“These Bad Boys are a Game-Changer” Scaling 2D Vaccine Barcode Scanning

AIRA 2018 National Meeting
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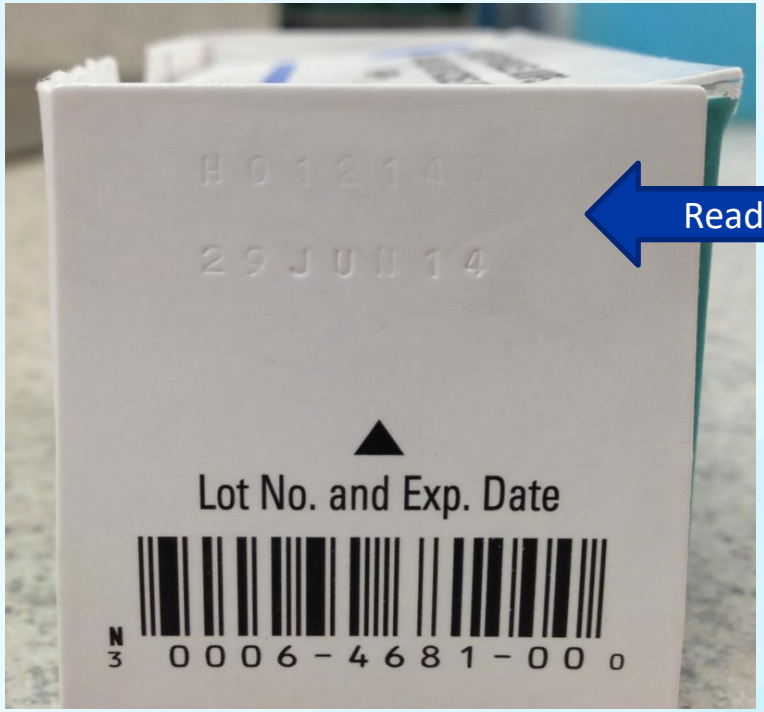
Session Outline

- Context
- Previous Pilots and Findings
- Scalability Pilot
- Next Steps

Context

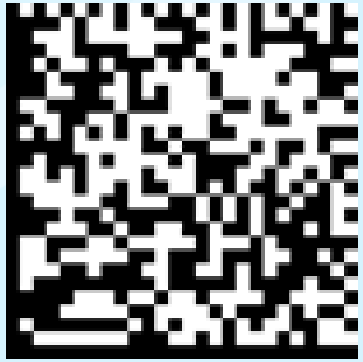
Remember - Why We Are Doing This

Current State: Linear



Linear barcode only has NDC
Lot number and Expiration only 'human readable'

Future State: 2D



Contain:

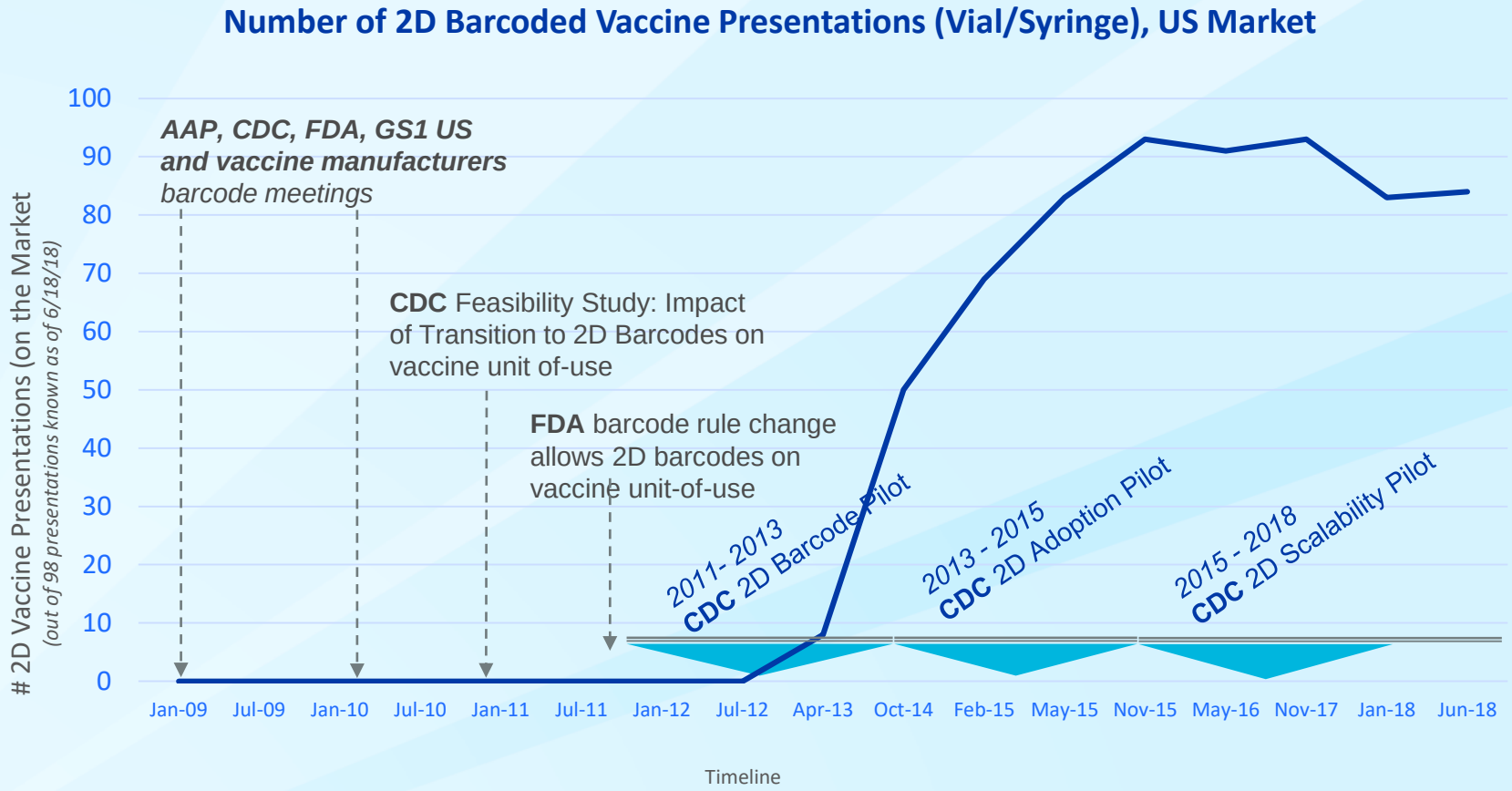
- Lot number
- Expiration date
- NDC code

'Human readable' still there!

48 ⟷ 2,335

Maximum Alphanumeric Character Capacity

2D Barcoded Vaccines Timeline



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

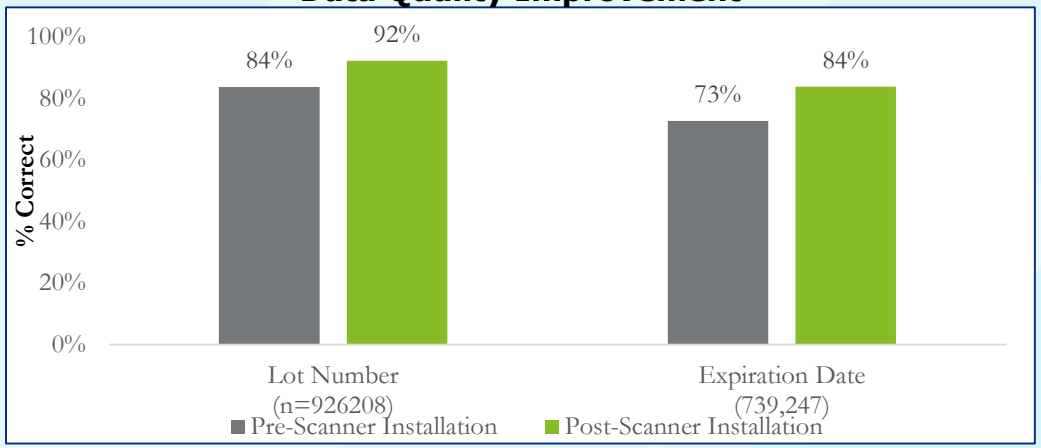
Participants

- 1 large healthcare system
- 27 sites
- 4 Vaccine manufacturers

***** Periods of primary data collection and project activities provided

2D Adoption Pilot (2013 – 2015)
Data Quality, Time Savings and User Experience

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

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

Difference statistically significant at an alpha of 0.05 (t(1,024)=30.91, p=0.001).

User Experience Feedback

75% of users agree
(86% of leaders)
Improves accuracy

60% of users agree
Easy to integrate into existing data recording process

60% of users agree
Easy to use

Benefits

- improved accuracy
- improved efficiency
- less manual entry of vaccine data

Challenges

- inconsistencies with scanning and scanners
- faded barcodes
- incorrect entries after scanning

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)***

Scalability Pilot

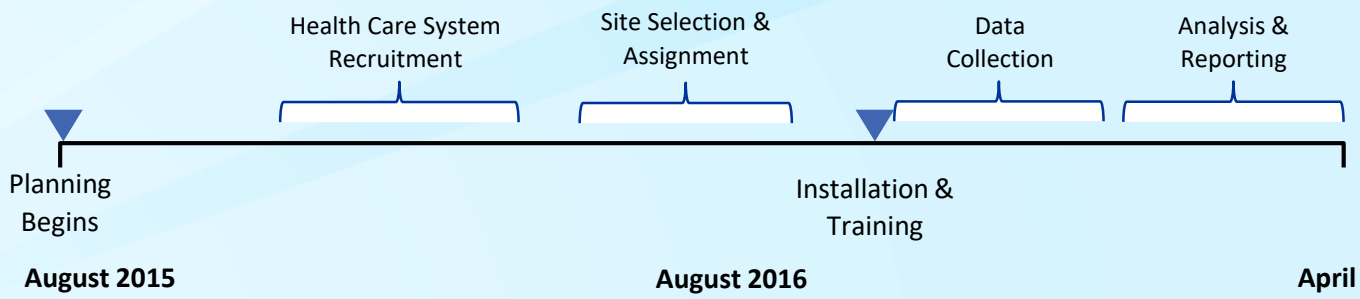
2D Scalability Pilot Overview - Recruitment

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 barcode scanning

Selection of Sites

- Selection of 27 Sites
  - Sites were selected based on:
    - Interest and willingness to participate
    - Diversity of sites 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

Sites 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

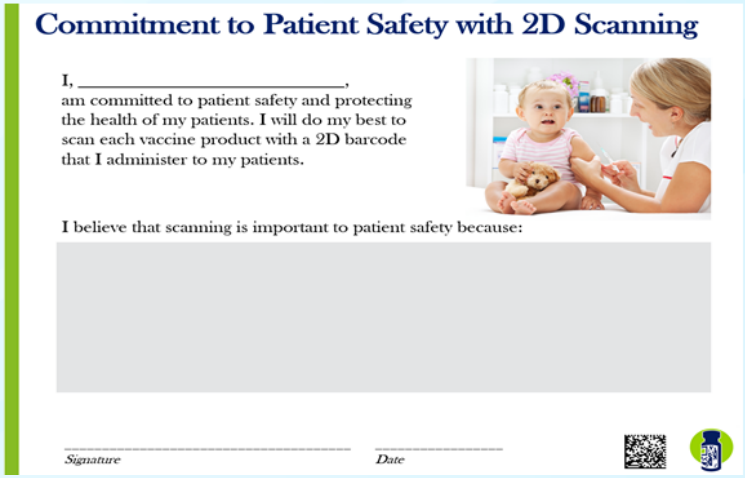
- Training + Adherence Report

Combination

Combination of all strategies:

- Training + Commitment Card + Adherence Report

Sample Scanning Commitment Card



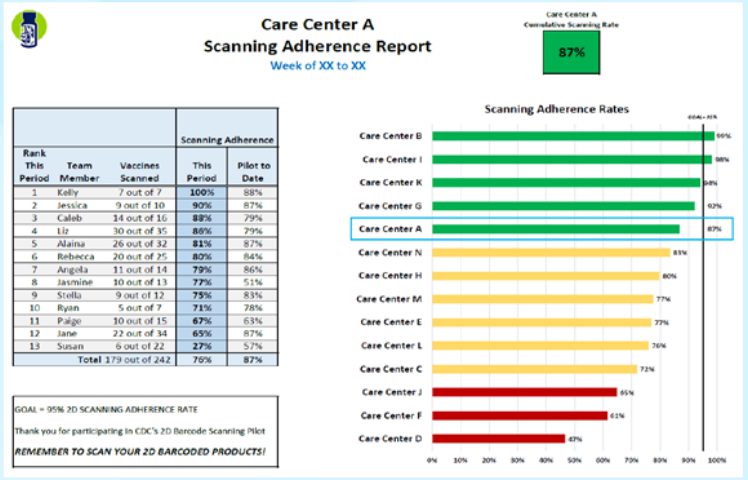
Commitment to Patient Safety with 2D Scanning

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 Date

Sample Scanning Adherence Report



Care Center A
Scanning Adherence Report
Week of XX to XX

Care Center A Cumulative Scanning Rate: 87%

Rank This Period	Team Member	Vaccines Scanned	Scanning Adherence This Period	Scanning Adherence Pilot to 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!

Scanning Adherence Rates

Care Center B
Care Center I
Care Center K
Care Center G
Care Center A
Care Center N
Care Center H
Care Center M
Care Center E
Care Center L
Care Center C
Care Center J
Care Center F
Care Center D

Scalability Pilot Data Sources

EMR Data files

Collected from all 27 participating sites, for vaccines administered prior to project start and during course of project period

Online Survey Data

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

Workflow Analysis (WFA)

High-level, on-site collaborations at each site

Detailed follow-up observations and time measurements at selected sites

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**

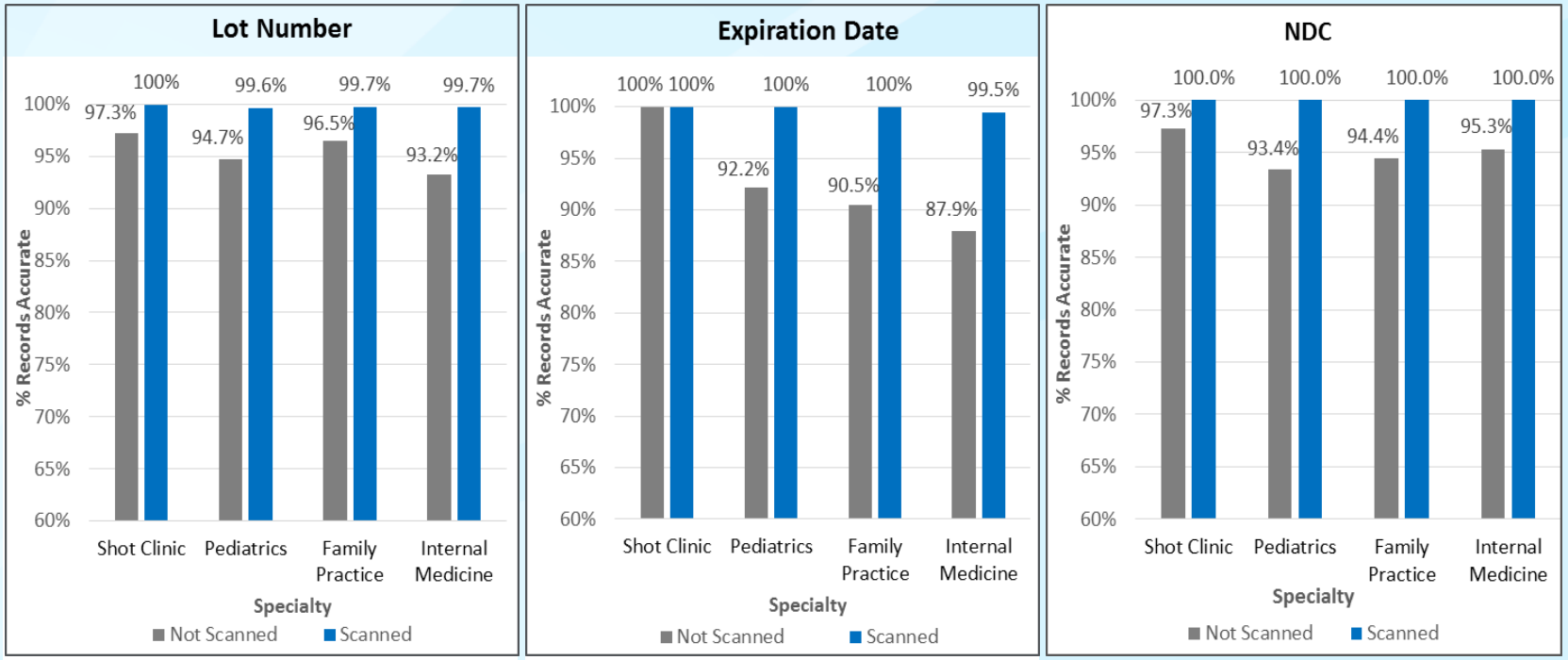
Challenges Documented

- Scanner locations, workflow fit, workarounds to the new scanning process, and staff buy-in **were challenges**

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 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.

Lessons Learned

1. **Scanning 2D vaccine barcodes improves data quality & saves time**

2. **2D barcode functionality of EMRs is key**

3. **Role of organization leadership in support of 2D barcode scanning is critical**

4. **Early planning and decisions make a big difference**
   - Revise workflow process and protocol ***from the start***
   - Strategically select scanner location ***with input from staff***

5. **Adherence strategies "nudge" participants to scan more frequently**
   - Highest scanning rates resulted from ***training plus another strategy*** to promote scanning
6. **Adjustments to resolve challenges mid-course improve scanning use**
   - Revisiting foundational planning decisions and making revisions improves scanning rates and buy-in
   - Offer troubleshooting support to staff to work through specific challenges
   - Prove data on scanning rates to staff and leaders
   - Engage leaders at sites and within organization to promote use

Four Pillars of Vaccine Barcode Scanning

Vaccine Manufacturers/Pharmaceutical

- 2D barcode all vaccines
- Label printing of high quality/contrast
- Consider 2D barcodes for medications

EMR Vendors

- EMR functionality supports scanning
- Indicator (scan flag) available to track scanning
- Pop-up alerts identify vaccines expired, not matching order (or other factors)

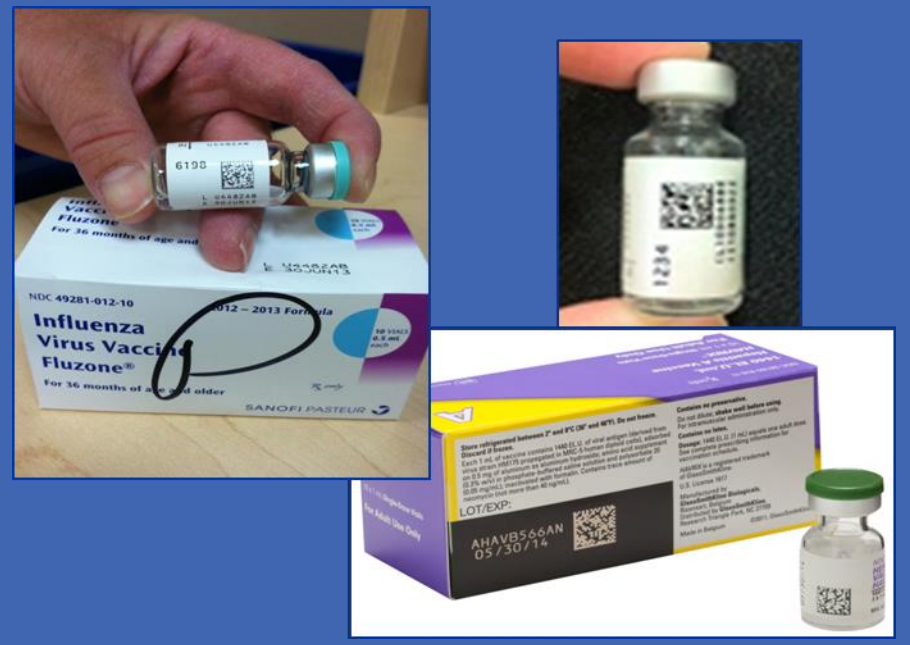
Scanner Vendors

- Scanners compatible with 2D barcodes/EMRs
- Easily configured to various EMRs
- Sensitivity to scan curved vials, prefilled syringes or labels with limited contrast

Health Systems/Practitioners

- Communicate needs and how vendors can support scanning for your organization
- Adoption/scaling of 2D vaccine scanning
- Ensure right scanner locations, workflow process and staff buy-in; share lessons learned

Next Steps

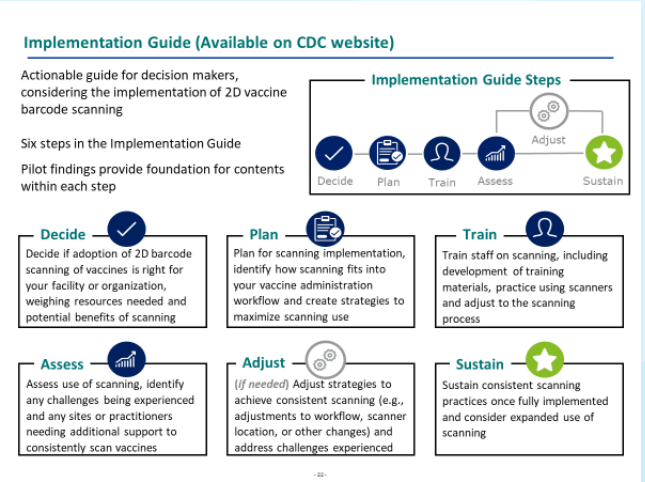

NDC 49281-012-10
Influenza
Virus Vaccine
Fluzone®
For 36 months of age and older
SANOFI PASTEUR
LOT/EXP:
AHAVB566AN
05/30/14

Share Pilot Findings and Encourage Adoption

Disseminate Pilot Findings to Share Knowledge

- Report of key pilot findings and methodology
- Implementation Guide for decision makers - considering 2D barcode scanning

- Other materials including peer-reviewed publications, newsletters and articles, and presentations



Communicate Role with 4 Pillars to Promote Barcode Scanning

- Vaccine manufacturers
- Health Information System (EMR) vendors / developers
- Scanner vendors
- Providers - Practitioners

Continue to provide infrastructure support, e.g. 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

Drug Supply Chain Security Act (DSCSA)

DSCSA became law in November 2013.[1]

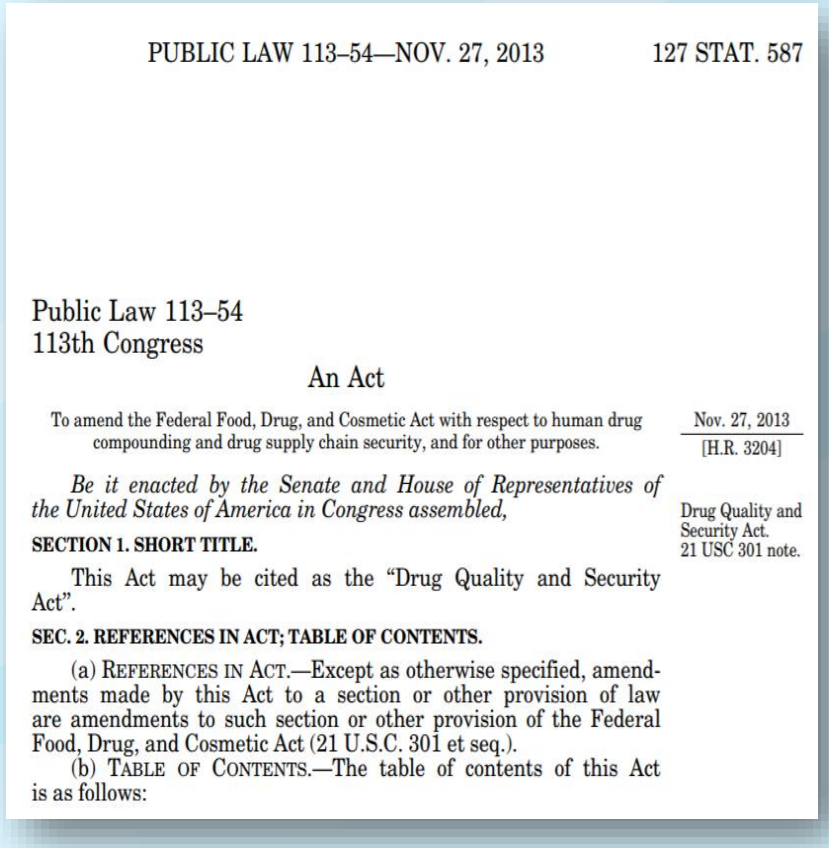
Purpose: To identify and trace prescription drugs through U.S. supply chain

Requires manufacturers and repackagers "to put a unique product identifier on certain prescription drug packages"

Data carrier – 2D barcode

Encoded with …

- National Drug Code (NDC) - embedded in GTIN
- Serial Number
- Expiration Date
- Lot Number



PUBLIC LAW 113–54—NOV. 27, 2013 127 STAT. 587

Public Law 113–54
113th Congress

An Act

To amend the Federal Food, Drug, and Cosmetic Act with respect to human drug compounding and drug supply chain security, and for other purposes.

Nov. 27, 2013
[H.R. 3204]

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

Drug Quality and Security Act.
21 USC 301 note.

SECTION 1. SHORT TITLE.

This Act may be cited as the "Drug Quality and Security Act".

SEC. 2. REFERENCES IN ACT; TABLE OF CONTENTS.

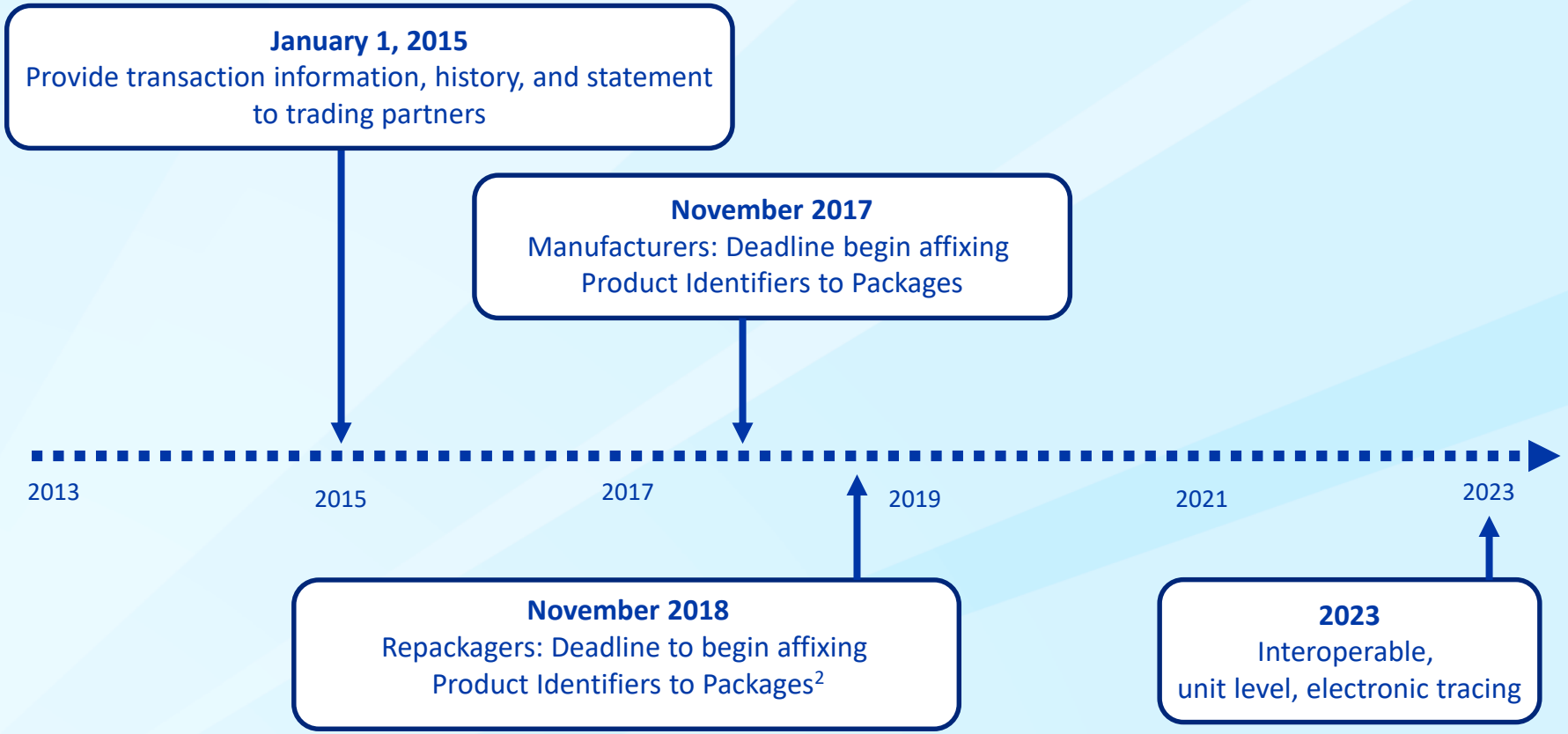
(a) REFERENCES IN ACT.—Except as otherwise specified, amendments made by this Act to a section or other provision of law are amendments to such section or other provision of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

(b) TABLE OF CONTENTS.—The table of contents of this Act is as follows:

Timeline: Requirements will be phased in over the course of 10 years. The final phase will occur in 2023. [1]

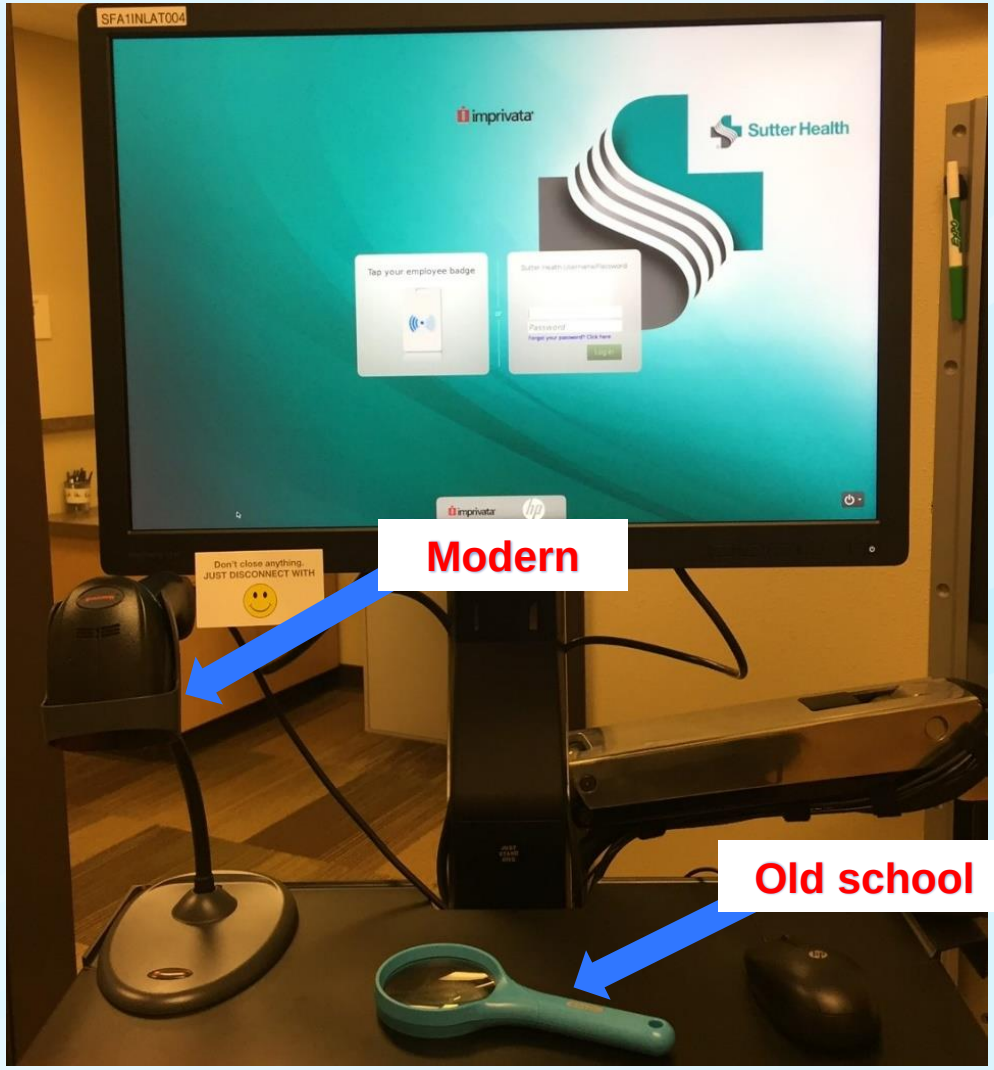
1. Food and Drug Administration. Drug Supply Chain Security Act (DSCSA): Title II of the Drug Quality and Security Act (2013).

DSCSA Timeline



2: Product Identifier Requirements Under the Drug Supply Chain Security Act – Compliance Policy

Where to find more information

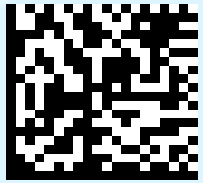


Visit the CDC 2D barcode page for 2D vaccine barcode resources: http://www.cdc.gov/vaccines/programs/iis/2d-vaccine-barcodes/

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