

Mapping of Standards to Facilitate Immunization Information Exchange through Two-Dimensional Bar Coding of Vaccine Products

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Abstract

Purpose—A two-dimensional barcode that includes both static information (vaccine identifier) and variable information (expiration date and lot number) can facilitate streamlined documentation and sharing of vaccine administration. We sought to identify how vaccine tracking information in the two-dimensional barcode is represented in systems that are used by pharmacies, providers, and public health agencies.

Methods—We identified and reviewed relevant information technology standards that govern data storage and exchange for providers, pharmacy systems, billing systems, and manufacturers to identify how each system codes the vaccine identifier, expiration date, and lot number. We selected standards commonly used by manufacturers, providers, and pharmacies and mapped the critical vaccine data elements across them. We shared the mapping with stakeholders to identify areas of alignment across standards and discussed how to address misalignment going forward.

Results—Data elements were not consistently formatted in each type of information system. The vaccine lot number and expiration date were consistent, which would facilitate sharing across information systems. However, the way to identify a given vaccine is not consistent in each standard and would require manual entry. This inconsistency is related to the segmentation of the National Drug Code into three components. Therefore, vaccine identification methods differ across the systems governed by different standards.

Conclusion—Patient safety can be enhanced by automated verification of the vaccine ordered versus the vaccine administered. Immunizers' back-end systems would benefit from automated documentation and reporting.

Keywords: immunization; information exchange; public health; immunization information systems (registries); bar coding

Introduction

Immunizations are an important public health intervention for preventing the spread of vaccine-preventable disease. To understand the effect of vaccination on a community, it is important to track vaccination rates. Generally, this tracking is done through immunization information systems (IISs), also known as immunization registries. Immunizations administered in a given community are reported to an

IIS after being recorded at the point of administration.¹ In addition, IISs are used to support important public health activities, such as tracking and monitoring vaccination rates and managing vaccine recalls. These activities are predicated on vaccine administrators sending information to the IIS and the IIS being able to receive and process it.²

One way to facilitate sharing information about vaccine administration is through use of a two-dimensional (2D) barcode on vaccine products. This type of barcode allows necessary information to be encoded in a small space. If the barcode can be read and uploaded at the point of vaccine administration and then the information can be sent to downstream systems, this process can save time and improve accuracy. Several policies affect the documentation and sharing of information for 2D barcodes on vaccine products. These policies include the National Childhood Vaccine Injury Act (NCVIA) of 1986, US Food and Drug Administration (FDA) labeling requirements, and the federal electronic health record (EHR) incentive program. We describe each of these below.

The NCVIA mandates that immunization documentation include manufacturer and product information, lot number, and expiration date (hereafter referred to as vaccine-specific information) and that this vaccine-specific information be sent to an IIS for tracking and monitoring. Currently, processes for tracking vaccine-specific information are largely manual and labor-intensive. These processes particularly affect the workflow of providers who administer vaccines in the midst of other activities.³ Encoding vaccine-specific information into a barcode can reduce time and improve the accuracy of vaccine tracking if barcodes can automatically be read and parsed by EHRs. The primary advantages of the barcode are improved accuracy and speed of data entry, as seen in a Canadian study integrating bar coding into vaccine administration.⁴ This finding was mirrored by those of a pilot project in the United States.⁵ This pilot study pointed to the need for systems and processes to be adapted so that information in the barcode can be integrated into information systems and used. To do so, it is necessary to understand the elements that make up the 2D barcode and identify how they are operationalized in different information systems.

The FDA requires that all human drug and biological products include a linear barcode with the product's National Drug Code (NDC) number, which identifies the manufacturer, product name, and packaging information.⁶ The vaccine lot number and expiration date must be coded separately because they are not part of the NDC. It is difficult to encode all the vaccine-specific information into a linear barcode because the barcode would become too long to fit on a syringe, 0.5-mL vaccine vial, or ampoule, which are common forms of vaccine packaging. The use of 2D barcodes would allow inclusion of vaccine-specific information in a small space, thereby making the labeling compliant with the NCVIA. Thus, a barcode affixed to product labels could include all the vaccine-specific information that is required by the NCVIA as well as the vaccine identifier, and be read by a barcode reader. Figure 1 provides examples of linear and 2D barcodes. Barcodes would include the Global Trade Item Number (GTIN), which would be assigned in cooperation with GS1, the organization that coordinates barcodes internationally.^{7,8} The NDC is embedded in the GTIN.

As a consequence of federal incentives,⁹ more healthcare providers are moving from manual, paper-based charting to the use of EHRs. To qualify for the financial incentives, providers must adopt EHRs that meet certain metrics for meaningful use, one of which is sharing immunization information between the EHR and the IIS.¹⁰ Vaccine barcodes can facilitate data sharing and exchange if they can be read and recognized by the individual providers' EHRs, pharmacy information systems, and IISs.¹¹⁻¹⁴ Information exchange is facilitated by interoperability, that is, the "ability of different information technology systems and software applications to communicate, exchange data, and use the information that has been exchanged. Data exchange schema and standards should permit data to be shared across clinicians, lab, hospital, pharmacy, and patient regardless of the application or application vendor."¹⁵

Tracking immunization data across manufacturing, administration, and billing systems requires sharing vaccine-specific product information. Information systems used by those who manufacture, administer, and bill for immunizations use different standards, which outline the definitions, formats, and representations of data. Thus, standards promote consistency in data exchange and data sharing.¹⁶⁻¹⁸

In this study, we sought to understand the implications of the use of 2D barcodes on vaccine products. We identified and evaluated the different standards used by EHRs and IISs so that a 2D vaccine barcode could be automatically uploaded and shared across multiple systems. This process would be necessary to allow mobile device apps for vaccine identification to be developed and integrated throughout the path of the vaccine.¹⁹ Although existing studies have addressed interoperability generally, specific research on how the information in a 2D barcode would flow through information systems from administration to billing and reporting has not been conducted.

Methods

We conducted data mapping between the standards governing barcoded vaccine data, EHRs, and IISs to more fully understand the interoperability considerations associated with bar coding of vaccines.²⁰ This research was part of a larger study evaluating the effects of the 2D barcode that included economic and public health aspects.²¹ This work is necessary so that pharmacy systems, EHRs, and IISs can share information about vaccines and achieve the potential benefits of 2D bar coding.

Selection of Standards for Review

We identified the information systems and the associated standards that are relevant to vaccines and immunization practice. To ensure that we were addressing multiple stakeholder perspectives, we discussed the available standards for mapping with representatives from GS1 Healthcare US, the Centers for Disease Control and Prevention (CDC), organizations representing immunization provider stakeholders (including the American Academy of Pediatrics), EHR and IIS vendors, and Health Level Seven (HL7).²² Because GS1 provides the actual product barcodes that are used internationally,²³ vaccine manufacturers use GS1 standards for their barcodes. A different standard, HL7, governs how information is used and shared within EHRs.²⁴

In order to allow vaccine barcodes to be uploaded to EHRs, we mapped the HL7 segments associated with vaccine administration and messaging. We also mapped the CDC's *HL7 Version 2.5.1: Implementation Guide for Immunization Messaging*.²⁵ For claims processing, healthcare providers and health plans use the ASC X12 standard,^{26, 27} whereas pharmacies that administer immunizations use the National Council for Prescription Drug Programs (NCPDP) standards.²⁸ Table 1 provides an overview of the standards we reviewed, how they are used, the stakeholders who use them, and the systems in which they are used.

Review of Standards, Mapping of Standards, and Mapping Validation

We conducted source-based mapping, in which items from a source document (GS1 2D barcode) are compared to corresponding items in the other target documents.

GS1 and the American Academy of Pediatrics developed joint guidance for operationalizing the 2D barcode on vaccine products.²⁹ We applied this guidance to identify placements for the vaccine identifier, lot number, and expiration date (referred to in the aggregate as “elements”) to meet the other standards. Our process was as follows. First, we reviewed these elements and documented the number of characters the standard allocated for each of the elements (length), the data type of each element (format), and how the standard parsed each element (definition). Then, we reviewed each standard and identified where the elements would be located, and we documented the length, format, definition, and other identifying elements of each field. During the mapping, we took notes and cited examples for further information and reference. In addition to reviewing the standards, we reviewed background reports and white papers provided by interviewees and FDA guidance. We reviewed the results with stakeholders and incorporated their feedback into final results as appropriate.

Results

The importance of interoperability for exchanging immunization-related information is emphasized by the number of systems, such as IISs, pharmacy systems, and EHRs, involved in different stages of the data flow. Each system has its own representation of vaccine-specific information.

Path of a Vaccine

One of the findings involved documenting the path of the vaccine, the systems associated with each step of the path, and the relevant standards. We identified immunization processes, systems, and standards in concert with subject-matter experts. The path of the vaccine and the relevant standards are outlined in Figure 2. This figure represents a high-level overview of the steps, systems, and standards involved in administering vaccines and sharing information with downstream systems. In this figure, *VFC* refers to vaccines provided through the Vaccines for Children program, which provides vaccines to children without insurance coverage.³⁰ Vaccines provided through this program have a slightly different workflow, as reflected in the figure.

NDC Construction

Because the NDC is part of the GTIN, it is important to understand how it is constructed and the implications of the structure. The NDC is a combination of three segments: labeler code, product code, and package code, with the labeler code assigned by the FDA. Because each manufacturer is permitted to create product and package codes, and there is no FDA requirement that these codes have a set field length, it is not possible to write automated logic to parse the NDC without delimiters such as hyphens separating the three components. Thus, because the FDA has control of only the labeler code, the following numbers could refer to three hypothetical vaccine products, depending on the configuration chosen:

- 12345-678-09
- 1234-5678-09
- 12345-6780-9

GS1 does not recommend or support parsing the GTIN or NDC numbers, but recommends that they be read as a whole to reduce the chance of confusion due to variable length fields and to avoid the risk of incorrect parsing. As a result, all of these numbers would be 1234567809 in the NDC segment of the GTIN. Further, because there is no way to identify which of these three hypothetical products is referred to in the GTIN without delimiters, a given 10-character NDC code may not be directly linkable to a single vaccine product.

NDC Position in the GTIN

The GS1 standard uses the 10-digit NDC as is and does not pad the NDCs with leading or trailing zeros or make any other adjustments. GS1 maintains a registry of unique GTINs that refer to only one specific product, based on the NDC.

Figure 3 illustrates the specific positions of each character of the NDC encoded within the GTIN:

- Position 1: A one-digit indicator (value from 0 to 8).
- Position 2: Always zero.
- Position 3: Always 3 to indicate that what follows is the NDC number.
- Positions 4 through 13: Always the 10-digit NDC code. The NDC labeler code must be registered with GS1 to be valid as a GTIN.
- Position 14: Check digit (calculated from the first 13 digits of the GTIN as a system check).

Relationship of the GTIN to Vaccine Product Fields

The vaccine product field is the vaccine identifier and corresponds to the product code of the NDC. The GTIN does not map to a single code for the other standards.³¹ Rather, there is a one-to-many relationship between the GTIN and the vaccine product fields of most data exchange standards. Table 2

summarizes the mapping of different 2D barcode elements across standards. The table is organized so that the fields that would constitute the 2D barcode are on the far left. Each of the other columns identifies how the components of the 2D barcode are stored using different standards. The standards identified relate to the path of the vaccine (see Figure 2).

The variable pieces of information in the barcode—the expiration date and lot number—map directly to individual fields across standards. There is no expiration date or lot number information in the X12 or pharmacy Electronic Data Interchange (EDI) standards because the expiration date and lot number of a given vaccine are not necessary for billing purposes. Thus, there is not a direct correlation from the 2D barcode to the systems that it must populate. We examine the implications of this in the Discussion section.

Discussion

The benefits of 2D bar coding of vaccines are predicated on technology integration and interoperability.³² Providers administer immunizations as part of their normal responsibilities and must manually enter information about the vaccine. A 2D barcode that is scanned and has information automatically uploaded could prevent some of this manual data entry and improve accuracy and efficiency. The financial incentives established in the Health Information Technology for Economic and Clinical Health Act, part of the American Recovery and Reinvestment Act, do not apply to pharmacies.³³ Pharmacies also have a different workflow and set of information needs than other vaccine providers. Thus, pharmacy system vendors may not necessarily prioritize updates that would allow them to share immunization information.³⁴ If IISs can receive data from vaccine providers more generally, they can monitor immunization safety more broadly.

Multiple Lot Numbers

Bar coding shows great promise for workflow improvement and ultimately for patient safety. However, barcode standards cannot automate all vaccine documentation, nor can they ensure that administration and documentation occur at the same time. Bar coding cannot address existing concerns about products with multiple lot numbers. Administration of some vaccines requires combining components that have their own lot numbers. Systems can accommodate information from one component, but not both. This means that either the systems need to be changed to allow scanning multiple codes or there needs to be a codified understanding of which barcode should be scanned. Also, methods should be put in place for use in case the incorrect item is scanned so that the incorrect information can be replaced with the appropriate information.

Another reason for the existence of multiple product identifiers and lot numbers is repackaging, which occurs for a small number of vaccines. In this case, the repackager applies its own lot number and NDC, as it does for drugs. In this scenario, we expect the manufacturer's label to be superseded by the repackager's label, which is the practice today. This means that the repackager would require its own GTIN to generate the barcode. Repackagers are required to maintain a database of their product identifiers and lot numbers for recall purposes, and they will continue to do so. We do not expect that current procedures would change.

GTIN and NDC

Because of the construction of the NDC, mapping the GTIN to multiple fields across different standards is challenging. If the NDC segments had a fixed character length, then a decision rule could be written to extract segments of the NDC based on the characters' positions. However, the three segments do not have consistent field lengths, precluding the option of writing a decision rule.

Unless the NDC can be parsed from the GTIN, a workaround such as a lookup table between the GTIN and a segmented NDC code will be required to facilitate electronic data exchange. The use of a lookup table will facilitate meeting the criteria for meaningful use, which specifically cite the CDC implementation guide and IIS reporting requirements.

Conclusion

The use of 2D barcodes to facilitate exchange of immunization information has the potential to improve data quality and efficiency in the documentation of vaccine data. These benefits are predicated on the technical ability to read the 2D barcode and its integration into systems and processes. In other areas in which bar coding is used, such as in medication administration or as patient identifiers, technical accommodations are made, such as the use of mapping tables or crosswalks to facilitate mapping. Because immunizations are administered in a variety of settings with different systems, individual vendor-specific mapping tables are not feasible. Mapping is a critical step in implementation that will help facilitate information exchange by outlining where the information in the barcode would fall in each standard, thereby providing those who implement the barcode with the specifications necessary to read and interpret the GTIN.

In the near term, for the implementation of 2D barcodes to be successful, the following will be necessary: education and outreach for all stakeholders, dissemination of technical specifications and business requirements for data exchange, and collaboration between a number of stakeholders. Thus, setting the foundation for collaboration and information sharing now will help ensure smooth implementation and update efforts for the 2D barcode.

The benefits of 2D bar coding go beyond the efficiency gained by reducing manual processes. By incorporating 2D barcodes into EHRs, providers can use integrated decision support features to ensure that patients get the appropriate vaccines. This benefit depends on a workflow in which the barcode is scanned prior to administration so that decision support can occur at the point of immunization. Automated exchange between the provider and IISs can support improved IIS coverage and completeness of vaccine information. Adding more immunization information to IISs will help improve vaccine management and immunization reporting and monitoring. Mapping of standards is an important precursor for achieving these benefits in the pharmacy and beyond.

Acknowledgments

The authors acknowledge Warren W. Williams for his contributions to this work. The authors are grateful to representatives from GS1 Healthcare US; organizations representing immunization provider stakeholders, particularly the American Academy of Pediatrics; electronic health record and immunization information system vendors; and HL7 for their participation in this effort. This work was funded by the Centers for Disease Control and Prevention, contract number GS10F0097L, with a period of performance from October 1, 2010, through September 21, 2012. The findings and conclusions in this report are those of the authors and do not necessarily represent the views of the Centers for Disease Control and Prevention.

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Table 1

Standards Reviewed and Their Use

Standard	Usage	Major Stakeholders	Systems
GS1	Used by manufacturers to register GTINs and print the two-dimensional barcodes; used by other systems that read the barcode	Vendors, providers, registries, CDC, IIS program managers, health plans, pharmacy immunizers	EHR vendors, IISs, practice management systems, payer billing systems, pharmacy systems
HL7 EHR Functional Model	Used for information exchange in health information technology	Vendors, providers, registries, CDC	EHR vendors, IISs, practice management systems
CDC 2.5.1 implementation guide	Provides translation of HL7 standards for the provider community	Vendors, providers, IIS program managers, CDC	EHR vendors, IISs, practice management systems
X12 837P transaction standard (4010 and 5010)	Used by providers to submit claims	Providers, health plans	EHR vendors, practice management systems, payer billing systems
NCPDP (pharmacy EDI)	Used by pharmacies for documentation and billing of immunizations administered in pharmacies	Pharmacy immunizers	Pharmacy systems

Abbreviations: CDC, Centers for Disease Control and Prevention; EDI, Electronic Data Interchange; EHR, electronic health record; GTIN, Global Trade Item Number; HL7, Health Level Seven; IIS, immunization information system; NCPDP, National Council for Prescription Drug Programs.

Table 2

Summary of Mapping across Standards

GS1	FDA's National Drug Code	HL7—Bar Coding Message Segment	2.5.1 Implementation Guide (CDC)	ASC X12—837-P Transaction	HITSP Immunization Messages	NCPDP
Global Trade Item Number (GTIN)	Label code	Administered code	Substance manufacturer name	Labeler code	Substance manufacturer	Labeler code
	Product segment	Substance manufacturer name	Administered code	Product segment	Administered code	Product segment
	Package segment	Administered barcode identifier	Administered drug strength volume	Package segment		Package segment
			Administered drug strength volume units			
Expiration date (YYMMDD)		Substance expiration date	Substance expiration date			
Batch or lot number		Substance lot number	Substance lot number		Substance lot number	

Abbreviations: CDC, Centers for Disease Control and Prevention; FDA, Food and Drug Administration; Healthcare Information Technology Standards Panel (HITSP,) HL7, Health Level Seven; NCPDP, National Council for Prescription Drug Programs.

Figure 1

Examples of Linear and Two-Dimensional (2D) Barcodes

**Example of linear barcode**

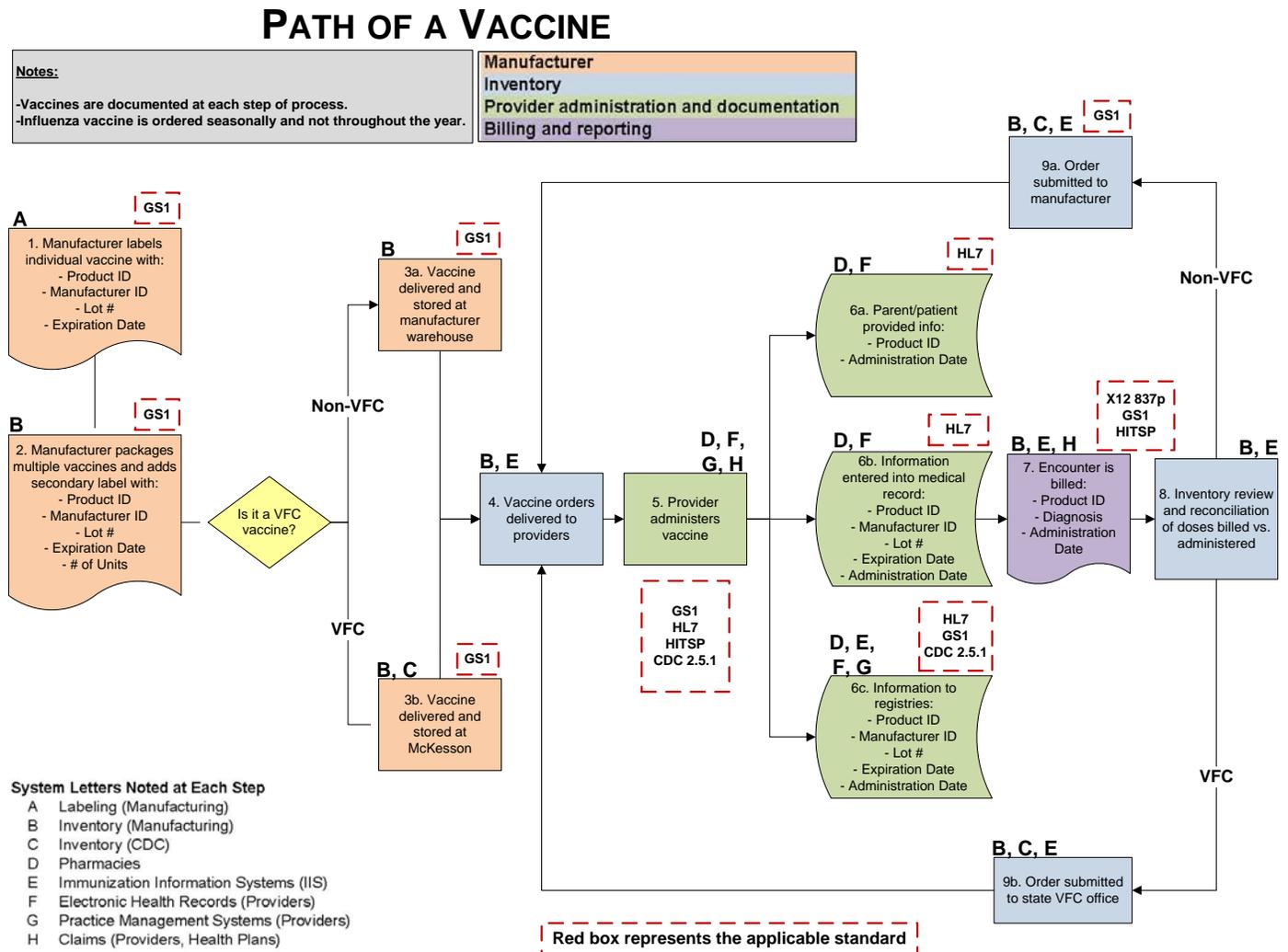
Current linear barcodes required by the Food and Drug Administration contain only the vaccine product identification information.

**Example of 2D barcode**

A 2D, or data matrix, barcode can include the expiration date and lot number as well as product identification information.

Figure 2

Path of a Vaccine and Related Information Systems



Abbreviations: CDC, Centers for Disease Control and Prevention; Healthcare Information Technology Standards Panel (HITSP) ; HL7, Health Level Seven; VFC, Vaccines for Children program.

Figure 3

Encoding of the National Drug Code (NDC) in the Global Trade Item Number (GTIN)

