



USA

Better Immunisation Management for Patient Safety

ABSTRACT

The US Government’s National Childhood Vaccine Injury Act of 1986 requires that clinicians record specific information about the administered vaccine and Vaccine Information Statement (VIS) in patient medical records. The Centers for Disease Control and Prevention (CDC) launched two projects using GS1 Standards to automate vaccine and VIS information management processes. One pilot is testing how vaccine data – the GS1 Global Trade Item Number (GTIN), Lot Number, and Expiration Date encoded in a GS1 DataMatrix bar code – can be scanned on vaccine vials and syringes for populating electronic medical records (EMRs). The CDC is now adding a GS1 DataMatrix bar code encoded with the GS1 Global Document Type Identifier (GDTI) to each VIS so that providers can automatically capture and record VIS document type and edition date into EMRs. The CDC expects that providers will save time and gain efficiencies in immunisation management, as well as reduce the risk of errors by scanning bar codes versus manually transcribing vaccine and VIS information. This improved accuracy means improved safety for patients.



by Ken Gerlach and Warren Williams

A recent study conducted by RTI International and published in the June issue of *Vaccine*¹ also found that implementing 2D bar codes on vaccines will increase the probability to locate a patient should a vaccine be recalled. The results also showed that between 2011 and 2023 the net economic benefits from switching vaccines to using 2D bar codes were forecasted to be between \$310 and \$334 million.

From manual to electronic

Vaccines are manufactured and given each year in the US to millions of newborns, children, and adults. Whether part of seasonal immunisations or scheduled vaccinations, or one of the many newer immunologic agents designed to protect against harmful viruses, a vaccine travels through an intricate healthcare supply chain – from its manufacturer to patients – passed from one organisation to another along the way.

The net economic benefits from switching vaccines to using 2D bar codes are forecasted to be between \$310 and \$334 million.

automated processes and EMRs. As this movement progresses, information about each vaccine must be shared completely and accurately among these organisations for patient safety and operational efficiencies.

Tools and technologies are becoming more and more usable and mature, spurring an increase in EMR adoption. In turn, EMR implementations are helping to facilitate healthcare initiatives like the CDC’s 2D bar coding projects.

Consider that there are more than 650,000 different organisations in the US alone, including manufacturers, distributors, carriers, group purchasing organisations, and hospitals involved in healthcare supply chains². These industry players are quickly transitioning from manual processes to

Bar coding the vaccine

One project is the CDC’s vaccine identification pilot that is testing 2D bar coding on vaccines, specifically the GS1 DataMatrix bar code. Participants include two manufacturers and approximately 220 healthcare providers or immunisers. In the pilot, the Immunization Information Systems Support Branch in the CDC’s National Center for Immunization and Respiratory Diseases is testing how bar codes on vaccine vials and syringes can be scanned into patients’ electronic medical

¹ RTI International, “Prospective cost–benefit analysis of a two-dimensional barcode for vaccine production, clinical documentation, and public health reporting and tracking”, *Vaccine*, Volume 31, Issue 31, 28 June 2013.

² Locklair, Dale L., “Transforming Healthcare Supply Chains Into Healthcare Value Chains.” *Supply Chain Strategies and Solutions*. May/June 2012.

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records, and then used to populate downstream systems such as Immunization Information Systems.

In its part of the CDC, the Immunization Information Systems Support Branch team is interested in exploring how to make providers more efficient when it comes to immunisation management practices. Using technology and standards, the team believes it can help providers enhance patient safety with more accurate and complete vaccine data.

With the GS1 DataMatrix technology, significantly more data can be encoded into the bar code in a much smaller area than with a linear bar code. The NDC (National Drug Code) can be included using a GS1 GTIN, Expiration Date, and Lot Number all in one bar code that is appropriately sized for vaccine vials and syringes.

The decision to use GS1 Standards for vaccine identification in this pilot emerged from multiple meetings between the CDC, the American Academy of Pediatrics (AAP), and GS1 US®. The CDC team wanted to take a standards-based approach to have a broad impact across the diverse healthcare supply chain.

Vaccine Bar Codes

The concept of vaccine bar coding has evolved during the past decade. In 2004, the Food and Drug Administration (FDA) finalised its guidance to industry on bar coding, requiring the use of linear bar codes, like the GS1 Universal Product Code (U.P.C.) or GS1-128 bar code, on vaccines. While the vaccine's Lot Number and Expiration Date are not required by the FDA, the National Childhood Vaccine Injury Act of 1986 requires these attributes, thus necessitating that immunisers manually register them in patient records. However, in August 2011, the FDA released its final guidance to industry on vaccine bar code label requirements, which allowed manufacturers to use alternative symbologies like the 2D bar code. With this expanded direction, the CDC moved quickly to test the 2D bar code, announcing the vaccine identification pilot in the same month.

Bar coding the VIS

The CDC team received feedback from its partners stating that if it were to bar code vaccine vials and syringes, consideration should be given to the VIS. The team agreed that it made a lot of sense to put a bar code on the Vaccine Information Statement. Providers could then scan and record required VIS information in patients' medical records along with vaccine identification information.

"We decided to implement a set of standards that is widely used by industry – here in the US as well as around the world."

Warren Williams, Team Lead, Immunization Information Systems Support Branch, CDC

Produced by the CDC, the Vaccine Information Statement is an information sheet that explains to vaccine recipients, or to their parents or legal representatives, both the benefits and risks associated with a particular vaccine. The National Childhood Vaccine Injury Act requires that the appropriate VIS be provided to the patient each time a vaccine is administered. Certain VIS information must be recorded in the patient's medical record or on a permanent office log, the edition date being the key piece of data. By bar coding the VIS, the CDC team responded to the partner's request, giving them a great way to gain record-keeping efficiencies.

Part of the GS1 System of Standards, the GS1 Global Document Type Identifier uniquely identifies a document by type and may be encoded into a GS1-128 bar code, a GS1 Electronic Product Code™ (EPC)-enabled radio-frequency identification (RFID) tag, or a GS1 DataMatrix bar code. The GDTI can now offer healthcare providers an opportunity to electronically capture the VIS document type, like influenza or MMR, and the VIS edition date.

To implement the GDTI-encoded bar codes on Vaccine Information Statements, the team partnered with the CDC's branch responsible for VIS development. They tested scanning the bar code on different types of papers, in different colours, and with copies of the original VIS document. Many offices, for example, colour-code their VISs by vaccine type. The CDC team wanted to make sure providers could effectively scan the bar code in different situations . . . and it proved they could.

After just six months, the CDC announced the availability of the first Vaccine Information Statements with bar codes.

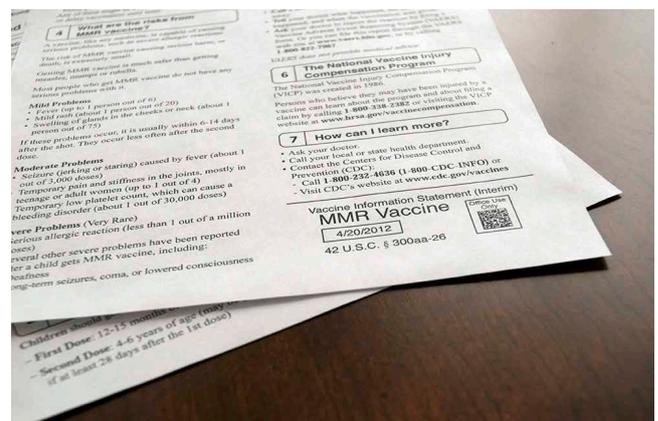


Figure 1: Part of the GS1 System of Standards, the Global Document Type Identifier is encoded in a GS1 DataMatrix bar code on the VIS. Healthcare providers can now scan the bar code to electronically capture the VIS document type, like MMR and VIS edition date.

Using a web-based service, the CDC creates a GDTI for each new and revised VIS. Any healthcare provider can take advantage of the benefits associated with the new bar coded VIS by purchasing a 2D bar code scanner and having its EMR system modified.

Advancing patient safety

Healthcare providers can benefit in multiple ways by using the new bar coded Vaccine Information Statements. Scanning the bar code reduces the time needed to record the VIS information. Providers may gain efficiencies in their immunisation management processes.

Yet, perhaps a more important benefit is reducing the risk of errors when transcribing vaccine information. If someone is manually updating a patient's medical record, there is always the chance for human error.

Near-perfect accuracy can be achieved when a provider scans a bar code to update a patient's medical record, a level of accuracy not attainable from manual methods. And in the future, with vaccine identification bar codes used by more and more manufacturers, healthcare providers can validate vaccines administered against vaccines listed in patients' EMRs, a major advancement in patient safety.

As America's public health agency, the CDC is focused on disease prevention and health preparedness. Yet, the team concludes it is also part of a global community that must be ready for "what is around the corner".

About the authors

Ken Gerlach, MPH, CTR, NCIRD/Immunization Services Division, Health Scientist - Centers for Disease Control and Prevention.

Mr. Gerlach has worked at Centers for Disease Control and Prevention (CDC) since 1998 in the areas of cancer registration and immunisation services. Prior to that time, he worked at Emory University as the Administrator of the Georgia Center for Cancer Statistics (GCCS), a unit of the Rollins School of Public Health. His research interests and expertise lie in the area of disease registration and public health informatics. Currently, Mr. Gerlach serves as the Contracting Officer Representative (COR) for the Implementation Pilot for Two-Dimensional Vaccine Bar Code Utilization project within the Immunization Information Systems Support Branch in the National Center for Immunization and Respiratory Diseases at the CDC.

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Mr. Williams received his MPH degree from Emory University in 1991. Since 1991, he has been working at the Centers for Disease Control and Prevention. He has experience with maternal and child health programmes, cancer registries, and most recently immunisation registries. His research interests and expertise lie in the development and utilisation of informatics efforts to promote public health programme development. Mr. Williams is involved in programme planning, system evaluation, and technical assistance. Currently, Mr. Williams is the team leader of the informatics unit in the Immunization Information Systems Support Branch in the National Center for Immunization and Respiratory Diseases at the CDC.

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Project Coordinator,
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