Two-Dimensional (2D) Vaccine Barcode Pilot Project

Association of Immunization Managers / Immunization Program Managers Meeting
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Ken Gerlach, MPH, CTR
Immunization Services Division
National Center for Immunization & Respiratory Diseases
INTRODUCTION AND BACKGROUND
Barcoding definitions – Vaccines

- **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
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\(^4\)

\(^1\) CDC, unpublished data, VAERS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

- Vaccine Identification Standards Initiative (VISI) - 1997
  - 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- AAP and GS1: Draft Guidance Data Matrix Barcodes to Vaccines for Point-of-Care
  - 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 – forthcoming
- Recommendation – Pilot Implementation
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’s Three Parts

- **Part 1** – Pilot Project to Implement 2D Barcodes on Vaccine Vials and Syringes
- **Part 2** – Incorporate 2D Barcodes onto Vaccine Information Statements (VIS)
- **Part 3** – Provide Technical Support and Guidance for Future Implementers
PART 1: PILOT IMPLEMENTATION
Pilot Implementation: 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
  - 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 Information Flow

Add a 2D barcode to the primary packaging:
- Data Matrix barcode to contain
  - GTIN*
  - Expiration date
  - Lot number
- Distribute to pilot participants

Record and track data:
- Scan barcode when inventorying and dispensing vaccine products and enter into the medical record

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: 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 geographical 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 time and motion study and in depth evaluation
Barcode Standard and Format

- **GS1 – Barcoding Standards Development Organization**
  - International not-for-profit association with Member Organizations in over 100 countries.
  - Chapter in the US
  - GS1 system of standards is the most widely used supply chain standards system in the world.

- **Global Trade Identification Number (GTIN), which includes National Drug Code (NDC)**

- **Expiration Date**

- **Lot Number**

- **GS1 Web:** [www.gs1.org](http://www.gs1.org) or [http://www.gs1us.org/](http://www.gs1us.org/)
## Pilot Implementation: Timeline

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### Monthly Status Updates
- **Pilot Planning**
  - Pilot Protocol
  - Immunizer Enrollment
  - Immunizer HW Provisioned
  - Immunizer SW Needs Report

- **Pilot Execution**
  - Manufacturer Enrollment
  - EMR, IIS, Inventory SW
  - Immunization Tracking begins

- **Post Pilot**
  - Final Pilot Report
Pilot Implementation: Progress

- Two Manufacturers Enrolled
  - GlaxoSmithKline
  - Sanofi Pasteur

- Currently recruiting immunizers from all participating immunization grantees
  - 146 immunizers enrolled
  - 40 additional immunizers deemed suitable for participation

- Scanner Model Selected
PART 2: VACCINE INFORMATION STATEMENTS (VIS)
Data Items

- **Pilot Implementation – Unit of Use**
  - Product identification
  - Expiration Date (Expiry or maximum durability date)
  - Lot Number

- **VIS**
  - VIS publication date
  - VIS document identification
Vaccine Information Sheets (VIS)

- Published by CDC
- Required by Law
- Given to or read by patients/parents when getting a vaccine
- Certain information should be recorded when a VIS is given.
  - Date given to the patient/parent
  - Date of the VIS publication

- Barcodes on the VIS?
VIS Encoding: Potential Benefits

- Increases in completeness for data elements
- 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
- Testing of Scanners
- Developed technical assistance documents for users
- Added barcode to all current VIS
PART 3: TECHNICAL SUPPORT AND GUIDANCE
Technical Support and Guidance: Objectives

- Conduct forum for vaccine manufacturers to discuss standards and 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 January 26, 2012
  - Summary of meeting expected in early March 2012

- Forum of education planned for 2012
  - Summary of meeting expected in mid-October 2012

- Centralized portal planned for March 2013

- Manual for 2D barcoding use and integration planned for August 2013
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 and data capture
  - Document best practices and lessons learned
Thank you

Ken Gerlach
kgerlach@cdc.gov
404-718-4646

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