Outline

2D Barcode Pilot Background
• National Childhood Vaccine Injury Act
• Data Completeness and Accuracy
• 2D Barcode History – Highlights
• Feasibility Study on 2D Vaccine Barcode
• Potential Benefits of 2D Barcodes

Pilot Implementation
• Pilot Objectives
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• Pilot Timeline
• Pilot Composition
National Childhood Vaccine Injury Act

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\(^1\) CDC, unpublished data, VAERS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)
2D Barcode History - Highlights

• Vaccine Identification Standards Initiative (VISI) - 1997
• American Academy of Pediatrics (AAP) 2D Barcoding Conference – January 2009
  • Amends 2006 guidance
  • Allows manufactures to request a waiver to use alternative coding, (e.g. two dimensional symbology)
  • References – vaccines and adverse event reporting requirements
• AAP and GS1: Issued guidance on use of Data Matrix Barcodes
  o Foundation for appropriate use of GS1 Data Matrix Barcodes on vaccine-related items
Feasibility Study on 2D Vaccine Barcode

• October 2010 – CDC contracted with RTI International
• Feasibility Study – impact of a transition to 2D barcodes containing product identification, expiration date, and lot number on vaccine vials and syringes
  • Vaccine production
  • Clinical documentation
  • Public health reporting
• A final report of findings published

• Recommendation – Pilot Implementation
Pilot Objectives

• Assist in implementation of 2D barcoded vaccines
• Examine implementation challenges at all stages from vaccine production to vaccination encounter to data capture
• Evaluate use of 2D barcodes
  • User experience
  • Work flow analysis and time and motion studies
• Document best practices and lessons learned
• Assess the extent to which using 2D barcoded vaccines and scanners affect the completeness and accuracy of vaccine data.
• Implement 2D barcodes on Vaccine Information Statements (VIS)
Pilot Vaccine and Information Workflow

**Manufacturer**
- Add 2D barcode to primary packaging:
  - Data Matrix barcode containing
    - GTIN
    - Expiration date
    - Lot number
  - Distribution to pilot participants via existing vaccine supply chain.

**Immunizer**
- Scan vaccine data:
  - Entering vaccine into inventory
  - Administering vaccine

**Record System**
- Record system types:
  - Electronic medical records (EMR)
  - Immunization Information Systems (IIS)
  - Track GTIN, expiration date, and lot number

**IIS**
- Receive data from the immunizers’ record system:
  - Acts as a source of evaluation for data accuracy and completeness
Pilot Timeline

3 Data Capture Periods
• Baseline: Linear barcoded vaccine administrations
• Learning: Linear + 2D barcoded vaccine administrations
• Maturity: Linear + 2D barcoded vaccine administrations

Additional Data Captured Through
• User Expectation Survey
• 2 User Experience Surveys
• Workflow Analysis
Pilot Participation

- 2 Vaccine Manufacturers
- 217 Immunizers
- 10 Immunization Awardees
Pilot Immunizer Demographics

Immunizer Segments

- Public: 145
- Private: 1
- Commercial: 71

Practice Specialties

- Family Practice: 66
- General Practice: 88
- Internal Medicine: 4
- Pediatric: 9
- Other: 47

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- Over 70% of “Other” are Public Health Depts.
- The single commercial practice is a commercial pharmacy that administers vaccinations.
EMR Systems in Use at Pilot Sites

Distribution of Pilot Sites by EMR Vendor

Note: Sites with “No EMR” are IIS Only sites – they report directly to the state registry
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: 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.