Barcodes Part 2:
CDC 2D Vaccine Barcode Pilot

National Vaccine Advisory Committee Meeting

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Barcoding definitions – Vaccines

- **Linear**
  - Currently on all vaccine products and required by FDA
  - Contains National Drug Code (NDC) only
  - Other variables cannot be included due to space constraints and need to be recorded manually

- **Two-Dimensional (2D)**
  - Can contain NDC and additional information, such as expiration date and lot number
  - Coexist or Replace (with an FDA waiver) with linear barcodes on vaccine vials and syringes

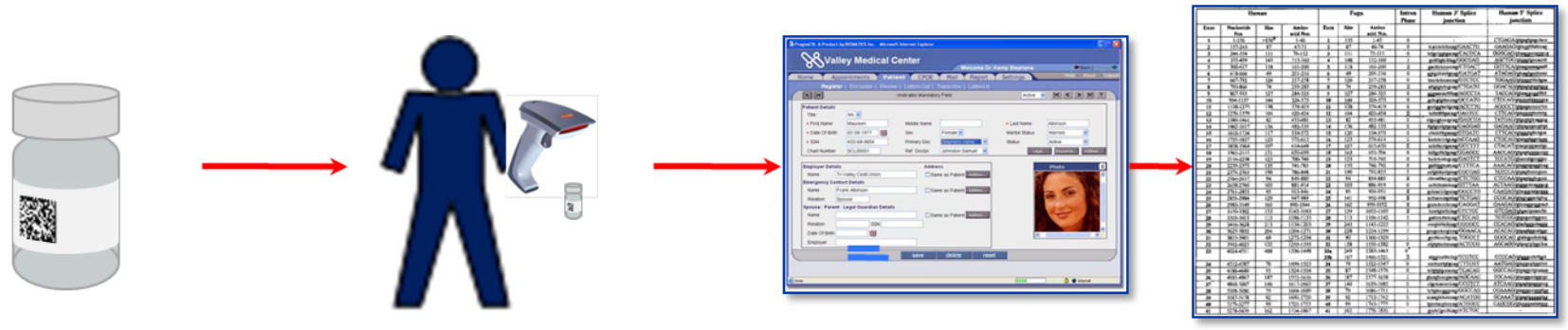
History - Highlights

- **Vaccine Identification Standards Initiative (VISI) - 1997**
- **American Academy of Pediatrics (AAP) 2D Barcoding Conference – January 2009**
- **FDA "Guidance for Industry: Bar Code Label Requirements – Questions and Answers: Availability" August 11, 2011**
  - Amends the 2006 guidance to the barcode rule published in 2004
  - Allows manufactures to use alternative coding, (e.g. two dimensional symbology)
  - References – vaccines and adverse event reporting requirements
- **CDC Funded Feasibility Study**

Economic Model Results from Feasibility Study

- **Time–motion study**
  - practices with EHRs will save approximately 39.4 seconds per dose
  - practices without EHRs will save about 36.5 seconds per dose
- **Net economic benefits**
  - $333.6 million if primary care practices and LHDs follow their stated preferences to use the 2D barcode
  - $326.8 million if the rate of adoption were slowed by 50%
  - $311.3 million if the rate of adoption were slowed by 67%
- **Benefit-to-cost ratio of 2.7 to 2.8**
  - For every $1 expended, $2.70 to $2.80 in benefits are expected to accrue over the period from 2011 through 2023
- **Report pending**

CDC 2-D PILOT IMPLEMENTATION PLAN



Manufacturer

Add a 2D barcode to the primary packaging:

- ❑ DataMatrix barcode to contain
  - ❑ GTIN*
  - ❑ Expiration date
  - ❑ Lot number
- ❑ Distribute to pilot participants

Imz provider

Record and track data:

- ❑ Scan barcode when inventorying and dispensing vaccine products and enter into the medical record

Record system

Medical record types:

- ❑ Electronic medical records (EMR)
- ❑ Custom applications
- ❑ Acts as a source of evaluation for data accuracy and completeness

IIS

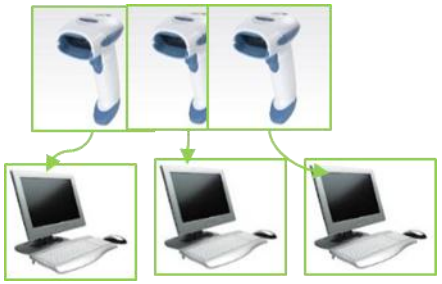
Receive data from the immunizers' EMR or equivalent electronic system:

- ❑ Acts as a source of evaluation for data accuracy and completeness

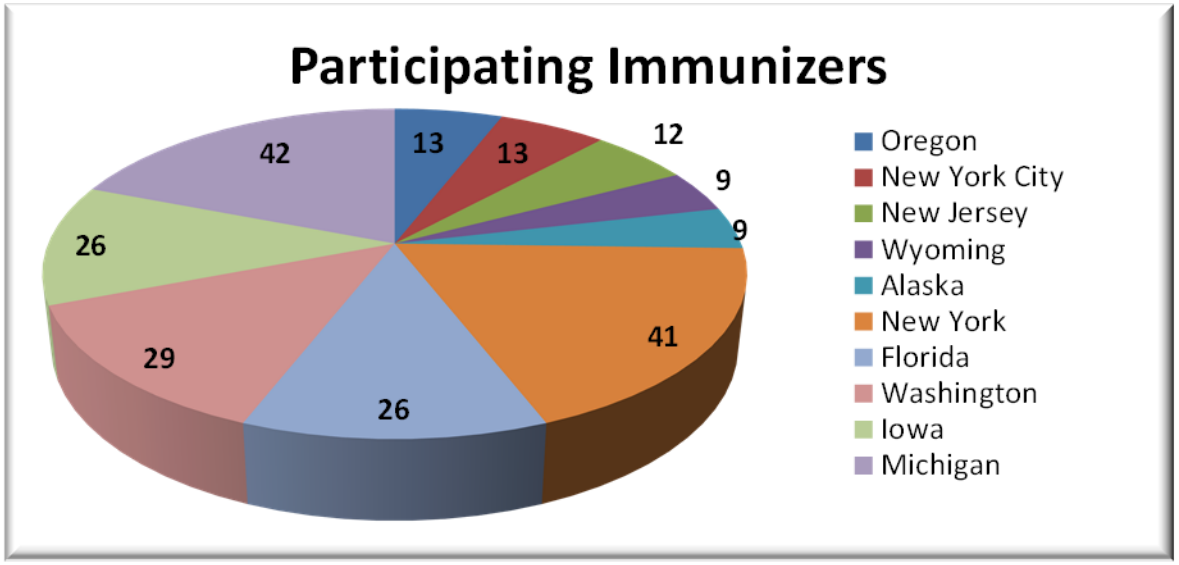
**The Global Trade Item Number (GTIN) is a unique identifier used globally to identify an item. For vaccines and other health care products, the GTIN is specifically used to carry the National Drug Code (NDC)—a unique identifier used in the US as mandated by the FDA.*

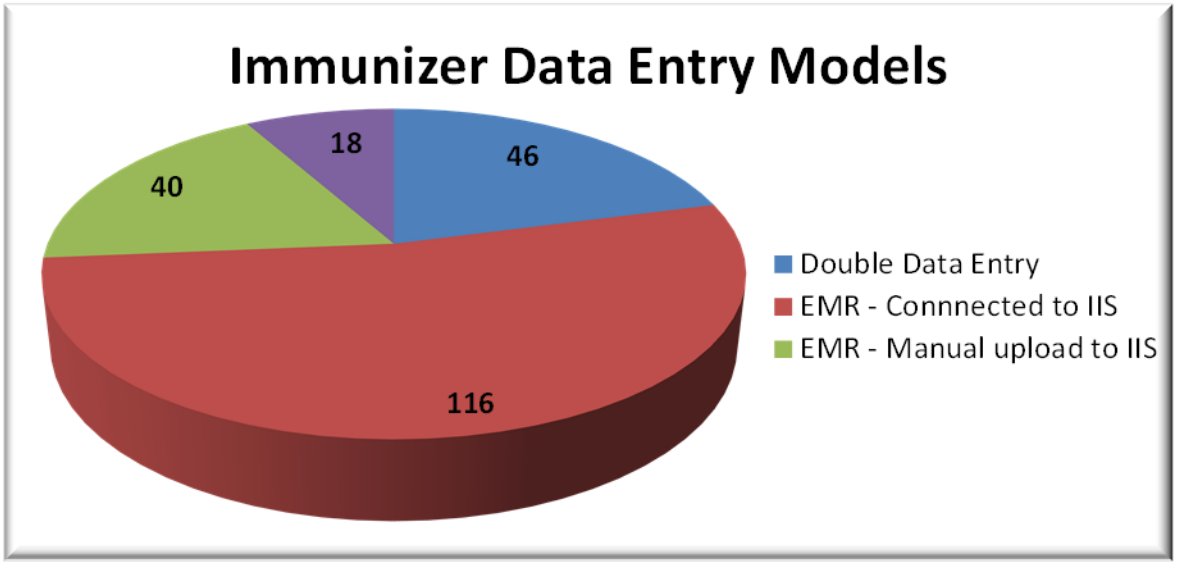
Participants

- **Manufacturers and vaccines**
  - Sanofi – Menactra, Pediatric DT, + 6 new ones on the way
  - GSK – HAVRIX Adult
- **CDC Immunization Grantees**
  - 10 selected (WA, OR, AK, WY, IA, MI, FL, NYC, NY, NJ)
- **Providers - Immunizers**
  - 220 immunizers enrolled
  - 13 selected for work flow analysis (WFA) - depth evaluation
  - ~28 different EHR encountered
  - On-site deployment training completed
- **Key Collaborators**
  - AAP, FDA, GS1, BARDA, AIM, AIRA
  - Deloitte Consulting



Immunizer Demographics





Evaluation Phase of Project

- **Evaluation Components**
  - Accuracy and Completeness
  - User Feedback
  - Workflow Analysis

- **Analysis:** Descriptive and inferential statistics, Confidence intervals, T-tests, Linear regression

- **Data:** 2D and linear barcoded vaccination data

- **Data Sources:** IIS records, EMR records, Shipping manifests, Vaccine inventory logs, Manufacturer product logs

Workflow Analysis – Some Early Preliminary Observations

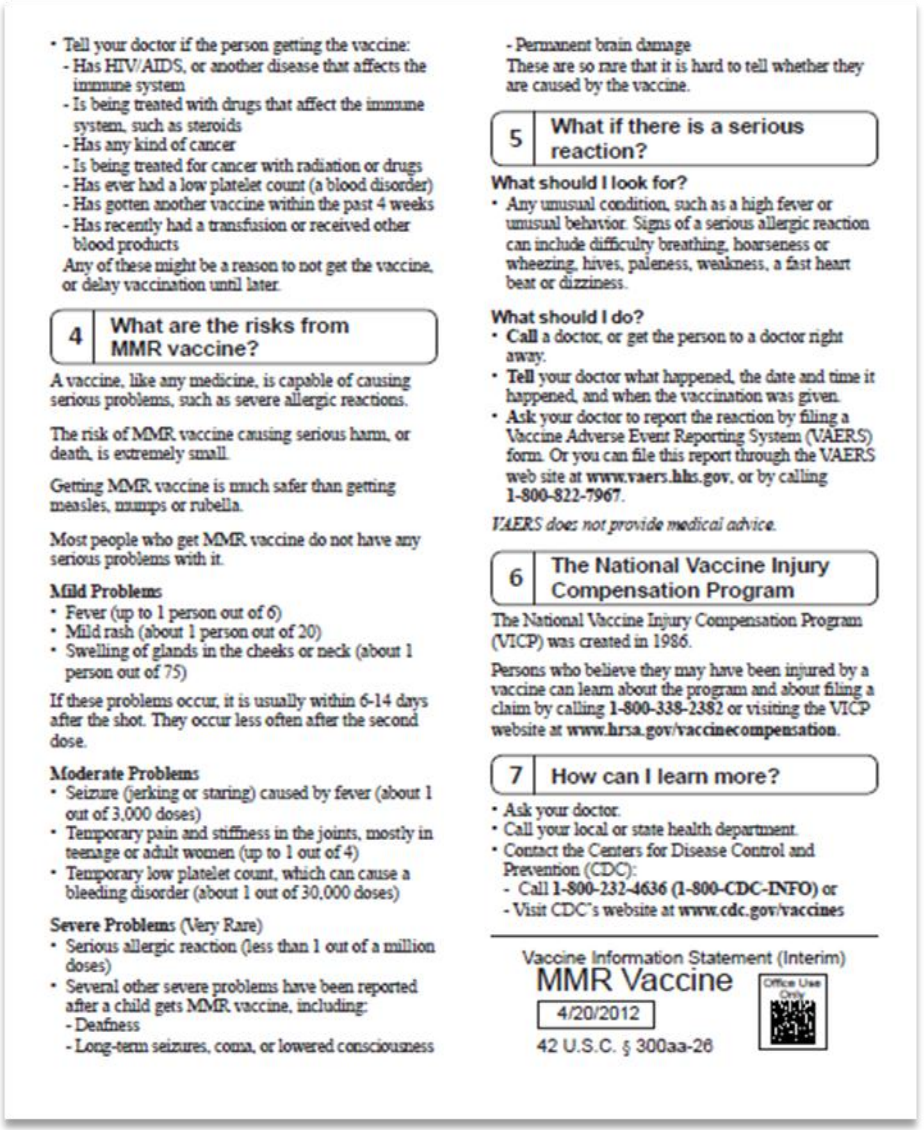
- **Standards: Inventory and vaccination procedures have minimal variance regardless of practice size or type**
- **Opportunities: Similar EHR functional enhancement requests were observed in most practices.**
- **Challenges: Adoption may lag due to reluctance to change established procedures**

- **Perceptions: Interviews have provided candid practitioner expectations and thoughts:**
  - *"Really it is the best thing that has happened for the practice with respect to vaccines. We have been asking for it for 8 years."*
  - *"This new process will be more about accuracy; not so much a time saver."*
  - *"For high volume practices the time savings will be great. It adds up to a small lunch break every week."*
  - *"As I am getting older they make the numbers smaller".*

PART 2B: VACCINE INFORMATION STATEMENTS (VIS)

VIS Barcoding

- **Identified barcode**
  - Selected GS1's Global Document Type Identifier (GDTI) to encode VIS document type
  - Added VIS edition date to GS1 DataMatrix
- **Developed frequently asked questions for users**
- **CDC VIS Barcode Web-page**
- **Rolling out barcodes on new VIS**



- Tell your doctor if the person getting the vaccine:
  - Has HIV/AIDS, or another disease that affects the immune system
  - Is being treated with drugs that affect the immune system, such as steroids
  - Has any kind of cancer
  - Is being treated for cancer with radiation or drugs
  - Has ever had a low platelet count (a blood disorder)
  - Has gotten another vaccine within the past 4 weeks
  - Has recently had a transfusion or received other blood products

Any of these might be a reason to not get the vaccine, or delay vaccination until later.

4 What are the risks from MMR vaccine?

A vaccine, like any medicine, is capable of causing serious problems, such as severe allergic reactions.

The risk of MMR vaccine causing serious harm, or death, is extremely small.

Getting MMR vaccine is much safer than getting measles, mumps or rubella.

Most people who get MMR vaccine do not have any serious problems with it.

Mild Problems
- Fever (up to 1 person out of 6)
- Mild rash (about 1 person out of 20)
- Swelling of glands in the cheeks or neck (about 1 person out of 75)

If these problems occur, it is usually within 6-14 days after the shot. They occur less often after the second dose.

Moderate Problems
- Seizure (jerking or staring) caused by fever (about 1 out of 3,000 doses)
- Temporary pain and stiffness in the joints, mostly in teenage or adult women (up to 1 out of 4)
- Temporary low platelet count, which can cause a bleeding disorder (about 1 out of 30,000 doses)

Severe Problems (Very Rare)
- Serious allergic reaction (less than 1 out of a million doses)
- Several other severe problems have been reported after a child gets MMR vaccine, including:
  - Deafness
  - Long-term seizures, coma, or lowered consciousness
  - Permanent brain damage

These are so rare that it is hard to tell whether they are caused by the vaccine.

5 What if there is a serious reaction?

What should I look for?
- Any unusual condition, such as a high fever or unusual behavior. Signs of a serious allergic reaction can include difficulty breathing, hoarseness or wheezing, hives, paleness, weakness, a fast heart beat or dizziness.

What should I do?
- **Call** a doctor, or get the person to a doctor right away.
- **Tell** your doctor what happened, the date and time it happened, and when the vaccination was given.
- **Ask** your doctor to report the reaction by filing a Vaccine Adverse Event Reporting System (VAERS) form. Or you can file this report through the VAERS web site at **www.vaers.hhs.gov**, or by calling **1-800-822-7967**.

VAERS does not provide medical advice.

6 The National Vaccine Injury Compensation Program

The National Vaccine Injury Compensation Program (VICP) was created in 1986.

Persons who believe they may have been injured by a vaccine can learn about the program and about filing a claim by calling **1-800-338-2382** or visiting the VICP website at **www.hrsa.gov/vaccinecompensation**.

7 How can I learn more?

- Ask your doctor.
- Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC):
  - Call **1-800-232-4636 (1-800-CDC-INFO)** or
  - Visit CDC's website at **www.cdc.gov/vaccines**

Vaccine Information Statement (Interim)
MMR Vaccine
4/20/2012
42 U.S.C. § 300aa-26

Office Use Only

Thank You-Happy Scanning

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