Implementation Pilot for Two-Dimensional Vaccine Barcode Utilization

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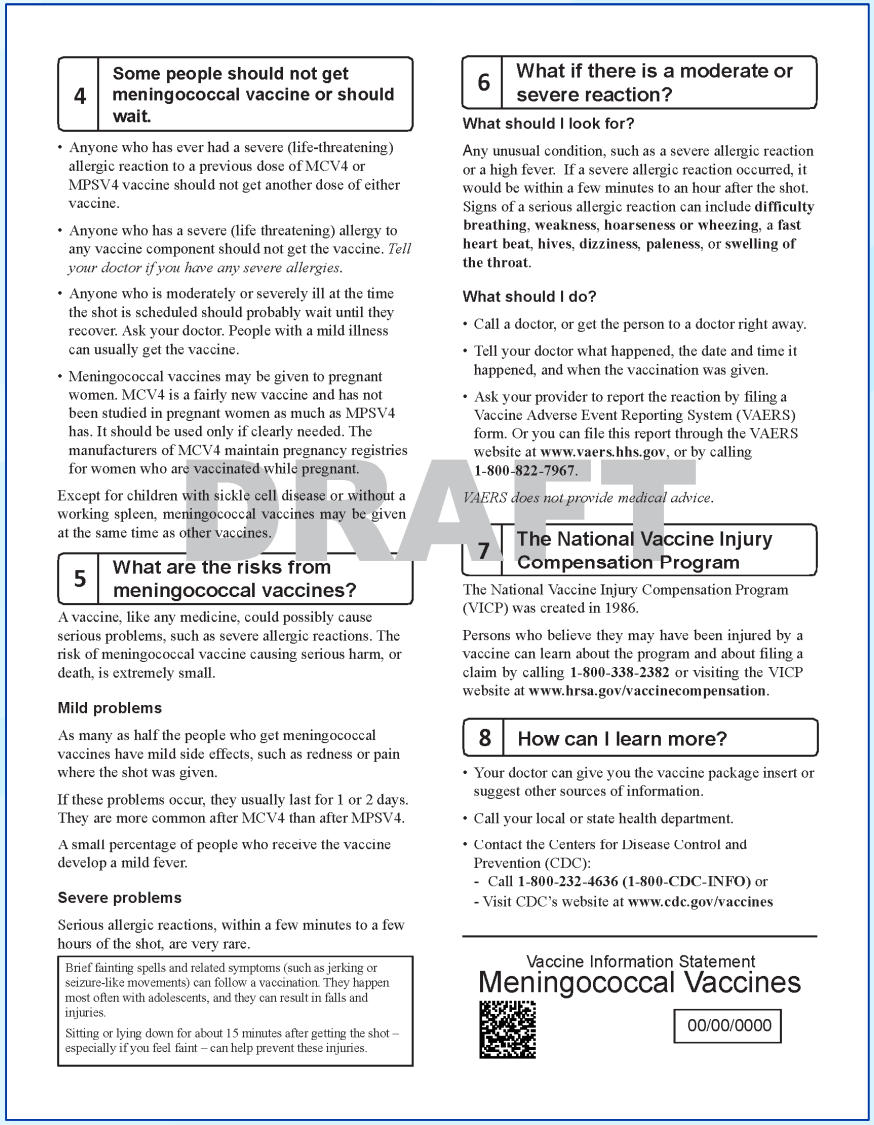
2D BARCODING HISTORY AND PUBLIC HEALTH

National Childhood Vaccine Injury Act (NCVIA)

- **Requires documentation of:**
  - Manufacturer
  - Lot number
  - Provider identity
  - Date administered
  - Vaccine Information Statement (VIS)
    - version date
    - date provided
- **Provide copy of the relevant VIS prior to administration**
- **Report serious adverse events to CDC/FDA's Vaccine Adverse Event Reporting System (VAERS)**

VIS Encoding

- **Identified barcode**
  - Selected GS1's Global Document Type Identifier (GDTI) to encode VIS document type
  - Added VIS edition date to GS1 DataMatrix
- **Developed technical assistance documents for users**
- **Added barcode to all up-to-date VIS**



4 Some people should not get meningococcal vaccine or should wait.

- Anyone who has ever had a severe (life-threatening) allergic reaction to a previous dose of MCV4 or MPSV4 vaccine should not get another dose of either vaccine.
- Anyone who has a severe (life threatening) allergy to any vaccine component should not get the vaccine. *Tell your doctor if you have any severe allergies.*
- Anyone who is moderately or severely ill at the time the shot is scheduled should probably wait until they recover. Ask your doctor. People with a mild illness can usually get the vaccine.
- Meningococcal vaccines may be given to pregnant women. MCV4 is a fairly new vaccine and has not been studied in pregnant women as much as MPSV4 has. It should be used only if clearly needed. The manufacturers of MCV4 maintain pregnancy registries for women who are vaccinated while pregnant.

Except for children with sickle cell disease or without a working spleen, meningococcal vaccines may be given at the same time as other vaccines.

5 What are the risks from meningococcal vaccines?

A vaccine, like any medicine, could possibly cause serious problems, such as severe allergic reactions. The risk of meningococcal vaccine causing serious harm, or death, is extremely small.

Mild problems

As many as half the people who get meningococcal vaccines have mild side effects, such as redness or pain where the shot was given.

If these problems occur, they usually last for 1 or 2 days. They are more common after MCV4 than after MPSV4.

A small percentage of people who receive the vaccine develop a mild fever.

Severe problems

Serious allergic reactions, within a few minutes to a few hours of the shot, are very rare.

Brief fainting spells and related symptoms (such as jerking or seizure-like movements) can follow a vaccination. They happen most often with adolescents, and they can result in falls and injuries.

Sitting or lying down for about 15 minutes after getting the shot – especially if you feel faint – can help prevent these injuries.

6 What if there is a moderate or severe reaction?

What should I look for?

Any unusual condition, such as a severe allergic reaction or a high fever. If a severe allergic reaction occurred, it would be within a few minutes to an hour after the shot. Signs of a serious allergic reaction can include **difficulty breathing**, **weakness**, **hoarseness or wheezing**, a **fast heart beat**, **hives**, **dizziness**, **paleness**, or **swelling of the throat**.

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 provider to report the reaction by filing a Vaccine Adverse Event Reporting System (VAERS) form. Or you can file this report through the VAERS website at **www.vaers.hhs.gov**, or by calling **1-800-822-7967**.

VAERS does not provide medical advice.

7 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**.

8 How can I learn more?

- Your doctor can give you the vaccine package insert or suggest other sources of information.
- 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**

Vaccine Information Statement
Meningococcal Vaccines

00/00/0000

DRAFT

Barcodes on Vaccines

Linear

- Contains National Drug Code (NDC) only
- Other variables cannot be included due to space constraints
  - Need to be recorded manually
- Currently on all vaccine products and required by FDA

Two-Dimensional (2D)

- Can contain NDC and additional information, such as expiration date and lot number
- Replace (with an FDA waiver) or coexist with linear barcodes on vaccine vials and syringes

Data Completeness and Accuracy

- **Completeness**
  - Approximately 20% of primary VAERS reports are missing lot number[1]
  - 55-65% of Immunization Information Systems (IIS) records are missing lot numbers[2]
- **Accuracy**
  - Study conducted at UCLA's Children's Health Center found that 10% of immunized children had transcription errors in their electronic immunization records[3]
  - A review of MEDMARX database found that 10% of all vaccination errors were transcription or documentation errors[4]

[1] CDC, unpublished data, VAERS

[2] 2005-2009 Immunization Information Systems Annual Report. Accessed at: http://www.cdc.gov/vaccines/programs/iis/rates/default.htm

[3] Wilton R, et al. Evaluating the accuracy of transcribed computer-stored immunization data. Pediatrics. 1994 Dec;94(6 Pt 1):902-6.

[4] Bundy DG, et al. Pediatric vaccination errors: Application of the "5 Rights" framework to a national error reporting database. Vaccine. Volume 27, Issue 29, 12 June 2009, Pages 3890–3896

Potential Benefits of 2D Barcodes

- Improve accuracy of immunization information recorded in patient health records
- Improve consistency in availability of immunization information captured in IIS and VAERS reports
- Lot number information can help identify a safety concern with a specific lot and identify patients who may have been vaccinated with that lot in the case of a recall
- Reduce administration errors (incorrect, expired, or recalled vaccine)

PILOT IMPLEMENTATION

Pilot Implementation: Objectives

- **Assist in implementation of 2D barcoded vaccines**
- **Examine implementation challenges at all stages from vaccine production to vaccination encounter**
- **Evaluate use of 2D barcodes**
  - Data completeness and accuracy of vaccinations recorded
  - User experience
  - Work flow analysis and time and motion studies
- **Document best practices and lessons learned**

Pilot Information

- **History**
  - Sept 2011 - 2D Barcode Pilot Initiated
  - Aug 2012 – Apr 2013 – Implementation Period
- **Participants**
  - 2 Vaccine Manufacturers
    - 8 vaccines
  - 217 Immunizers
  - 10 Immunization Information Systems
- **Vaccination Records Assessed**

	EMR	IIS
Total	916,000	1.1M
2D Barcoded	53,000	46,000

GS1 2D Datamatrix Vaccine Date Items

Contained Information	Description
Vaccine Global Trade Item Number (GTIN) with embedded NDC	14 characters long, contains National Drug Code (NDC)
Vaccine Expiration Date	6 characters long, in “yymmdd” format, e.g. 120726
Vaccine Batch/Lot Number	Up to 10 characters long, e.g. CFA111

Pilot Vaccine and Information Workflow

Manufacturer

Add 2D barcode to primary packaging :

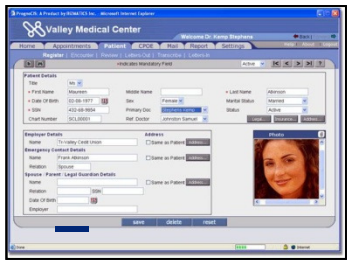
- Data Matrix barcode containing
  - GTIN
  - Expiration date
  - Lot number
- Distribution to pilot participants via existing vaccine supply chain.

Immunizer

Scan vaccine data:

- Entering vaccine into inventory
- Administering vaccine

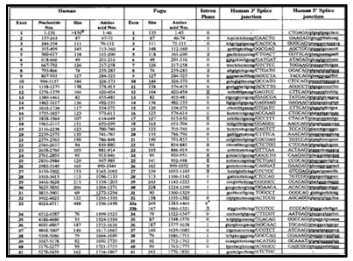
Record System



Record system types:

- Electronic medical records (EMR)
- Immunization Information Systems (IIS)
- Track GTIN, expiration date, and lot number

IIS



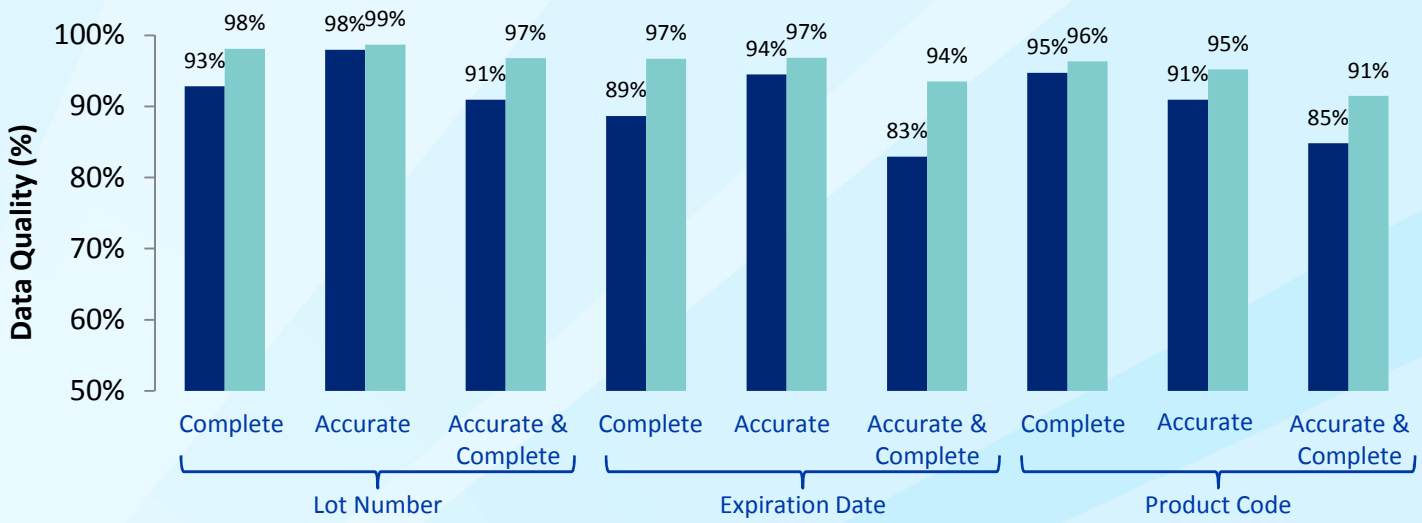
Receive data from the immunizers' record system:

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

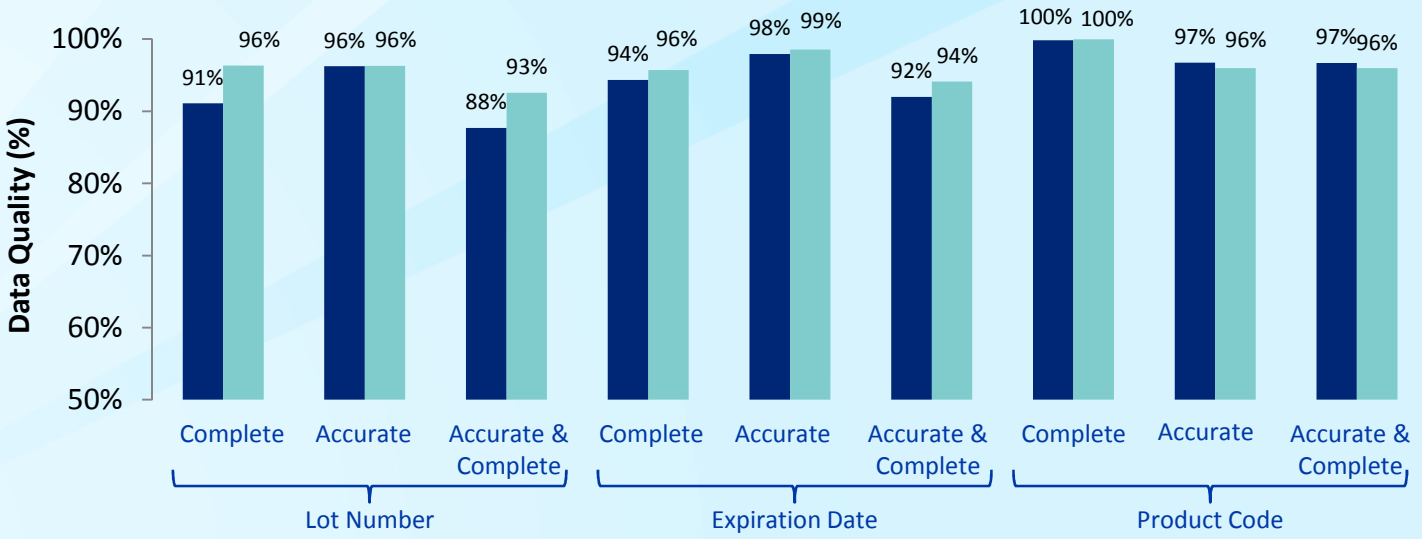
PRELIMINARY RESULTS

Key Findings

Average EMR/EHR Pre- and Post-Implementation Data Quality

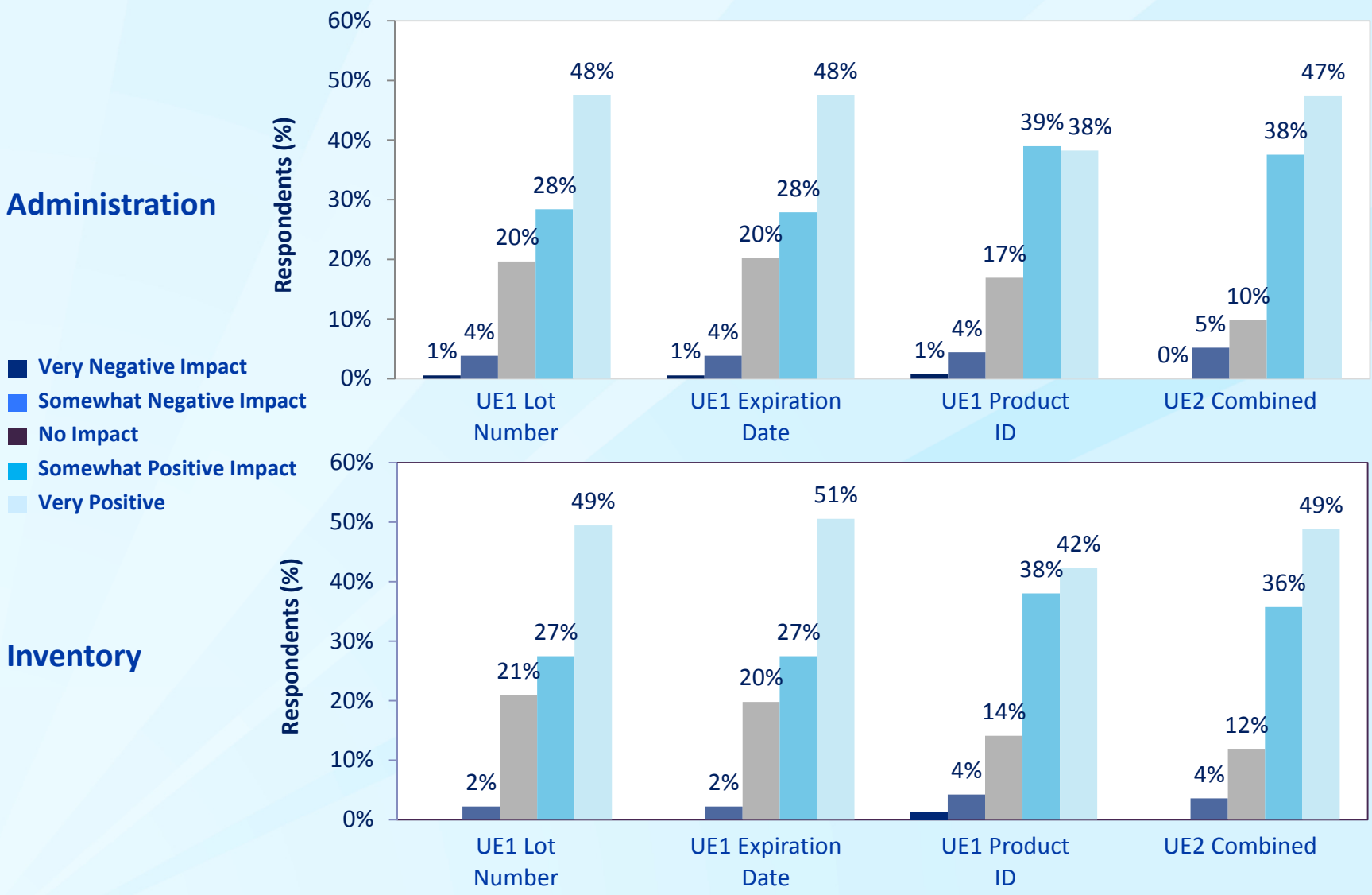


Average IIS Pre- and Post-Implementation Data Quality



Preliminary results

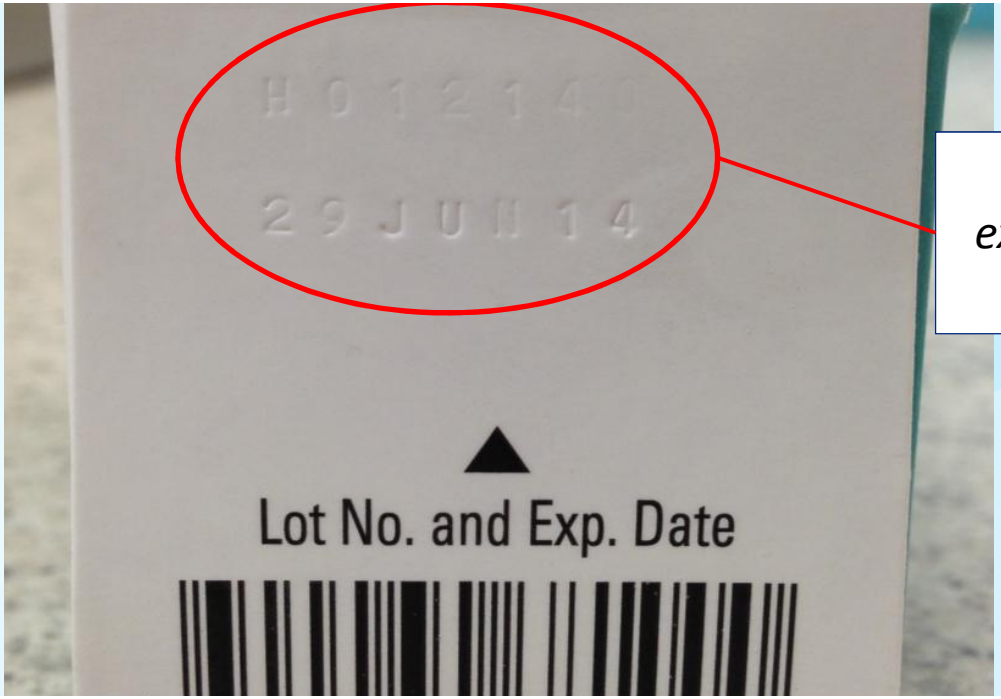
User Experience Survey: Pilot Participant Accuracy Perceptions



Preliminary results

- **Workflow Analysis: Clinician Feedback**

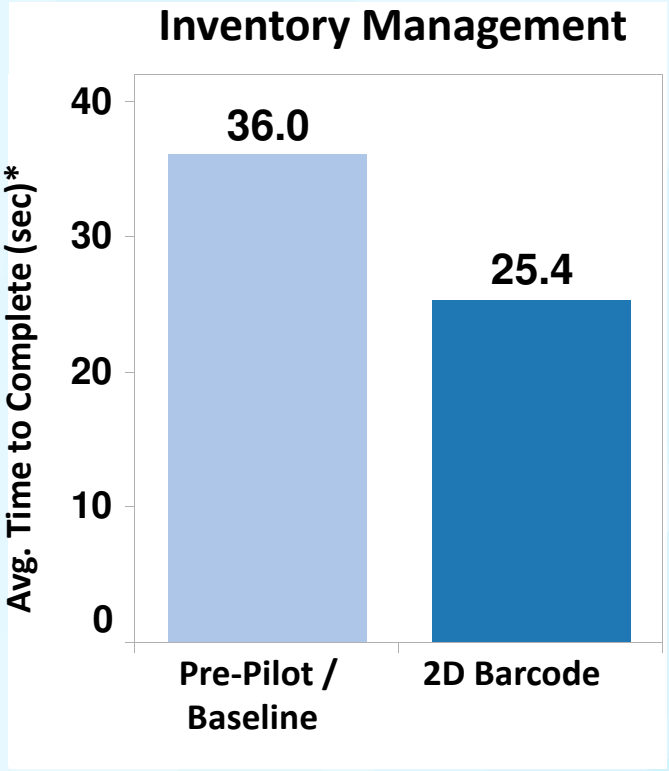
"The lot number and expiration date are hard to read on some of the vaccines we get. When those vaccines get barcodes we can scan, it will be a huge help."



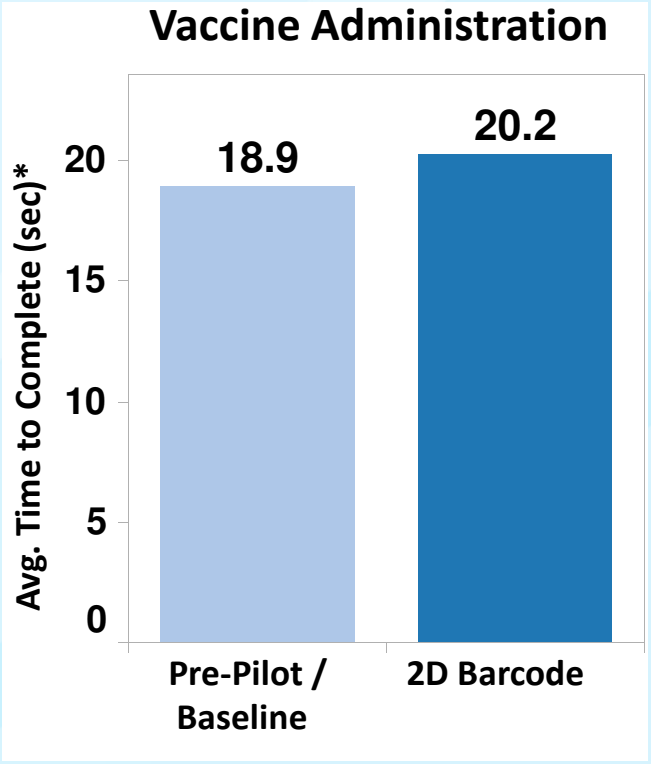
Lot number and expiration date stamped on M-M-R package

"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."

Workflow Analysis: Summary Efficiency Findings



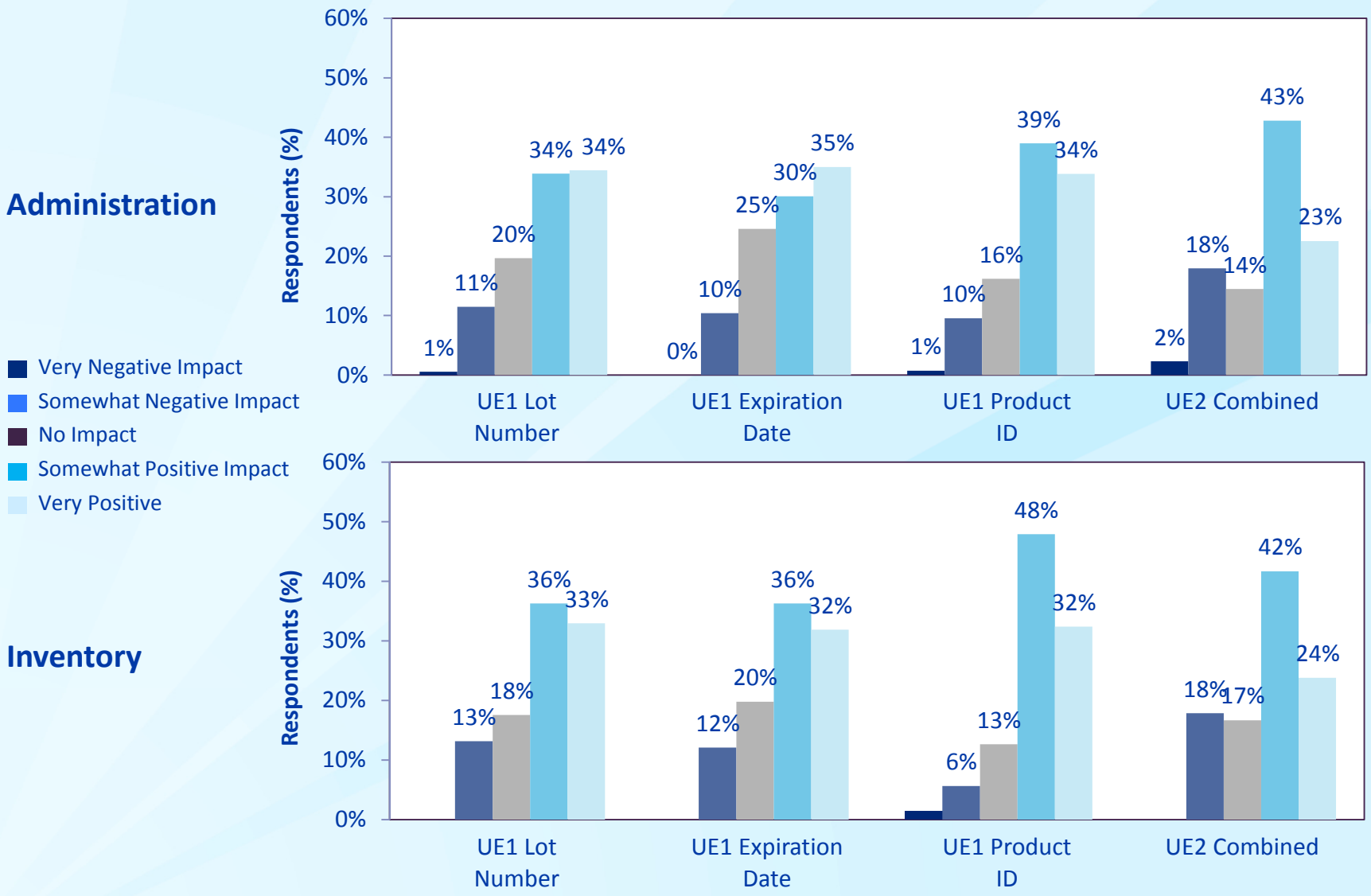
- Inventory is initial point of vaccine data entry
- Lot number and expiration date manual transcription eliminated



- Experienced users maximized process efficiencies
- Scanning efficiency will improve as the number of vaccines scanned per patient increases

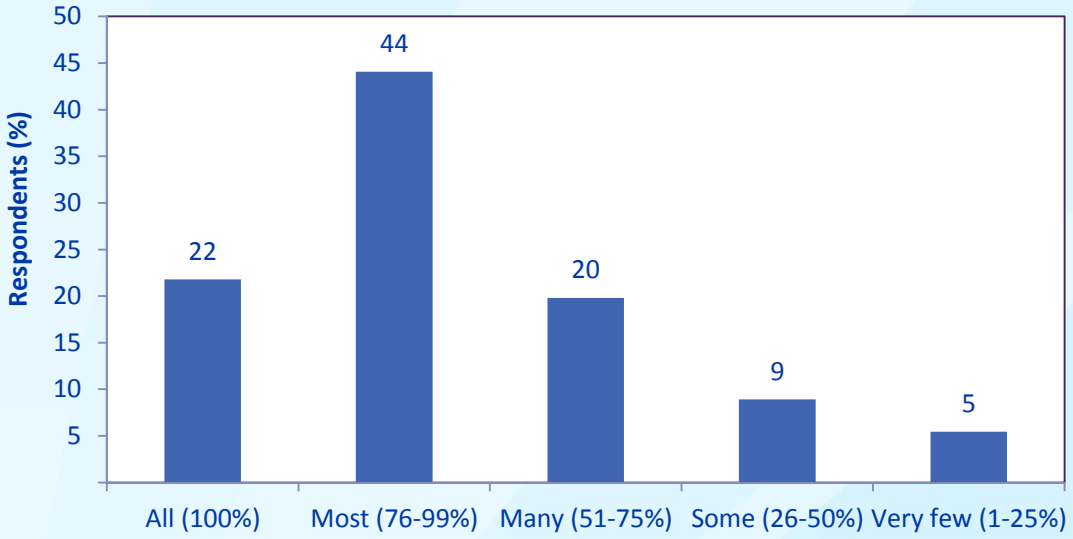
Preliminary results

User Experience Survey: Pilot Participant Efficiency Perceptions

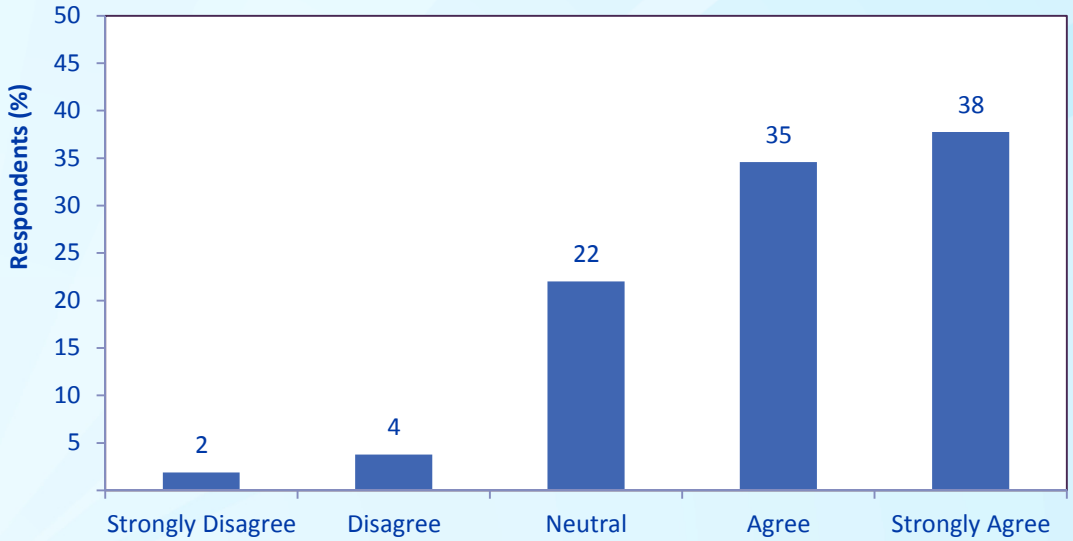


Preliminary results

User Experience Survey: Sustainability



Percentage of vaccines that would need to have 2D barcodes on them to sustain the use of 2D barcode scanning in the respondent's practice



Level of agreement/disagreement with the statement "When available on most vaccines, 2D barcode scanning should be used consistently to record vaccines administered in my clinic"

Preliminary results

Summary

- Preliminary results confirm a positive effect on vaccine data accuracy and completeness
- Providers have positive perceptions regarding impact of 2D barcoding on efficiency and accuracy
- Providers are willing to adopt practices to incorporate 2D barcode vaccine use but not until the majority of vaccines are 2D barcoded

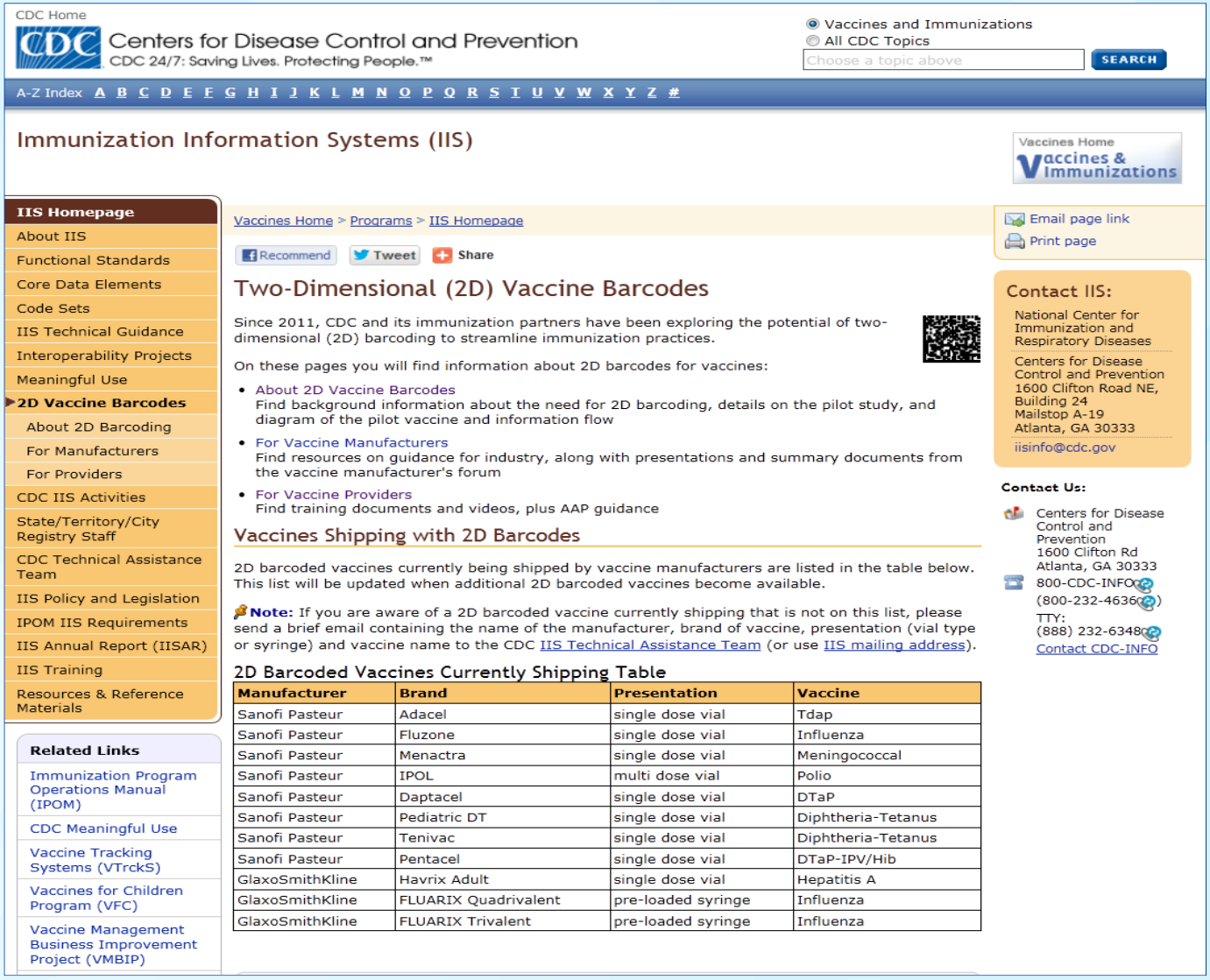
Other Key Findings

- Pharmaceutical supply chain stakeholders have indicated 2D will be the data carrier of choice
- Vaccine manufacturers have demonstrated a commitment to the application of 2D barcodes on the unit-of-use
- Most EMR and IIS systems require modification to process 2D barcodes

Next Steps

- **Finalize 2D Barcode Pilot Report**
- **Continue work with Prevention and Public Health Fund (PPHF) Awardees to implement 2D barcode vaccine scanning in immunization registries**
- **Monitor 2D Barcoded Vaccines – in the supply chain**
- **Adoption Strategies for 2D Barcodes – Pilot**
  - 2014 – 2015 flu season
  - Pharmacies, community vaccinators, public, and private immunizers
  - Work flow analysis

CDC 2D Barcode Website



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CDC Meaningful Use
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Vaccines Home > Programs > IIS Homepage

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Two-Dimensional (2D) Vaccine Barcodes

Since 2011, CDC and its immunization partners have been exploring the potential of two-dimensional (2D) barcoding to streamline immunization practices.

On these pages you will find information about 2D barcodes for vaccines:

- About 2D Vaccine Barcodes
  Find background information about the need for 2D barcoding, details on the pilot study, and diagram of the pilot vaccine and information flow
- For Vaccine Manufacturers
  Find resources on guidance for industry, along with presentations and summary documents from the vaccine manufacturer's forum
- For Vaccine Providers
  Find training documents and videos, plus AAP guidance

Vaccines Shipping with 2D Barcodes

2D barcoded vaccines currently being shipped by vaccine manufacturers are listed in the table below. This list will be updated when additional 2D barcoded vaccines become available.

Note: If you are aware of a 2D barcoded vaccine currently shipping that is not on this list, please send a brief email containing the name of the manufacturer, brand of vaccine, presentation (vial type or syringe) and vaccine name to the CDC IIS Technical Assistance Team (or use IIS mailing address).

2D Barcoded Vaccines Currently Shipping Table

Manufacturer	Brand	Presentation	Vaccine
Sanofi Pasteur	Adacel	single dose vial	Tdap
Sanofi Pasteur	Fluzone	single dose vial	Influenza
Sanofi Pasteur	Menactra	single dose vial	Meningococcal
Sanofi Pasteur	IPOL	multi dose vial	Polio
Sanofi Pasteur	Daptacel	single dose vial	DTaP
Sanofi Pasteur	Pediatric DT	single dose vial	Diphtheria-Tetanus
Sanofi Pasteur	Tenivac	single dose vial	Diphtheria-Tetanus
Sanofi Pasteur	Pentacel	single dose vial	DTaP-IPV/Hib
GlaxoSmithKline	Havrix Adult	single dose vial	Hepatitis A
GlaxoSmithKline	FLUARIX Quadrivalent	pre-loaded syringe	Influenza
GlaxoSmithKline	FLUARIX Trivalent	pre-loaded syringe	Influenza

Contact IIS:
National Center for Immunization and Respiratory Diseases
Centers for Disease Control and Prevention
1600 Clifton Road NE,
Building 24
Mailstop A-19
Atlanta, GA 30333
iisinfo@cdc.gov

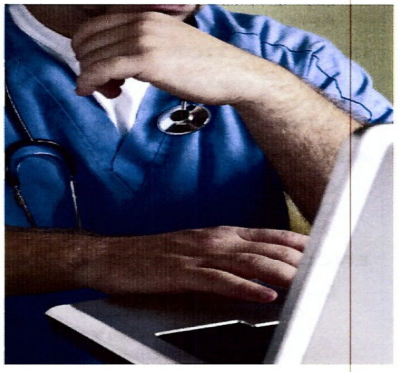
Contact Us:
Centers for Disease Control and Prevention
1600 Clifton Rd
Atlanta, GA 30333
800-CDC-INFO
(800-232-4636)
TTY:
(888) 232-6348
Contact CDC-INFO

http://www.cdc.gov/vaccines/programs/iis/2d-vaccine-barcodes/

GS1 US

ApplicationGuideline



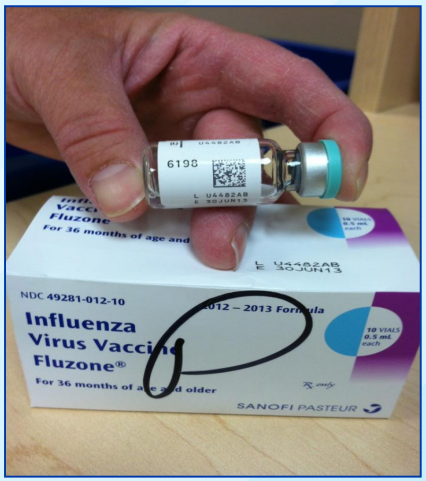


American Academy of Pediatrics & GS1 Healthcare US Guideline for Suppliers

The Application of GS1® DataMatrix Barcodes to Vaccines for Point of Care

Published: February 2012

Thank you!



Please contact Erin D. Kennedy (EDKennedy@cdc.gov) with any questions

For more information please contact Centers for Disease Control and Prevention

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