

2D Barcode Pilot

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Outline

2D Barcode Pilot Background

- National Childhood Vaccine Injury Act
- Data Completeness and Accuracy
- 2D Barcode History – Highlights
- Feasibility Study on 2D Vaccine Barcode
- Potential Benefits of 2D Barcodes

Pilot Implementation

- Pilot Objectives
- Pilot Vaccine and Information Flow
- Pilot Timeline
- Pilot Composition

National Childhood Vaccine Injury Act

Requires documentation of:

- Manufacturer
- Lot number
- Provider identity
- Date administered
- VIS version date and 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)

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 numbers²

Accuracy

- Study conducted at UCLA's Children's Health Center found that 10% of immunized children had transcription errors in their electronic immunization records³
- A review of MEDMARX database found that 10% of all vaccination errors were transcription or documentation errors⁴

¹ CDC, unpublished data, VAERS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)

2D Barcode History - Highlights

- Vaccine Identification Standards Initiative (VISI) - 1997
- American Academy of Pediatrics (AAP) 2D Barcoding Conference – January 2009
- FDA “Guidance for Industry: Bar Code Label Requirements – Questions and Answers: Availability” August 11, 2011
 - Amends 2006 guidance
 - Allows manufactures to request a waiver to use alternative coding, (e.g. two dimensional symbology)
 - References – vaccines and adverse event reporting requirements
- AAP and GS1: Issued guidance on use of Data Matrix Barcodes
 - Foundation for appropriate use of GS1 Data Matrix Barcodes on vaccine-related items

Feasibility Study on 2D Vaccine Barcode

- October 2010 – CDC contracted with RTI International
- Feasibility Study – impact of a transition to 2D barcodes containing product identification, expiration date, and lot number on vaccine vials and syringes
 - Vaccine production
 - Clinical documentation
 - Public health reporting
- A final report of findings published

<http://www.cdc.gov/vaccines/programs/iis/activities/downloads/2d-barcode-trkg-rpt.pdf>

- Recommendation – Pilot Implementation

Pilot Objectives

- Assist in implementation of 2D barcoded vaccines
- Examine implementation challenges at all stages from vaccine production to vaccination encounter to data capture
- Evaluate use of 2D barcodes
 - User experience
 - Work flow analysis and time and motion studies
- Document best practices and lessons learned
- Assess the extent to which using 2D barcoded vaccines and scanners affect the completeness and accuracy of vaccine data.
- Implement 2D barcodes on Vaccine Information Statements (VIS)

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.

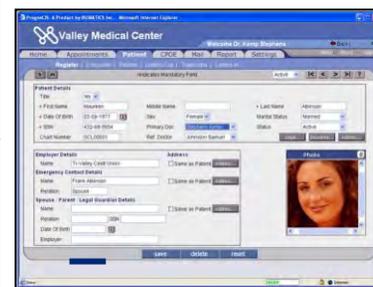
Immunizer



Scan vaccine data:

- Entering vaccine into inventory
- Administering vaccine

Record System



Record system types:

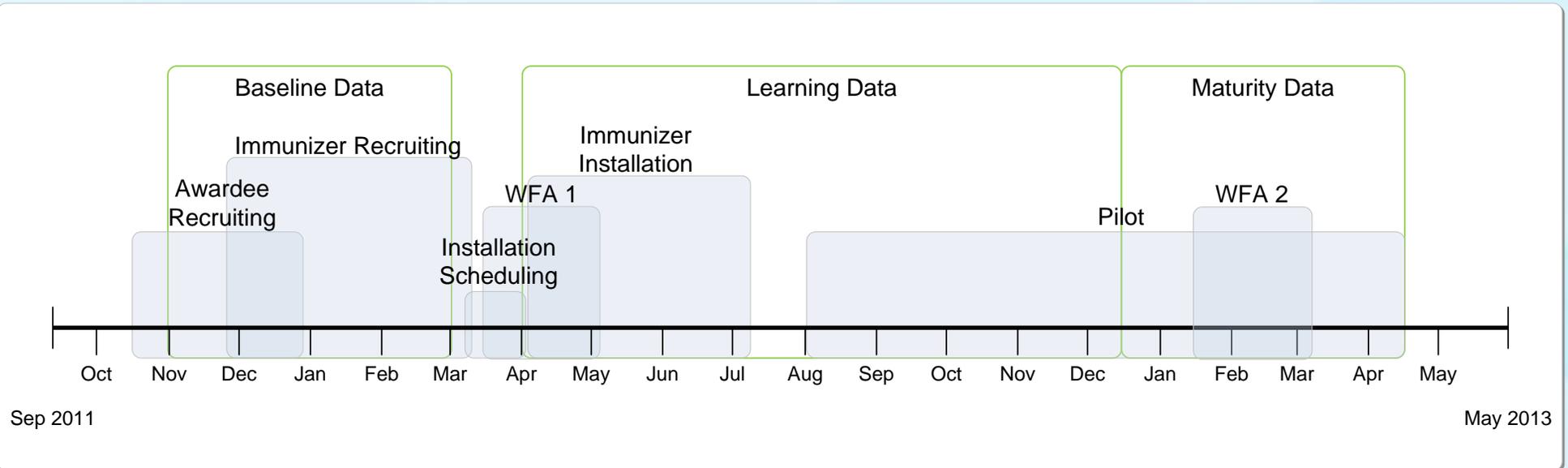
- Electronic medical records (EMR)
- Immunization Information Systems (IIS)
- Track GTIN, expiration date, and lot number

IIS

Receive data from the immunizers' record system:

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

Pilot Timeline



3 Data Capture Periods

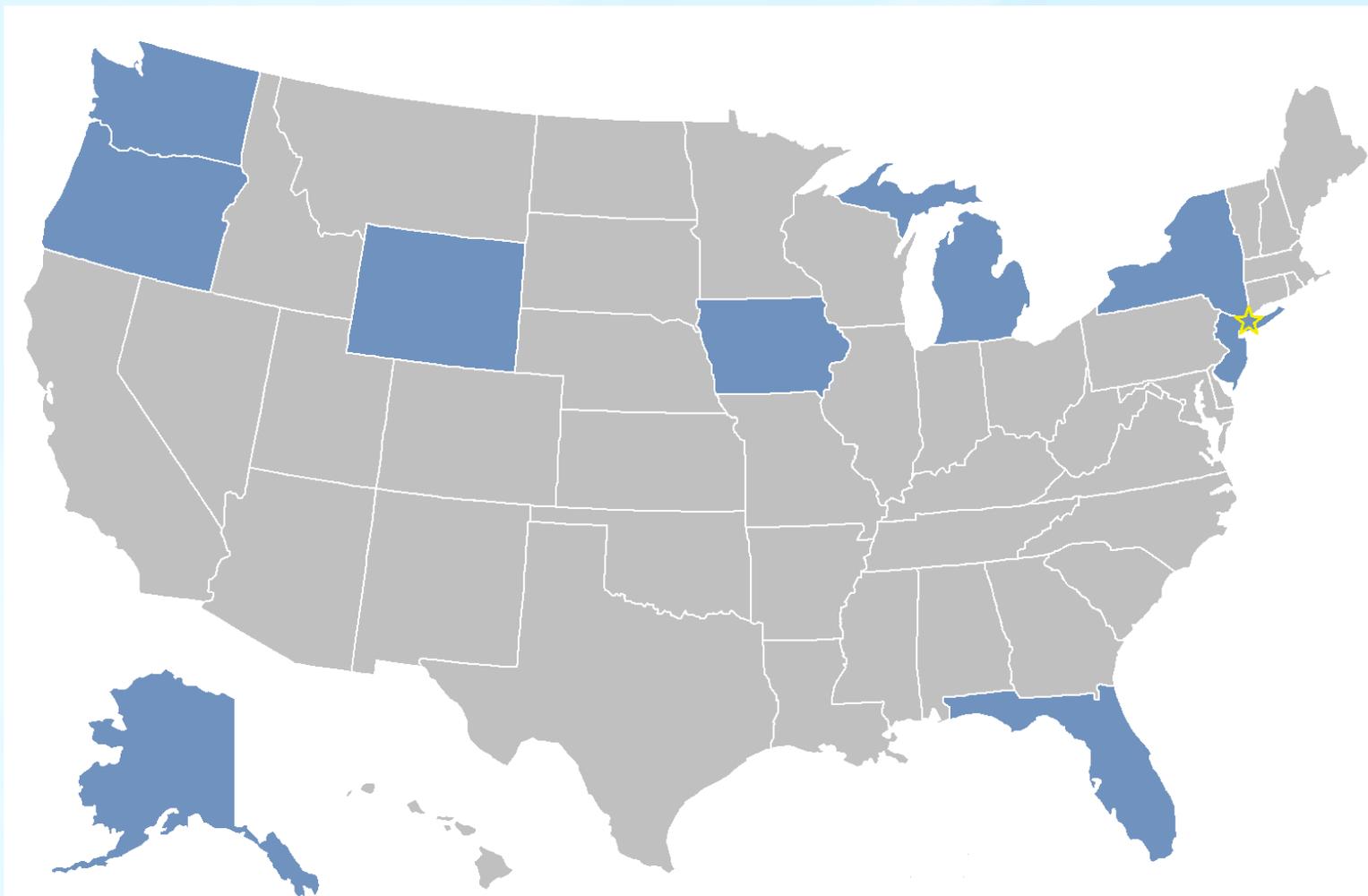
- Baseline: Linear barcoded vaccine administrations
- Learning: Linear + 2D barcoded vaccine administrations
- Maturity: Linear + 2D barcoded vaccine administrations

Additional Data Captured Through

- User Expectation Survey
- 2 User Experience Surveys
- Workflow Analysis

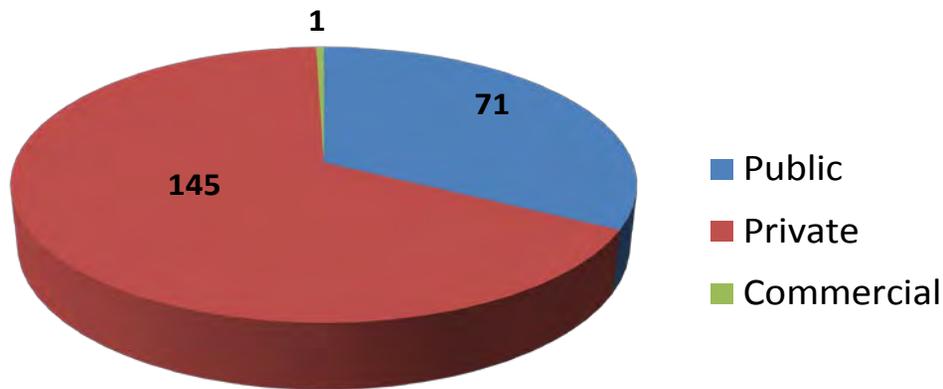
Pilot Participation

- 2 Vaccine Manufacturers
- 217 Immunizers
- 10 Immunization Awardees

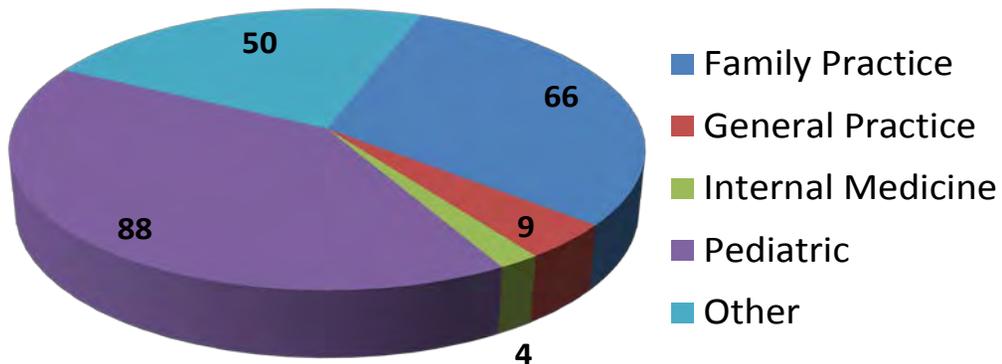


Pilot Immunizer Demographics

Immunizer Segments



Practice Specialties

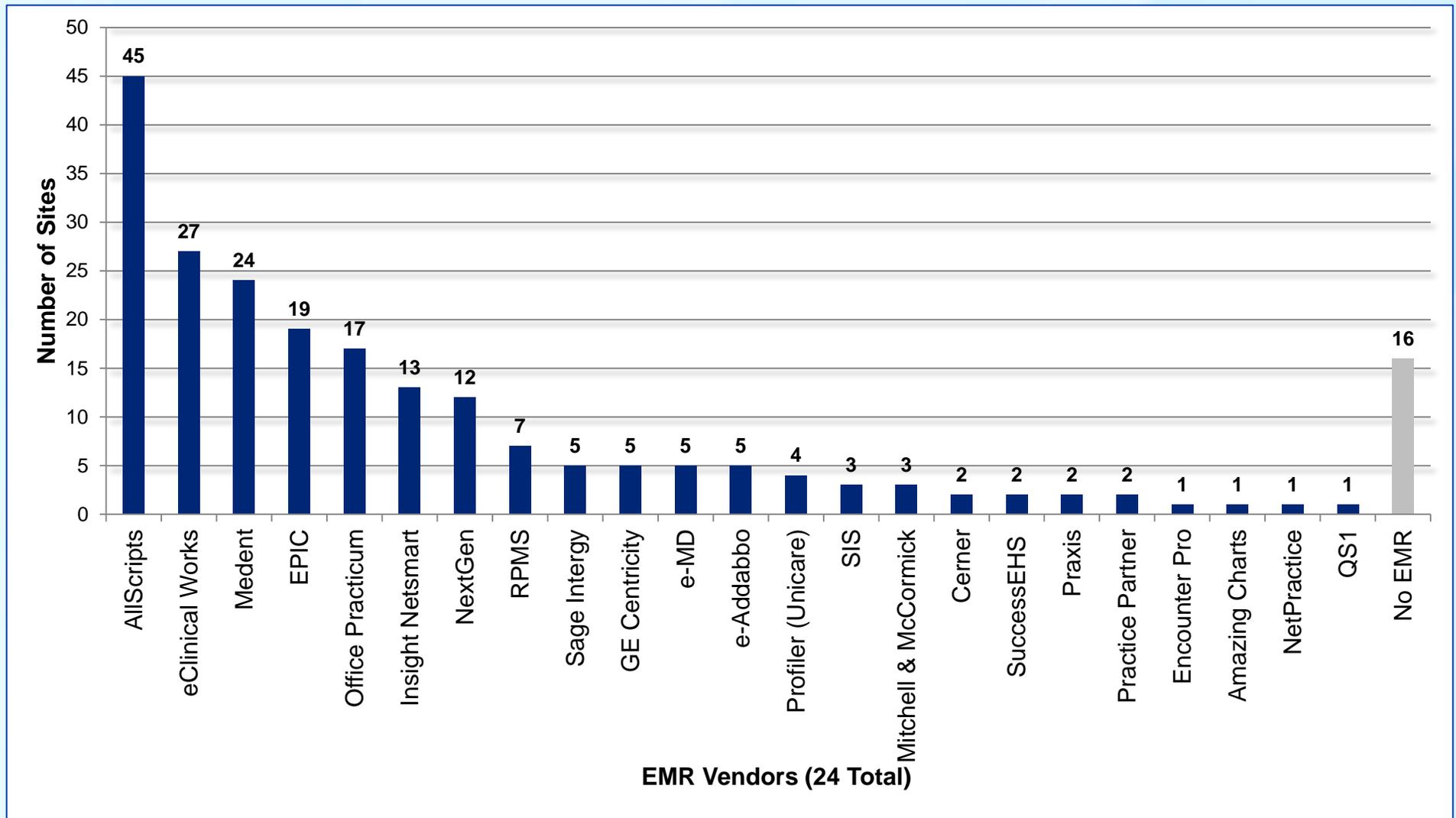


	Public	Private	Commercial
Family Practice	13	53	0
General Practice	7	2	0
Internal Medicine	0	4	0
Pediatric	4	84	0
Other	47	2	1

- Over 70% of "Other" are Public Health Depts.
- The single commercial practice is a commercial pharmacy that administers vaccinations

EMR Systems in Use at Pilot Sites

Distribution of Pilot Sites by EMR Vendor



Note: Sites with "No EMR" are IIS Only sites – they report directly to the state registry

Questions?

For more information please contact Centers for Disease Control and Prevention

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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.

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