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Scaling Two-Dimensional (2D) Vaccine Barcode Scanning

48th National Immunization Conference (NIC)

May 15, 2018

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Immunization Services Division, CDC

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Deloitte Consulting, LLP
Session Outline

- Context
- Previous Pilots and Findings
- Scalability Pilot
- Challenges and Lessons Learned
- Next Steps
Context
Remember - Why We Are Doing This

Current State: Linear

Future State: 2D

- Lot number
- Expiration date
- NDC code

Linear barcode only has NDC
Lot number and Expiration only ‘human readable’

‘Human readable’ still there!

Maximum Alphanumerical Character Capacity

48 2,335
Previous Pilots and Findings
CDC 2D Barcoded Vaccine Initiatives

2D Pilot (2D): Assess Impact (2011 – 2013)*

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

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

2D Adoption: Facilitate Adoption (2013 – 2015)

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

2D Scalability (2015 – 2018)

Objectives
- Assess 2D impact in a large healthcare system
- Assess compliance with scanning and interventions
- Identify and develop solutions to address remaining challenges

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

* Periods of primary data collection and project activities provided
2D Adoption Pilot
Data Quality, Time Savings and User Experience

Data Quality Improvement

User Experience Feedback

- **75% of users (and 86% of leaders) agree** – 2D scanning improves accuracy
- **60% of users agree** – easy to integrate 2D barcode scanning into their usual process of recording data
- **60% of users agree** – 2D barcode scanning is easy to use
- **Benefits identified** - improved accuracy, improved efficiency, less manual entry of vaccine data
- **Challenges identified** - inconsistencies with scanning and scanners, faded barcodes, incorrect entries after scanning

Data Quality Improvement:

Lot number (correct) difference statistically significant at an alpha of 0.05 ($t(893761)=142.7, p=0.001$); Expiration date (correct) difference statistically significant at an alpha of 0.05 ($t(690111)=116.7, p=0.001$)

Time Savings Improvement:

<table>
<thead>
<tr>
<th>Entry Method</th>
<th>Average Time to Record</th>
<th># of Recordings</th>
<th>SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>With 2D barcode scanning</td>
<td>6.86 seconds</td>
<td>495</td>
<td>8.14</td>
</tr>
<tr>
<td>Without 2D barcode scanning</td>
<td>10.30 seconds</td>
<td>531</td>
<td>8.07</td>
</tr>
</tbody>
</table>

Difference statistically significant at an alpha of 0.05 ($t(1,024)=30.91, p=0.001$).
Compliance ... or lack thereof

Unanticipated Findings:

• Practitioners self-reported scanning frequently, but tracking scans at site-level said otherwise (50+% time vs. ~20%)

• Compliance quite low, decreased over time, differed by vaccine type, time of year

• To truly realize 2D scanning benefits: technology needs to work as expected and people need to scan regularly (high compliance)
Scalability Pilot
Selection of Health Care System

- Recruitment Criteria for Health Care System
  - Sutter was selected based on:
    - Interest and willingness to participate
    - Participation of care center in previous pilot
    - Use of a single EMR system that supported scanning

Selection of Care Centers

- Selection of 27 Care Centers
  - Centers were selected based on:
    - Interest and willingness to participate
    - Diversity of centers administering vaccines (e.g., pediatrics, vaccine clinic, family medicine)
    - Agreement to installation and use of scanners
    - Agreement to data collection and use of adherence strategy
Overview of Adherence to Scanning Protocol

Care Centers were stratified and randomly assigned to an adherence strategy:

- **Training Only**
  - Use of scanners and protocol for 2D barcode scanning
  - No other steps

- **Commitment Card**
  - Written personal rationale for scanning & signed commitment to scanning
  - Training + Commitment Card

- **Adherence Report**
  - Publicly posted report – compares individuals at center and center to other centers
  - Training + Adherence Report

- **Combination**
  - Combination of all strategies:
    - Training + Commitment Card + Adherence Report

**Sample Scanning Commitment Card**

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

I, __________________________, am committed to patient safety and protecting the health of my patients. 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 __________________________

**Sample Scanning Adherence Report**

*Image of adherence report showing adherence rates for different care centers.*
2D Scalability Pilot Data Sources

EMR Data files
- Collected from all 27 participating care centers, for vaccines administered prior to project start and during course of project period

Reference File
- Care center inventory taken to create a file to compare accuracy of lot number and expiration date for vaccines in EMR extracts

Online Survey Data
- Practitioners at each site asked to provide feedback on their experiences with 2D barcode scanning

Workflow Analysis (WFA)
- High-level onsite observations at each facility
- Detailed follow up observations and time measurements at select facilities
**Key Findings - 2D Scanning Implementation**

- **Accuracy Increased**
  - Accuracy: **lot number improved 4.6%** (to 99.7%), **expiration date improved 9.2%** (to 99.97%) and **NDC improved 5.7%** (to 99.9%) when scanned

- **Time Savings Observed**
  - **21 seconds saved per vaccine entered when scanned** (average 7.04 seconds when scanned, 28.19 seconds when not scanned)

- **Scanning Rates High, but Varied**
  - Users scanned **94% of vaccines** administered during pilot (~68,000 vaccines)
  - **Fast up-take by many** early in pilot, with continued increases through pilot end
  - **Scanning rates varied** by: specialty, volume, adherence strategy group, site, practitioner

- **Adherence Strategies Worked**
  - Scanning rates higher with use of **scanning reports and commitment cards**
  - Unplanned strategies also increased scanning adherence, such as **leader visits**

- **Some Challenges Experienced**
  - **Challenges early in the pilot** (scanner location/workflow fit, buy-in, glitches) and **remaining by pilot end** (workarounds, scanner location, buy-in) identified
Challenges and Lessons Learned
Challenges

• Not all vaccine vials/syringes have 2D barcodes

• Health information Systems, (e.g. EMR, IIS) lack 2D barcode functionality

• Inconsistent scanning results
  • Staff training and skill
  • Barcode scanner technology
  • Barcode print quality

• NDCs on vials/syringes differ from those on salable packages
  • Inventory – typically use, salable packages
  • Vaccine administration – use vials/syringes

• Lot number differences (vials/syringes vs. salable packages) for 6 vaccines
Lessons Learned

1. Early Planning and Decisions Made a Big Difference (Take the Time to Get It Right From the Start)
   - Revised their workflow process and protocol from the start
   - Strategically selected scanner location, with input from staff

2. Patterns of Use and Implementation Were Evident Early
   - High volume sites, such as Pediatrics/ Shot Clinic, scanned at high rates from the start, until pilot end
   - Low vaccine volume sites, including Internal Medicine, struggled the most to scan consistently

3. Adherence Strategies “Nudged” Participants to Scan More Frequently
   - All groups with some strategy to promote scanning beyond only training had the highest scanning rates, with scanning increases aligning with the timing of strategy implementation

4. Adjustments to Resolve Challenges Mid-Course Improved Scanning Use
   - Revisiting foundational planning decisions and making revisions improved scanning rates and buy-in
   - Offering troubleshooting support to work through specific challenges,
   - Providing data on scanning rates to staff and leaders, and
   - Engaging leaders at sites and within organization
Next Steps
Implementation Guide

Actionable guide for decision makers, considering the implementation of 2D vaccine barcode scanning

Six steps in the Implementation Guide

Pilot findings provide foundation for contents within each step

**Decide**

Decide if adoption of 2D barcode scanning of vaccines is right for your facility or organization, weighing resources needed and potential benefits of scanning

**Plan**

Plan for scanning implementation, identify how scanning fits into your vaccine administration workflow and create strategies to maximize scanning use

**Train**

Train staff on scanning, including development of training materials, practice using scanners and adjust to the scanning process

**Assess**

Assess use of scanning, identify any challenges being experienced and any sites or practitioners needing additional support to consistently scan vaccines

**Adjust**

Adjust strategies to achieve consistent scanning (e.g., adjustments to workflow, scanner location, or other changes) and address challenges experienced

**Sustain**

Sustain consistent scanning practices once fully implemented and consider expanded use of scanning
Share Pilot Findings and Encourage Adoption

**Disseminate Pilot Findings to Share Knowledge**
- Findings Report of key pilot findings and methodology
- Other materials including peer-reviewed publications, newsletters and articles, and presentations enable sharing of findings in meaningful formats for specific audiences

**Communicate Role for Immunization Community to Improve Scanning Efforts**
- Vaccine manufacturers
- Health Information System (EHR) vendors / developers
- Scanner vendors
- Providers - Practitioners

**Encourage adoption of 2D barcode scanning**

**Continue to provide infrastructure support such as the NDC Crosswalk Table**

**Monitor unfoldment of the Drug Supply Chain Security Act (DSCSA)**
- Pharmacy track and trace, – 2D barcoded on unit of sale, with serial number
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:
  • AAP Guidance
  • GS1 Guidance
  • 2D Functional Capabilities Report (for Developers)
• 2018 Findings Report
• 2D Implementation Guide
“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.
Use and Impact of Clinical Decision Support for Immunization (CDSi) Resources

Lauren Shrader, MA
Northrop Grumman
Use and Impact of Clinical Decision Support for Immunization (CDSi) Resources

- Overview of CDSi
- Overview of CDSi Evaluation
- Results from Online Assessment
- Success Case Method
- Next Steps
- Question
CDSi

- CDSi = Clinical Decision Support for Immunization
- CDC created and managed set of resources
- Designed to map ACIP recommendations into IT-friendly resources
- Goal = Consistent implementations aligned with ACIP recommendations
With CDSi

ACIP Recommendations and Clarifications

CDSiResources

Workgroup Interpretation and Documentation

Individual Implementation

Consistent System Recommendations

https://www.cdc.gov/vaccines/programs/iis/cdsi.html
CDSiResources

The CDSi project focuses on documenting ACIP recommendations and test cases. It does not have or maintain a CDS engine.

The complete suite of CDSi Resources comprises:

- **Logic Specification**
  - Vocabulary
  - Business Rules
  - Decision Tables
  - Processing Definitions
  - Domain Model

- **Supporting Data**
  - Excel Format
  - XML Format
  - Release Notes

- **Test Cases**
  - Excel Format

- **Training Materials**
  - Brochure
  - Quick Guides
  - Practice Exercises
  - Quiz
  - Videos

https://www.cdc.gov/vaccines/programs/iis/cdsi.html
What is IIS?
CDSi Evaluation

- Online Assessment
- Success Case Method
- Pilots/Site Visits
- Status Check Project
- In-depth In-person Interviews
CDSi Evaluation Logic Model

Program: CDSi Childhood Immunization Logic Model
Goal: Determine the uptake and impact of CDSi resources

**Inputs**
- CDC staff and resources
- Funding
- ACIP Schedules / recommendations
- Clinical resources and experts
- Business rules / methodologies

**Activities**
- Disseminate ACIP communications / recommendations
- Provide CDSi resources and methodologies
- Incorporate clarification / guidance from clinical experts
- Build business rules to express logic
- Improve use of resources: cost, time, people

**Outputs**
- Respondents using non-CDSi recommendations
- Respondents using CDSi resources
- Respondents use process within CDSi
- Vendors (IIS and EHR) who offer CDS

**Participation**
- Respondents use Logic Specification
- Respondents use Supporting Data
- Respondents use Testing Methodology
- Respondents use Test Cases

**Short**
- Increased accuracy and consistency of immunization evaluation and forecasting

**Medium**
- Improved awareness and knowledge of CDSi Immunization resources
- Institutionalize CDSi logic into business processes

**Long**
- Respondents use resources more efficiently (cost, time, people, etc.)
- Documented improvements in use and impact of CDSi process, tools, and integration of ACIP recommendations into immunization practices

**Assumptions**
- Stakeholders want assistance improving their tools, processes (e.g., ACIP schedule integration), and efficiencies
- Audiences include CDSi grantees, IIS and EHR vendor communities and members of national organizations

**External Factors**
- Stakeholders are not required to use resources
- Schedule is owned by ACIP determinations and timeframes
- Local variability in environments and systems (e.g., software / EHRs)
Online Assessment
Survey Methods

- Round 1 deployed in January 2015
- Round 2 deployed in January 2016
- Round 3 deployed in January 2018
- Respondents
  - IIS grantees
  - IIS vendors, EHR vendors, and independent consultants
- Survey Methods
  - Pre-notification email
  - Survey Invitation email
  - Reminder email
  - Final targeted reminder email
<table>
<thead>
<tr>
<th>Year</th>
<th>Invited</th>
<th>Responded</th>
<th>Response Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Round 1 - 2015</td>
<td>64 States/Territories</td>
<td>Responses from 52 states/territories</td>
<td>81% of states/territories</td>
</tr>
<tr>
<td>Round 2 - 2016</td>
<td>64 States/Territories</td>
<td>Responses from 48 states/territories</td>
<td>75% of states/territories</td>
</tr>
<tr>
<td>Round 3 - 2018</td>
<td>64 States/Territories</td>
<td>Responses from 57 states/territories</td>
<td>89% of states/territories</td>
</tr>
</tbody>
</table>
# IIS Vendors, EHR Vendors, and Independent Consultants Response Rates

<table>
<thead>
<tr>
<th>Year</th>
<th>Invited</th>
<th>Responded</th>
<th>Response Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Round 1 - 2015</td>
<td>26 respondents</td>
<td>11 responses</td>
<td>42% of Vendors</td>
</tr>
<tr>
<td>Round 2 - 2016</td>
<td>31 respondents</td>
<td>10 responses</td>
<td>32% of Vendors</td>
</tr>
<tr>
<td>Round 3 - 2018</td>
<td>25 respondents</td>
<td>8 responses</td>
<td>32% of Vendors</td>
</tr>
</tbody>
</table>
Online Assessment
CDSi Resource Awareness

Which of the following have you heard about?

From Round 1 to Round 3 awareness increased for each resource.

<table>
<thead>
<tr>
<th>Resource</th>
<th>Round 1</th>
<th>Round 2</th>
<th>Round 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Logic Specification</td>
<td>65%</td>
<td>79%</td>
<td>86%</td>
</tr>
<tr>
<td>Supporting Data</td>
<td>57%</td>
<td>74%</td>
<td>81%</td>
</tr>
<tr>
<td>Test Cases</td>
<td>67%</td>
<td>78%</td>
<td>82%</td>
</tr>
<tr>
<td>Aware of at least one CDSi Resource</td>
<td>75%</td>
<td>88%</td>
<td>89%</td>
</tr>
</tbody>
</table>

Round 1 N = 72
Round 2 N = 68
Round 3 N = 64
Use of CDSi Resources

Of those aware of the CDSi Resources, Have you used the CDSi resources to improve evaluation and forecasting of ACIP recommendations?

From Round 1 to Round 3 use increased for each resource.
The majority of respondents who have used the resources report that they plan to continue to use the resources in the future.
Reasons Respondent Has Not Used CDSi

- Vendor utilizes the resources
- Use a third party evaluation tool or vendor
- Work load / competing priorities/ lack of time
- Not aware of the resource
- Need training/ not sure how to use it
- Not ready to use it yet / working on implementing a new forecaster/ will be using it soon
- System was already in place before CDSi
- Not useful for role (technical support/clinical)
Satisfaction with CDSi Resources

Of those who have used the CDSi resource, how satisfied or dissatisfied are you with the resource?

Satisfaction levels are high across each resource.
Impact of CDSi Resources

Of those who have used the CDSi resource, what type of impact have the resource had in terms of the ease of use in developing and maintaining CDS logic?

Impact levels are high across each resource

*Somewhat Negative Impact and Very Negative Impact = %
Overall Conclusions

- Awareness and use increased from Round 1 to Round 3 across all resources

- Across Round 1 and Round 2 satisfaction was high among users
  - About 80% or more respondents reported they were very or somewhat satisfied with the resources

- Across Round 1 and Round 2 impact was high among users
  - Over 80% of respondents reported a very or somewhat positive impact
  - None of the users reported a negative impact
How Online Assessment Data Has and Will Be Used for Improvement

- Track awareness and use of CDSi resources
  - Improve communication and promotion
  - Improve training and learning resources

- Improve CDSi Resources

- Guide CDSi Resources future directions
CDSiSuccess Case Method Evaluation

- **Background**
  - The author’s accidental SCM study at a major pharmaceutical organization

- **Benefits**
  - A "relatively quick and easy method of finding out what is working and what is not, which also provides accurate and trustworthy information that can be used to make timely decisions." (p 3)
  - “The Success Case Method employs stories, but it combines storytelling with rigorous — albeit balanced and practical— evaluation methods and principles to combine the credibility of scientific finding with the emotional impact stories. The stories produced by the SCM cite solid evidence that would “stand up in court” and is backed by the rigorous rules of judicial evidence: corroboration and documentation.” (p xi)
### CDSiSCM Impact Model

<table>
<thead>
<tr>
<th>Capability</th>
<th>Behavior/Critical Applications</th>
<th>Goals</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Disseminate ACIP communications/recommendations through CDSi resources</td>
<td>• Stakeholders become aware of and use CDSi resources</td>
<td>• Single source of reference</td>
<td>• Increased accuracy and consistency of immunization evaluation and forecasting</td>
</tr>
<tr>
<td>• Update CDSi Resources based on new or changed ACIP guidelines</td>
<td>• Gain knowledge about CDSi resources though reviewing the materials and trainings</td>
<td>• Reduced complexity</td>
<td></td>
</tr>
<tr>
<td>• Translate clinical language into technical data that can be used to update Clinical Decision Support (CDS) engines</td>
<td>• Use CDSi resources for standard ACIP recommendations for children, adolescents, and adults</td>
<td>• Ease of use</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Time/Cost savings</td>
<td></td>
</tr>
</tbody>
</table>
Identify and Interview Success Cases

- Analyze survey results to identify potential success cases
- Choose cases for interview
- Develop interview protocol
- Success case interview buckets: Interview as a bucket filling process
- Conducting interviews
- Documenting success cases

Our interview protocol will focus on filling the following buckets:

- What was used?
- What results were achieved?
- What good did it do? (value)
- What helped?
- What do you suggest?
# Impact Profile

## Impact Profile: CDSiResources IIS Success Story

**Stakeholder Name:**

**Stakeholder Type:**

| Impact at a Glance | • Key Impact 1  
|                   | • Key Impact 2  
|                   | • Key Impact 3  |

<table>
<thead>
<tr>
<th>The Impact Story</th>
<th>Summary of the impact</th>
</tr>
</thead>
<tbody>
<tr>
<td>What They Used</td>
<td>Summary of how the CDSi resources were used</td>
</tr>
<tr>
<td>What They Achieved</td>
<td>Summary of the results they achieved</td>
</tr>
<tr>
<td>What helped and what did not</td>
<td>Summary of what helped and what barriers they had</td>
</tr>
<tr>
<td>Suggestions</td>
<td>Summary of suggestions for improvement</td>
</tr>
<tr>
<td>Future Plans</td>
<td>Summary of future plans related to CDSiResources</td>
</tr>
</tbody>
</table>
Generate Conclusions from Interview Data

- Identification/Description of resource usage and results
- Document parts that work and those that don’t
- Factors that help or impede impact
- Scope of impact
- Estimating return on impact
- Estimating unrealized value
Next Steps

Finalizing Success Case Method Evaluation

Using results to inform and improve CDSi Resources

Continuing evaluation of use and impact
Questions

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CDC Project Lead      Evaluation Specialist Informatics Specialist
CDC                  Northrop Grumman     Northrop Grumman

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