

# Two-Dimensional (2D) Vaccine Barcoding

**2015 AIRA Annual Conference**  
**April 23, 2015**

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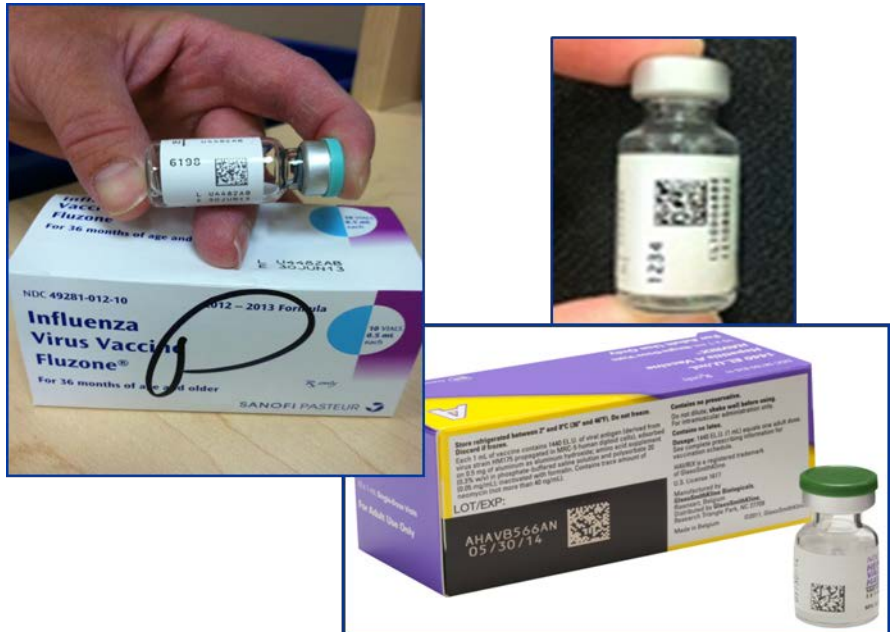
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# Session Outline

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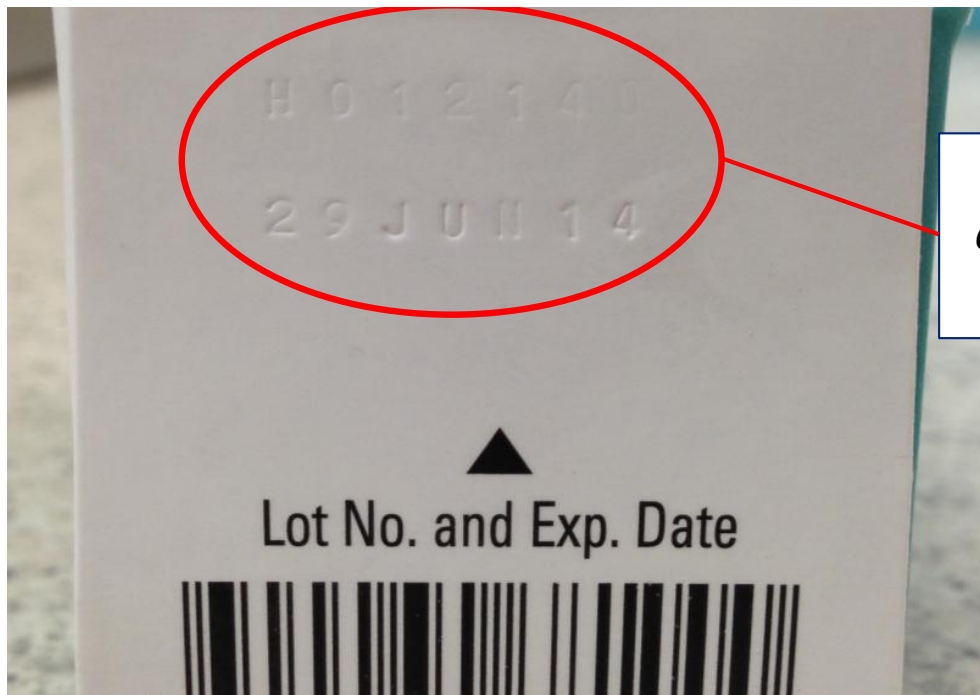
- Background
- Pilots – Overview
- Findings & Systems Lessons Learned
- Next Steps



# Background

## “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.”



*Lot number and  
expiration date stamped  
on M-M-R package*

“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.”

# CDC 2D Barcoded Vaccine Initiatives

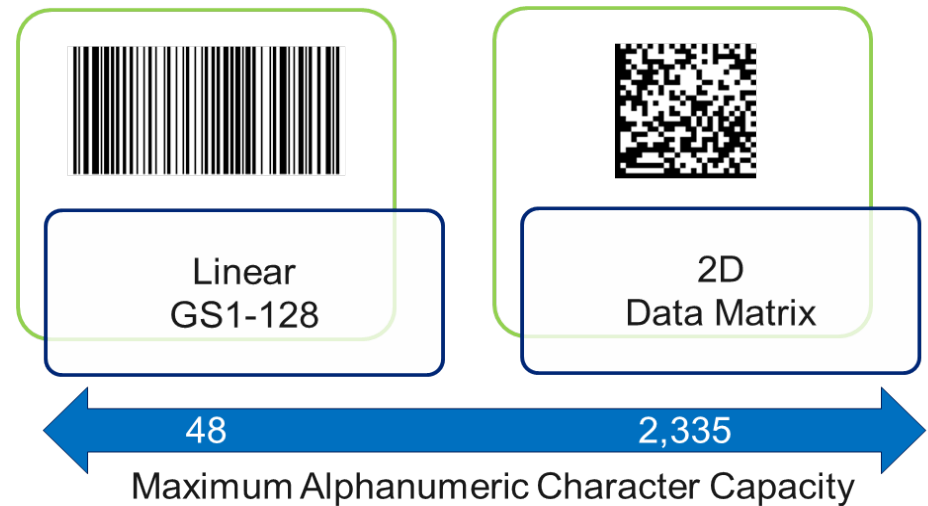
## 2D Barcoded Vaccine Information



### What's in a 2D barcode on a vaccine?

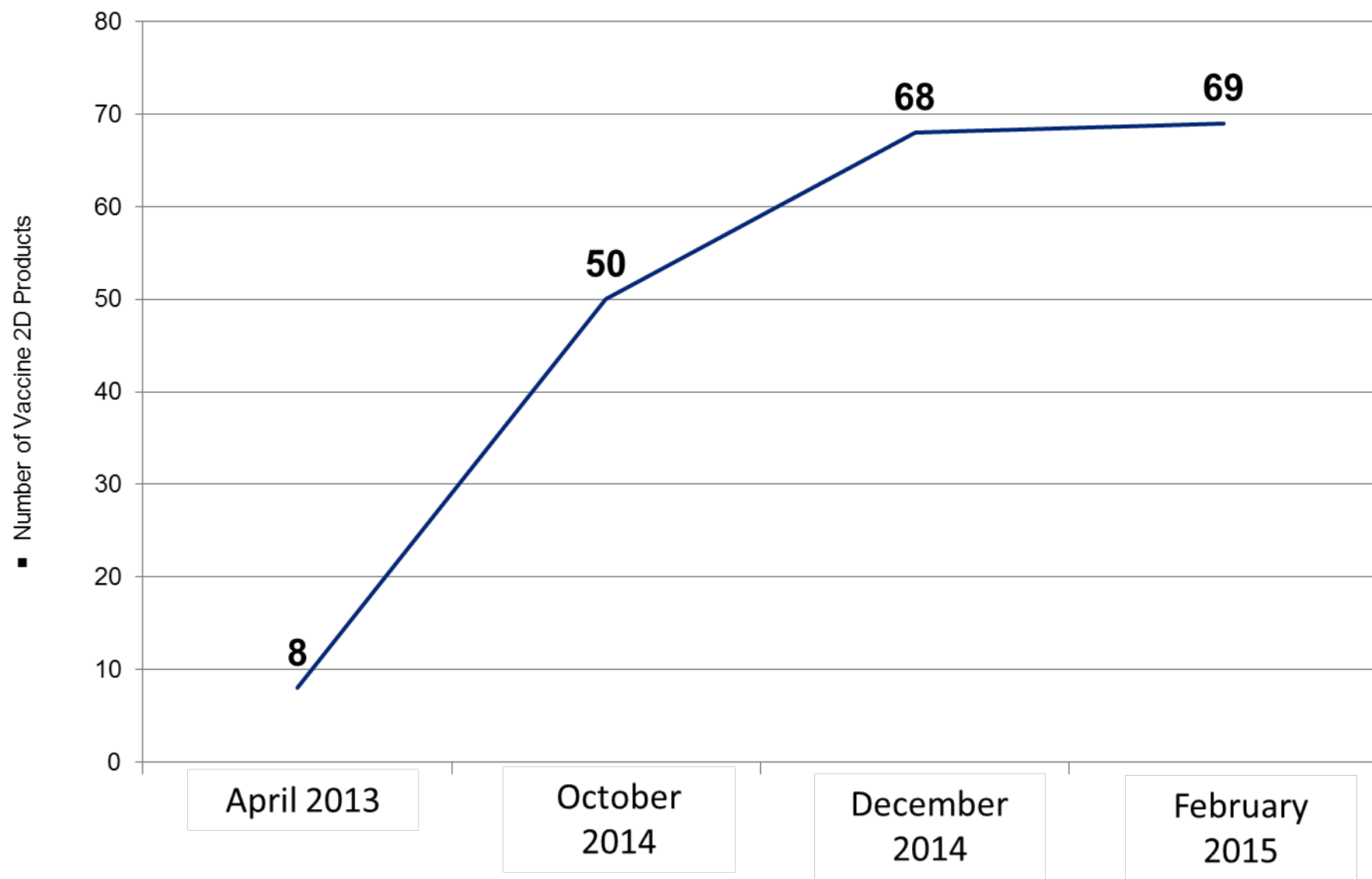
Vaccine two-dimensional (2D) barcodes contain more data than traditional, linear barcodes.

Vaccine Barcode Contents by Type	
Linear	2D
NDC	NDC Lot Number Expiration Date



2D Barcodes provide a significant data capacity increase over linear barcodes

## Number of 2D Barcoded Vaccine Products in the Marketplace



## Unit of Use Two-Dimensional (2D) Barcoded Vaccines on VFC Price List – February 2015

	Total 2D Shipping Total Products	% Total 2D Shipping/Total Products	Total 2D VFC Products Total VFC	% Total 2D VFC Products/Total VFC
<b>GSK</b>	25 30	83%	21 25	84%
<b>Merck</b>	25 34	74%	15 20	75%
<b>Sanofi Pasteur</b>	19 38	50%	14 15	93%
<b>Pfizer</b>	0 3	0%	0 1	0%
<b>Novartis</b>	0 6	0%	0 4	0%
<b>Medimmune</b>	0 3	0%	0 1	0%
<b>Totals</b>	69 114	61%	50 66	76%

# Pilots - Overview



# CDC 2D Barcoded Vaccine Initiatives

## Two Pilots



### 2D Pilot (2D) - Assess Impact

Initial Pilot (2011-2014)

#### Objectives

- Assess 2D impact to vaccination data quality
- Assess 2D workflow impact
- Identify 2D scanning opportunities and challenges
- Implement 2D barcodes on Vaccine Information Statements (VIS)

#### Participants

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

#### Data

- 8 months of vaccine administration data
- Workflow analysis
- Participant surveys

### 2D Adoption (2DA) - Facilitate Adoption

Adoption Pilot (2013 – 2015)

#### Objectives

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

#### Participants

- 100 Diverse practices
- 7 Immunization Awardees
- 3 Vaccine manufacturers

#### Data

- 4- 7 months of vaccine administration data
- Workflow analysis
- Participant surveys



# Pilot Vaccine and Information Workflow

## Manufacturer



Add 2D barcode to primary packaging :

- Data Matrix barcode containing
  - GTIN – NDC
  - Expiration date
  - Lot number
- Distribution to pilot participants via existing vaccine supply chain.

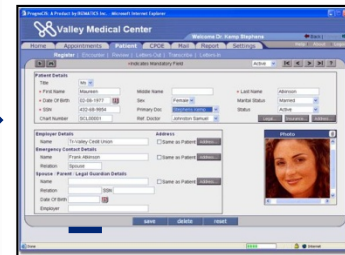
## Providers



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

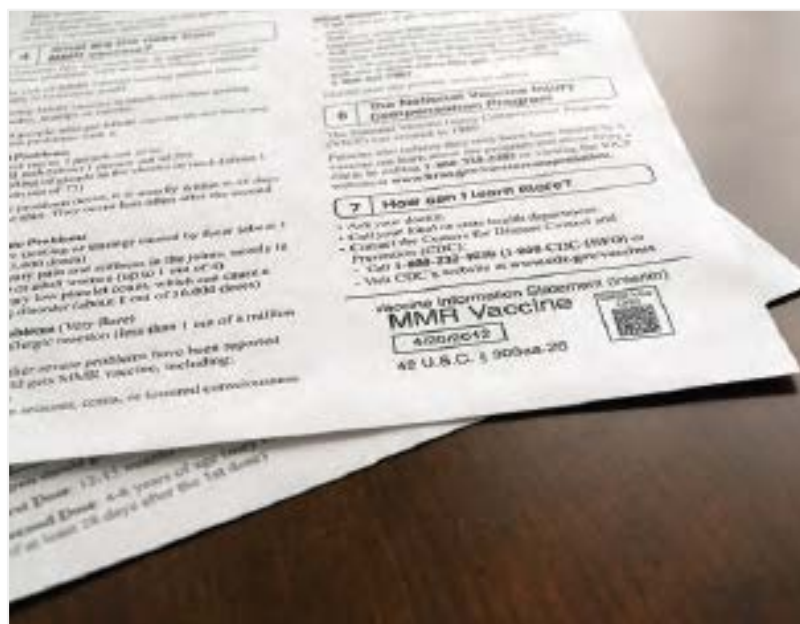
Receive data from the immunizers' record system:

- Acts as a source of evaluation for data accuracy and completeness

# Vaccine Information Statements (VIS) - 2D Barcoding

## Key Points

- All VIS documents - 2D barcoded
- Barcodes: VIS Identifiers & Publication Date
- VIS Lookup Table & CVX-VIS Maps



- Tell your doctor if the person getting the vaccine:
  - Has HIV/AIDS, or another disease that affects the immune system
  - Is being treated with drugs that affect the immune system, such as steroids
  - Has any kind of cancer
  - Is being treated for cancer with radiation or drugs
  - Has ever had a low platelet count (a blood disorder)
  - Has gotten another vaccine within the past 4 weeks
  - Has recently had a transfusion or received other blood products

Any of these might be a reason to not get the vaccine, or delay vaccination until later.

### 4 What are the risks from MMR vaccine?

A vaccine, like any medicine, is capable of causing serious problems, such as severe allergic reactions.

The risk of MMR vaccine causing serious harm, or death, is extremely small.

Getting MMR vaccine is much safer than getting measles, mumps or rubella.

Most people who get MMR vaccine do not have any serious problems with it.

#### Mild Problems

- Fever (up to 1 person out of 6)
- Mild rash (about 1 person out of 20)
- Swelling of glands in the cheeks or neck (about 1 person out of 75)

If these problems occur, it is usually within 6-14 days after the shot. They occur less often after the second dose.

#### Moderate Problems

- Seizure (jerking or staring) caused by fever (about 1 out of 3,000 doses)
- Temporary pain and stiffness in the joints, mostly in teenage or adult women (up to 1 out of 4)
- Temporary low platelet count, which can cause a bleeding disorder (about 1 out of 30,000 doses)

#### Severe Problems (Very Rare)

- Serious allergic reaction (less than 1 out of a million doses)
- Several other severe problems have been reported after a child gets MMR vaccine, including:
  - Deafness
  - Long-term seizures, coma, or lowered consciousness

- Permanent brain damage
- These are so rare that it is hard to tell whether they are caused by the vaccine.

### 5 What if there is a serious reaction?

What should I look for?

- Any unusual condition, such as a high fever or unusual behavior. Signs of a serious allergic reaction can include difficulty breathing, hoarseness or wheezing, hives, paleness, weakness, a fast heart beat or dizziness.

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 doctor to report the reaction by filing a Vaccine Adverse Event Reporting System (VAERS) form. Or you can file this report through the VAERS web site at [www.vaers.hhs.gov](http://www.vaers.hhs.gov), or by calling 1-800-822-7967.

VAERS does not provide medical advice.

### 6 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](http://www.hrsa.gov/vaccinecompensation).

### 7 How can I learn more?

- Ask your doctor.
- 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](http://www.cdc.gov/vaccines)

Vaccine Information Statement (Interim)

MMR Vaccine

4/20/2012

42 U.S.C. § 300aa-26



# Findings & Lessons Learned

# Data Sources: 2D and 2D Adoption (2DA) Pilots

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## 2D Pilot

### Vaccination Data

**3,034,203** Vaccination Records

**3.3%** of Vaccination Records - 2D Barcoded

### Survey Data

User Experience Survey 1: **293** individuals completed survey (171 sites)

User Experience Survey 2: **295** individuals completed survey (162 sites)

### Workflow Analysis Participation

**13** Participants during pilot (WF1); **10** Participants post pilot (WF2) – subset of the above 13; **10** Participants in follow up WFA – not in previous WFA

## 2D Adoption (2DA) Pilot\*

### Vaccination Data

**1,424,877** Vaccination Records

**18.1%** of Vaccination Records - 2D Barcoded

### Survey Data

Leader Experience Survey: **67** individuals completed survey (67 sites : 82% response rate)

User (Staff) Experience Survey: **116** individuals completed survey (63 sites : 55% response rate of individuals; 77% response rate of sites)

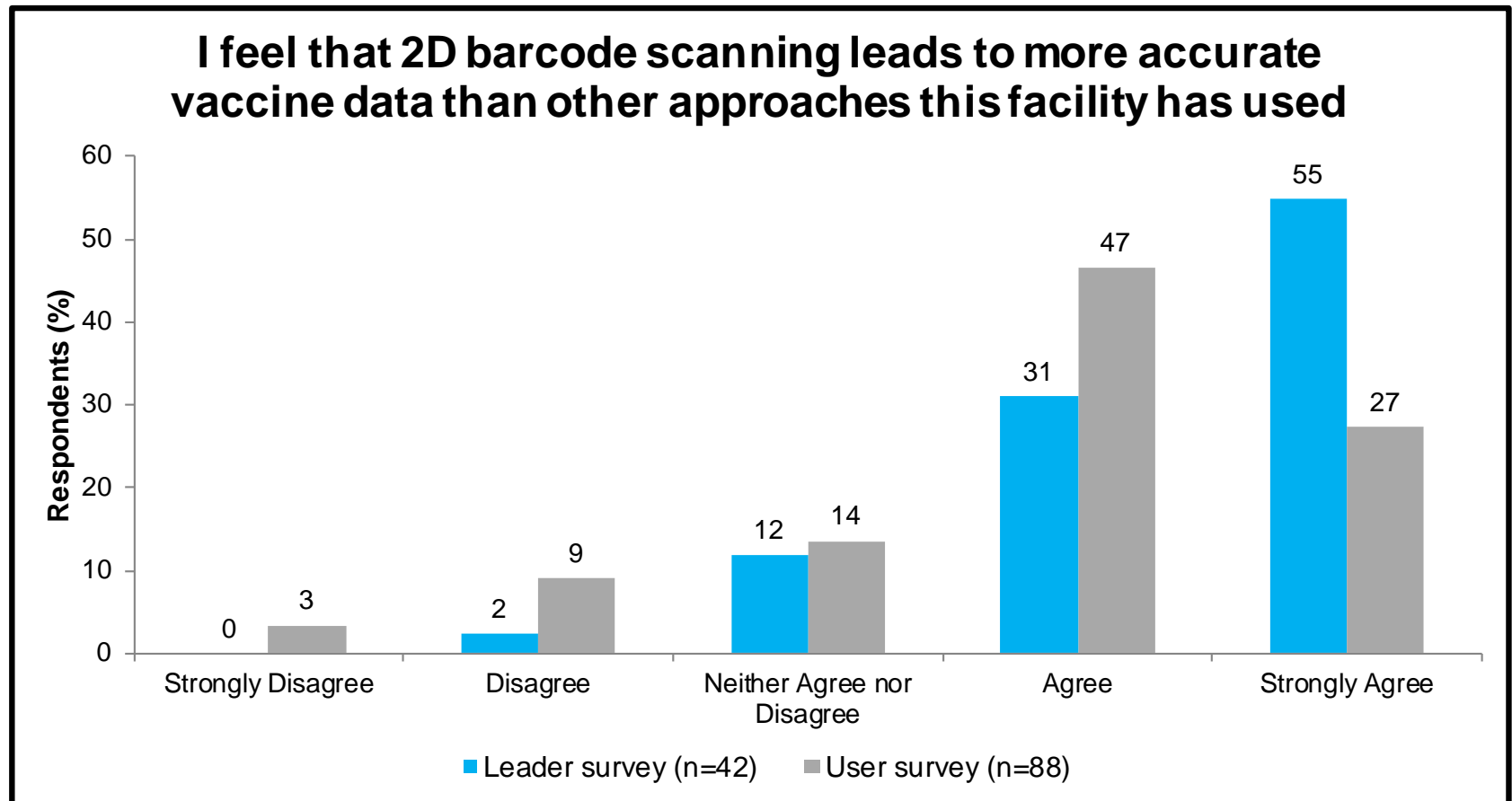
### Workflow Analysis Participation

**20** facilities visited during pilot (observation of work process, time measurements of data entry, and interviews with facility staff)

\*All 2DA data are preliminary

## 2DA Surveys – Perceived Accuracy with 2D Scanning\*

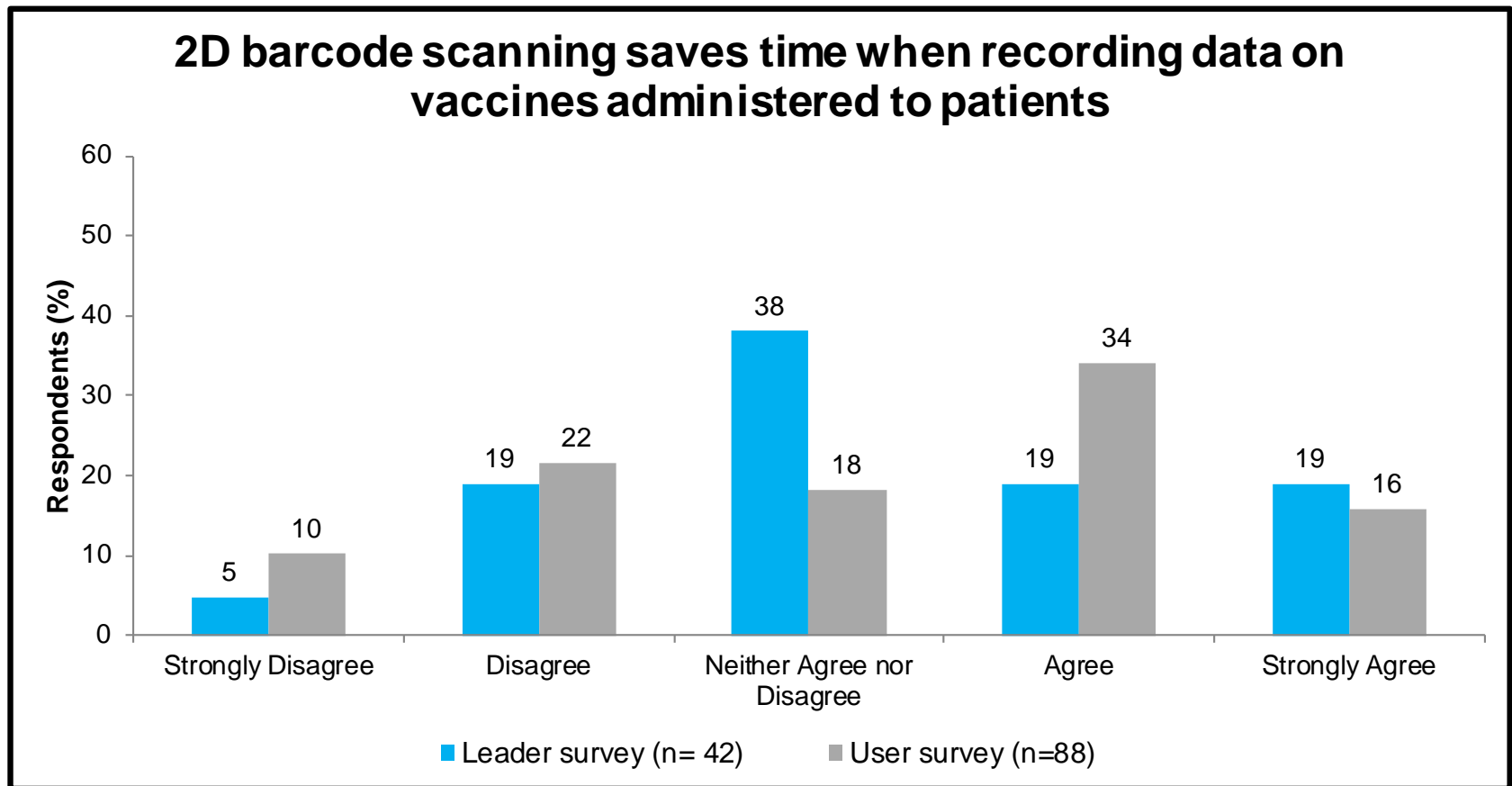
- Strong positive perception by both Leaders (blue) and direct Users (grey) that 2D barcode scanning improves accuracy of data compared to approaches previously used



\*All 2DA data are preliminary

## 2DA Surveys – Perceived Time Savings with 2D Scanning\*

- Perceptions of time savings differed by perspective of Leaders (blue) and direct Users (grey), though sizable numbers in both groups perceived time savings with 2D scanning
- Most frequent response from Leaders was neutral option; Users most frequently selected agreement with time savings option



\*All 2DA data are preliminary

## 2DA Surveys - Comments

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### Challenges

- “Still had to manually enter data since only exp date and lot no. were encoded” (Leader)
- “Will be better when all vaccines have the code” (User)
- “When MA's had to give a vaccine with a barcode and also a vaccine without a barcode, sometimes they defaulted to just not using the scanner because it was easier to do one process instead of two.” (Leader)
- “Simply not having all vaccines 2D barcoded. Often I give a set of vaccines with only 1 of the 3 containing a 2D barcode so then you are using both systems which is disruptive.” (User)

### Benefits

- “We have had far less data entry errors since implementing the scanners” (Leader)
- “This method of data entry decreases error in vaccine lot numbers and expiration dates.” (User)
- “It definitely saves time when all of your vaccines have barcodes, and is more accurate, no transposing digits, etc.” (Leader)
- “It is a fast way to document important information that often does not get recorded in the computer system.” (User)
- “The other advantage is having the data easily accessible for a recall...” (Leader)



## 2D Pilot - Key Findings

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1. Results confirm a positive effect on vaccine data accuracy and completeness
2. Providers are willing to adopt practices for 2D vaccine barcode use but not until the majority of vaccines are 2D barcoded
3. Vaccine manufacturers have demonstrated a commitment to the application of 2D barcodes on the unit-of-use
4. Pharmaceutical supply chain stakeholders have indicated 2D will be the data carrier of choice

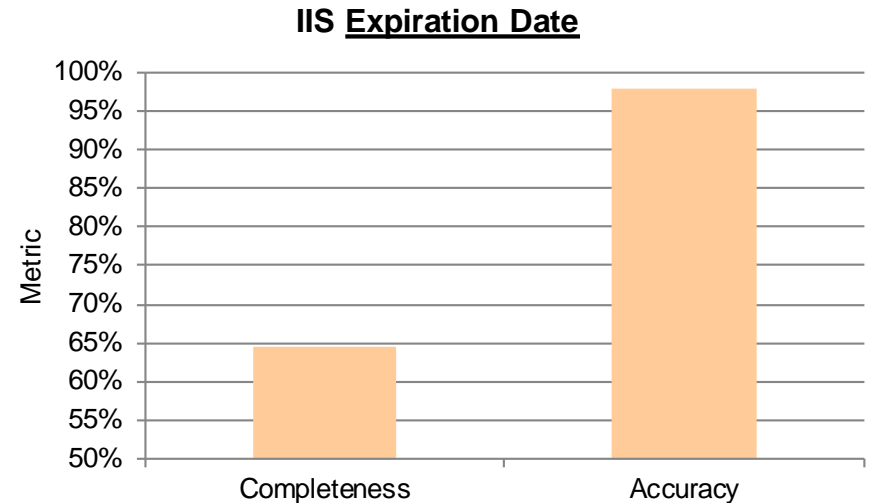
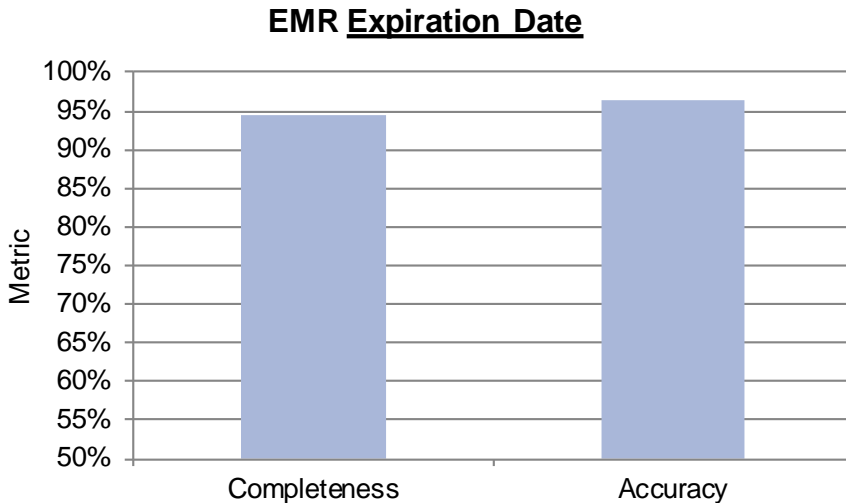
## 2D Pilot - Systems Lessons Learned

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- Health Information Management systems, e.g. EMR & IIS, lack 2D barcode functionality
- Scanners – Able to read 2D vaccine barcodes
  - Vials/Syringes – Contain both linear and 2D barcodes
  - Clinical participants able to scan 2D barcodes
- NDC Crosswalk Tables - for Unit-of-Use / Unit-of-Sale Packaging
  - Inventory NDC – Vaccine Administration NDC
  - Posted on CDC Code Set web-page
- Lot Number Patterns by Manufacturer and Vaccine Table – for Unit-of-Use / Unit-of-Sale Packaging - DRAFT
- Expiration Date Data in the IIS Data Set

## 2D Pilot - Preliminary Findings: EMR vs. IIS Expiration Date Quality

- Completeness is high (>90%) in EMR and low in IIS (<65%)
- Accuracy is similar in EMR and IIS



Completeness is high (>90%) in EMR and low in IIS (<65%)



## 2D Pilot - Expiration Date Data – IIS Data Set Findings

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### ☐ Research & Findings

- Expiration Date data was sent from Providers but not loaded into IIS database
- Expiration Date data was being derived from other fields

### ☐ Recommendation: capture Expiration Date data sent from providers into the IIS

# 2D Pilot Reports, Resources, and Tools

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## Summary Report of the Pilot (2D)

### Impact of 2D Barcodes on Vaccine Secondary Packaging

- Evaluates how the introduction of 2D barcodes onto unit of sale (package) will impact participants in the vaccine supply chain

### EHR-IIS 2D Barcode Functional Capabilities Report

- Provides considerations for the implementation of 2D scanning functionality based on EHR-IIS interviews
- Updated November 2014:
  - Read entire Lot Number
  - Expiration Date format
  - Number of VIS documents per vaccine

## Vaccines Shipping with 2D Barcodes table

## NDC Crosswalk Tables

## Lot Number Patterns by Manufacturer and Vaccine (Draft)

# Next Steps

## Next Steps

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- Complete - Adoption Strategies for 2D Barcodes – 2DA Pilot
- Monitor 2D Barcoded Vaccines – in the supply chain
- Maintain NDC Crosswalk Table
- Develop & Maintain table for Lot Number Patterns by Manufacturer and Vaccine
- Maintain VIS Barcodes and Supporting Tables
- Encourage EMR/IIS vendors to incorporate 2D barcode functionality
- Recommendation: IIS to capture Expiration Date data sent from providers into the IIS database
- Collaboration with Partner Organization and Vaccine Manufacturers
- Monitor Drug Supply Chain Security Act (DSCSA)

# 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

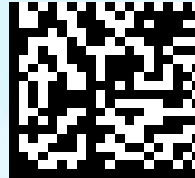
### For Manufacturers

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





# Thank You & A Special Thanks to the Pilot Participants!



**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](mailto:cdcinfo@cdc.gov) Web: [www.cdc.gov](http://www.cdc.gov)

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