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# **OVERVIEW OF 2D VACCINE BARCODING PILOT**

# Implementation Pilot for Two-Dimensional Vaccine Barcode Utilization

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2D Barcode Vaccine Manufacturers Forum  
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# Outline

- ❑ **Barcoding definitions**
- ❑ **2D Barcoding and Public Health**
  - National Childhood Vaccine Injury Act
  - Data completeness and accuracy
  - Potential Benefits
- ❑ **Pilot phases**
  - Pilot Implementation
  - Technical support and guidance
  - Vaccine Information Statement (VIS) encoding

# **BARCODING DEFINITIONS**

# Barcoding Definitions

## □ Linear

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



## □ Two-Dimensional (2D)

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



# **2D BARCODING AND PUBLIC HEALTH**

## **National Childhood Vaccine Injury Act (NCVIA)**

- ❑ Requires documentation of:**
  - Manufacturer
  - Lot number
  - Provider identity
  - Date administered
  - VIS version date and date provided
- ❑ Provide copy of the relevant VIS prior to administration**
- ❑ Report serious adverse events to CDC/FDA's Vaccine Adverse Event Reporting System (VAERS)**

# Data Completeness and Accuracy

## □ Completeness

- Approximately 20% of primary VAERS reports are missing lot number<sup>1</sup>
- 55-65% of Immunization Information Systems (IIS) records are missing lot numbers<sup>2</sup>

## □ Accuracy

- Study conducted at UCLA's Children's Health Center found that 10% of immunized children had transcription errors in their electronic immunization records<sup>3</sup>
- A review of MEDMARX database found that 10% of all vaccination errors were transcription or documentation errors<sup>4</sup>

<sup>1</sup> CDC, unpublished data, VAERS

<sup>2</sup> 2005-2009 Immunization Information Systems Annual Report. Accessed at: <http://www.cdc.gov/vaccines/programs/iis/rates/default.htm>

<sup>3</sup> Wilton R, et al. Evaluating the accuracy of transcribed computer-stored immunization data. *Pediatrics*. 1994 Dec;94(6 Pt 1):902-6.

<sup>4</sup> Bundy DG, et al. Pediatric vaccination errors: Application of the "5 Rights" framework to a national error reporting database. *Vaccine*. Volume 27, Issue 29, 12 June 2009, Pages 3890-3896

## **Potential Benefits of 2D Barcodes**

- ❑ Improve accuracy of immunization information recorded in patient health records**
- ❑ Improve consistency in availability of immunization information captured in IIS and VAERS reports**
- ❑ Lot number information can help identify a safety concern with a specific lot and identify patients who may have been vaccinated with that lot in the case of a recall**
- ❑ Reduce administration errors (incorrect, expired, or recalled vaccine)**

Pilot Implementation

# **PILOT PHASES**

## **Pilot Implementation: Objectives**

- ❑ **Assist in implementation of 2D barcoded vaccines**
- ❑ **Examine implementation challenges at all stages from vaccine production to vaccination encounter**
- ❑ **Evaluate use of 2D barcodes**
  - Data completeness and accuracy of vaccinations recorded
  - User experience
  - Work flow analysis and time and motion studies
- ❑ **Document best practices and lessons learned**

# Pilot Implementation: Recruitment

## ❑ Vaccine Manufacturers

- 1-3 will be selected
- Selection based on ability to produce 2D barcoded vaccines available for use during the pilot

## ❑ CDC Immunization Grantees

- 10 selected
- Selection based on geographic diversity, immunization information system maturity, and ability to provide data necessary for evaluation

## ❑ Immunizers

- 340 will be selected (43% public, 50% private, 7% commercial)
- Selection based on use of 2D barcoded vaccines, practice type, immunization data entry model, and participation in state IIS
- 30 selected for work flow analysis and time and motion study

# Pilot Information Flow



Human			Page			Internal	Human F System	Human F System
Event	Personnel	Site	Event	Site	Address	Flow	Injection	Injection
1	1000	1000	1000	1000	1000	1000	1000	1000
2	1000	1000	1000	1000	1000	1000	1000	1000
3	1000	1000	1000	1000	1000	1000	1000	1000
4	1000	1000	1000	1000	1000	1000	1000	1000
5	1000	1000	1000	1000	1000	1000	1000	1000
6	1000	1000	1000	1000	1000	1000	1000	1000
7	1000	1000	1000	1000	1000	1000	1000	1000
8	1000	1000	1000	1000	1000	1000	1000	1000
9	1000	1000	1000	1000	1000	1000	1000	1000
10	1000	1000	1000	1000	1000	1000	1000	1000
11	1000	1000	1000	1000	1000	1000	1000	1000
12	1000	1000	1000	1000	1000	1000	1000	1000
13	1000	1000	1000	1000	1000	1000	1000	1000
14	1000	1000	1000	1000	1000	1000	1000	1000
15	1000	1000	1000	1000	1000	1000	1000	1000
16	1000	1000	1000	1000	1000	1000	1000	1000
17	1000	1000	1000	1000	1000	1000	1000	1000
18	1000	1000	1000	1000	1000	1000	1000	1000
19	1000	1000	1000	1000	1000	1000	1000	1000
20	1000	1000	1000	1000	1000	1000	1000	1000
21	1000	1000	1000	1000	1000	1000	1000	1000
22	1000	1000	1000	1000	1000	1000	1000	1000
23	1000	1000	1000	1000	1000	1000	1000	1000
24	1000	1000	1000	1000	1000	1000	1000	1000
25	1000	1000	1000	1000	1000	1000	1000	1000
26	1000	1000	1000	1000	1000	1000	1000	1000
27	1000	1000	1000	1000	1000	1000	1000	1000
28	1000	1000	1000	1000	1000	1000	1000	1000
29	1000	1000	1000	1000	1000	1000	1000	1000
30	1000	1000	1000	1000	1000	1000	1000	1000
31	1000	1000	1000	1000	1000	1000	1000	1000
32	1000	1000	1000	1000	1000	1000	1000	1000
33	1000	1000	1000	1000	1000	1000	1000	1000
34	1000	1000	1000	1000	1000	1000	1000	1000
35	1000	1000	1000	1000	1000	1000	1000	1000
36	1000	1000	1000	1000	1000	1000	1000	1000
37	1000	1000	1000	1000	1000	1000	1000	1000
38	1000	1000	1000	1000	1000	1000	1000	1000
39	1000	1000	1000	1000	1000	1000	1000	1000
40	1000	1000	1000	1000	1000	1000	1000	1000
41	1000	1000	1000	1000	1000	1000	1000	1000
42	1000	1000	1000	1000	1000	1000	1000	1000
43	1000	1000	1000	1000	1000	1000	1000	1000
44	1000	1000	1000	1000	1000	1000	1000	1000
45	1000	1000	1000	1000	1000	1000	1000	1000
46	1000	1000	1000	1000	1000	1000	1000	1000
47	1000	1000	1000	1000	1000	1000	1000	1000
48	1000	1000	1000	1000	1000	1000	1000	1000
49	1000	1000	1000	1000	1000	1000	1000	1000
50	1000	1000	1000	1000	1000	1000	1000	1000

## Manufacturer

Add a 2D barcode to the primary packaging:

- GS1 DataMatrix barcode to contain
  - GTIN\*
  - Expiration date
  - Lot number
- Distribute to pilot participants

## Immunizer

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

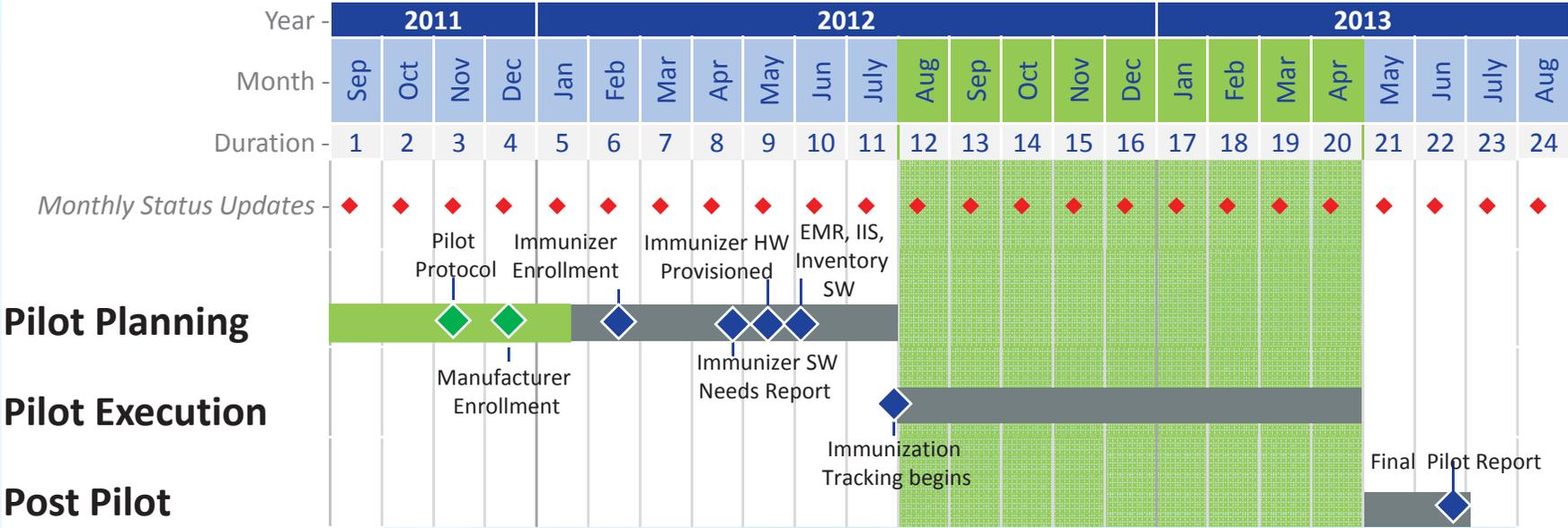
## IIS

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.

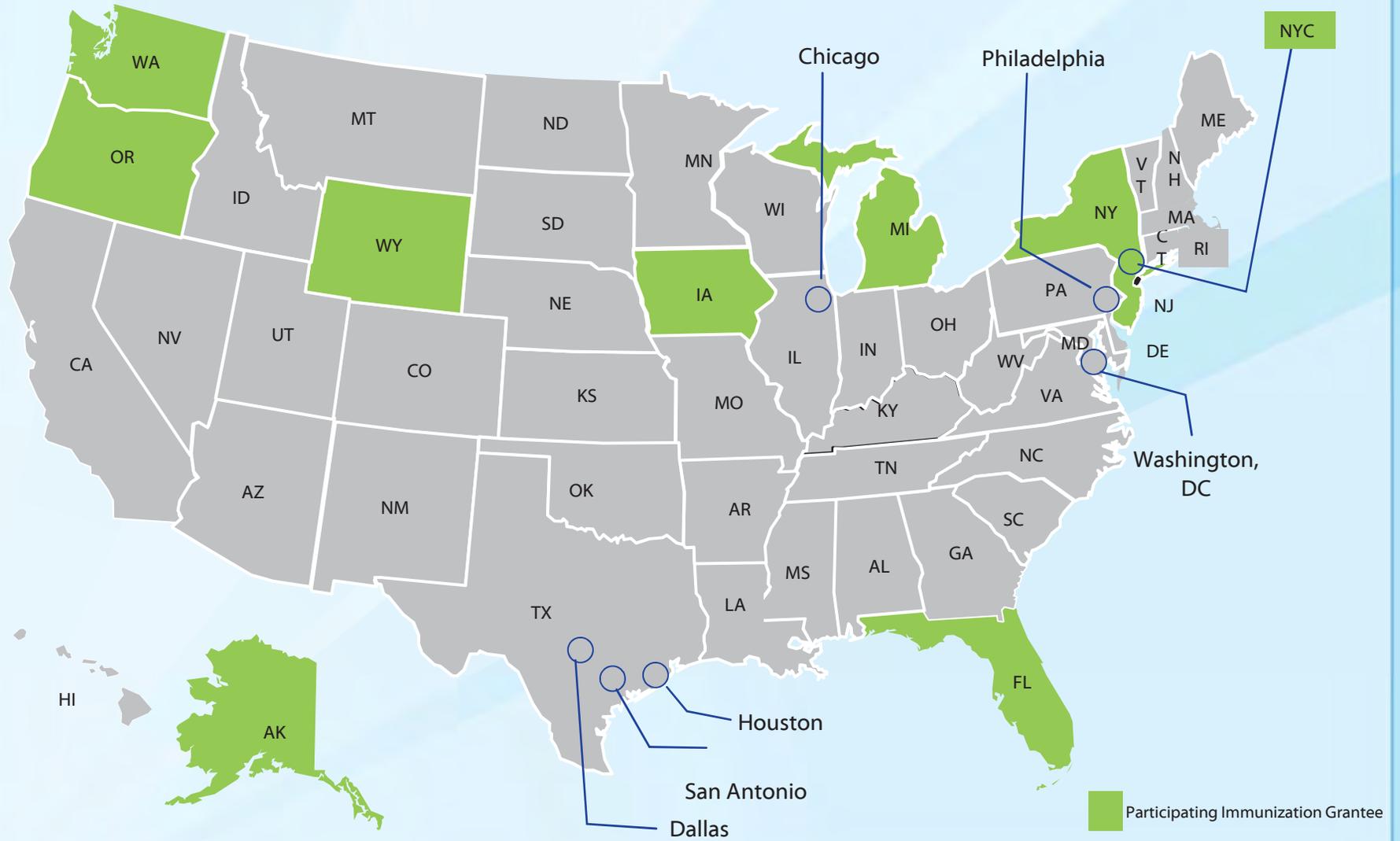
# Pilot Implementation: Timeline



## **Pilot Implementation: Progress**

- ❑ **Two manufacturers enrolled**
  - GlaxoSmithKline
  - Sanofi Pasteur
- ❑ **Currently recruiting immunizers from all participating immunization grantees**
  - 58 immunizers enrolled
  - 40 additional immunizers deemed suitable for participation

# Participating Immunization Grantees



Technical Support and Guidance

# **PILOT PHASES**

## **Technical Support and Guidance: Objectives**

- ❑ Conduct forum for vaccine manufacturers to discuss and establish standards and discuss other relevant issues**
- ❑ Conduct forum of education for all immunization stakeholders**
- ❑ Create centralized web-based portal of barcode related resources**
- ❑ Develop manual for 2D barcoding use and integration**

## **Technical Support and Guidance: Progress**

- ❑ **Conducting forum for vaccine manufacturers today**
  - Summary of meeting expected in early March 2012
  
- ❑ **Forum of education planned for September or October 2012**
  - Summary of meeting expected in mid-November 2012
  
- ❑ **Centralized portal planned for March 2013**
  
- ❑ **Manual for 2D barcoding use and integration planned for August 2013**

VIS Encoding

# **PILOT PHASES**

## **VIS Encoding: Benefits**

- ❑ Increase completeness for data elements**
  - VIS version date is required by NCVIA
  
- ❑ Enhance record keeping for providers**
  
- ❑ Promote use of barcoding technology**

## **VIS Encoding: Objectives**

- ❑ **Implement barcoding on all VIS**
  - Identify appropriate barcode and placement
  - Create and establish process
  
- ❑ **Registration and publication of VIS data**
  
- ❑ **Provide technical guidance and assistance for users**

# VIS Encoding: Progress

- ❑ **Identified barcode**
  - Selected GS1's Global Document Type Identifier (GDTI) to encode VIS document type
  - Added VIS edition date to GS1 DataMatrix
- ❑ **Developed technical assistance documents for users**
- ❑ **Added barcode to all up to date VIS**

## 4 Some people should not get meningococcal vaccine or should wait.

- Anyone who has ever had a severe (life-threatening) allergic reaction to a previous dose of MCV4 or MPSV4 vaccine should not get another dose of either vaccine.
- Anyone who has a severe (life threatening) allergy to any vaccine component should not get the vaccine. *Tell your doctor if you have any severe allergies.*
- Anyone who is moderately or severely ill at the time the shot is scheduled should probably wait until they recover. Ask your doctor. People with a mild illness can usually get the vaccine.
- Meningococcal vaccines may be given to pregnant women. MCV4 is a fairly new vaccine and has not been studied in pregnant women as much as MPSV4 has. It should be used only if clearly needed. The manufacturers of MCV4 maintain pregnancy registries for women who are vaccinated while pregnant.

Except for children with sickle cell disease or without a working spleen, meningococcal vaccines may be given at the same time as other vaccines.

## 5 What are the risks from meningococcal vaccines?

A vaccine, like any medicine, could possibly cause serious problems, such as severe allergic reactions. The risk of meningococcal vaccine causing serious harm, or death, is extremely small.

### Mild problems

As many as half the people who get meningococcal vaccines have mild side effects, such as redness or pain where the shot was given.

If these problems occur, they usually last for 1 or 2 days. They are more common after MCV4 than after MPSV4.

A small percentage of people who receive the vaccine develop a mild fever.

### Severe problems

Serious allergic reactions, within a few minutes to a few hours of the shot, are very rare.

Brief fainting spells and related symptoms (such as jerking or seizure-like movements) can follow a vaccination. They happen most often with adolescents, and they can result in falls and injuries.

Sitting or lying down for about 15 minutes after getting the shot – especially if you feel faint – can help prevent these injuries.

## 6 What if there is a moderate or severe reaction?

What should I look for?

Any unusual condition, such as a severe allergic reaction or a high fever. If a severe allergic reaction occurred, it would be within a few minutes to an hour after the shot. Signs of a serious allergic reaction can include **difficulty breathing, weakness, hoarseness or wheezing, a fast heart beat, hives, dizziness, paleness, or swelling of the throat.**

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 provider to report the reaction by filing a Vaccine Adverse Event Reporting System (VAERS) form. Or you can file this report through the VAERS website at [www.vaers.hhs.gov](http://www.vaers.hhs.gov), or by calling 1-800-822-7967.

*VAERS does not provide medical advice.*

## 7 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](http://www.hrsa.gov/vaccinecompensation).

## 8 How can I learn more?

- Your doctor can give you the vaccine package insert or suggest other sources of information.
- 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](http://www.cdc.gov/vaccines)

Vaccine Information Statement  
Meningococcal Vaccines



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## Summary

- ❑ **2D barcoded vaccines have many potential public health benefits**
  - Increasing accuracy and completeness of recorded immunization information
  - Improving patient safety
- ❑ **CDC's Implementation Pilot for Two-Dimensional Vaccine Barcode Utilization will**
  - Examine implementation challenges at all stages from vaccine production to vaccination encounter
  - Document best practices and lessons learned
  - Increase awareness of 2D barcode technology and help enable user adoption

## The Future:



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# Thank you for your participation in the 2D Barcode Manufacturers Forum!

Please contact Erin D. Kennedy ([EDKennedy@cdc.gov](mailto:EDKennedy@cdc.gov)) with any questions

**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](mailto:cdcinfo@cdc.gov) Web: <http://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.

National Center for Immunization & Respiratory Diseases  
Immunization Services Division



**QUESTIONS?**

# Thank You

**For more information please contact Centers for Disease Control and Prevention**

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