



## Case Study

# Scanning Two-Dimensional Barcodes Enhances Vaccine Clinical Practice

An Adoption Pilot Conducted by the Centers for Disease Control and Prevention

## Challenge

With millions of vaccines administered to patients each year, accurately recording vaccine information in patient records is essential. Vaccine information (like product identifier, lot number, and expiration date) helps healthcare providers determine which vaccines should be administered next, and is vitally important should a vaccine recall or a disease pandemic occur. Traditionally, vaccine information has been recorded in patient records manually by either typing the information into an electronic system or handwriting it in a paper chart. These types of manual approaches are error-prone and time-consuming in general, and are even more so with small vaccine vials and syringes where the font size is tiny. Unfortunately, this increases the risk of inaccurate and/or incomplete vaccine information in patient records.

## Solution

From 2013 to 2015, the Centers for Disease Control and Prevention (CDC) conducted a major pilot to assess the impact of two-dimensional (2D) barcoded vaccine vials and syringes. Called the 2D Adoption Pilot, it aimed to facilitate the adoption of 2D barcode scanning by a diverse group of healthcare providers.

## Benefits

Results were measured based on four metrics: data accuracy, time savings, user experience, and scanning adherence.

- By scanning 2D barcodes, 92% data accuracy per lot number was reported compared with 84% using traditional entry methods like manual entry, drop-down menu, or a combination.
- Time savings was measured at 3.44 seconds.
- Seventy-five percent (75%) of users agreed that 2D barcode scanning improves accuracy and 60% said that 2D barcode scanning is easy to use.
- Sixty percent (60%) of users reported that it's easy to integrate 2D barcode scanning into their usual process of recording data, yet a subset of users scanned only 20% - 50% of vaccine barcodes.<sup>1</sup>

## A Shot in the Arm for Safety

Recognizing the importance of standards,<sup>2</sup> CDC partnered with GS1 US<sup>®</sup> in 2011 to leverage GS1 Standards for 2D barcodes on vaccines; specifically the GS1 Global Trade Item Number<sup>®</sup> (GTIN<sup>®</sup>),<sup>3</sup> lot number, and expiration date encoded in a 2D GS1 DataMatrix barcode printed on a vaccine vial or syringe.<sup>4</sup>

Stuart Myerburg, CDC Immunization Information Systems Support Branch's (IISB) informatics team lead, points to the data captured in barcodes and its impact on patient and public health: "Barcoding helps improve the data quality in immunization information systems confidential, population-based databases that record all information about immunizations administered. Information is critical in properly evaluating whether the right vaccine was given at the right time to the right patient, and then forecasting the due date for the next dose."

Working with providers' electronic health records (EHRs), the immunization information systems (IIS) also help healthcare providers to encourage vaccinations and send reminders to patients that subsequent doses are due. Because patients may go to more than one doctor for their vaccines, an accurate record—both within the EHR and the IIS—is crucial to proper care. The IIS registry is typically based within the state's health department, and it compiles aggregate data that help guide public health actions for the common good.

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**Stuart Myerburg**

Team Lead, Immunization Information Systems Support Branch, CDC

## Scanning Barcodes, the Next Critical Step

According to the CDC, since these first initiatives, four vaccine manufacturers have affixed 2D GS1 DataMatrix barcodes onto vaccine vials and syringe presentations. "During the 2D Adoption Pilot (2013 to 2015), only 18 percent of vaccines had 2D barcodes," says Ken Gerlach, Health Scientist, IISB, at CDC. "Today, we estimate that over 80 percent of vaccine vials and syringe presentations in the U.S. have a 2D barcode."

Yet, having manufacturers apply barcodes to vaccine vials and syringes is only one part of a multifaceted, patient safety solution. The other critical component is having healthcare providers scan the barcodes.

"The American Academy of Pediatrics was visionary in seeing the potential for 2D barcodes," explains Gerlach. "They brought us together with the FDA, GS1 US, and vaccine manufacturers to discuss the potential of using barcodes."

According to the CDC, many of the manufacturers recognized 2D barcodes as a tool to improve data quality and patient safety. Gerlach continues, "In five years, we've gone from zero to over 80 percent of U.S. vaccine product presentations (vials or syringes) barcoded. Now, we are excited to share our findings to encourage more practitioners to adopt 2D vaccine barcoding at the point of vaccine administration."



1 CDC. (September 15, 2015). *Summary Report: Reporting for the Adoption Strategies for 2D Barcode Project*. Retrieved from <https://www.cdc.gov/vaccines/programs/iis/2d-vaccine-barcodes/downloads/summary-report.pdf>

2 GS1 US. (2013). *Better Immunization Management for Patient Safety*. Retrieved from [https://www.gs1us.org/documents?Command=Core\\_Download&EntryId=601](https://www.gs1us.org/documents?Command=Core_Download&EntryId=601)

3 The National Drug Code (NDC) is contained within the GTIN. The CDC conducts its analyses using the NDC.

4 Working with the CDC and the U.S. Food and Drug Administration, in February 2012, GS1 Healthcare US<sup>®</sup> and the American Academy of Pediatrics developed a guideline for U.S. suppliers entitled, *The Application of GS1 DataMatrix Barcodes to Vaccines for Point of Care*. This guideline provides detailed guidance for encoding the GTIN, lot number, and expiration date in GS1 DataMatrix barcodes. Retrieved from [https://www.gs1us.org/documents?Command=Core\\_Download&EntryId=628](https://www.gs1us.org/documents?Command=Core_Download&EntryId=628)

## 2D Adoption Pilot: 2013–2015<sup>5</sup>

To assess adoption rates of barcode scanning, CDC collected EHR data files from 87 participating healthcare provider sites for vaccines administered prior to the project start and during the course of the project's data capture period. There was a robust dataset of 1.4 million vaccine records.

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

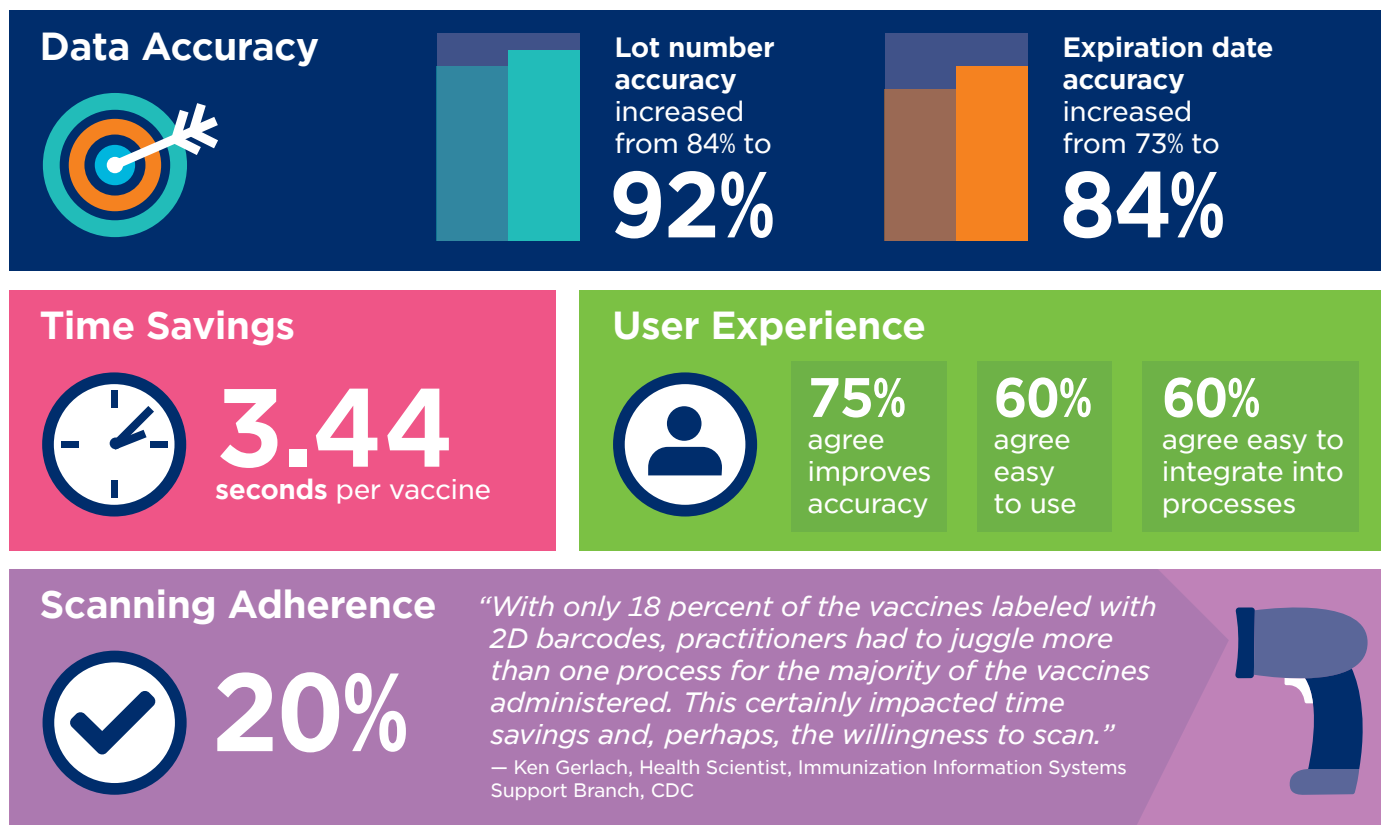
Thirty-two sites enabled tracking to show whether they scanned in vaccine information or entered it through another method such as manual data entry, drop-down menu, or a combination of both.

Finally, on-site observations, interviews, and time measurements were collected from 20 facilities.

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**Ken Gerlach**  
Health Scientist, Immunization Information Systems Support Branch, CDC

## 2D Adoption Pilot | 2013-2015 | Scanning Results



Source: CDC

<sup>5</sup> CDC. (September 15, 2015). *Summary Report: Reporting for the Adoption Strategies for 2D Barcode Project*. Retrieved from <https://www.cdc.gov/vaccines/programs/iis/2d-vaccine-barcodes/downloads/summary-report.pdf>

## Key Takeaways from the Pilot

**Seconds and users count.** While it may seem that a few seconds would be insignificant, the time saved when scanning 2D barcodes is not just statistically significant, but at high volume healthcare facilities can translate into hours over the long-term. Perhaps as meaningful is that users acknowledge benefits in addition to the time savings of scanning versus manual data entry, including increased accountability and convenience fostered by the new technology.

And experience is the best saver. Even after accounting for factors such as lack of previous experience with standardized recording processes and varied data entry systems, time-savings were still realized. In fact, time-saved differences ranged from just 0.39 seconds to 11.22 seconds per vaccine, owing to factors including vaccine type, manufacturer, EHR type, and specific characteristics of the individuals recording the data.<sup>6</sup>

**Data quality and quantity matter to compliance.** When examining data quality for all vaccination records submitted during the pilot (both scanned and non-scanned), correctness was relatively good for both lot number and expiration date. Although *total* correctness using traditional methods was 94.3 percent and for scanned vaccination records 95.3 percent, the one percent improvement corresponds to an additional 1,200 accurate vaccine records out of approximately 125,000 records in the EHR dataset.

**Removing obstacles to healthcare.** It became evident that facilities in which staff took longer to scan encountered one or more of the following challenges:

- Inconsistent response from the scanner
- Faint or smeared barcodes
- Limited volume of 2D barcoded vaccines
- Lot number and/or expiration date incorrectly entered with 2D barcode scanning
- EHR and scanner software integration
- Lack of 2D barcode training

These challenges typically introduced process inefficiencies such as requiring several scan attempts before getting to a successful one, reverting to manual data entry, or switching back and forth between manual and 2D barcode scanned data entry.

And in the area of data quality, most errors were associated with human error in manual entry such as data entered within the wrong EHR field, or intentional edits to lot numbers made by facilities, such as appending to the lot number an internally recognized code. In addition to affecting data quality, the errors mean the data can no longer be easily searched during a recall.

Knowing the obstacles that need to be overcome, the benefits of 2D barcode scanning can only improve further, and the efficient delivery of life-altering vaccines with it.



6 CDC. (September 15, 2015). Summary Report: Reporting for the Adoption Strategies for 2D Barcode Project. Retrieved from <https://www.cdc.gov/vaccines/programs/iis/2d-vaccine-barcodes/downloads/summary-report.pdf>

## A Powerful Package of Information

Widely used in the healthcare industry, the GS1 DataMatrix is a 2D barcode that can hold large amounts of data—up to 2,335 characters—in a very small footprint. It can encode all of the GS1 identification keys, like the Global Trade Item Number and Global Location Number, and more than 100 other data elements like batch/lot, expiration date, and serial number to meet the specific data needs of healthcare stakeholders.

The GS1 DataMatrix barcode is perfect for healthcare environments where vital information needs to be captured for thousands of medical products that are very small in size—like prescription drug blisters, bottles, vials, and syringes. It is also the GS1-recommended symbol for direct marking.

It's easy to apply and use. GS1 DataMatrix barcodes use image-based scanners and training needs are relatively low with a short learning curve. It utilizes built-in error correction to promote scanability, even if the barcode is damaged or less than optimal.



GTIN (01) 00314141999995  
EXP 2021-12-31  
Batch/Lot (10) 987654321GFEDCBA  
Serial (21) 10000000234

This barcode is for illustration purposes only and does not reflect the actual size.

The GS1 DataMatrix:

- Is widely used in healthcare since it meets the data needs of healthcare stakeholders and regulatory bodies
- Carries up to 2,335 characters in a very small footprint
- Encodes all GS1 identification keys and all of the GS1 Application Identifiers
- Is the perfect option for direct marking—and does not need a label
- Has an omnidirectional barcode, meaning that it can be scanned from any angle
- Requires image-based scanners
- Comes with built-in error correction to help promote scanability

## About the Organizations

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### About CDC

CDC is a U.S. federal agency under the Department of Health and Human Services, and provides information to enhance health decisions and promote health through partnerships with state health departments and other organizations. CDC's Immunization Services Division (ISD) has a mission to protect individuals and communities from vaccine-preventable diseases by providing federal funds and contracts to purchase vaccine and offering technical and financial support of immunization programs, provider and public education, and evaluation and research. [www.cdc.gov](http://www.cdc.gov)



### About GS1 Healthcare US

GS1 Healthcare US<sup>®</sup> is an industry group that focuses on driving the adoption and implementation of GS1 Standards in the healthcare industry in the United States to improve patient safety and supply chain efficiency. GS1 Healthcare US brings together members from all segments of the healthcare industry to address the supply chain issues that most impact healthcare in the United States. Facilitated by GS1 US, GS1 Healthcare US is one of more than 30 local GS1 Healthcare user groups around the world that support the adoption and implementation of global standards developed by GS1. [www.gs1us.org/healthcare](http://www.gs1us.org/healthcare)



### About GS1 US

GS1 US<sup>®</sup>, a member of GS1<sup>®</sup> global, is a not-for-profit information standards organization that facilitates industry collaboration to help improve supply chain visibility and efficiency through the use of GS1 Standards, the most widely-used supply chain standards system in the world. Nearly 300,000 businesses in 25 industries rely on GS1 US for trading-partner collaboration that optimizes their supply chains, drives cost performance and revenue growth while also enabling regulatory compliance. They achieve these benefits through solutions based on GS1 global unique numbering and identification systems, barcodes, Electronic Product Code-based RFID, data synchronization, and electronic information exchange. GS1 US also manages the United Nations Standard Products and Services Code<sup>®</sup> (UNSPSC<sup>®</sup>). [www.gs1us.org](http://www.gs1us.org)

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For CDC's 2D vaccine resources, visit

[www.cdc.gov/vaccines/programs/iis/2d-vaccine-barcodes](http://www.cdc.gov/vaccines/programs/iis/2d-vaccine-barcodes).

To learn more about GS1 Standards in healthcare, visit

[www.gs1us.org/healthcare](http://www.gs1us.org/healthcare).

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