

CDC 2D Vaccine Barcode Pilot-Manufacturers Forum Outcome

By Ken Gerlach

The Centers for Disease Control and Prevention (CDC) organized and hosted the Forum in Atlanta, Georgia, as part of the [Implementation Pilot for Two Dimensional \(2D\) Vaccine Barcode Utilization project](#). CDC, together with Deloitte Consulting (the project contractor), brought together vaccine manufacturers, and regulatory and standards stakeholders to discuss the opportunities, challenges, and next steps for implementing 2D barcoding on vaccine products.

Forum Outcome and Findings

Prior to the Forum, registrants were asked to identify three opportunities or challenges that the implementation of 2D barcoding presented for the vaccine manufacturer and immunizer community. Several common themes emerged from the input and they were categorized as follows:

- Standards – Both opportunities and challenges were identified with respect to standards. While the [GS1](#) standard has emerged as the industry-accepted standard for barcoding, there were various levels of understanding about the use of the standards and implementation timeframes.
- User Adoption – User Adoption was interpreted not only as adoption by the provider and customers of manufacturers, but also trading partners. While education and benefits will need to be a focus in the future, working through some of the current impacts to user processes will take time.
- Cost and Time Commitment – It will take time for manufacturers to upgrade lines, redesign labels, and purchase and reconfigure equipment in order to begin applying 2D barcodes to vaccine products. Ensuring use in the field is of utmost importance to help manufacturers invest in 2D barcoding.

There were many key lessons learned from the Forum, several that will continue to be focal points for the vaccine industry. As the discussions continued throughout the day, several factors became clear:

- Vaccine manufacturers recognize the value of 2D barcoding to the provider community, but struggle with a cost-effective implementation.
- Confusion and concern about regulatory requirements is a major barrier to adoption. The FDA is willing to work with the manufacturers to address these concerns.
- There may be a period when vaccine products will carry both linear and 2D barcodes, lasting until sufficient adoption of 2D barcodes by providers allows migration away from linear barcodes.
- GS1 is the barcode standard that vaccine manufacturers have adopted.
- Forum participants welcome the opportunity to work collaboratively with agencies and peers on defining benefits and seeking ways to solve issues and enhance patient safety. Additional forums are suggested which also include providers and electronic medical record (EMR) vendors.
- There is a need for alignment between vaccine manufacturers and vaccine end-users, or immunizers.

Forum Background and Objectives

By moving to a 2D barcode, manufacturers can provide more data about vaccine products, such as a Global Trade Identification Number (GTIN) that contains an embedded national drug code (NDC), along with expiration data and lot/batch number. By scanning a 2D barcode into an electronic recording system, immunizers can easily capture with a single scan such data to ensure vaccination accuracy and safety. The industry as a whole is evaluating the potential benefits of adopting this new technology.

The goals and objectives of the Forum were to engage the vaccine manufacturing community in the discussion of the benefits, impacts, and challenges of implementing 2D barcoding, to understand the regulations and standards landscape in more detail, and to explore the options and considerations for moving the industry forward toward the implementation of 2D barcoding of vaccine products.

It was attended by over 60 industry stakeholders including 26 representatives from 10 vaccine manufacturing companies, representing functions of packaging, distribution, policy, regulatory affairs, technical services, customer service, and new products. In addition to the manufacturers, the Forum was attended by representatives of retail pharmacy supply chain participants, standards organizations, and trade associations. Regulatory and global agencies including World Health Organization (WHO), the Food and Drug Administration (FDA), and CDC participated in the event, providing a rare opportunity for the industry and regulators to connect and discuss the changing requirements and standards for vaccines.

The agenda included opening remarks by Dr. Anne Schuchat and a series of informative presentations.

- Dr. Erin Kennedy, CDC - Overview of 2D Vaccine Barcoding Pilot
- Captain Vada Perkins, FDA - Overview and Guidance on Vaccine 2D Barcoding
- Dr. Edward Zissman, AAP - Industry Goals and Progress for Vaccine Barcoding - A Perspective from the AAP
- Alan O'Connor, RTI - Overview of Vaccine Bar Coding Feasibility Report
- John Roberts, GS1-US Healthcare - Emerging Standards for Vaccine Barcoding - GS1 Overview
- Breakout sessions - Standards, User Adoption, Cost and Time

Forum details and downloadable [presentation slides](http://www.cdc.gov/vaccines/programs/iis/activities/2D-Vaccine-Barcoding.html) are available online at <http://www.cdc.gov/vaccines/programs/iis/activities/2D-Vaccine-Barcoding.html>.