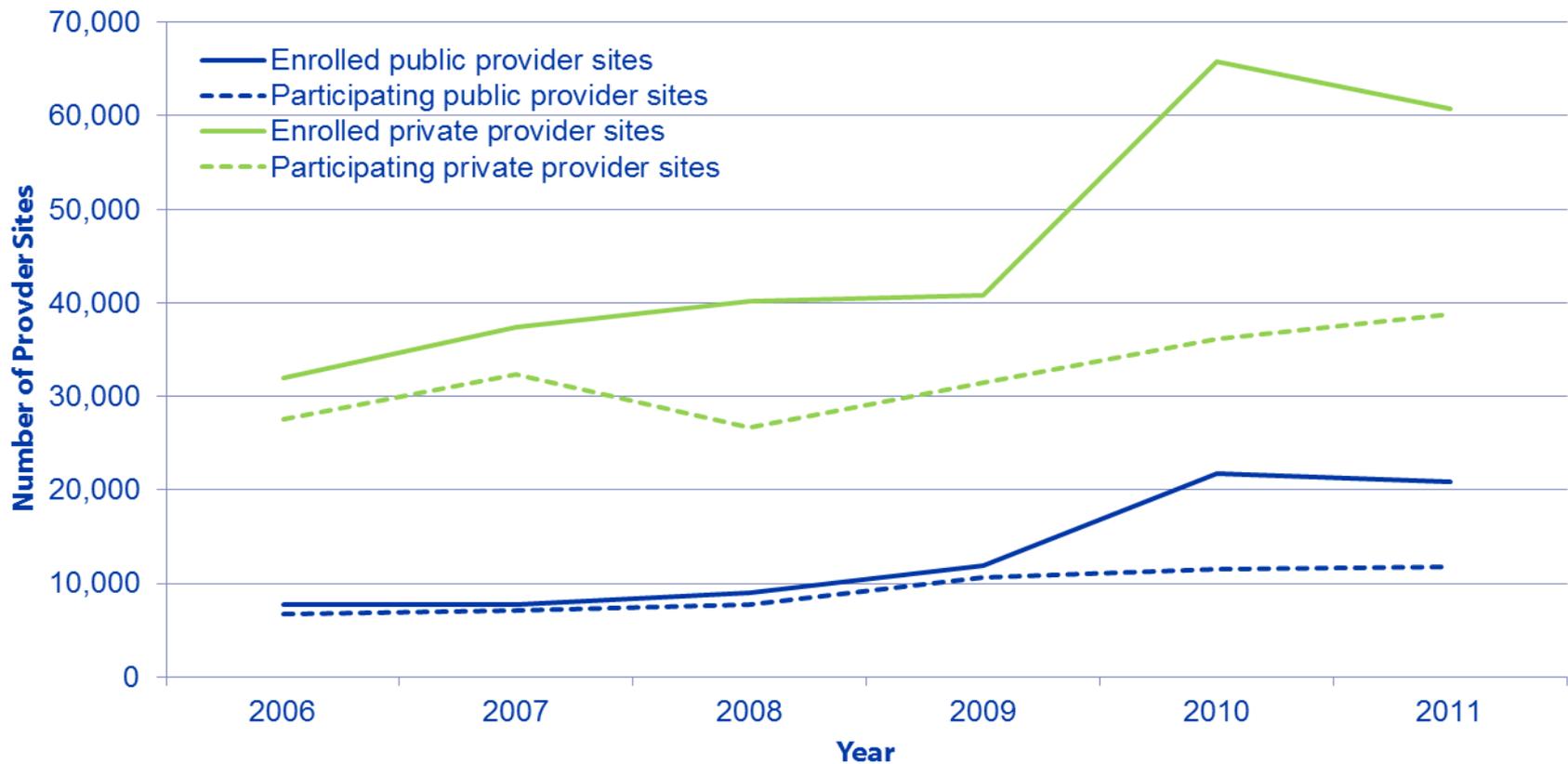
Healthy People 2020 IIS Objective Status



National Participation: 84% (excluding Territories)

Source: State and Local Health Departments via the 2011 Immunization Information System Annual Report

Number of Public and Private Vaccine Provider Sites Enrolled and Participating* in IIS† 2006-2011



* Participation is defined as having submitted data to the IIS in the past 6 months

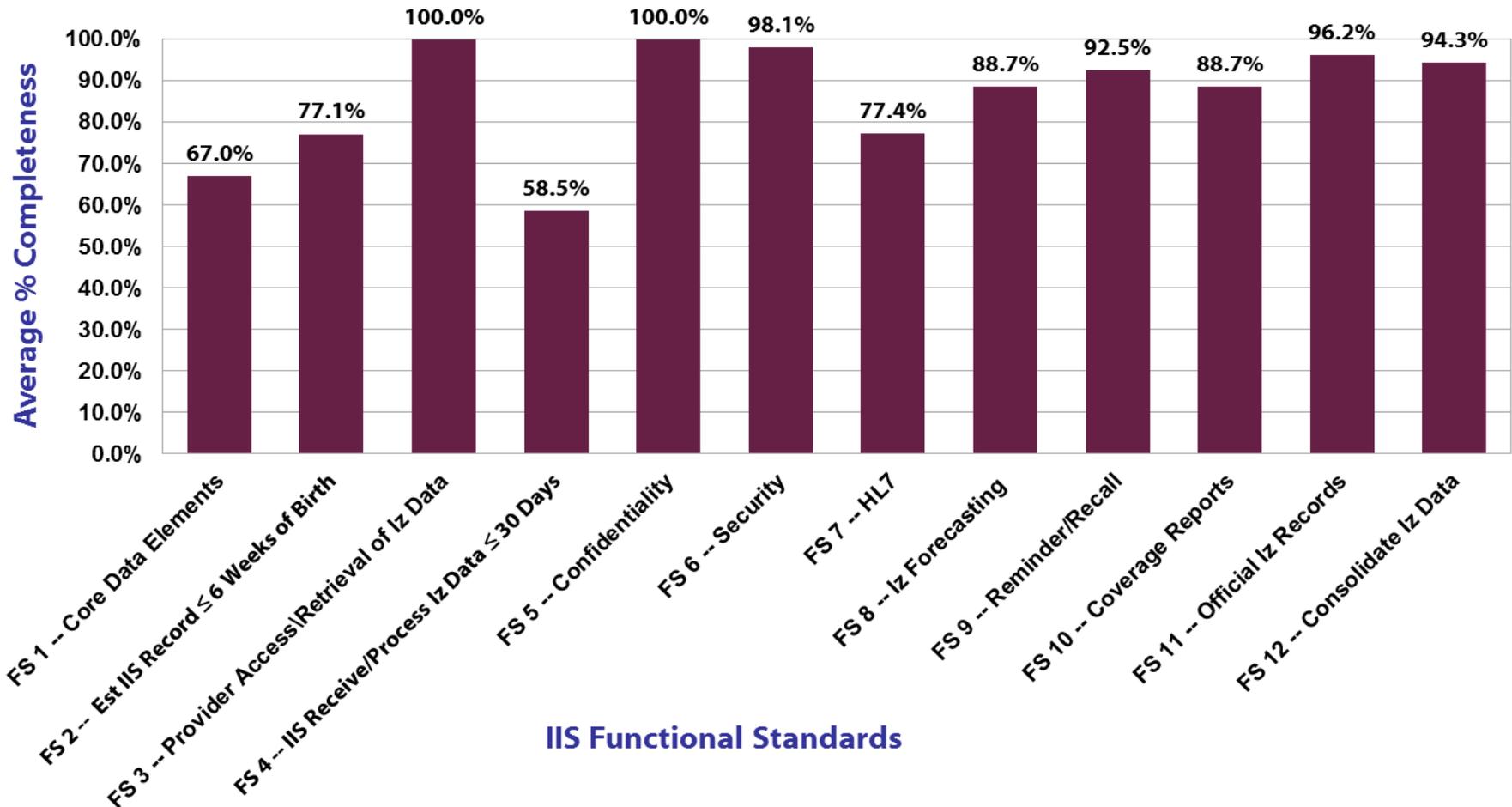
† Among 48 grantees reporting each year from 2006 - 2011

IIS Funding Sources, 2010

| Funding Source | Amount | % |
|---|---------------------|-------|
| CDC immunization 317 grant funds (include VFC and DA) | \$36,922,434 | 55.3% |
| State | \$11,714,326 | 17.6% |
| Local | \$2,159,779 | 3.2% |
| Private | \$304,624 | 0.5% |
| In-kind | \$200,000 | 0.3% |
| CMS/MMIS | \$1,674,465 | 2.5% |
| CMS/HITECH | \$1,595,410 | 2.4% |
| HRSA | \$25,273 | 0.0% |
| Other federal programs | \$5,475,131 | 8.2% |
| Emergency preparedness | \$1,488,983 | 2.2% |
| Non-profit | \$0 | 0.0% |
| Other | \$5,157,606 | 7.7% |
| | | |
| Total Funding | \$66,718,031 | |

Source: State and Local Health Departments via the 2010 Immunization Information System Annual Report

IIS Functional Standards, 2010



Source: State and Local Health Departments via the 2010 Immunization Information System Annual Report

Selected CDC IIS Initiatives

- 1. Enhance EHR-IIS Interoperability**
- 2. Clinical Decision Support**
- 3. Implement the Use of 2D Bar Codes**
- 4. IIS Sentinel Sites Project**
- 5. Trends in Immunization Practices System (IIS-TIPS)**
- 6. VTrckS and EXIS**
- 7. IIS Functional Standards Revision**

EHR-IIS Interoperability

- National HIT Initiatives will facilitate EHR-IIS interoperability by:**
 - Promoting the development and use of certified EHR systems that use national standards for interoperability with IIS and other healthcare systems**
 - Incentivizing clinical practice interoperability to improve overall patient care.**
 - Promoting the development and implementation of Health Information Exchanges (HIE).**
 - Promoting consumer e-health that empowers patients to access and review their own health care.**

EHR-IIS Interoperability

- ❑ Enhancements may assist practices in receiving Meaningful Use incentives.
- ❑ Enhancing EHR-IIS interoperability will improve data quality challenges by addressing:
 - Accuracy
 - Timeliness
 - Completeness

Proposed Immunization Information Systems Functional Standards, 2013- 2017

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National Vaccine Advisory Committee
Washington, D. C.
September 11, 2012



Overview of Proposed Changes

- **Clarify focus of standards on:**
 - Quality of care
 - Support of public health programs
- **Re-structured Standards document into three parts:**
 - General Considerations
 - Programmatic Goals
 - Functional Standards
- **Added additional Core Data Elements**

General Considerations

- A. These functional standards are intended to identify operational, programmatic, and technical capacities that all IIS should achieve by the end of 2017.**

- B. Some standards are environmental, and can only be implemented in conjunction with the broader Department of Health or State/Local infrastructure. The Functional Standards are intended to reflect necessary functions, whether those functions are implemented by the IIS program or others.**

General Considerations

- C. In some cases, current law or policy may preempt full implementation unless changed. In these instances, an unmet standard may serve as a suggestion for possible revisions to such law or policy.**

- D. Metrics must capture IIS progress toward achieving the programmatic goals and functional standards in accurate and meaningful ways. CDC will define the metrics with input from immunization programs.**

Programmatic Goal 1

Support the delivery of clinical immunization services at the point of immunization administration, regardless of setting.

Functional Standards 1

Support the delivery of clinical immunization services at the point of immunization administration, regardless of setting.

- 1.1 The IIS provides individual immunization records accessible to authorized users at the point and time where immunization services are being delivered.**
- 1.2 The IIS has an automated function that determines vaccines due, past due, or coming due (“vaccine forecast”) in a manner consistent with current ACIP recommendations. Any deficiency is visible to the clinical user each time an individual’s record is viewed.**
- 1.3 The IIS automatically identifies individuals due/past due for immunization(s), to enable the production of reminder/recall notifications from within the IIS itself or from interoperable systems.**

Functional Standards 1

Support the delivery of clinical immunization services at the point of immunization administration, regardless of setting.

- 1.4 When the IIS receives queries from other health information systems, it can generate an automatic response in accordance with interoperability standards endorsed by CDC for message content/format and transport.**

- 1.5 The IIS can receive submissions in accordance with interoperability standards endorsed by CDC for message content/format and transport.**

Programmatic Goal 2

Support the activities and requirements for publicly-purchased vaccine, including the Vaccines For Children (VFC) and state purchase programs.

Functional Standards 2

Support the activities and requirements for publicly-purchased vaccine, including the Vaccines For Children (VFC) and state purchase programs.

- 2.1 The IIS has a vaccine inventory function that tracks and decrements inventory at the provider site level according to VFC program requirements.**
- 2.2 The IIS vaccine inventory function is available to direct data entry users and can interoperate with EHR or other inventory systems.**
- 2.3 The IIS vaccine inventory function automatically decrements as vaccine doses are recorded.**

Functional Standards 2

Support the activities and requirements for publicly-purchased vaccine, including the Vaccines For Children (VFC) and state purchase programs.

- 2.4 Eligibility is tracked at the dose level for all doses administered.**
- 2.5 The IIS interfaces with the national vaccine ordering, inventory, and distribution system (currently VTrckS).**
- 2.6 The IIS can provide data and/or produce management reports for VFC and other public vaccine programs.**

Programmatic Goal 3

Maintain data quality (accurate, complete, timely data) on all immunization and demographic information in the IIS.

Functional Standards 3

Maintain data quality (accurate, complete, timely data) on all immunization and demographic information in the IIS.

- 3.1 The IIS provides consolidated demographic and immunization records for persons of all ages in its geopolitical area, except where prohibited by law, regulation, or policy.**
- 3.2 The IIS can regularly evaluate incoming and existing patient records to identify, prevent, and resolve duplicate and fragmented records.**
- 3.3 The IIS can regularly evaluate incoming and existing immunization information to identify, prevent, and resolve duplicate vaccination events.**
- 3.4 The IIS can store all IIS Core Data Elements.**

Functional Standards 3

Maintain data quality (accurate, complete, timely data) on all immunization and demographic information in the IIS.

- 3.5 The IIS can establish a record in a timely manner from sources such as Vital Records for each newborn child born and residing at the date of birth in its geopolitical area.**
- 3.6 The IIS records and makes available all submitted vaccination and/or demographic information in a timely manner.**
- 3.7 The IIS documents active/inactive status of individuals at both the provider organization/site and geographic levels.**

Programmatic Goal 4

Preserve the integrity, security, availability and privacy of all personally-identifiable health and demographic data in the IIS.

Functional Standards 4

Preserve the integrity, security, availability and privacy of all personally-identifiable health and demographic data in the IIS.

- 4.1 The IIS program has written confidentiality and privacy practices and policies based on applicable law or regulation that protect all individuals whose data are contained in the system.**
- 4.2 The IIS has user access controls and logging, including distinct credentials for each user, least-privilege access, and routine maintenance of access privileges.**
- 4.3 The IIS is operated or hosted on secure hardware and software in accordance with industry standards for protected health information, including standards for security/encryption, uptime and disaster recovery.**

Programmatic Goal 5

Provide immunization information to all authorized stakeholders.

Functional Standards 5

Provide immunization information to all authorized stakeholders.

- 5.1 The IIS can provide immunization data access to healthcare providers, public health, and other authorized stakeholders (e.g., schools, public programs, payers) according to law, regulation or policy.**
- 5.2 The IIS can generate predefined and/or ad hoc reports (e.g., immunization coverage, vaccine usage, and other important indicators by geographic, demographic, provider, or provider groups) for authorized users without assistance from IIS personnel.**
- 5.3 With appropriate levels of authentication, IIS can provide copies of immunization records to individuals or parents/guardians with custodial rights.**
- 5.4 The IIS can produce an immunization record acceptable for official purposes (e.g., school, child care, camp).**

Programmatic Goal 6

Promote vaccine safety in public and private provider settings.

Functional Standards 6

Promote vaccine safety in public and private provider settings.

- 6.1 Provide the necessary reports and/or functionality to facilitate vaccine recalls when necessary, including the identification of recipients by vaccine lot, manufacturer, provider, and/or time frame.**

- 6.2 Facilitate reporting and/or investigation of adverse events following immunization.**

Core Data Elements

Core Data Elements

- An IIS is required to store each of the core data elements listed as per Functional Requirement 3.4.
 - The decision whether to require these elements in submitted data is a separate question and varies with jurisdiction
 - Note that requirements may vary for EHRs, Vital Stats feeds, etc.
- Starred items (*) are newly-proposed elements not included on the current approved list from National Vaccine Advisory Committee dated 2007.

Core Data Elements

- ❑ Patient ID (previously listed as “Medicaid Number”)
- ❑ * Patient ID: Assigning Authority ID (i.e., owning source)
- ❑ * Patient ID: Type (e.g., medical record number, IIS ID)
- ❑ Patient Name: First
- ❑ Patient Name: Middle
- ❑ Patient Name: Last
- ❑ Patient Alias Name: First
- ❑ Patient Alias Name: Middle
- ❑ Patient Alias Name: Last
- ❑ Patient Date of Birth
- ❑ Patient Gender
- ❑ * Patient Multiple Birth Indicator
- ❑ Patient Birth Order
- ❑ * Responsible Person Name: First
- ❑ * Responsible Person Name: Middle
- ❑ * Responsible Person Name: Last
- ❑ * Responsible Person Name: Relationship to Patient

These new elements support F.S. 3.1 & 3.2, data quality and patient deduplication

* denotes newly proposed since last NVAC approval

Core Data Elements

- ❑ Mother's Name: First
- ❑ Mother's Name: Middle
- ❑ Mother's Name: Last
- ❑ Mother's Name: Maiden Last
- ❑ Patient Address: Street
- ❑ Patient Address: City
- ❑ Patient Address: State
- ❑ Patient Address: Country
- ❑ Patient Address: Zip code
- ❑ * Patient Address: County of Residence
- ❑ Race
- ❑ Ethnicity
- ❑ Birthing Facility Name
- ❑ Patient Birth State
- ❑ Patient Primary Language
- ❑ Patient Telephone Number
- ❑ * Patient Telephone Number Type (e.g., home, cell)
- ❑ * Patient E-mail Address
- ❑ Patient status indicator—Provider facility level
- ❑ Patient status indicator—IIS level

New contact information supports F.S. 1.3 reminder/recall and 6.1 vaccine safety recalls

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Core Data Elements

- Vaccine Product Type Administered
- Vaccination Administration Date
- Vaccine Manufacture Name
- Vaccine Lot Number
- Vaccine Expiration Date
- * Vaccine dose volume and unit
- Vaccine Site of Administration
- * Vaccine Route of Administration
- * Vaccine Ordering Provider Name
- Vaccine Administering Provider Name
- Vaccine Administering Provider Suffix (e.g., MD, RN, LPN)
- Vaccination Event Information Source (i.e., administered or historical)
- VFC/grantee program vaccine eligibility at dose level
- * VIS Type & Publication Date
- * VIS Date given to patient

These elements support F.S. 2.1 (inventory & accountability), 2.4 (eligibility), 2.5 (VTrckS), and 3.3 (vaccine deduplication)

* denotes newly proposed since last NVAC approval

Core Data Elements

*These elements support
Programmatic Goals 1 (clinical
support) and 6 (vaccine safety)*

- ❑ * Contraindication(s)/Precaution(s)
- ❑ * Contraindication(s)/Precaution(s) Observation Date(s)
- ❑ * Exemption(s)/Parent Refusal(s) of Vaccine
- ❑ * Date of Exemption/Parent Refusal of Vaccine
- ❑ * Vaccine Reaction(s)
- ❑ History of vaccine preventable disease (e.g., varicella)
- ❑ * Date of History of Vaccine Preventable Disease

* denotes newly proposed since last NVAC approval

Thank You / Discussion

For more information please contact Centers for Disease Control and Prevention

1600 Clifton Road NE, Atlanta, GA 30333

Telephone, 1-800-CDC-INFO (232-4636)/TTY: 1-888-232-6348

E-mail: cdcinfo@cdc.gov Web: www.cdc.gov

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



Extra Slides

Core Data Elements – Meaningful Use (MU) Crosswalk with IIS

- ❑ Patient ID (previously listed as “Medicaid Number”)
- ❑ * Patient ID: Assigning Authority ID (i.e., owning source)
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red denotes elements not required in MU Stage 1

Core Data Elements MU Crosswalk with IIS

- ❑ Mother's Name: First
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- ❑ Patient Address: Country
- ❑ Patient Address: Zip code
- ❑ * Patient Address: County of Residence
- ❑ Race
- ❑ Ethnicity
- ❑ Birthing Facility Name
- ❑ Patient Birth State
- ❑ Patient Primary Language
- ❑ Patient Telephone Number
- ❑ * Patient Telephone Number Type (e.g., home, cell)
- ❑ * Patient E-mail Address
- ❑ Patient status indicator—
Provider facility level
- ❑ Patient status indicator—IIS level

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Core Data Elements MU Crosswalk with IIS

- ❑ Vaccine Product Type Administered
- ❑ Vaccination Administration Date
- ❑ Vaccine Manufacture Name
- ❑ Vaccine Lot Number
- ❑ Vaccine Expiration Date
- ❑ * Vaccine dose volume and unit
- ❑ Vaccine Site of Administration
- ❑ * Vaccine Route of Administration
- ❑ * Vaccine Ordering Provider Name
- ❑ Vaccine Administering Provider Name
- ❑ Vaccine Administering Provider Suffix (e.g., MD, RN, LPN)
- ❑ Vaccination Event Information Source (i.e., administered or historical)
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