Update on 2D Vaccine Barcode Scanning

National Vaccine Advisory Committee (NVAC)
New Vaccine Technologies

September 13, 2018

Kenneth Gerlach, MPH
Immunization Services Division, CDC
<table>
<thead>
<tr>
<th>Outline</th>
</tr>
</thead>
<tbody>
<tr>
<td>2D Barcoded Vaccines Timeline &amp; Pilots Overview</td>
</tr>
<tr>
<td>Recent Pilot Findings</td>
</tr>
<tr>
<td>Next Steps</td>
</tr>
</tbody>
</table>
2D Barcoded Vaccines Timeline & Pilots Overview
“The Problem”

“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.”
2D Barcoded Vaccines Timeline

Number of 2D Barcoded Vaccine Presentations (Vial/Syringe), US Market

0 10 20 30 40 50 60 70 80 90 100
# 2D Vaccine Presentations (on the Market) (out of 98 presentations known as of 6/18/18)

AAP, AIM, CDC, FDA, GS1 US and vaccine manufacturers barcode meetings

CDC Feasibility Study: Impact of Transition to 2D Barcodes on vaccine unit-of-use

FDA barcode rule change allows 2D barcodes on vaccine unit-of-use

-2011-2013 CDC 2D Barcode Pilot
-2013-2015 CDC 2D Adoption Pilot
-2015-2018 CDC 2D Scalability Pilot
<table>
<thead>
<tr>
<th>Company</th>
<th>Total 2D Shipping</th>
<th>% of Vaccine Portfolio 2D Barcoded</th>
<th>Total VFC and 2D Shipping</th>
<th>% of VFC Price List 2D Barcoded</th>
</tr>
</thead>
<tbody>
<tr>
<td>GSK</td>
<td>28/28</td>
<td>100%</td>
<td>21/21</td>
<td>100%</td>
</tr>
<tr>
<td>Merck</td>
<td>31/31</td>
<td>100%</td>
<td>23/23</td>
<td>100%</td>
</tr>
<tr>
<td>Sanofi Pasteur</td>
<td>19/23</td>
<td>83%</td>
<td>13/13</td>
<td>100%</td>
</tr>
<tr>
<td>Wyeth</td>
<td>2/2</td>
<td>100%</td>
<td>2/2</td>
<td>100%</td>
</tr>
<tr>
<td>Medimmune</td>
<td>0/4</td>
<td>0%</td>
<td>0/0</td>
<td>0%</td>
</tr>
<tr>
<td>Seqirus</td>
<td>0/8</td>
<td>0%</td>
<td>0/8</td>
<td>0%</td>
</tr>
<tr>
<td>Dynavax</td>
<td>1/1</td>
<td>100%</td>
<td>0/0</td>
<td>0%</td>
</tr>
<tr>
<td>Totals</td>
<td>81/97</td>
<td>84%</td>
<td>59/68</td>
<td>88%</td>
</tr>
</tbody>
</table>

Information is obtained directly from the manufacturers through regular outreach
CDC 2D Barcode Scanning Pilots

**Objectives**
- Assess 2D impact on vaccination data quality & workflow impact
- Identify 2D scanning opportunities and challenges
- Implement 2D barcodes

**Participants**
- 217 healthcare practices
- 10 Immunization Awardees
- 2 Vaccine manufacturers

**Objectives**
- 2D Pilot Objectives
- Broaden observations of the initial pilot
- Facilitate the adoption of 2D barcode scanning

**Participants**
- 87 Diverse practices
- 7 Immunization Awardees
- 3 Vaccine manufacturers

**Recent Pilot 2D Scalability (2015 – 2018)**

**Objectives**
- Assess 2D scanning in a large health system
- Assess compliance with scanning
- Identify and develop solutions to address challenges

**Participants**
- 1 large healthcare system
- 27 care centers
- 4 Vaccine manufacturers

**Ongoing Work with Vaccine Community Members:**
Vaccine Manufacturers, EMR Vendors, Practitioners, Health Systems, Scanner Vendors

* Periods of primary data collection and project activities provided
2D Adoption: Compliance … or lack thereof

Determining whether a 2D barcoded vaccine was actually scanned by the user

Unanticipated Findings:

• Variance between self-reported scanning rates and system-tracked scanning
  (50+% for self-report vs. ~20% for system-tracked)

• Compliance to using scanners decreased over time and differed by vaccine type and time of year

Needs Identified:

To realize the most benefits from 2D scanning the technology needs to work as expected and immunizers need to scan regularly (high compliance)

Piloting 2D barcode scanning implementation within one health care system

Selection of Health Care System

- Recruitment Criteria for Health Care System
  - Sutter Health selected based on criteria, including:
    • Interest and willingness to participate
    • Use of a single EMR systemwide that supported scanning
    • Ability to confirm whether vaccine record scanned or not

Selection of Sites

- Selection of 27 Sites within the Health Care System
  - Sites selected based on:
    • Interest and willingness to participate
    • Diversity of centers administering vaccines (e.g., pediatrics, vaccine clinic, internal medicine)
    • Agreement to installation and use of scanners
    • Agreement to data collection and assigned adherence strategy group

Pilot Timeline

- Analysis & Reporting: Jul. 2017 – Apr. 2018
New: Seeking to “Nudge” Practitioner Behavior with Strategy Groups

Sites were stratified and randomly assigned to an adherence strategy group

**Training Only**
Training on use of 2D scanners and protocol for scanning

**Commitment Card**
Written personal rationale for scanning/signed commitment to scanning

**Training + Commitment Card**  
(below left)

**Scanning Report**
Posted report – compares individuals at center and center to other centers

**Combination**
Combination of all previous strategies

**Combination**
Training + Commitment Card + Scanning Report

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**Commitment to Patient Safety with 2D Scanning**

I, [Name], am committed to patient safety and protecting the health of any patient. I will do my best to scan each vaccine product with a 2D barcode that I administer to my patients.

I believe that scanning is important to patient safety because:

[Signature]
[Date]

---

**Sample Scanning Report**

Care Center A  
Scanning Adherence Report  
Week of 5/27 to 6/2

[Graph showing adherence rates across different care centers]
Recent Pilot Findings
## Summary Findings from the Recent Pilot

<table>
<thead>
<tr>
<th><strong>Accuracy Increased</strong></th>
<th>Accuracy: lot number improved 4.6%, expiration date improved 9.2%, and product identifier (NDC) improved 5.7% when scanned</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Time Savings Observed</strong></td>
<td>21 seconds saved per vaccine entered when scanned (average 7.04 seconds when scanned, 28.19 seconds when not scanned)</td>
</tr>
<tr>
<td><strong>Scanning Rates</strong></td>
<td>Most vaccines administered were scanned - 94% - (~68,000), Rates varied by specialty, volume, adherence strategy group, site</td>
</tr>
<tr>
<td><strong>Strategies Worked</strong></td>
<td>Scanning rates higher with use of scanning rate reports and commitment cards – plus unplanned strategies (leader visits)</td>
</tr>
<tr>
<td><strong>Staff Survey</strong></td>
<td>Reduced eye strain, reduced hand / joint-related problems, disposing of syringes in room instead of carrying for later entry (safety)</td>
</tr>
<tr>
<td><strong>Challenges Existed</strong></td>
<td>Roadblocks to consistent scanning included: scanning difficulties, scanner location, limited buy-in, and unclear expectations/protocol</td>
</tr>
</tbody>
</table>
Accuracy Improvements Varied by Data Element and Specialty

- Improvements to record accuracy when vaccines scanned (compared with not scanned) ranged from 2.7%-6.5% for lot number; 0%-11.6% for expiration date; and 2.7%-6.6% for product identifier (NDC)

- Differences when scanned or not scanned statistically significant (except where noted)*

*Statistically significant difference (p<.01) between scanned and not scanned accuracy of vaccine records for each specialty, within each data element, with the exception of the expiration date field comparison for the shot clinic.
Scanning Rates Ranged from 39% to 99% Across Pilot Sites

<table>
<thead>
<tr>
<th>Pilot Site</th>
<th>Scanning Rate (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pediatrics 1</td>
<td>99%</td>
</tr>
<tr>
<td>Pediatrics 4</td>
<td>99%</td>
</tr>
<tr>
<td>Pediatrics 5</td>
<td>99%</td>
</tr>
<tr>
<td>Pediatrics 9</td>
<td>99%</td>
</tr>
<tr>
<td>Injection Clinic</td>
<td>98%</td>
</tr>
<tr>
<td>Pediatrics 2</td>
<td>98%</td>
</tr>
<tr>
<td>Pediatrics 3</td>
<td>98%</td>
</tr>
<tr>
<td>Pediatrics 6</td>
<td>97%</td>
</tr>
<tr>
<td>Family Practice 10</td>
<td>96%</td>
</tr>
<tr>
<td>Pediatrics 7</td>
<td>96%</td>
</tr>
<tr>
<td>Family Practice 5</td>
<td>95%</td>
</tr>
<tr>
<td>Pediatrics 8</td>
<td>95%</td>
</tr>
<tr>
<td>Family Practice 1</td>
<td>94%</td>
</tr>
<tr>
<td>Internal Medicine 2</td>
<td>93%</td>
</tr>
<tr>
<td>Family Practice 2</td>
<td>88%</td>
</tr>
<tr>
<td>Family Practice 4</td>
<td>88%</td>
</tr>
<tr>
<td>Internal Medicine 4</td>
<td>87%</td>
</tr>
<tr>
<td>Internal Medicine 3</td>
<td>86%</td>
</tr>
<tr>
<td>Family Practice 7</td>
<td>85%</td>
</tr>
<tr>
<td>Family Practice 6</td>
<td>84%</td>
</tr>
<tr>
<td>Family Practice 9</td>
<td>83%</td>
</tr>
<tr>
<td>Internal Medicine 1</td>
<td>79%</td>
</tr>
<tr>
<td>Family Practice 8</td>
<td>76%</td>
</tr>
<tr>
<td>Internal Medicine 5</td>
<td>60%</td>
</tr>
<tr>
<td>Internal Medicine 6</td>
<td>60%</td>
</tr>
<tr>
<td>Family Practice 3</td>
<td>59%</td>
</tr>
<tr>
<td>Internal Medicine 7</td>
<td>39%</td>
</tr>
</tbody>
</table>

Pilot Avg: 94%
Significant Variation in Scanning Rates by Specialty*

**Highest rates** = Pediatric sites (97%) and a Shot Clinic (99%)

**Lowest rates** = Internal Medicine sites (71%)

*Significant at p < .0001 level*
Scanning Rates Increased as Weekly Volume Increased

Significant difference in scanning rates by volume,* from 74% for low-volume sites to 97% for high-volume sites

*Significant at p < .0001 level

Adherence Strategies Significantly Improved Scanning Rates

**Training-only group** had the **lowest average scanning rate**

Groups with an **additional strategy** had **significantly higher scanning rates***

<table>
<thead>
<tr>
<th>Strategy</th>
<th>Scanning Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Training Only</td>
<td>92%</td>
</tr>
<tr>
<td>Commitment Card</td>
<td>96%</td>
</tr>
<tr>
<td>Scanning Adherence Report</td>
<td>94%</td>
</tr>
<tr>
<td>Combination (Card + Reports)</td>
<td>96%</td>
</tr>
</tbody>
</table>

*Statistically significant at the p<.0001 level*
Adherence Strategies Most Effective at Family & Internal Medicine Sites

Strategies performed similarly for **Pediatric and Shot Clinic** sites

Significant variation at **Family Practice and Internal Medicine** sites*

<table>
<thead>
<tr>
<th></th>
<th>Pediatric &amp; Shot Clinic</th>
<th>Family Practice &amp; Internal Medicine</th>
</tr>
</thead>
<tbody>
<tr>
<td>Training Only</td>
<td>95%</td>
<td>72%</td>
</tr>
<tr>
<td>Commitment Card</td>
<td>98%</td>
<td>80%</td>
</tr>
<tr>
<td>Scan Report</td>
<td>99%</td>
<td>82%</td>
</tr>
<tr>
<td>Combination</td>
<td>98%</td>
<td>91%</td>
</tr>
</tbody>
</table>

*Differences statistically significant at the p<.001 level*
Next Steps
Next Steps

Share Pilot Findings – Reports/Articles/Presentations

Promote and Refine - Implementation Guide __ for Decision-Makers

Maintain National Drug Codes (NDC) Crosswalk Tables
   Unit of Sale (UoS) & Unit of Use (UoU)

Maintain Functional Capabilities Report – for software developers

Engagement with Immunization Community Partners
   Vaccine Manufacturers – EMR Vendors – Scanner Vendors - Providers

Monitor - Drug Supply Chain Security Act (DSCSA)
Where to find more information

Visit the CDC 2D barcode page for 2D vaccine barcode resources: 
http://www.cdc.gov/vaccines/programs/iis/2d-vaccine-barcodes/

Search Key Words: “CDC 2D Barcode”

What’s on the site?
• Current list of 2D barcoded vaccine presentations (vials/syringes)
• 2D Pilot artifacts, including:
  • 2018 Findings Report
  • 2D Implementation Guide
  • AAP Guidance
  • GS1 Guidance
  • 2D Functional Capabilities Report (for Developers)
"Thank You-Happy Scanning"

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.
ADVANCES IN COLD CHAIN HANDLING: GLOBAL TEMPERATURE CONTROL

September 13, 2018
National Vaccine Advisory Committee

GEOFFREY GLAUSER LLC.
ADVANCES IN COLD CHAIN HANDLING

- Logistics
- Distribution / Last Mile deliveries
- Quality Management Systems
- Stability Budgeting
- Temperature Data Loggers
- Insulated Containers
- Technical Advances
Previous
Temperature
Data Solutions

- One-time use
- Limited programming
- Limited data downloading capabilities
- Validation limitations
- Comparatively expensive
Electronic Data Recorders

- Miniaturization is progressing
- Programmable
- Varied functionality
- Up to five year battery life
- Specific to the cold chain function
  - Long term storage recording
  - Short-time single use
- Adaptable to unique stability budgeting
- Uploading capabilities
- Robust
- Validated
Competitive Market
Miniaturation

- 4-Year monitoring life
- Small enough for individual packages
- Cost competitive
- Upload capability
- Programmable to individual stability budgets
- Complete TOR record
- Multi-level alarms LED
- Automatic PDF reporting
- Validated
- NIST traceable
- Bluetooth enabled to Cell Phone with app
- Data can be loaded to a central database
Insulated Designs w/ Phase Change Materials

- Significant assembly enhancements
- Lower time out of refrigeration
- Reusable
- Replaceable components
- Phase change materials
- Ability to use for 2-8°C, -20°C, Controlled Room Temperature
Vacuum Insulated Panel Shippers

• More frequent use
• Cost competitive
• Reusability / recyclability
• Lifecycle considerations
• Replaceable components
• Returns’ effectiveness
• Pallet Quantity Shipping

• Critical temperature control accuracy for 2-8°C (E.g. Clinical, Heat labile materials)
• Refrigeration and heater mode are disabled during air transport.
• Regenerative cooling and heating in recharge mode and transport mode
• Tight configuration allowing for use in multiple aircraft
• **Arktek**

• Developed by Intellectual Ventures to transport 2-8°C for up to 30 days in sub-Saharan temperature

• Utilized in Sierra Leone Ebola vaccine trial at ≤-60°C with -80°C phase change materials

• Limited vial capacity

• Solution for inaccessible or remote vaccination locations
Thank you!

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Advances in Vaccination Technologies: The Microneedle Patch

September 13, 2018
National Vaccine Advisory Committee

Šeila Selimović, PhD
I declare that I do not have a financial interest, arrangement or affiliation with any commercial or other organization that may have a material interest in the subject matter of my presentation.
Microneedle Patch Technology
<table>
<thead>
<tr>
<th>Coated</th>
<th>Dissolving</th>
<th>Hollow</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chikungunya virus [51]</td>
<td>Diphtheria [52-56]</td>
<td>Influenza [55, 57-83]</td>
</tr>
<tr>
<td>Hepatitis C [90]</td>
<td>Influenza [55, 57-83]</td>
<td>Poliovirus [91]</td>
</tr>
<tr>
<td>Herpes simplex virus [92, 93]</td>
<td>Malaria [41, 52, 94]</td>
<td>Rabies virus [95]</td>
</tr>
<tr>
<td>Influenza [55, 57-83]</td>
<td>Poliovirus [98]</td>
<td>Yersinia pestis [45, 99]</td>
</tr>
<tr>
<td>Measles [100]</td>
<td>Tetanus [52]</td>
<td></td>
</tr>
<tr>
<td>Modified Vaccinia Ankara [39, 94]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rotavirus [101]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Small Pox [102]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>West Nile virus [51]</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Microneedle Patch Technology

- Patch is applied to skin
- Microneedles dissolve and release their active
- Sharps-free backing is removed and discarded
Microneedle Patch Technology

Enhanced immunogenicity due to skin route of vaccination (assessed by antibody and cell-mediated responses) – instead of novel antigens and adjuvants.

Dose sparing of influenza vaccine when administered via skin compared to intramuscular injection.

Water-soluble microneedles containing vaccine: minutes after patch shaft removal.
Hypodermic Needles

- **COMPLEX**: administered by health professional
- **INVASIVE**: intramuscular / subcutaneous / intradermal
- **PAINFUL**: larger needle -> more painful
- **THERMALLY SENSITIVE**: vaccine in liquid form
- **VERSATILE**: applicable to multiple vaccines, not only influenza
- **REGULATED DISPOSAL**: sharps
Microneedle Patch Technology

- **SIMPLE**: can be self-administered
- **TARGETS SKIN**: minimally invasive
- **IMPROVED EFFICACY**: provokes immune reaction in skin
- **PAINLESS**: reducing needle size reduces pain; patient acceptance
- **STABLE**: single dose, thermostable, no reconstitution
- **VERSATILE**: applicable to multiple vaccines, not only influenza
- **EASY DISPOSAL**: no sharps
- **LOW COST**: microfabrication tech; $0.01 in mass production; no cold chain
Phase I Clinical Trial

The safety, immunogenicity, and acceptability of inactivated influenza vaccine delivered by microneedle patch (TIV-MNP 2015): a randomised, partly blinded, placebo-controlled, phase 1 trial


www.thelancet.com Vol 390 August 12, 2017

Intramuscular (hypodermic needle)
Patch – administered by med professional
Patch – self-administered
Patch – placebo

Serological response to study drug administration
Origins and Future

- Quantum Award to Prausnitz et al (Georgia Tech / Emory), 2013
- Now being commercialized by Micron Biomedical

CDC awards Micron research contract to develop a patch for co-administration of inactivated rotavirus vaccine (IRV) and inactivated polio vaccine (IPV)
Sep 1, 2016

Phase 1 clinical trial shows safety and immunogenicity of microneedle patch for flu vaccination for the first time
Jun 28, 2017

Micron to collaborate with Georgia Tech and CDC on measles-rubella project funded by UNICEF
Jun 19, 2017
Considerations

- Application to other vaccinations requires new vaccine formulations (stabilizing compounds may affect immunogenicity.).
- Slow-release materials instead of multi-dose delivery.
- Quick dissolving materials (1 minute or less).
- Mechanical strength of microneedles when exposed to short periods of humidity outside of storage packaging?
- Microneedle patch technology applicable to other uses, e.g. interstitial fluid extraction (diagnostics) / other drug delivery.
- Self-administration -> minimally trained personnel sufficient
- Assess policy issues associated with self-administered influenza vaccination using a microneedle patch.
Thank you!

Šeila Selimović, PhD
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