Implementation Pilot for Two-Dimensional Vaccine Barcode Utilization

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

Global GS1 Healthcare Conference
October 3, 2013
Erin D. Kennedy, DVM, MPH, MS
LCDR, United States Public Health Service
Office of the Associate Director for Adult Immunizations
Immunization Services Division
Centers for Disease Control and Prevention
1600 Clifton Rd, MS A19
Atlanta, GA 30333
Phone: 404-718-8733
BlackBerry: 404-518-3313
Email: EDKennedy@cdc.gov
2D BARCODING HISTORY AND PUBLIC HEALTH
National Childhood Vaccine Injury Act (NCVIA)

- Requires documentation of:
  - Manufacturer
  - Lot number
  - Provider identity
  - Date administered
  - Vaccine Information Statement (VIS)
    - version date
    - 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)
VIS Encoding

- 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
Barcodes on Vaccines

- **Linear**
  - Contains National Drug Code (NDC) only
  - Other variables cannot be included due to space constraints
    - 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
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\(^1\) CDC, unpublished data, VAERS


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 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 Information

History
- Sept 2011 - 2D Barcode Pilot Initiated
- Aug 2012 – Apr 2013 – Implementation Period

Participants
- 2 Vaccine Manufacturers
  - 8 vaccines
- 217 Immunizers
- 10 Immunization Information Systems

Vaccination Records Assessed

<table>
<thead>
<tr>
<th></th>
<th>EMR</th>
<th>IIS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>916,000</td>
<td>1.1M</td>
</tr>
<tr>
<td>2D Barcoded</td>
<td>53,000</td>
<td>46,000</td>
</tr>
</tbody>
</table>
## GS1 2D Datamatrix Vaccine Date Items

<table>
<thead>
<tr>
<th>Contained Information</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Vaccine Global Trade Item Number</strong> (GTIN) with embedded NDC</td>
<td>14 characters long, contains National Drug Code (NDC)</td>
</tr>
<tr>
<td><strong>Vaccine Expiration Date</strong></td>
<td>6 characters long, in “yymmdd” format, e.g. 120726</td>
</tr>
<tr>
<td><strong>Vaccine Batch/Lot Number</strong></td>
<td>Up to 10 characters long, e.g. CFA111</td>
</tr>
</tbody>
</table>

*Contact us: support@2dbarcodepilot.com; 1(800) 380-5147*
Pilot Vaccine and Information Workflow

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

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

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

**Receive data from the immunizers’ record system:**
- Acts as a source of evaluation for data accuracy and completeness
PRELIMINARY RESULTS
Key Findings

Average EMR/EHR Pre- and Post-Implementation Data Quality

Average IIS Pre- and Post-Implementation Data Quality

Preliminary results
User Experience Survey: Pilot Participant Accuracy Perceptions

Preliminary results

Administration

<table>
<thead>
<tr>
<th>UE1 Lot Number</th>
<th>UE1 Expiration Date</th>
<th>UE1 Product ID</th>
<th>UE2 Combined</th>
</tr>
</thead>
<tbody>
<tr>
<td>2%</td>
<td>2%</td>
<td>14%</td>
<td>0%</td>
</tr>
<tr>
<td>4%</td>
<td>4%</td>
<td>17%</td>
<td>5%</td>
</tr>
<tr>
<td>4%</td>
<td>4%</td>
<td>17%</td>
<td>10%</td>
</tr>
<tr>
<td>28%</td>
<td>28%</td>
<td>39%</td>
<td>38%</td>
</tr>
<tr>
<td>48%</td>
<td>48%</td>
<td>38%</td>
<td>47%</td>
</tr>
</tbody>
</table>

Inventory

<table>
<thead>
<tr>
<th>UE1 Lot Number</th>
<th>UE1 Expiration Date</th>
<th>UE1 Product ID</th>
<th>UE2 Combined</th>
</tr>
</thead>
<tbody>
<tr>
<td>2%</td>
<td>2%</td>
<td>4%</td>
<td>4%</td>
</tr>
<tr>
<td>4%</td>
<td>4%</td>
<td>17%</td>
<td>10%</td>
</tr>
<tr>
<td>4%</td>
<td>4%</td>
<td>17%</td>
<td>10%</td>
</tr>
<tr>
<td>27%</td>
<td>27%</td>
<td>42%</td>
<td>38%</td>
</tr>
<tr>
<td>27%</td>
<td>27%</td>
<td>42%</td>
<td>38%</td>
</tr>
<tr>
<td>49%</td>
<td>51%</td>
<td>49%</td>
<td>49%</td>
</tr>
</tbody>
</table>

Respondents (%)
 Workflow Analysis: Clinician Feedback

“The lot number and expiration date are hard to read on some of the vaccines we get. When those vaccines get barcodes we can scan, it will be a huge help.”

“I often see transcription errors where eight (8) and “B” or zero (0) and “O” have been mixed up. Scanning will fix these issues and reduce the number of times I can’t find the lot I’m looking for in our inventory.”
- Inventory is initial point of vaccine data entry
- Lot number and expiration date manual transcription eliminated

- Experienced users maximized process efficiencies
- Scanning efficiency will improve as the number of vaccines scanned per patient increases

**Workflow Analysis: Summary Efficiency Findings**

**Inventory Management**

<table>
<thead>
<tr>
<th></th>
<th>Pre-Pilot / Baseline</th>
<th>2D Barcode</th>
</tr>
</thead>
<tbody>
<tr>
<td>Avg. Time to Complete (sec)*</td>
<td>36.0</td>
<td>25.4</td>
</tr>
</tbody>
</table>

**Vaccine Administration**

<table>
<thead>
<tr>
<th></th>
<th>Pre-Pilot / Baseline</th>
<th>2D Barcode</th>
</tr>
</thead>
<tbody>
<tr>
<td>Avg. Time to Complete (sec)*</td>
<td>18.9</td>
<td>20.2</td>
</tr>
</tbody>
</table>

Preliminary results
User Experience Survey: Pilot Participant Efficiency Perceptions

Preliminary results

**Administration**

- **UE1 Lot Number**
  - Very Negative Impact: 1%
  - Somewhat Negative Impact: 11%
  - No Impact: 34%
  - Somewhat Positive Impact: 34%
  - Very Positive: 20%

- **UE1 Expiration Date**
  - Very Negative Impact: 0%
  - Somewhat Negative Impact: 0%
  - No Impact: 25%
  - Somewhat Positive Impact: 30%
  - Very Positive: 35%

- **UE1 Product ID**
  - Very Negative Impact: 1%
  - Somewhat Negative Impact: 10%
  - No Impact: 16%
  - Somewhat Positive Impact: 39%
  - Very Positive: 34%

- **UE2 Combined**
  - Very Negative Impact: 2%
  - Somewhat Negative Impact: 14%
  - No Impact: 18%
  - Somewhat Positive Impact: 43%
  - Very Positive: 23%

**Inventory**

- **UE1 Lot Number**
  - Very Negative Impact: 13%
  - Somewhat Negative Impact: 36%
  - No Impact: 33%
  - Somewhat Positive Impact: 32%
  - Very Positive: 32%

- **UE1 Expiration Date**
  - Very Negative Impact: 12%
  - Somewhat Negative Impact: 20%
  - No Impact: 6%
  - Somewhat Positive Impact: 13%
  - Very Positive: 6%

- **UE1 Product ID**
  - Very Negative Impact: 6%
  - Somewhat Negative Impact: 18%
  - No Impact: 18%
  - Somewhat Positive Impact: 7%
  - Very Positive: 24%

- **UE2 Combined**
  - Very Negative Impact: 16%
  - Somewhat Negative Impact: 42%
  - No Impact: 42%
  - Somewhat Positive Impact: 24%
  - Very Positive: 24%
**User Experience Survey: Sustainability**

Percentage of vaccines that would need to have 2D barcodes on them to sustain the use of 2D barcode scanning in the respondent’s practice:

- All (100%): 22 respondents
- Most (76-99%): 44 respondents
- Many (51-75%): 20 respondents
- Some (26-50%): 9 respondents
- Very few (1-25%): 5 respondents

Level of agreement/disagreement with the statement “When available on most vaccines, 2D barcode scanning should be used consistently to record vaccines administered in my clinic”:

- Strongly Disagree: 2 respondents
- Disagree: 4 respondents
- Neutral: 22 respondents
- Agree: 35 respondents
- Strongly Agree: 38 respondents
Summary

- Preliminary results confirm a positive effect on vaccine data accuracy and completeness
- Providers have positive perceptions regarding impact of 2D barcoding on efficiency and accuracy
- Providers are willing to adopt practices to incorporate 2D barcode vaccine use but not until the majority of vaccines are 2D barcoded
Other Key Findings

- Pharmaceutical supply chain stakeholders have indicated 2D will be the data carrier of choice.
- Vaccine manufacturers have demonstrated a commitment to the application of 2D barcodes on the unit-of-use.
- Most EMR and IIS systems require modification to process 2D barcodes.
Next Steps

- Finalize 2D Barcode Pilot Report
- Continue work with Prevention and Public Health Fund (PPHF) Awardees to implement 2D barcode vaccine scanning in immunization registries
- Monitor 2D Barcoded Vaccines – in the supply chain
- Adoption Strategies for 2D Barcodes – Pilot
  - 2014 – 2015 flu season
  - Pharmacies, community vaccinators, public, and private immunizers
  - Work flow analysis
CDC 2D Barcode Website

http://www.cdc.gov/vaccines/programs/iis/2d-vaccine-barcodes/
American Academy of Pediatrics & GS1 Healthcare US Guideline for Suppliers
The Application of GS1® DataMatrix Barcodes to Vaccines for Point of Care

Published: February 2012
Thank you!

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.