An Update on Two-Dimensional (2D) Vaccine Barcoding

AIRA Annual Conference April 2017

Ken Gerlach
Centers for Disease Control and Prevention

Regina Cox, MPH
Deloitte Consulting, LLP

Judi Vallero, MD, PhD Sutter Medical Group



Session Outline

- Background
- Previous Pilots and Findings
- Pilot Description
- Feedback from the Field
- Next Steps



Background

2D Barcoded Vaccines Timeline

Key events & number of 2D vaccine presentations on the market

2003 - FDA requires linear barcode on the vaccine unit-of-use



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 – 2017)

Objectives

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

Participants

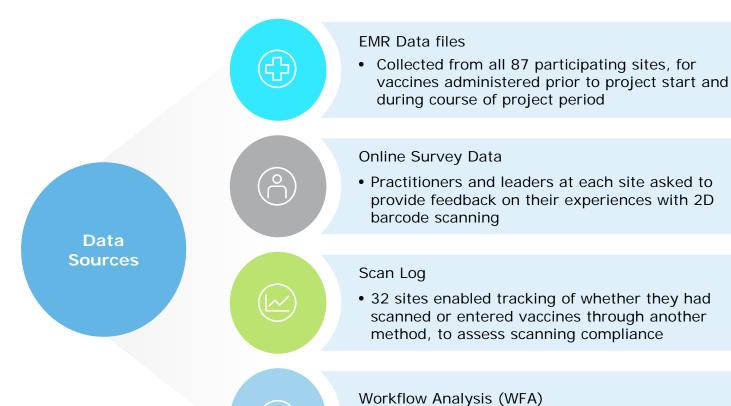
- 1 large healthcare system
- 29 care centers

^{*} Periods of primary data collection and project activities provided

2D Adoption (2DA) Pilots and Findings

2D Adoption Evaluation Questions and Data Sources

- Data Quality and Compliance 5 questions
- Time Savings 4 questions
- User Experience 2 questions



On-site observations, interviews and time

measurements from 20 facilities

Data Quality



Evaluation Question

To what extent does vaccine administration data quality change with the introduction of 2D barcode scanning?

Data

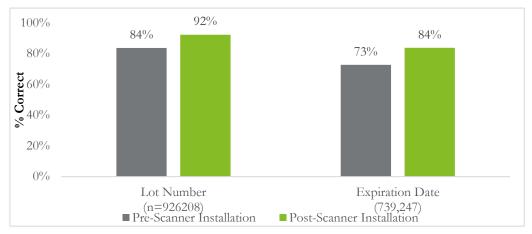
- 1,424,877 vaccination records analyzed from EMR data files (87 sites)
- 18% of vaccination records were 2D barcoded after installation

Finding

Data Quality Improves after Installation of 2D Barcode Scanners

Lot Number improved 8%* and Expiration Date improved 11%* after

installation of scanners



^{*} 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



Evaluation Question

Does the use of 2D barcodes to record data about vaccine administrations change the amount of time it takes to record vaccine information?

Data

- 1,026 time measurements collected on-site from 16 facilities
- 495 (48%) entries used 2D barcode scanner; 531 (52%) used a traditional entry method (manual entry, drop-down menu, combination)

Finding

- Time Savings Improves with 2D Barcode Scanning
- Average time to record vaccine administration data:

Entry Method	Average Time to Record	# of Recordings	SD
With 2D barcode scanning	6.86 seconds	495	8.14
Without 2D barcode scanning	10.30 seconds	531	8.07

 Average time savings of 3.44 seconds per entry with 2D barcode scanning (versus traditional methods)*

^{*}difference statistically significant at an alpha of 0.05 (t(1,024)=30.91, p=0.001).

User Experience



Evaluation Question

What is the experience of the end user when adopting 2D barcodes to record vaccine data?

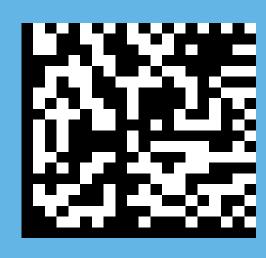
Data

 Online surveys of practitioners/users (n=116) and leaders (n=67) at participating sites (77% and 82% response rates, respectively)

Finding

- 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
- Challenges identified inconsistencies with scanning and scanners, faded barcodes, incorrect entries after scanning
- Benefits identified improved accuracy, improved efficiency, less manual entry of vaccine data

And something else...



Compliance

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

New area of exploration

- Limitations based on technology to directly measure at all sites
- Limited data, uncertain analysis options until end of project
- Two evaluation questions explored:
 - variation of compliance rates across the sites (32 sites), and
 - comparison of measured compliance rates with self-reported survey data (26 sites)



Compliance... or lack thereof

Findings and informed decision-making

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
- Survey responses identified challenges impeding scanning
- To truly realize 2D scanning benefits: technology needs to work as expected and people need to scan regularly (high compliance)



Use of findings to inform decision-making:

- Current phase directly measures scanning compliance at all sites (and for individual practitioners)
- Interventions to test changes in compliance
- Solution development to address remaining challenges

2D3 Pilot

Pilot Overview - Recruitment

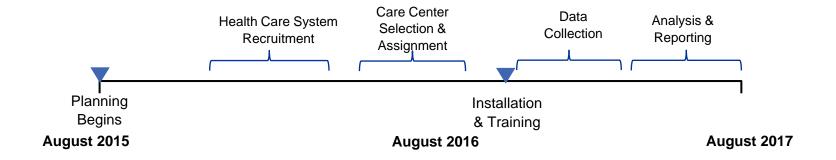
Selection of Health Care System

- 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



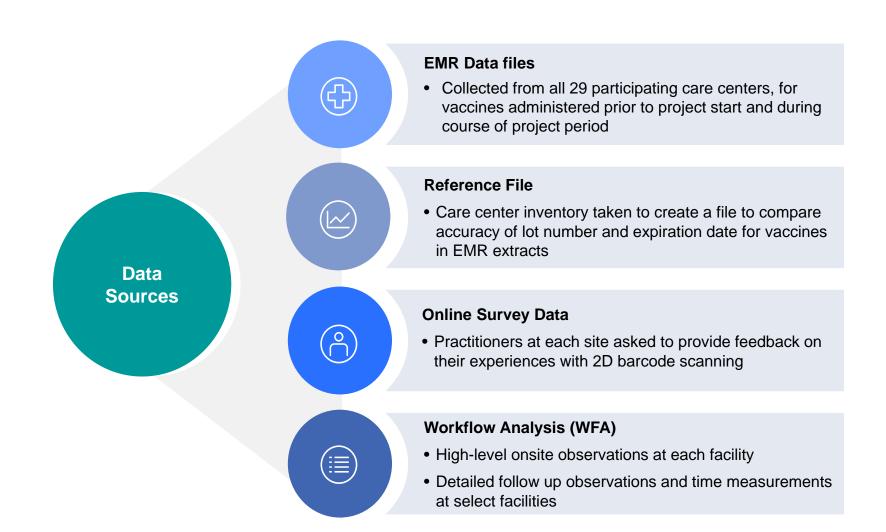
Selection of Care Centers

- Selection of 29 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





Data Sources



Overview of Adherence to Scanning Protocol

Care Centers were stratified and randomly assigned to an adherence strategies

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

Publically posted report – compares individuals at center and center to other centers

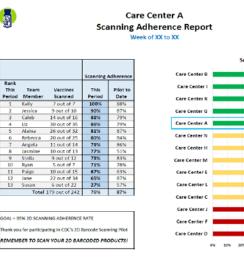
 Training + Adherence Report **Combination**

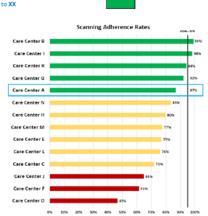
Combination of all strategies:

 Training + Commitment Card + Adherence Report

Sample Scanning Commitment Card

Sample Scanning Adherence Report

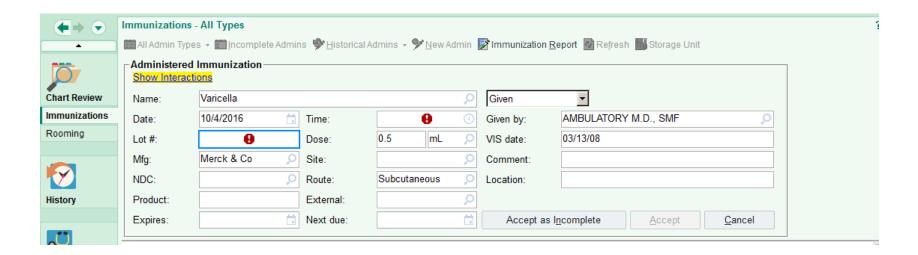




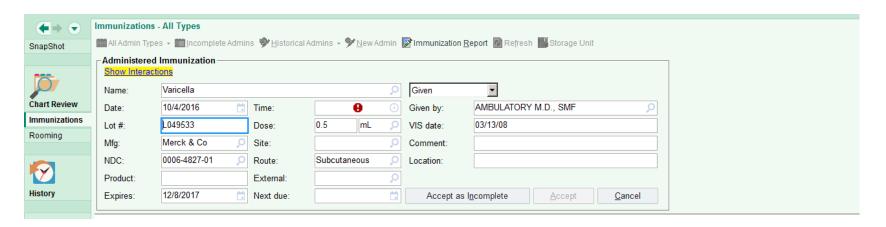
User Feedback: Dr. Judi Vallero

Sutter Scanning Implementation

Prior to Scan-



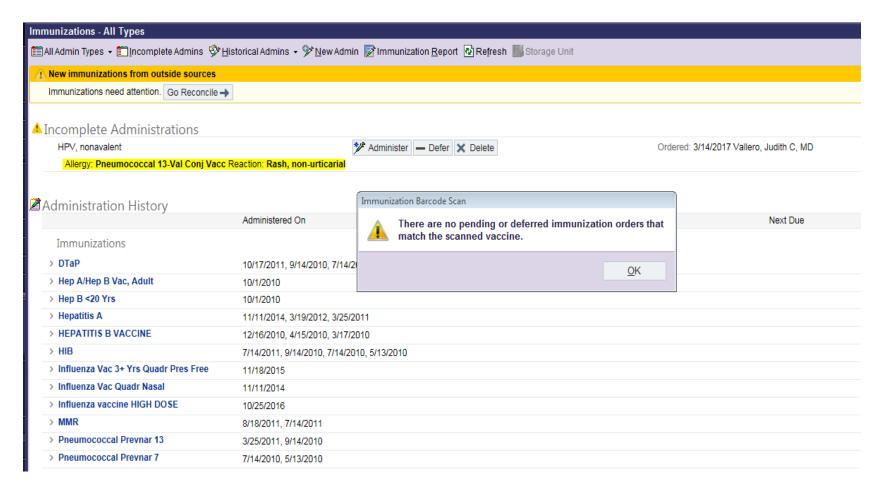
After Scan-



Screenshots are notional only (not real patients) and do not contain any Patient Identifiable Information.

Sutter Scanning Implementation

Sample Error Flag:



Next Steps

Next Steps

- Promote pilot educational materials
- Continue to monitor 2D Barcoded Vaccines in the supply chain and encourage addition of 2D barcodes to new products
- Continue to Maintain NDC Crosswalk Table as a resource for Health Information Systems (HIS)
- Monitor Drug Supply Chain Security Act (DSCSA)
- Encourage HIS vendors to incorporate 2D barcode functionality
- Explore opportunities to improve compliance

CDC 2D Barcoded Vaccine Initiatives

Where to find more information

Where can I find additional information?

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

What's on the site?

- Current list of 2D barcoded vaccines
- 2D Pilot artifacts

For Providers

- Training materials
- AAP guidance

For Developers

- NDC Crosswalk Tables with Global Trade Identification Numbers (GTIN)
- 2D Scanning functional capabilities requirements

For Manufacturers

- Secondary packaging 2D report
- AAP and GS1 2D guidance







"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.



Example of Adherence Rate Report



Care Center A Scanning Adherence Report

Week of XX to XX

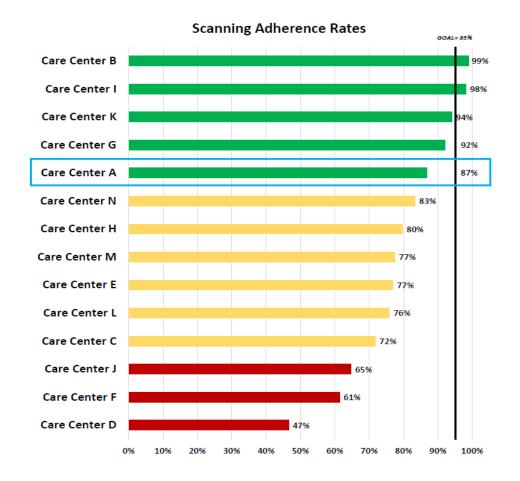


		Scanning Adherence		
Rank				
This	Team	Vaccines	This	Pilot to
Period	Member	Scanned	Period	Date
1	Kelly	7 out of 7	100%	88%
2	Jessica	9 out of 10	90%	87%
3	Caleb	14 out of 16	88%	79%
4	Liz	30 out of 35	86%	79%
5	Alaina	26 out of 32	81%	87%
6	Rebecca	20 out of 25	80%	84%
7	Angela	11 out of 14	79%	86%
8	Jasmine	10 out of 13	77%	51%
9	Stella	9 out of 12	75%	83%
10	Ryan	5 out of 7	71%	78%
11	Paige	10 out of 15	67%	63%
12	Jane	22 out of 34	65%	87%
13	Susan	6 out of 22	27%	57%
Total 179 out of 242		76%	87%	

GOAL = 95% 2D SCANNING ADHERENCE RATE

Thank you for participating in CDC's 2D Barcode Scanning Pilot

REMEMBER TO SCAN YOUR 2D BARCODED PRODUCTS!





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:



