Implementation Pilot for Two-Dimensional Vaccine Barcode Utilization

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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

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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 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/are planning to become 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.

- Swelling, hives, or dizziness in the area where the shot was given
- Difficulty breathing, weakness, hoarseness or wheezing, a fast heart beat, dizziness, pale skin, 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, or by calling 1-800-822-7967.

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

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 severe allergic reaction can include difficulty breathing, weakness, hoarseness or wheezing, a fast heart beat, dizziness, pale skin, or swelling of the throat.

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.

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

Vaccine Information Statement
Meningococcal Vaccines

[Image of vaccine information statement]
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\(^4\)

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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 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>EMR</th>
<th>IIS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>916,000</td>
</tr>
<tr>
<td>2D Barcoded</td>
<td>53,000</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

**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
PRELIMINARY RESULTS
Key Findings

Preliminary results

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

<table>
<thead>
<tr>
<th>Data Quality (%)</th>
<th>Pre-Implementation</th>
<th>Post-Implementation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Complete</td>
<td>93%</td>
<td>98%</td>
</tr>
<tr>
<td>Accurate</td>
<td>97%</td>
<td>98%</td>
</tr>
<tr>
<td>Accurate &amp; Complete</td>
<td>89%</td>
<td>97%</td>
</tr>
</tbody>
</table>

Average IIS Pre- and Post-Implementation Data Quality

<table>
<thead>
<tr>
<th>Data Quality (%)</th>
<th>Pre-Implementation</th>
<th>Post-Implementation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Complete</td>
<td>91%</td>
<td>96%</td>
</tr>
<tr>
<td>Accurate</td>
<td>93%</td>
<td>96%</td>
</tr>
<tr>
<td>Accurate &amp; Complete</td>
<td>94%</td>
<td>96%</td>
</tr>
</tbody>
</table>

Preliminary results
User Experience Survey: Pilot Participant Accuracy Perceptions

Preliminary results

Administration

Inventory

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.”
Workflow Analysis: Summary Efficiency Findings

- 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

Pre-Pilot / Baseline

Inventory Management

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

Vaccine Administration

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

Preliminary results
User Experience Survey: Pilot Participant Efficiency Perceptions

**Administration**

- **UE1 Lot Number**
  - Very Negative Impact: 1%
  - Somewhat Negative Impact: 11%
  - No Impact: 0%
  - Somewhat Positive Impact: 10%
  - Very Positive: 1%

- **UE1 Expiration Date**
  - Very Negative Impact: 10%
  - Somewhat Negative Impact: 25%
  - No Impact: 10%
  - Somewhat Positive Impact: 10%
  - Very Positive: 0%

- **UE1 Product ID**
  - Very Negative Impact: 1%
  - Somewhat Negative Impact: 16%
  - No Impact: 10%
  - Somewhat Positive Impact: 18%
  - Very Positive: 2%

- **UE2 Combined**
  - Very Negative Impact: 14%
  - Somewhat Negative Impact: 23%
  - No Impact: 18%
  - Somewhat Positive Impact: 24%
  - Very Positive: 43%

**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: 18%

- **UE1 Product ID**
  - Very Negative Impact: 6%
  - Somewhat Negative Impact: 13%
  - No Impact: 18%
  - Somewhat Positive Impact: 7%
  - Very Positive: 24%

- **UE2 Combined**
  - Very Negative Impact: 18%
  - Somewhat Negative Impact: 24%
  - No Impact: 42%

**Preliminary results**
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

Preliminary results
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
Two-Dimensional (2D) Vaccine Barcodes

Since 2011, CDC and its immunization partners have been exploring the potential of two-dimensional (2D) barcoding to streamline immunization practices. On these pages you will find information about 2D barcodes for vaccines:

- About 2D Vaccine Barcodes
  Find background information about the need for 2D barcoding, details on the pilot study, and diagram of the pilot vaccine and information flow
- For Vaccine Manufacturers
  Find resources on guidance for industry, along with presentations and summary documents from the vaccine manufacturer's forum
- For Vaccine Providers
  Find training documents and videos, plus AAP guidance

Vaccines Shipping with 2D Barcodes

2D barcoded vaccines currently being shipped by vaccine manufacturers are listed in the table below. This list will be updated when additional 2D barcoded vaccines become available.

[Note: If you are aware of a 2D barcoded vaccine currently shipping that is not on this list, please send a brief email containing the name of the manufacturer, brand of vaccine, presentation (vial type or syringe) and vaccine name to the CDC IIS Technical Assistance Team (or use IIS mailing address).]

### 2D Barcoded Vaccines Currently Shipping Table

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Brand</th>
<th>Presentation</th>
<th>Vaccine</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sanofi Pasteur</td>
<td>AdCecel</td>
<td>single dose vial</td>
<td>Tdap</td>
</tr>
<tr>
<td>Sanofi Pasteur</td>
<td>Fluzone</td>
<td>single dose vial</td>
<td>Influenza</td>
</tr>
<tr>
<td>Sanofi Pasteur</td>
<td>Menedex</td>
<td>single dose vial</td>
<td>Meningococcal</td>
</tr>
<tr>
<td>Sanofi Pasteur</td>
<td>IPIOL</td>
<td>multi dose vial</td>
<td>Polio</td>
</tr>
<tr>
<td>Sanofi Pasteur</td>
<td>Depaceol</td>
<td>single dose vial</td>
<td>DTaP</td>
</tr>
<tr>
<td>Sanofi Pasteur</td>
<td>Pediatric DT</td>
<td>single dose vial</td>
<td>Diphtheria-Tetanus</td>
</tr>
<tr>
<td>Sanofi Pasteur</td>
<td>Tenvac</td>
<td>single dose vial</td>
<td>Diphtheria-Tetanus</td>
</tr>
<tr>
<td>Sanofi Pasteur</td>
<td>Pentaceol</td>
<td>single dose vial</td>
<td>DTP,IPV,HB</td>
</tr>
<tr>
<td>GlaxoSmithKline</td>
<td>Havrix Adult</td>
<td>single dose vial</td>
<td>Hepatitis A</td>
</tr>
<tr>
<td>GlaxoSmithKline</td>
<td>FLUARIX Quadrivalent</td>
<td>pre-loaded syringe</td>
<td>Influenza</td>
</tr>
<tr>
<td>GlaxoSmithKline</td>
<td>FLUARIX Trivalent</td>
<td>pre-loaded syringe</td>
<td>Influenza</td>
</tr>
</tbody>
</table>
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

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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.