OVERVIEW OF 2D VACCINE BARCODING PILOT

Erin Kennedy, DVM, MPH
Medical Officer, NCIRD/Immunization Services
Implementation Pilot for Two-Dimensional Vaccine Barcode Utilization

Erin D. Kennedy, DVM, MPH
Medical Epidemiologist
Immunization Services Division

2D Barcode Vaccine Manufacturers Forum
January 26, 2012
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\(^1\)
  - 55-65% of Immunization Information Systems (IIS) records are missing lot numbers\(^2\)

- **Accuracy**
  - Study conducted at UCLA’s Children’s Health Center found that 10% of immunized children had transcription errors in their electronic immunization records\(^3\)
  - A review of MEDMARX database found that 10% of all vaccination errors were transcription or documentation errors\(^4\)

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\(^1\) CDC, unpublished data, VAERS
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
Record and track data:
- Scan barcode when inventorying and dispensing vaccine products and enter into the medical record
- Add a 2D barcode to the primary packaging:
  - GS1 DataMatrix barcode to contain
    - GTIN*
    - Expiration date
    - Lot number
  - Distribute to pilot participants
- Medical record types:
  - Electronic medical records (EMR)
  - Custom applications
  - Acts as a source of evaluation for data accuracy and completeness
- 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

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### Monthly Status Updates
- Pilot Execution: Final Pilot Report
- Post Pilot: Final Pilot Report

### Details
- Manufacturer Enrollment
- Immunization Tracking begins
- Immunizer SW Provisioned
- Final Pilot Report
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

- WA
- OR
- IA
- NY
- Washington, DC
- NYC
- Chicago
- Philadelphia
- Houston
- San Antonio
- Dallas
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
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

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) allergic to any vaccine component should not get the vaccine. Ask 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.

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 after the shot, are very rare.
- Pain, redness, and swelling at the site of the shot are common side effects. Sometimes the skin will turn bluish or purple as well. The skin may peel off the site of the injection or become tender and purple. This is rare and lasts for only a few days.
- High fever.
- Headache.
- Seizures.
- Cough.
- Difficulty breathing.
- Swelling of the neck or throat.
- Nausea.
- Vomiting.
- Pain in the joints.
- Rash or red, itchy skin that spreads. It may be difficult for the doctor to tell how serious the rash is.

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. You can file this report through the VAERS website at www.vaers.hhs.gov, or by calling 1-800-822-7967.
- VAERS does not provide medical advice.

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 1-800-325-4558 or visiting the VICP website at www.hrsa.gov/vaccinecompensation.

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-INFOW) or visit CDC’s website at www.cdc.gov/vaccines

Vaccine Information Statement

Meningococcal Vaccines

![Barcode Image]
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) 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       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.
QUESTIONS?
Thank You

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2dbarcodepilotinfo@cdc.gov

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