

Two-Dimensional (2D) Vaccine Barcode Pilot Project

**Association of Immunization Managers /
Immunization Program Managers Meeting
February 3, 2012**

Ken Gerlach, MPH, CTR
Immunization Services Division
National Center for Immunization & Respiratory Diseases



INTRODUCTION AND BACKGROUND

Barcoding definitions – Vaccines

□ Linear

- Contains National Drug Code (NDC) only
- Other variables cannot be included due to space constraints and 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



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 number¹
- 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¹ CDC, unpublished data, VAERS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

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: Draft Guidance Data Matrix Barcodes to Vaccines for Point-of-Care**
 - 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 – forthcoming**
- ❑ **Recommendation – Pilot Implementation**

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's Three Parts

- ❑ **Part 1** – Pilot Project to Implement 2D Barcodes on Vaccine Vials and Syringes
- ❑ **Part 2** – Incorporate 2D Barcodes onto Vaccine Information Statements (VIS)
- ❑ **Part 3** – Provide Technical Support and Guidance for Future Implementers



PART 1: PILOT IMPLEMENTATION

Pilot Implementation: Objectives

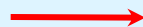
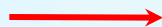
- ❑ Assist in implementation of 2D barcoded vaccines**

- ❑ Examine implementation challenges at all stages from vaccine production to vaccination encounter to data capture**

- ❑ Evaluate use of 2D barcodes**
 - Data completeness and accuracy of vaccinations recorded
 - User experience
 - Work flow analysis and time and motion studies

- ❑ Document best practices and lessons learned**

Pilot Implementation Information Flow



First Name	Last Name	MRN	DOB	Age	Sex	Race	Primary Care Physician	Referring Physician	Referring Department	Referring Date	Referring Time	Referring Location	Referring Source	Referring Method	Referring Status	Referring Reason	Referring Notes	
John	Doe	123456	01/01/1980	28	M	W	Dr. Smith	Dr. Jones	Internal Medicine	01/15/2010	10:00	Room 101	Emergency	Urgent	Urgent	Urgent	Urgent	Urgent
Jane	Smith	789012	03/03/1985	25	F	W	Dr. Brown	Dr. Green	Obstetrics/Gynecology	02/01/2010	14:00	Room 202	Outpatient	Urgent	Urgent	Urgent	Urgent	Urgent

Manufacturer

Add a 2D barcode to the primary packaging:

- Data Matrix barcode to contain
 - GTIN*
 - Expiration date
 - Lot number
- Distribute to pilot participants

Immunizer

Record and track data:

- Scan barcode when inventorying and dispensing vaccine products and enter into the medical record

Record system

Medical record types:

- Electronic medical records (EMR)
- Custom applications
- Acts as a source of evaluation for data accuracy and completeness

IIS

Receive data from the immunizers' EMR or equivalent electronic system:

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

*The Global Trade Item Number (GTIN) is a unique identifier used globally to identify an item. For vaccines and other health care products, the GTIN is specifically used to carry the National Drug Code (NDC)—a unique identifier used in the US as mandated by the FDA.

Pilot Implementation: Recruitment

❑ Vaccine Manufacturers

- 1-3 will be selected
- Selection based on ability to produce 2D barcoded vaccines available for use during the pilot

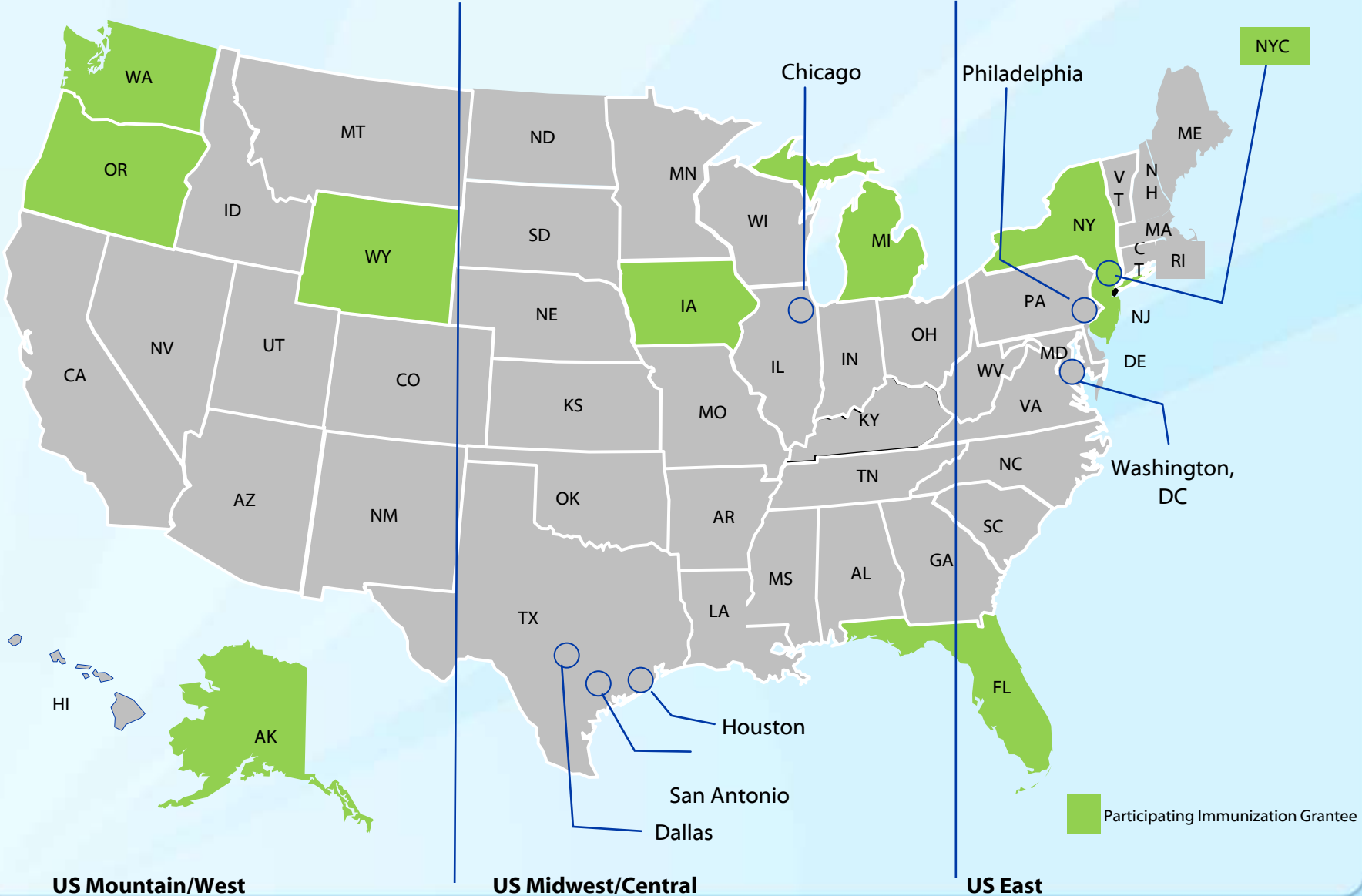
❑ CDC Immunization Grantees

- 10 selected
- Selection based on geographical diversity, immunization information system maturity, and ability to provide data necessary for evaluation

❑ Immunizers

- 340 will be selected (43% public, 50% private, 7% commercial)
- Selection based on use of 2D barcoded vaccines, practice type, immunization data entry model, and participation in state IIS
- 30 selected for time and motion study and in depth evaluation

Participating Immunization Grantees



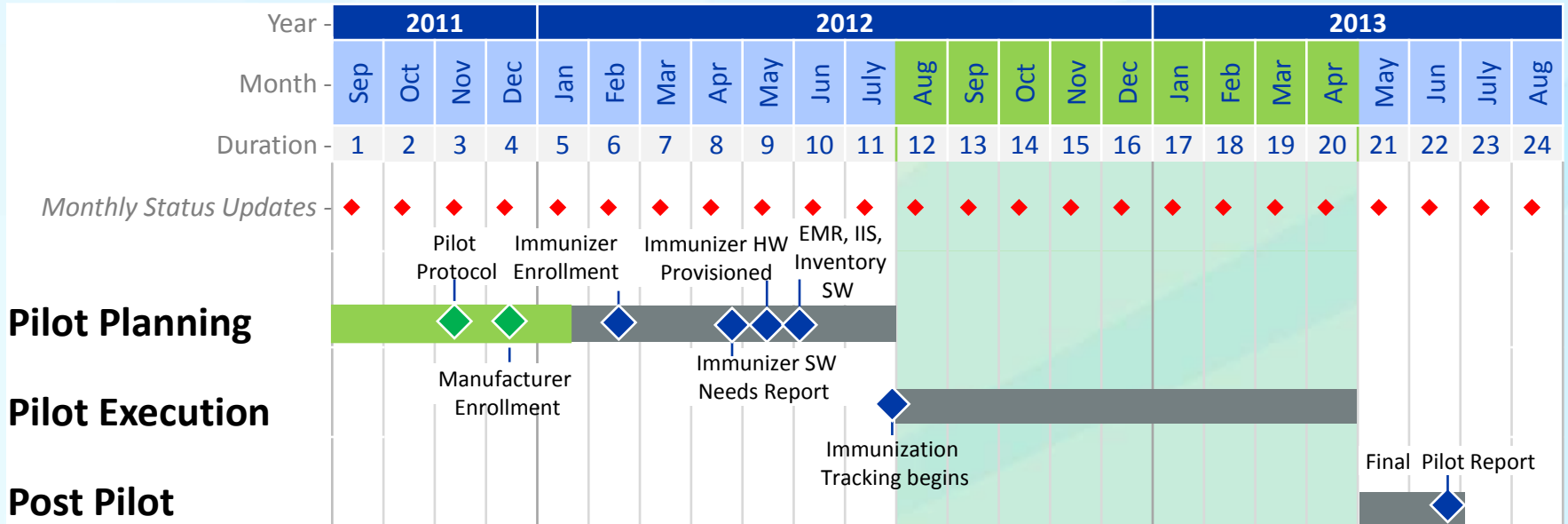
Barcode Standard and Format

- ❑ **GS1 – Barcoding Standards Development Organization**
 - International not-for-profit association with Member Organizations in over 100 countries.
 - Chapter in the US
 - GS1 system of standards is the most widely used supply chain standards system in the world.

- ❑ **Global Trade Identification Number (GTIN), which includes National Drug Code (NDC)**
- ❑ **Expiration Date**
- ❑ **Lot Number**

- ❑ **GS1 Web: www.gs1.org or <http://www.gs1us.org/>**

Pilot Implementation: Timeline



Pilot Implementation: Progress

- ❑ **Two Manufacturers Enrolled**
 - GlaxoSmithKline
 - Sanofi Pasteur
- ❑ **Currently recruiting immunizers from all participating immunization grantees**
 - 146 immunizers enrolled
 - 40 additional immunizers deemed suitable for participation\
- ❑ **Scanner Model Selected**

PART 2: VACCINE INFORMATION STATEMENTS (VIS)

Data Items

❑ Pilot Implementation – Unit of Use

- Product identification
- Expiration Date (Expiry or maximum durability date)
- Lot Number



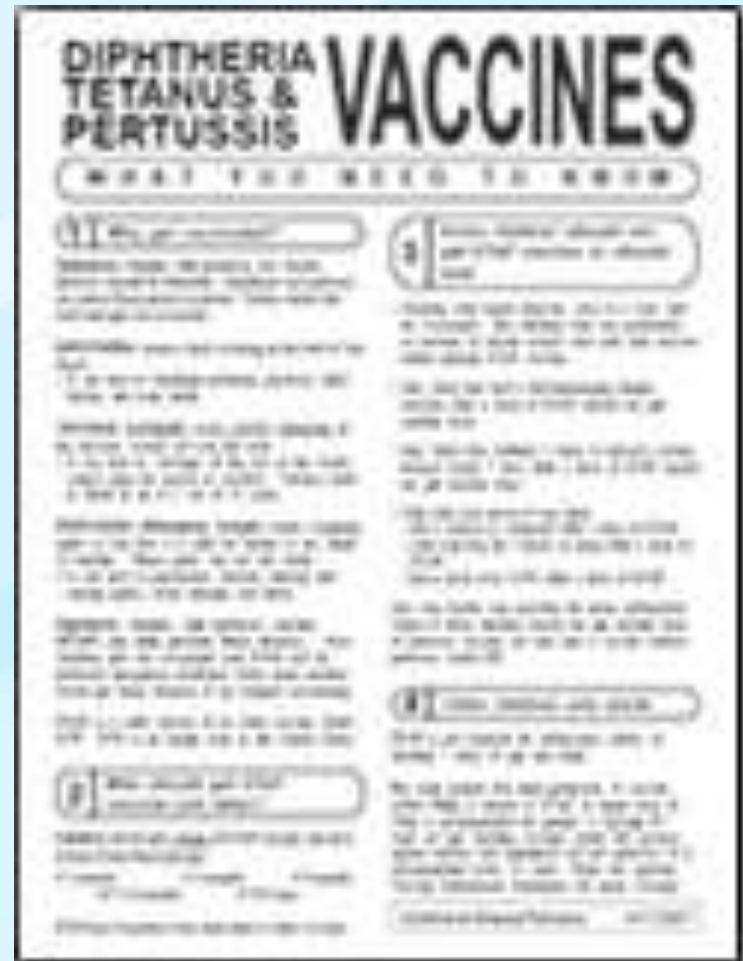
❑ VIS

- VIS publication date
- VIS document identification



Vaccine Information Sheets (VIS)

- ❑ Published by CDC
- ❑ Required by Law
- ❑ Given to or read by patients/parents when getting a vaccine
- ❑ Certain information should be recorded when a VIS is given.
 - Date given to the patient/parent
 - Date of the VIS publication
- ❑ Barcodes on the VIS?



VIS Encoding: Potential Benefits

- ❑ Increases in completeness for data elements**
- ❑ Enhance record keeping for providers**
- ❑ Promote use of barcoding technology**

VIS Encoding: Objectives

- ❑ Implement barcoding on all VIS**
 - Identify appropriate barcode and placement
 - Create and establish process

- ❑ Registration and publication of VIS data**

- ❑ Provide technical guidance and assistance for users**

VIS Encoding: Progress

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

Rare 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

PART 3: TECHNICAL SUPPORT AND GUIDANCE

Technical Support and Guidance: Objectives

- ❑ Conduct forum for vaccine manufacturers to discuss standards and other relevant issues**
- ❑ Conduct forum of education for all immunization stakeholders**
- ❑ Create centralized web-based portal of barcode related resources**
- ❑ Develop manual for 2D barcoding use and integration**

Technical Support and Guidance: Progress

- ❑ **Conducting forum for vaccine manufacturers January 26, 2012**
 - Summary of meeting expected in early March 2012

- ❑ **Forum of education planned for 2012**
 - Summary of meeting expected in mid-October 2012

- ❑ **Centralized portal planned for March 2013**

- ❑ **Manual for 2D barcoding use and integration planned for August 2013**

Summary

- ❑ **2D barcoded vaccines have many potential public health benefits**
 - Increasing accuracy and completeness of recorded immunization information
 - Improving patient safety
- ❑ **CDC's Implementation Pilot for Two-Dimensional Vaccine Barcode Utilization will**
 - Examine implementation challenges at all stages from vaccine production to vaccination encounter and data capture
 - Document best practices and lessons learned

Thank you

Ken Gerlach
kgerlach@cdc.gov
404-718-4646

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

