CASE STUDY

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

—WARREN WILLIAMS,
Team Lead, Immunization Information Systems Support Branch, CDC

Better Immunization Management for Patient Safety

CHALLENGE

Millions of vaccines are given each year by hundreds of thousands of healthcare providers (clinicians) across the U.S. To promote patient safety, the National Childhood Vaccine Injury Act of 1986 requires that providers record specific information about the administered vaccine and Vaccine Information Statement (VIS) in patient medical records. The Centers for Disease Control and Prevention (CDC) wanted to help providers improve efficiencies and accuracy when recording critical vaccine and VIS information.

SOLUTION

The 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 barcode – can be scanned on vaccine vials and syringes for populating electronic medical records (EMRs). The CDC is now adding a GS1 DataMatrix barcode encoded with the GS1 Global Document Type Identifier (GDTI) to each new VIS so that providers can automatically capture and record VIS document type and edition date into EMRs.

BENEFITS

With the new automated processes, the CDC expects that providers will save time and gain efficiencies in immunization management. Also, providers can reduce the risk of errors by scanning barcodes versus manually transcribing vaccine and VIS information. This improved accuracy means improved safety for patients.

FROM MANUAL TO ELECTRONIC

Vaccines are manufactured and given each year in the U.S. to millions of newborns, children and adults. Whether part of seasonal immunizations 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 organization to another along the way.

Consider that there are more than 650,000 different organizations in the U.S. alone, including manufacturers, distributors, carriers, group purchasing organizations, and hospitals, involved in healthcare supply chains[1]. These industry players are quickly transitioning from manual processes to automated processes and EMRs. As this movement progresses, information about each vaccine must be shared – completely and accurately – among these organizations for patient safety and operational efficiencies.

"Tools and technologies are becoming more and more usable and mature, spurring an increase in EMR adoption," says Warren Williams, team lead for the Immunization Information Systems Support Branch in the CDC's National Center for Immunization and Respiratory Diseases. "In turn, EMR implementations are helping to facilitate healthcare initiatives like this 2D barcoding project."

BARCODING THE VACCINE

One project is the CDC's vaccine barcode pilot that is testing 2D barcoding on vaccines, specifically the GS1 DataMatrix barcode. Participants in the pilot include two manufacturers and more than 220 healthcare providers or immunizers. Project Coordinator Ken Gerlach, a member of Williams' team, is leading the effort. "In the pilot, we are testing how barcodes on vaccine vials and syringes can be scanned into patients' electronic medical records, and then used to populate downstream systems, such as Immunization Information Systems."

Williams adds, "In our part of the CDC, we're interested in exploring how to make providers more efficient when it comes to immunization management practices. Using technology and standards, we believe we 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 barcode in a much smaller area

....

"Using technology and standards, we believe we can help providers enhance patient safety with more accurate and complete vaccine data."

—WARREN WILLIAMS,
Team Lead, Immunization Information Systems Support Branch, CDC

Vaccine Barcodes

The concept of vaccine barcoding has been evolving during the past decade. In 2004, the Food and Drug Administration (FDA) finalized its guidance to industry on barcoding, requiring the use of linear barcodes, like the GS1 Universal Product Code (U.P.C.) or GS1-128 barcode, on vaccines. While the vaccine 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 immunizers manually record them in patient records. However, in August 2011, the FDA released its final guidance to industry on vaccine barcode label requirements, which allowed manufacturers to use alternative symbologies, like the 2D barcode. With this expanded direction, the CDC moved quickly to test the 2D barcode, announcing the vaccine identification pilot in the same month.

than with a linear barcode, including the NDC [National Drug Code] using a GS1 GTIN, expiration date and lot number – all in one barcode 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®. "We wanted to take a standards-based approach to have a broad impact across the diverse healthcare supply chain," advises Williams. "We decided to implement a set of standards that is widely used by industry – here in the U.S. as well as around the world."

The implementation phase of the vaccine barcode pilot is planned to conclude in April 2013 after nine months of testing at provider sites. At that time, pilot participants will share best practices and any implementation challenges for labeling and tracking vaccines using DataMatrix barcodes. The pilot will also evaluate and document the impact of DataMatrix barcodes on these participants – manufacturers and healthcare providers – and their reporting systems.

BARCODING THE VIS

"We received feedback from our providers, 'if we're going to barcode the vaccine vials and syringes, what about the VIS?'" says Williams. "It made a lot of sense that we put a barcode on the Vaccine Information Statement. Providers can scan and record required VIS information in patients' medical records along with vaccine identification information."

Produced by the CDC, the Vaccine Information Statement is an information sheet that explains to vaccine recipients, or 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

[1] Locklair, Dale L.,"Transforming Healthcare Supply Chains Into Healthcare Value Chains." Supply Chain Strategies and Solutions. May/June 2012.

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

—WARREN WILLIAMS,

Team Lead, Immunization Information Systems Support Branch, CDC

. . . .

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," explains Williams. "By barcoding the VIS, we responded to providers' 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 barcode, or a GS1 Electronic Product Code™ (EPC)-enabled radio-frequency identification (RFID) tag, or a GS1 DataMatrix barcode. 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 barcodes on Vaccine Information Statements, Gerlach partnered with the CDC's branch responsible for VIS development. The team tested scanning the barcode on different types of papers, in different colors, and with copies of copies of copies of the original VIS document. "Many offices, for example, color-code their VISs by vaccine type," says Gerlach. "We wanted to make sure providers could effectively scan the barcode in different situations… and we proved they could."

After just six months, the CDC announced the availability of the first Vaccine Information Statements with barcodes. To date, the CDC offers 12 VISs with barcodes.

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 barcoded VISs by purchasing a 2D barcode scanner capable of reading a DataMatrix barcode and having their EMR system modified.

ADVANCING PATIENT SAFETY

Healthcare providers can benefit in multiple ways by using the new barcoded Vaccine Information Statements. "Scanning the barcode certainly reduces the time needed to record the VIS information," says Williams. "Providers can gain efficiencies in their immunization management processes."

Yet, perhaps the 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 barcode to update a patient's medical record – a level of accuracy not attainable from manual methods," says Gerlach. "And in the future, with vaccine identification barcodes used by more and more manufacturers, healthcare providers can validate vaccines administered against vaccines listed in patients' EMRs – a major advancement in patient safety."

Williams looks forward to sharing the projects' results and lessons learned with other immunization organizations and government agencies worldwide. Williams concludes, "As America's public health agency, the CDC is focused on disease prevention and health preparedness. Yet, we're also part of a global community that must be ready for 'what's around the corner.'"
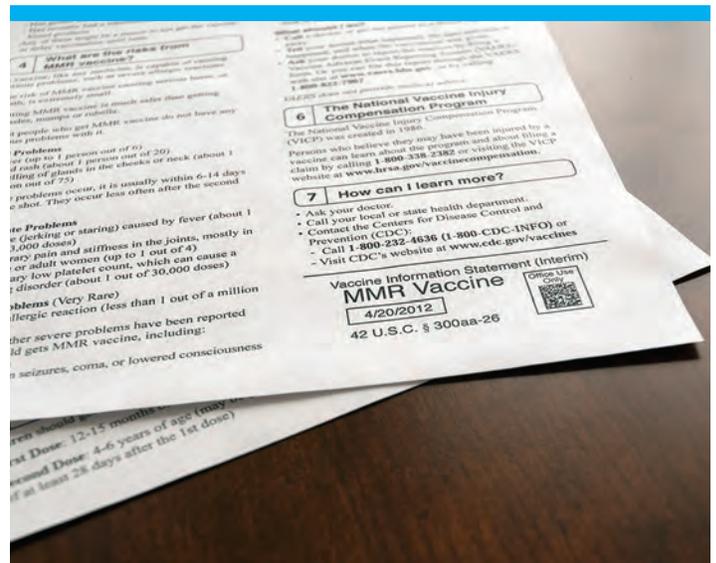
Part of the GS1 system of Standards, the Global Document Type Identifier is encoded in a GS1 DataMatrix barcode on the VIS. Healthcare providers can now scan the barcode to electronically capture the VIS document type, like MMR, and the VIS edition date.

CONTACT US

GS1 Healthcare US® provides expertise, tools and resources to help companies implement GS1 Standards to improve patient safety and supply chain efficiency. To learn more, contact GS1 Healthcare US at GS1HealthcareUS@GS1US.org or visit our website at: www.GS1US.org/healthcare

ABOUT GS1 US

GS1 US, a member of GS1, is an information standards organization that brings industry communities together to solve supply-chain problems through the adoption and implementation of GS1 Standards. More than 200,000 businesses in 25 industries rely on GS1 US for trading-partner collaboration and for maximizing the cost effectiveness, speed, visibility, security and sustainability of their business processes. 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® (UNSPSC®). www.GS1US.org

ABOUT GS1 HEALTHCARE US

GS1 Healthcare US is an industry group that focuses on driving the adoption and implementation of GS1 Standards in the U.S. healthcare industry 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. www.GS1US.org/healthcare

"Near-perfect accuracy can be achieved when a provider scans a barcode to update a patient's medical record – a level of accuracy not attainable from manual methods."

— **KEN GERLACH,** *Project Coordinator, Immunization Information Systems Support Branch, CDC*

THE GLOBAL LANGUAGE OF BUSINESS

CORPORATE HEADQUARTERS
Princeton Pike Corporate Center
1009 Lenox Drive, Suite 202, Lawrenceville, New Jersey 08648 USA
T +1 937.435.3870 E info@gs1us.org
www.gs1us.org