EMR/IIS 2D Barcode Functional Capabilities Guide

Version 2.2

September 2020

Table of Contents

Change Log

Date	Version	Change
July 2013	1.0	Initial publication
Oct 2014	1.1	a. Input change log b. Section 2, Introduction. Replaced "pilot" with "CDC 2D barcode initiatives" c. Entire report: Changed language describing pilot activities from present to past tense. d. Updated Table 1. 2D Vaccine Barcoded Products in Distribution to reflect current 2D barcoded vaccines. Added link to current table on CDC page. e. Updated Table 9: 2D Barcoded VIS to reflect current 2D barcoded VIS f. Entire report: Standardized inconsistent spacing following sentences g. Entire report: Replaced "product identification" with "product identifier" h. Entire report: Replaced instances of "EHR/IIS system" with "EHR/IIS" i. I-P-02, A-P-02: Added detail to read the entire lot number from a 2D barcode scan j. I-P-07, A-P-07: Added direction how to process "00" day in expiration date k. V-P-07: Added clarification on allowing multiple VIS per single injection. l. Entire report: Minor grammar adjustments
Sept 2016	1.2	a. Updated Section 3, Background, to reflect current state and updates for 2DA. b. Updated Table 1 to reflect current 2D barcoded vaccines. c. Removed Table 9 (Appendix F) as all VIS have 2D barcodes d. Removed Appendix A (advisors list) (and renumbered Appendices) e. Fixed references to Appendices throughout f. Added clarification to A-P-09 regarding inventory and unit of use/ unit of sale to decrementing process g. Added section 7.4 for special considerations for pharmacies
May 2017	1.3	a. Updated Section 7.1.1 to reflect current guidance on serial numbers contained in vaccine packaging. b. Updated Section 7.1.4 to incorporate additional detail on scanner configuration. c. Updated Section 7.3.1 to incorporate additional detail on VIS documentation d. Added additional documentation to Appendix D. e. Entire report: Minor grammar adjustments

Date	Version	Change

Oct 2018	2.0	a. Entire report: Updated content and streamlined document organization for improved usability.
		    a. Renumbered sections
		    b. Renamed appendices
		b. Entire report: Replaced instances of "EHR/IIS" with "EMR/IIS"
		c. Entire report: Replaced instances of "primary packaging" with "unit of use"
		d. Entire report: Replaced instances of "secondary packaging" with "unit of sale"
		e. Updated section 1.0: Updated language to clarify purpose of document.

September 2019	2.1	a. Changed title of document to Functional Capabilities Guide b. Updated section 4.1: added inventory module to the types of system modules c. Updated section 4.2, table 4: Added note that some vaccines have multiple components and systems should be able to scan data for all d. Updated section 4.2, A-P-02: added serial number to information for Unit of Sale; differentiated between UoS and UoU e. Updated section 5.1: updated DSCSA information f. Updated section 5.2.1: added paragraph "EMR/IIS can record both lyophilized and diluent (or adjuvant and vaccine) components of vaccine" g. Entire report: Formatted tables to ensure all content can be viewed
July 2020		a. Entire report: Reviewed entire report and separated EMR and IIS where applicable i. Added and Renumbered sections b. Entire report: Replaced 2D vaccine barcode with Vaccine 2D barcode c. Entire report: Replaced GTIN with GTIN/NDC where applicable d. Updated section 1.2: Added paragraph "Although the functional capabilities required to capture and process the 2D barcode are similar in both the EMR and IIS…as defined by the CDC" e. Updated 2.1: Replaced 2D Barcode Usage with 2D Barcode Utility f. Updated 3.1: Separated Scenario 1 (Vaccine Inventory) into Scenario 1a (Vaccine Inventory- EMR) and 1b (Vaccine Inventory- IIS) g. Updated 4.0: Tailored scenario 1 for Vaccine Inventory recording for EMR only h. Added 4.1: Added Scenario 1b which is tailored to vaccine inventory recording for IIS only i. Updated section 4.3: Added a last row to the EMR/IIS interaction table to document how EMR directly reports vaccine administration data to the IIS j. Updated section 4.4: Deleted instances of IIS k. Updated section 5.1: Added paragraph "IIS records inventory by entering… depletion" l. Updated section 5.1.2: Re-created figure into two figures namely EMR inventory management process flow and IIS inventory management & reporting process flows. Also updated section text to reflect changes to process flow and a paragraph about decrementation. m. Updated section 5.2.1: Added an assumption/consideration titled "Reporting of vaccine administration data to the IIS" n. Updated 5.2.2: Updated process flow o. Updated 5.3.2: Updated process flow

Feedback

If you have feedback regarding the content of this document or suggestions for improvement, please contact iissb2dbarcode@cdc.gov.

1.0 Introduction

A primary goal of the Centers for Disease Control and Prevention's (CDC) vaccine two-dimensional (2D) barcode initiatives is to explore the potential of scanning 2D barcodes on vaccine-related products in terms of data quality and timeliness of the data capture.

Since 2010, CDC has launched three pilots related to vaccine 2D barcode scanning. These pilot efforts have drawn attention to the benefits of 2D barcoding at provider sites. As a result, they have helped to initiate the adoption of 2D barcodes by vaccine manufacturers, providers, and EMR/IIS vendors. As 2D barcode adoption continues to increase, it is critical that EMR/IIS software solutions have the ability to read and translate data from the barcodes.

1.1 Purpose

The purpose of this document is to serve as a guide for software developers to describe the EMR/IIS 2D barcode functional capabilities identified throughout the implementation of the vaccine 2D barcode initiatives. It describes the technical capabilities of EMR/IIS software systems needed to allow providers giving immunizations to capture information encoded within the 2D barcode. EMR/IIS software developers should use this document as a reference when developing 2D barcode scanning capabilities.

1.2 Scope

This document includes core requirements and use cases that should be incorporated when developing 2D barcode scanning EMR/IIS technology. Although the functional capabilities required to capture and process the 2D barcode are similar in both the EMR and IIS, there is a primary difference in the purpose of each system. While the EMR is intended to be used for patient vaccine administration and documentation, the IIS serves as a system of record that contains complete demographic and immunization data for children, adolescents and adults residing or immunized within a jurisdiction. For the purpose of this document, the IIS is considered to be used for storing and tracking of immunization data and publicly funded vaccines – as defined by the CDC. More assumptions and limitations are also included in this document for consideration. This content should be seen as foundational and end-users of the EMR/IIS technology should be solicited for additional detailed requirements, as needed.

The content of this document is subject to change and will be updated in the future to reflect technological advancements and an evolving understanding of EMR/IIS 2D barcode capabilities.

1.3 Audience

This document is intended for EMR/IIS software developers. For decision makers in healthcare centers considering implementation of 2D barcode scanning, please refer to the Implementation Guide.

1.4 Contents

Below is an overview of the organization of this document:

- **2.0 Background Basics:** Provides the background on 2D vaccine barcode usage.

- **3.0 Functional Capabilities Overview:** Succinctly describes the general business needs and requirements that drive the functional capabilities described in Section 4.0: Use Cases.

- **4.0 Use Cases with Functional Capabilities:** Illustrates the distinct use cases that will allow developers to understand how vaccine 2D barcoding capabilities will be used.

- **5.0 Functional Capabilities Details:** Captures in-depth details regarding each of the functional capabilities (see Section 3.0).
- **Appendices:** Further details background information on the collection of functional capabilities and vaccine 2D barcode standards. Developers should refer to the Appendix for additional context.

2.0 Barcode Basics

2.1 2D Barcode Utility

Vaccine 2D barcodes are used to identify vaccine products and Vaccine Information Statements.

Understanding Vaccine Products

Vaccine products are vials of vaccine, intranasal sprays, or pre-filled syringes of vaccine that can be administered to patients. Vaccines can be ready-to-administer, or require mixing such as when a lyophilized component and diluent are to be mixed just prior to administration.

Unit of Use (UoU) and Unit of Sale (UoS): Pharmaceutical products are packaged in multiple layers. The primary packaging refers to the individual usable unit (i.e., Unit of Use or 'UoU'), the secondary packaging is the box or package that contains multiple UoU products (i.e., the Unit of Sale or 'UoS') and there is a tertiary layer that can be the carton that contains the UoS packages. In this report, we are going to focus on the UoU and UoS; each has distinct product information to support movement along the supply chain and for inventory management purposes.

The Global Trade Item Number (GTIN) is a GS1 product identifier which contains the National Drug Code (NDC). GS1 is a standards development organization for barcodes and the NDC is a U.S. Food & Drug Administration (FDA) product identifier. The label affixed to the UoS products includes the GTIN, serial number, expiration date, and lot number (in human readable form and within the 2D barcode). The Drug Supply Chain Security Act (DSCSA)[1] requires that 2D barcodes be affixed onto UoS packaging. For vaccines, a UoU could be one pre-filled syringe or one drawn dose from a single or multi-dose vial. For vaccines that require mixing, as described above, there are typically two UoU products – one for the diluent and one for the lyophilized vaccine. The label affixed to the UoU products includes the GTIN, expiration date, and lot number (in human readable form and within a 2D barcode).

As of this document's publication date, most major vaccine manufacturers are shipping their U.S. products with 2D barcodes on the UoU (vial/syringes) product presentations. The list of presentations is updated as products are introduced (or retired) and is maintained on the CDC website (https://www.cdc.gov/vaccines/programs/iis/2d-vaccine-barcodes/index.html).

Vaccine Information Statements (VIS)

Vaccine information statements (VIS) provide patients with information about vaccines they will receive. According to the National Childhood Vaccine Injury Act (42 U.S.C. §300aa-26), immunizers are required to provide patients a copy of the applicable VIS prior to vaccine administration, and are required to maintain notation about the VIS edition date and the date the VIS was provided to the patient.[2]

As part of CDC 2D barcoding initiatives, CDC added 2D barcodes to VIS. This technology allows immunization providers the ability to scan the code and edition date of a VIS into an EMR, IIS, or other electronic database.

The 2D barcoded VIS are available on the CDC website[4] (https://www.cdc.gov/vaccines/hcp/vis/). As of this document's publication date, all VIS documents contain 2D barcodes.

2.2 2D Vaccine Barcode Symbology
Information regarding standards for the GS1 DataMatrix symbology, unit of use 2D vaccine barcode structure, VIS 2D vaccine barcode structure, and the unit of sale vaccine 2D barcode structure can be found in Appendix C.

3.0 Functional Capabilities Overview

3.1 Need

There are three primary use cases that necessitate 2D barcode scanning integration within EMR/IIS systems:

- Scenario 1 – Vaccine Inventory
    - 1a – Vaccine Inventory (EMR)
    - 1b – Vaccine Inventory (IIS)
- Scenario 2 – Vaccine Administration
- Scenario 3 – VIS Recording

The functional capabilities that support the transmission of data in these three scenarios are detailed in the sections that follow.

For each use case, the functional capabilities are classified into three areas:

- Monitoring – State of readiness of an EMR/IIS to receive and process incoming data from a scanner
- Processing – Set of actions the EMR/IIS vendors should consider to successfully process data contained in 2D barcode of vaccines and VIS. Specifically, these represent actions taken after a 2D barcode is scanned and the EMR/IIS has received data from the scanner
- Alerts and Notifications – Warnings displayed to the users upon processing 2D barcodes

3.2 Assumptions and Considerations

This document assumes that users have the hardware necessary to facilitate 2D vaccine barcode scanning. To facilitate scanning, users require specific scanning devices (and computing devices, if needed) that collect the 2D barcode data elements. These devices can be handheld or mobile[5]. The handheld devices can have corded or cordless connectivity.

Assumptions and considerations for each of the scenarios are further detailed in the appendix (Scenario 1 – Vaccine Inventory, Scenario 2 – Vaccine Administration, and Scenario 3 – VIS Recording).

3.3 Requirements

The table below summarizes the key requirements for integrating 2D barcode scanning with an EMR/IIS system for the three scenarios identified above. These are further detailed in the sections that follow.

Table 1: Summary of Functional Capabilities Requirements for 2D Vaccine Barcodes

		Scenario 1 – Vaccine Inventory	Scenario 2 – Vaccine Administration	Scenario 3 – VIS Recording
Monitoring				
1	Monitor and establish connection with barcode scanner to receive 2D vaccine barcode data input from the scanner.	✔	✔	✔
2	Recognize scanner connection and 2D barcode data input in the module where 2D barcode data scanning is expected based on completed configuration of	✔	✔	✔

		Scenario 1 – Vaccine Inventory	Scenario 2 – Vaccine Administration	Scenario 3 – VIS Recording
Processing				
3	Validate if the barcode is applicable to the EMR/IIS module.	✓	✓	✓
4	Read the data elements present in the 2D barcode string using application identifiers (AI) as defined by the GS1 general specifications.	✓	✓	✓
5	Use the scanned data to look up other key data about the vaccine or VIS.	✓		✓
6	If the administration module is connected to an inventory module: • Validate barcode data against the NDC, expiration date, and lot number stored in inventory for the same vaccine • Warn users in the event of missing data or discrepancy • Use all three data elements or a combination to access stored inventory data for additional data such as manufacturer and other product information.	✓	✓	
7	If the administration module is not connected to an inventory module, use the scanned data elements (i.e., NDC, expiration date, and lot number) to look up additional information about the vaccine, such as manufacturer and other product information.		✓	
8	Display the scanned data elements and other key data in the respective fields.	✓	✓	✓
9	Save original scanned values if providing an option to modify them.	✓	✓	✓
10	Allow users to verify scanned data and manually enter additional data that cannot be automatically displayed.	✓	✓	✓
11	Provide separate set of VIS fields to capture information for each VIS given.			✓

4.0   Use Cases with Functional Capabilities

4.1 Scenario 1a - Record vaccine inventory (EMR)

User Story

As an inventory manager, I want to record a shipment of vaccines into the EMR system/Inventory system, so that I can have an accurate count of the vaccines on-hand.

System Interaction

The table below identifies the user system interaction for recording vaccine inventory.

Table 2: Inventory System Interaction

Inventory - System Interaction Table	
User	**EMR**
Opens the inventory module	Readies to accept scanner data input
Scans 2D barcode from vaccine unit of sale *	Validates if the barcode is applicable to the current EMR module Reads and populates required fields such as GTIN, lot number, expiration date; and serial number (optional field). Accesses mapping tables to look up additional product information Populates fields with vaccine information
Scans 2D barcode from one vaccine unit of use †	Validates if the barcode is applicable to the current EMR module Reads GTIN/NDC, expiration date, and lot number Accesses mapping tables to look up additional product information Populates fields with vaccine information
Confirms data populated and enters other vaccine inventory information such as quantity	-
User submits the inventory record	Saves vaccine information to the inventory

4.2 Scenario 1b - Record vaccine inventory (IIS)

As an inventory manager, I want to record a shipment of publicly funded vaccines received into the IIS so that I can track quantity available and accurately report how they were depleted.

System Interaction

The table below identifies the user system interaction for recording vaccine inventory.

Table 3: Inventory System Interaction

Inventory - System Interaction Table	
User	**IIS**
Opens IIS	Readies to accept scanner data input
Scans 2D barcode from vaccine unit of sale *	Validates if the barcode is applicable to the current IIS module Reads and populates required fields such as GTIN/NDC, lot number, expiration date; and serial number (optional field). Accesses mapping tables to look up additional product information Populates fields with vaccine information
Confirms data populated and enters other vaccine inventory information such as quantity	Fields such as NDC, expiration date, lot number, quantity etc. are all populated and validated.
User submits the inventory record	Saves vaccine information to the inventory

Functional Capabilities

The table below lists functional capabilities needed by the EMR/IIS to process vaccine 2D barcode for recording vaccine inventory. Please see the Appendix for further information regarding the assumptions and considerations, process flow, and functional capabilities details.

Table 4: Inventory Functional Capabilities (Note: Navigate to the Functional Capabilities Details section by clicking the hyperlinks.)

ID	Functional Capability Classification	Functional Capability Description
I-M-01	Monitoring	Monitor and establish connection with barcode scanner to receive 2D vaccine barcode data input from the scanner
I-M-02	Monitoring	Recognize scanner connection and 2D barcode data input in the inventory module where 2D barcode data scanning is expected
I-P-01	Processing	Validate if the barcode is applicable to the EMR/IIS module
I-P-02	Processing	Read the GTIN, expiration date, lot number and serial number[†] data elements from the 2D barcode data string using application identifiers (AI) as defined by the GS1 general specifications
I-P-03	Processing	Use the scanned data elements* (i.e., NDC, expiration date, and lot number) to look up other key data about the vaccine, such as manufacturer and product information (i.e. product name or dose)
I-P-04	Processing	Display the NDC, expiration date, and lot number and other key data in the respective fields*
I-P-05	Processing	Save original scanned values if providing an option to modify them
I-P-06	Processing	Allow users to verify scanned data and manually enter additional inventory data that is specific to the scanned product and cannot be automatically displayed
I-P-07	Processing	Reformat expiration date from the 2D vaccine barcode according to the default settings configured for the EMR/IIS
I-P-08	Processing	Update mapping and reference data on a regular basis
I-AN-01	Alerts and Notifications	Notify users when a barcode is not identifiable
I-AN-02	Alerts and Notifications	Warn users that an expired vaccine has been scanned

[†]**Note:** In the case that the unit of use 2D vaccine barcode is scanned, the following elements will be read from the scan: GTIN, expiration date, and lot number. There is no serial number on the unit of use.

*Note:** The availability of 2D barcodes on the UoS packaging should be considered when developing EMR/IIS vaccine inventory capabilities. Users may choose to scan the unit of sale packaging for inventory purposes. When ordering new vaccines providers typically use the unit of sale NDC.

Acceptance Criteria

The vaccine products are accurately recorded into the EMR/IIS inventory module.

4.3 Scenario 2 – Record vaccine administration (Administration)

User Story

As an immunizer, I want to record a vaccine administration in the EMR system, so that the patient's record will be updated with the relevant vaccine data elements.

System Interaction

The table below identifies the user system interaction for recording vaccine administrations.

Table 5: Administration System Interaction

Administration - EMR/IIS Interaction Table	
User	**System**
Navigates to patient administration screen	Readies to accept scanner data input
Scans 2D barcode from vaccine unit(s)* of use	Reads GTIN/NDC, expiration date, and lot number Accesses mapping tables/inventory information to look up additional product information Populates fields with vaccine information *Some vaccines contain a lyophilized component and a diluent component.
Confirms data populated and enters other administration information	-
User submits the administration record	Saves administration information to the EMR If applicable Updates vaccine quantity in inventory
-	The EMR directly reports vaccine administration data to the IIS †

Functional Capabilities

The table below lists functional capabilities needed by the EMR to process vaccine 2D barcode for recording vaccine administrations. Please see the Appendix for further information regarding the assumptions and considerations, process flow, and functional capabilities details.

Table 6: Administration Functional Capabilities (Note: Navigate to the Functional Capabilities Details section by clicking the hyperlinks.)

ID	Functional Capability Classification	Functional Capability Description
A-M-01	Monitoring	Monitor and establish connection with barcode scanner to receive vaccine 2D barcode data input from the scanner.
A-M-02	Monitoring	Recognize scanner connection and 2D barcode data input in the administration module where 2D barcode data scanning is expected.
A-P-01	Processing	Validate if the barcode is applicable to the EMR module.
A-P-02	Processing	For UoU: Read the GTIN/NDC, expiration date, and lot number data elements from the 2D barcode data string using application identifiers as defined by the GS1 general specifications. Some vaccines may have more than one unit of use (vaccines with diluent and lyophilized components).
A-P-03a	Processing	If administration module is connected to an inventory module: • Validate barcode data against the NDC, expiration date, and lot number stored in inventory for the same vaccine • Warn users in the event of missing data or discrepancy • Use all three data elements or a combination to access stored inventory data for additional data such as manufacturer and other product information
A-P-03b	Processing	If the administration module is not connected to an inventory module, use the scanned data elements (i.e., NDC, expiration date, and lot number) to look up additional information about the vaccine, such as manufacturer and other product information.
A-P-04	Processing	Display the NDC, expiration date, and lot number and other key data in respective fields.
A-P-05	Processing	Save original scanned values if providing an option to modify them.

ID	Functional Capability Classification	Functional Capability Description
A-P-06	Processing	Allow users to verify scanned data and manually enter additional administration data that are specific to the scanned product and cannot be automatically displayed.
A-P-07	Processing	Reformat expiration date from the vaccine 2D barcode according to the default settings configured for the EMR.
A-P-08	Processing	Update mapping and reference data on a regular basis.
A-P-09	Processing	When the administration module is connected to an inventory module, decrement the inventory count according to the vaccine(s) administered.
A-P-10	Processing	Administered vaccine data captured via scanner should have an 'scan confirmation' indicator
A-AN- 01	Alerts and Notifications	Notify users when a barcode is not identifiable.
A-AN- 02	Alerts and Notifications	Warn users that an expired vaccine has been scanned.
A-AN- 03	Alerts and Notifications	Validate the scanned vaccine against the patient medical record for accuracy.
A-AN- 04	Alerts and Notifications	When the administration module is connected to an inventory module, warn users if the vaccine is not present in the inventory.
A-AN- 05	Alerts and Notifications	Warn users that a recalled vaccine has been scanned.

†**Note:** In most cases, vaccine administration data will report directly from the EMR to the IIS. In the event that users have to manually update the IIS with the vaccine administration data, the same EMR Administration functional capabilities may be applied to the IIS directly.

Acceptance Criteria

The vaccine product is accurately recorded in the patient's EMR record and users are alerted if the scanned vaccine should not be administered based on expiration dates or recalls.

4.4 Scenario 3 – Record Vaccine Information Statements (VIS)

User Story

As an immunizer, I want to record a VIS information prior to administering the vaccine, so that the patient's EMR record is updated with the document code and edition date of the VIS.

System Interaction

The table below identifies the user system interaction for recording VIS.

Table 7: VIS System Interaction

VIS - EMR Interaction Table	
User	**System**
Opens the vaccine administration/VIS screen	Readies to accept scanner data input
Scans 2D barcode on VIS	Validates if the barcode is applicable to the current system module Reads VIS document type and edition date Accesses mapping tables to look up additional VIS information Populates fields with VIS information
Confirms data populated and enters other information related to VIS	-
User submits the VIS record	Saves VIS information to the patient's record

Functional Capabilities

The table below lists functional capabilities needed by the EMR to process vaccine 2D barcode for recording VIS. Please see the Appendix for further information regarding the assumptions and considerations, process flow, and functional capabilities details.

Table 8: VIS Functional Capabilities (Note: Navigate to the Functional Capabilities Details section by clicking the hyperlinks.)

ID	Functional Capability Classification	Functional Capability Description
V-M-01	Monitoring	Monitor and establish connection with barcode scanner to receive vaccine 2D barcode data input from the scanner.

ID	Functional Capability Classification	Functional Capability Description
V-M-02	Monitoring	Recognize scanner connection and 2D barcode data input in the administration module where 2D barcode data scanning is expected.
V-P-01	Processing	Validate if the barcode is applicable to the EMR/IIS module.
V-P-02	Processing	Read the document code and edition date from the 2D barcode data string using application identifiers (AI) as defined by the GS1 general specifications.
V-P-03	Processing	Use scanned data elements, i.e., VIS document code and edition date, to look up additional information about the VIS.
V-P-04	Processing	Display the VIS document type, edition date in the respective VIS fields.
V-P-05	Processing	Save original scanned values if providing an option to modify them.
V-P-06	Processing	Allow users to verify scanned data and manually enter additional VIS data.
V-P-07	Processing	Provide separate set of VIS fields to capture information for each VIS given.
V-P-08	Processing	Reformat edition date from the VIS barcode according to the default settings configured for the EMR/IIS.
V-P-09	Processing	Update mapping and reference data on a regular basis.
V-AN-01	Alerts and Notifications	Notify users when a barcode is not identifiable.
V-AN-02	Alerts and Notifications	Warn users when a more recent VIS is available.
V-AN-03	Alerts and Notifications	Validate that the VIS matches the vaccine administered. Warn users if a discrepancy exists.

Acceptance Criteria

The VIS document code and edition date are accurately recorded into the EMR and users are alerted if a more recent VIS is available

5. Functional Capabilities Details

5.1 Scenario 1 – Record Vaccine Inventory (EMR/IIS)

The sections below detail the assumptions and considerations, process flow, and functional capabilities for recording vaccine inventory. To return to the section in the main document click here.

5.1.1 Inventory Assumptions and Considerations

When 2D barcodes on vaccine unit of use are scanned
When scanning in to the EMR, users currently must open the unit of sale to inventory and scan vaccines at the unit of use level. To leverage 2D barcodes on vaccine unit of sale packaging, EMR must have a NDC –unit of sale to unit of use mapping feature. To facilitate this ability, CDC established and maintains a table that maps unit of use to unit of sale packaging NDC relationships: www2a.cdc.gov/vaccines/iis/iisstandards/vaccines.asp?rpt=ndc.

IIS records inventory by entering or scanning only the 2D barcode on the UoS. Inventory management in the IIS is intended for the purpose of tracking publicly funded vaccines from order request and shipment to reconciling depletion. Inventory scanning at the unit-of-sale is ideal. The DSCSA requirement for manufacturers to affix 2D barcodes on the unit of sale was enacted, so all sale packages of vaccines should have scannable 2D barcodes.

When 2D barcode on unit of sale is scanned
In the event that mapping between unit of use and unit of sale NDC is in place, the functional capabilities to process the 2D barcode will be similar to processing the 2D barcode on unit of use packaging. The primary difference will be the recording process. Per the DSCSA requirements, the UoS barcode includes the serial number of the product that is not included in the UoU barcode. This extra information would have to be taken into account when using the scanner to record data from the UoS barcode. It is not a required data element to map between UoS and UoU; however, the additional information in the data string will need to be addressed. In addition, the EMR solution should be able to track the quantity of unit of use in alignment to the NDC on the vaccine unit of sale.

When inventory module is absent or inventory is populated by staff
EMR may not always have an inventory module, or some providers may not have opted to enable optional inventory module with their EMR/IIS. As a result, the EMR/IIS may be limited to tracking vaccine administration only and not contain the functionality to maintain inventory information such as quantity of vaccines. Additionally, for immunization providers using IIS to track and maintain vaccine inventory information, the IIS staff may pre-load vaccine inventory into the IIS for the immunization provider. In both instances, functional capabilities for the Inventory scenario are not applicable.

User should verify scanned data elements
Users should always verify scanned data such as NDC, lot number, and expiration date displayed on the screen against the information printed on the label. This will help in identifying label misprints or

barcode encoding errors before the vaccine information is saved in the inventory module. In addition to the user performing the verification, the EMR/IIS should also have the necessary logic to verify barcode data to the extent possible. An example of barcode data verification is the determination that the data encoded complies with the GS1 2D DataMatrix data structure.

To return to the section in the main document click here.

5.1.2 Inventory Process Flows

EMR Inventory Management Process Flow
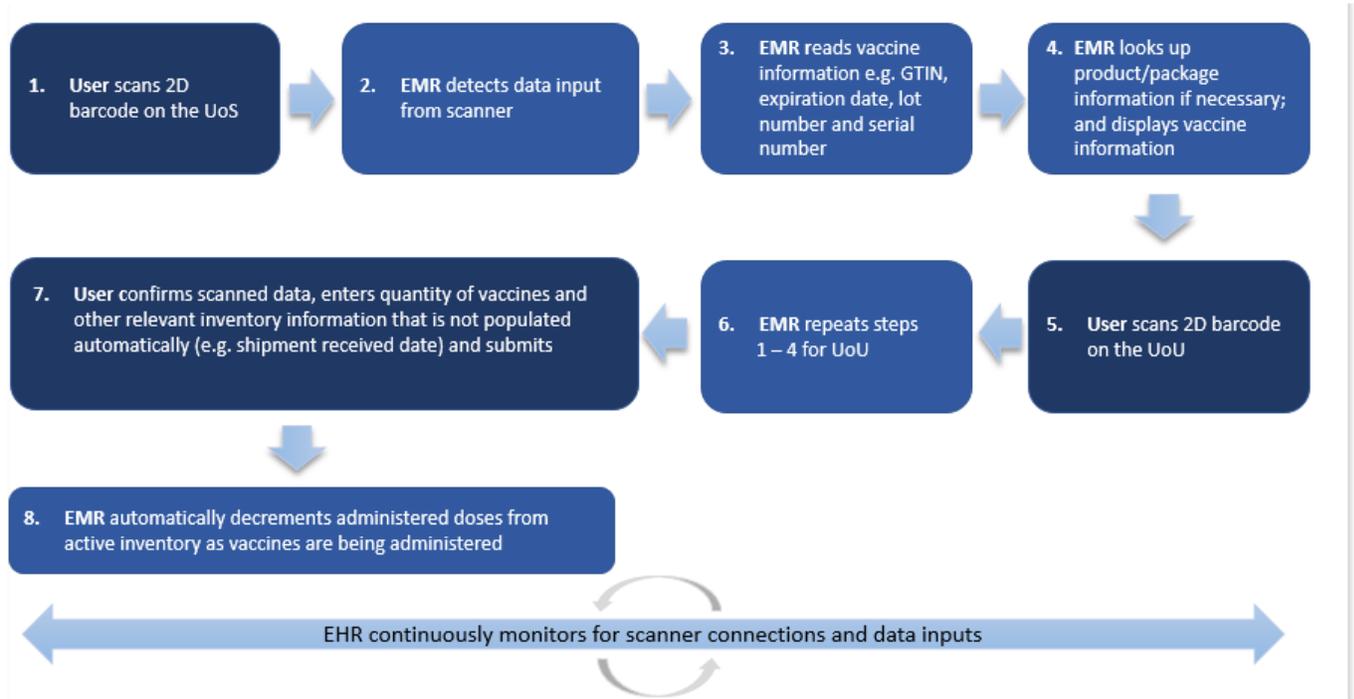
IIS Inventory Management and Reporting Process Flow
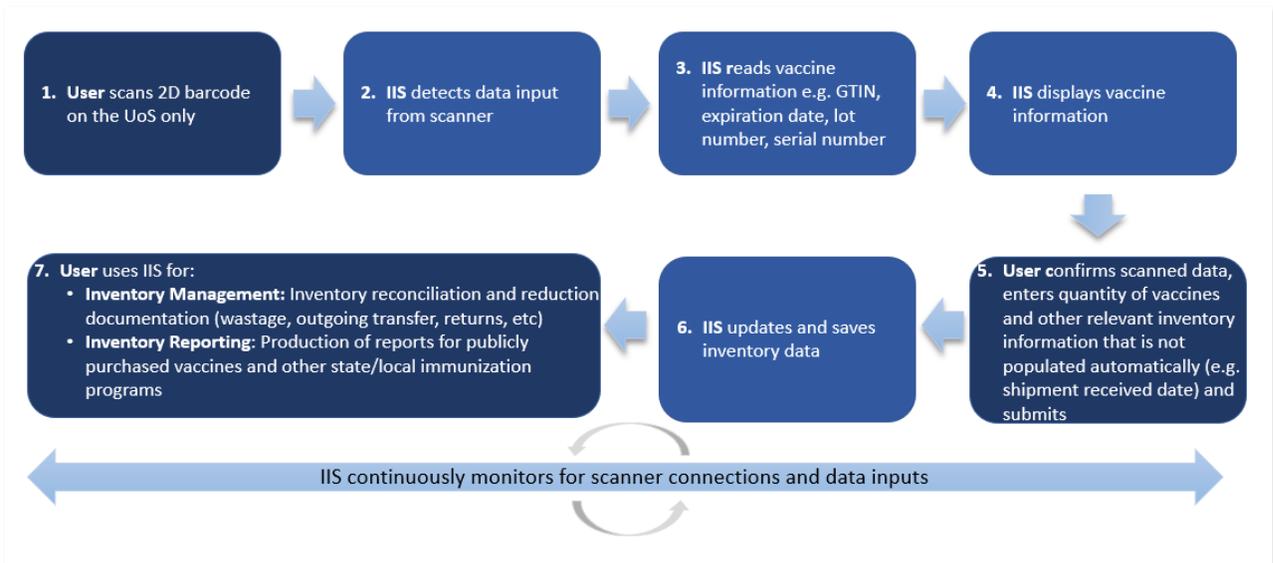
Figure 1: Inventory Process Flows

In the inventory process flows depicted in Figure 1, processing of 2D barcodes begins with the receipt of new vaccine products and the scanning of the 2D barcode on the vaccine unit of sale and unit of use (or unit of sale only- for IIS). After completing scanner configuration, the scanner reads the barcode and transmits the barcode data string to the EMR/IIS for processing. Configuration details the programming for the scanner to read and map data elements into the correct data fields within the EMR/IIS. Additional details can be found in Section I-M-01. As a prerequisite to this activity, a scanner must be connected to the computer and a connection between the EMR/IIS and the scanner must be established in order to receive and process data.

After receiving the data, the EMR/IIS reads the vaccine information such as GTIN/NDC, lot number, serial number (if used) and expiration date found in the vaccine 2D barcode. The EMR uses these data elements to look up reference tables for additional information about the vaccine product. The reference tables map vaccine product to manufacturer and other relevant information for inventory so that the EMR/IIS can populate this information automatically. For EMRs, these tables can be purchased files that the EMR vendor acquires and loads into the system or that the EMR and/or site can build out. After looking up the NDC, lot number, expiration date, and supporting information, the EMR/IIS displays the vaccine information and the user verifies the data. After confirmation, the user enters quantity of vaccines and other relevant inventory information that is not populated (e.g. date vaccine shipment was received) automatically and submits the record, which is then saved by the EMR/IIS.

Once the record is submitted, the EMR can automatically decrements administered doses from active inventory as vaccines are being administered (if the EMR administration module is connected to the inventory module). In contrast, vaccine decrementing in the IIS is carried out through different processes depending on technical capabilities. Some IIS are capable of automatic decrementation if the EMR administration module is connected to the IIS inventory module via electronic data exchange or

other methods, while other IIS systems require users to manually decrement during the inventory management and reconciliation process or once a UoS vaccine package has been completely used. The inventory management and reconciliation process in the IIS includes manually documenting wastage, returns, transfers, administrations, etc.

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5.1.3 Inventory Functional Capabilities Details

The sections below detail the functional capabilities for recording vaccine inventory. To return to the section in the main document click .

Monitoring Functional Capabilities

I-M-01: Monitor and establish connection with barcode scanner to receive 2D vaccine barcode data input from the scanner.
When a 2D barcode is scanned, the EMR/IIS must be capable of receiving and processing the data coming from the scanner. The EMR/IIS must monitor, detect, and establish a connection with the scanner attached to the computer. After a connection between the scanner and the EMR/IIS is established, the EMR/IIS must be able to detect incoming data from the scanner. Configuration of the scanner will be necessary prior to attempting to scan a barcode in order to detect data and route it to the proper fields within the EMR/IIS. Configuration refers to the programming of the scanner to read the data contained in the barcode and map to the relevant EMR fields. This process will vary based on the type of scanner and of the EMR/IIS used to scan.

Note: 2D barcode scanners are generally known to interact with computers over different interface protocols (modes). One such protocol is the Human Interface Device (HID) mode. A scanner configured in HID mode interacts with a computer in the same way a keyboard does. Incoming data from the scanner are accepted by the computer as if they are coming from a keyboard. As a result, EMR/IIS that require scanners to be configured in HID mode for interaction may not find this functional capability, i.e., to monitor for scanner connections and data input, applicable since the operating system software of the computer may handle this functionality on its own.

I-M-02: Recognize scanner connection and 2D barcode data input in the inventory module where 2D barcode data scanning is expected.
The EMR/IIS must have a connection established and be able to accept data input from the scanner in the inventory module of the EMR/IIS where scanning is expected. Specifically, this refers to the EMR/IIS window or screen of the inventory module where data scanned from the 2D barcode are to be applied. If this screen or window is not open or the user is interacting with a screen where scanning is not expected, the EMR/IIS may choose to ignore the data input from the scanner.

To return to the section in the main document click .

I-P-01: Validate if the barcode is applicable to the EMR/IIS module.
After scanning the barcode, the EMR/IIS receives data from the scanner, the EMR/IIS must validate if the barcode data are valid and applicable to the current window or screen of the inventory module.

The EMR/IIS should check for the presence of Application Identifiers (AIs) to validate that the barcode conforms to GS1 standards. Each 2D barcode should contain an AI preceded by a function character (FUNC 1), which indicates it is following the GS1 standard format. If the AIs are not present in the 2D barcode string, it is another indication that the barcode scanned is not a GS1 2D vaccine barcode. Web link for resources on the GS1 AIs can be found in Appendix D

Using the AIs, the EMR/IIS must then determine if the barcode applies to the current screen. This check is to differentiate vaccine barcodes from VIS barcodes and other barcodes that may be scanned. If data from the 2D barcode are not applicable to the EMR/IIS, the EMR/IIS should notify the user of the incompatibility.

I-P-02: Read the GTIN/NDC, serial number, expiration date, and lot number data elements from the UoS 2D barcode data string using application identifiers (AIs) as defined by the GS1 general specifications.
Data contained within the vaccine 2D barcode are transmitted to the EMR/IIS as a series of characters. Using the AIs and the length of the data elements as specified by GS1 standards, the EMR/IIS must read GTIN/NDC, expiration date, and lot number as separate data elements for processing. The GTIN data element should be processed further to extract the embedded NDC.

Additionally, the EMR/IIS should read the entire lot number from the barcode data string. Some EMR/IIS leverage the initial characters of a lot number to direct the user interface (UI) focus to the first instances of lot numbers with the same initial characters. Reading the entire lot number from the data string ensures the EMR/IIS considers all active lots to identify a match and avoid inaccurate association of the scanned lot with an existing lot.

I-P-03: Use the scanned data elements, i.e., NDC, serial number, expiration date, and lot number, to look up other key data about the vaccine, such as manufacturer and other product information.
Vaccine data other than NDC, lot number, and expiration date must be looked up using reference data. Reference data may be stored in tables within the EMR/IIS or accessed via third-party sources. The reference tables must provide a mapping of vaccine NDCs to their associated product and manufacturer information, as well as to upstream data elements such as CVX and CPT codes. Reference tables should not be limited to the associated information specified here. Utilizing mapping tables to look up additional information about the product enhances both the user experience and patient safety by reducing the time spent entering vaccine information manually, and by reducing the possibility of errors due to manual data entry.

I-P-04: Display the NDC, expiration date, and lot number and other key data in the respective fields.

The EMR/IIS must populate scanned data elements such as NDC, expiration date, and lot number and all additional information (accessed via reference tables) into their respective fields automatically without user intervention.

I-P-05: Save original scanned values if providing an option to modify them.
At times, 2D barcoded data must be modified. It was confirmed during the pilot that if a vaccine is left out of a storage unit such as the refrigerator for a brief period, providers may shorten the expiration date of the vaccine based on manufacturer input. Considering this practice, EMR/IIS should provide an option to modify scanned values. If providing this option, the EMR/IIS must also store original scanned values as they appear in the 2D barcode and ask the user to enter a reason for modifying the scanned value.

Note: When the original 2D barcode data of a vaccine are modified during inventory, the same vaccine may not find a match in the inventory during administration if the EMR/IIS tries to verify it against the inventory. The EMR/IIS must consider this potential mismatch when trying to verify vaccines against the inventory during administration.

I-P-06: Allow users to verify scanned data and manually enter additional inventory data that are specific to the scanned product and cannot be automatically displayed.
EMR/IIS must allow users to verify scanned data and enter additional information about the vaccine that is not accessible via reference tables or automatically populated by the EMR/IIS, such as date of administration.

Note: Users should always verify vaccine information populated in their respective fields against information printed on the vaccine label to catch any label misprints or barcoding errors before the vaccine is inventoried.

I-P-07: Reformat expiration date from the vaccine 2D barcode according to the default settings configured for the EMR/IIS.
The expiration date in the vaccine 2D barcode string is formatted YYMMDD. Before displaying the expiration date on the screen, it must be reformatted according to the user setting for the date configured in the EMR/IIS. Some vaccines may encode "00" as the day segment of the expiration date. Some vaccine manufacturers employ this practice when the vaccine does not include a day on the vaccine human readable expiration date. If the EMR/IIS identifies "00" as the day of the expiration date, the EMR/IIS should replace the "00" with the last date of the month noted in the expiration date.

I-P-08: Update mapping and reference data on a regular basis.
If the EMR/IIS leverages reference tables, either purchased files or created by the system, to look up and populate additional information about the vaccine that are not contained in the barcode (such as manufacturer and product name) then these tables must be updated regularly to reflect modifications or additions of new vaccine information. We recommend that EMR/IIS vendors incorporate a reference data refresh process into their existing EMR/IIS update procedures to address this capability.

To return to the section in the main document click [here](#).

For each of the capabilities addressing alerts and notifications, EMR vendors may choose from different notification cues such as pop-up windows, visual indicators on the screen, and sound notifications, according to the needs and specifications of the user.

I-AN-01: Notify users when a barcode is not identifiable.
When a scanned barcode is not identifiable according to GS1 standards for vaccine 2D barcodes, or the information contained in the barcode is not applicable to the screen in which it is scanned, users must be notified of the barcode incompatibility or inappropriate.

I-AN-02: Warn users that an expired vaccine has been scanned.
When a vaccine is found to be expired when logging it into inventory, the user must be notified before allowing the user to continue saving the vaccine to the inventory.

I-AN-03: Warn users that a recalled vaccine has been scanned.
When a vaccine is found to be recalled during inventory, the user must be notified and the EMR must allow the user to take the necessary follow-up actions. The EMR must leverage the recalled vaccine reference table to check the vaccine against and notify the user accordingly.

To return to the section in the main document click here.

5.2 Scenario 2 – Record Vaccine Administration

The sections below detail the assumptions and considerations, process flow, and functional capabilities for recording a vaccine administration. To return to the section in the main document click here.

5.2.1 Administration Assumptions and Considerations

Administration module may or may not be connected to an inventory module

The administration module of an EMR may or may not be connected to an inventory module. Similarly, the IIS vaccine inventory management functionality may or may not be connected to the administration module in order to decrement administered doses. This distinction is made while addressing the functional capabilities for this scenario.

Assumed inventory module terminology

When an associated inventory module exists, the functionality of the module may vary from one EMR/IIS to another and may not be referred to as the "inventory module." In the Administration scenario, the term "inventory module" refers to the EMR/IIS component that maintains and tracks the quantity of vaccine available to the health care professional for administration.

EMR/IIS can record both lyophilized and diluent (or adjuvant and vaccine[μ]) components of vaccine

For reconstituted vaccines with a lyophilized and a diluent component that need to be mixed prior to vaccine administration, the EMR/IIS should have the functionality to scan and capture data for both barcodes. It is recommended that an EMR/IIS provide fields that allow for scanning data from multiple separate UoU—one for each component—in order to ensure information about what is administered is captured completely and accurately.

> [μ]In the past during pandemic events, some vaccines required the mixing of the vaccine with an adjuvant at the point of vaccine administration. If this would ever be necessary in the future, the adjuvant could be entered in the second or diluent field."

User should verify scanned data elements

Users should always verify scanned data such as NDC, lot number, and expiration date displayed on the screen against the information printed on the label. This will help in identifying label misprints or barcode encoding errors before the vaccine is administered. In addition to the user performing the verification, the EMR/IIS should also have the necessary logic to verify barcode data to the extent possible, such as confirmation of a valid date.

2D barcode is scanned before vaccine is administered

We strongly recommend that a vaccine 2D barcode scan occur prior to administration. Scanning prior to administration permits necessary verification steps to help ensure patient safety prior to vaccine administration. This scenario assumes that the 2D barcode on the vaccine is scanned prior to administering the vaccine to the patient.

Reporting of vaccine administration data to the IIS

In most cases, vaccine administration data will report directly from the EMR to the IIS. In the event that users have to manually update the IIS with the vaccine administration data, the same EMR Administration functional capabilities may be applied to the IIS directly, although the IIS may need different data elements as they do not function as a patient care system.

To return to the section in the main document click here.

5.2.2 Administration Process Flow
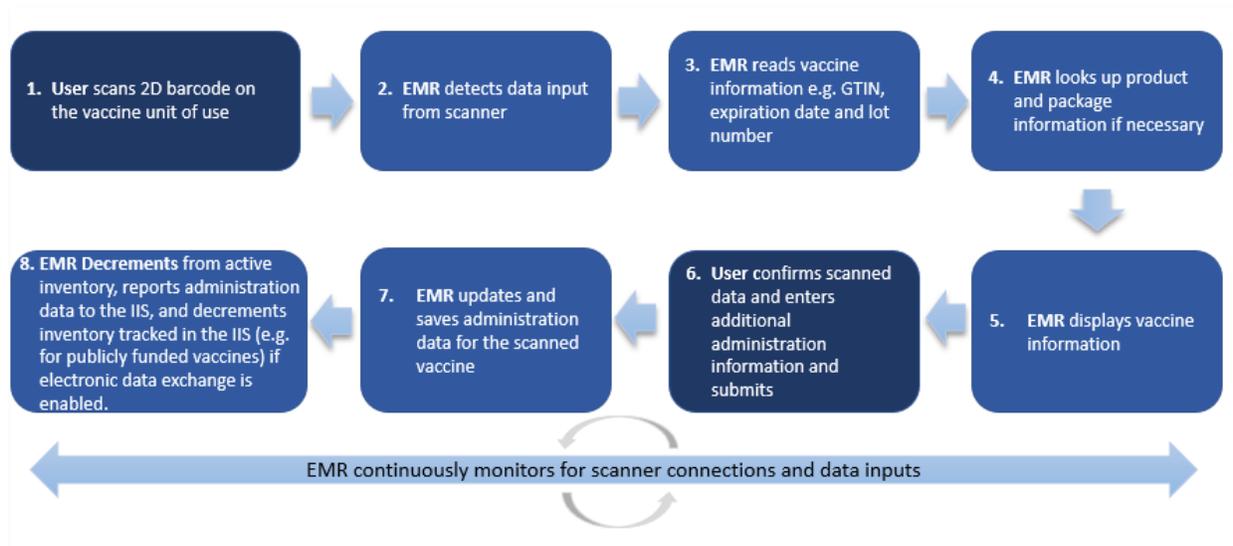
Figure 1: Administration Process Flow

The process flow depicted above for processing 2D barcodes during administration is similar to the inventory scenario with two main differences:

1. The EMR/IIS should update the inventory module if it is connected to the administration module.
2. The EMR/IIS should look up additional vaccine product information from inventory as needed when an inventory module is connected to the administration module.

Processing of 2D barcodes begins when the user scans the 2D barcode on the vaccine unit of use before administering the vaccine to the patient. The scanner reads the barcode and transmits the barcode data string to the EMR/IIS for processing. As a prerequisite to this activity, a scanner must be configured, connected to the computer and a connection between the EMR/IIS and the scanner must be established in order to receive and process data.

After receiving the data, the EMR/IIS reads the GTIN/NDC lot number, and expiration date found in the vaccine 2D barcode. The EMR/IIS uses these data elements to look up reference tables for additional information about the vaccine product. The reference tables map the vaccine product to the manufacturer and other relevant information for administration so that the EMR/IIS can populate this information automatically. After looking up the NDC, lot number, and expiration date, and supporting information, the EMR/IIS displays the vaccine information and the user verifies the data.

After confirmation, the user enters any administration information not populated automatically and submits the record, which is then saved by the EMR/IIS.

Where applicable, the EMR/IIS updates the inventory module according to the quantity of vaccine administered.

To return to the section in the main document click here.

5.2.3 Administration Functional Capabilities Details

The sections below detail the functional capabilities for recording a vaccine administration. To return to the section in the main document click here.

Monitoring Functional Capabilities

As stated earlier in the document, the Monitoring functional capabilities are the same for the Inventory, Administration, and VIS scenarios. Refer to section 5.1.3 for details of Monitoring functional capabilities.

To return to the section in the main document click here.

Processing Functional Capabilities

A-P-01: Validate if the barcode is applicable to the EMR/IIS module

After scanning the barcode, the EMR receives data from the scanner, the EMR must validate if the scanned data are valid and applicable to the current window or screen of the administration module.

The EMR should check for the presence of AIs to validate that the barcode conforms to GS1 standards. If the AIs are not present in the 2D barcode string, then it is an indication that the barcode scanned is not a vaccine 2D barcode. Information about the GS1 AIs can be found in Appendix C.

Using the AIs, the EMR must then determine if the barcode applies to the current screen. This check is to differentiate VIS barcodes from vaccine barcodes or other barcodes that may be scanned. If data from the2D barcode are not applicable to the EMR, the EMR should notify the user of the incompatibility.

Note: There may be an instance where the EMR may accept and process 2D barcode data from the vaccine unit of use and VIS on the same screen. In this case, barcode differentiation should be used to process and display barcode data according to the barcode type scanned.

A-P-02: Read the GTIN/NDC, expiration date, and lot number data elements from the 2D barcode data string using application identifiers (AIs) as defined by the GS1 general specifications.

Data contained within the vaccine 2D barcode are transmitted to the EMR as a series of characters. Using the AIs and the length of the data elements as specified by GS1 standards, the EMR must read

GTIN/NDC, expiration date, and lot number as separate data elements for processing. The GTIN data element should be processed further to extract the embedded NDC.

The EMR should read the entire lot number from the barcode data string. Some EMR leverage the initial characters of a lot number to direct the user interface (UI) focus to the first instances of lot numbers with the same initial characters. Reading the entire lot number from the data string ensures the EMR considers all active lots to identify a match and avoid inaccurate association of the scanned lot with an existing lot.

For reconstituted vaccines, each of the elements' barcodes may be read. For example, the lyophilized component and the diluent would each have their own GTIN/NDC, expiration date, and lot number to read.

A-P-03a: If the administration module is connected to an inventory module.

1. Validate barcode data against the NDC, expiration date, and lot number stored in inventory for the same vaccine, or vaccine component
2. Warn users in the event of missing data or discrepancy
3. Use all three data elements or a combination to access stored inventory data for additional data such as manufacturer and other product information

If the administration module is connected to an inventory module, the EMR/IIS must first check to determine if the scanned vaccine lot exists in inventory. To do this, the EMR/IIS validates the NDC, expiration date, and lot number from the vaccine 2D barcode against vaccine information stored in inventory. If the inventory does not contain the scanned vaccine, or if there is a discrepancy, user notification should occur. If there is no discrepancy and a valid match is found in the inventory, the EMR/IIS leverages vaccine information stored in the inventory to populate the fields on the screen.

Because the NDC on the unit of sale and NDC on unit of use differ, a mapping table must be used if only unit of sale NDCs are populated in inventory. In addition, it should be noted that lot numbers are not required to be consistent between unit of sale and unit of use; in approximately 10% of vaccines, they differ. In these instances, a mismatch may display.

Any additional information about the vaccine must be looked up using reference tables. Access the reference tables similar to the process described in the Inventory scenario.

A-P-03b: If the administration module is not connected to an inventory module, use the scanned data elements (i.e., NDC, expiration date, and lot number) to look up additional information about the vaccine, such as manufacturer and other product information.

If the EMR does not have an inventory module, then the system must look up vaccine data other than NDC, lot number, and expiration date using reference data. Reference data may be stored in tables within the EMR/IIS or accessed via third-party sources. The reference tables map vaccine NDCs to

associated information including, but not limited to, product and manufacturer information, as well as to upstream data elements such as CVX and CPT codes.

Utilizing mapping tables to look up additional information about the product enhances the user experience and patient safety by reducing the time spent entering vaccine information manually and by reducing the possibility of errors due to manual data entry.

A-P-04: Display the NDC, expiration date, and lot number and other key data in the respective fields.

The EMR must populate the Administration screen with scanned data elements such as NDC, expiration date, and other additional information (accessed via reference tables) into their respective fields automatically without user intervention.

A-P-05: Save original scanned values if providing an option to modify them.

If the EMR/IIS provides an option to modify the scanned values, the EMR/IIS should also store the original scanned values as they appear in the 2D barcode and ask the user to enter a reason for updating the scanned value.

A-P-06: Allow users to verify scanned data and manually enter additional administration data that are specific to the scanned product and cannot be automatically displayed.

EMR/IIS must allow users to verify scanned data and enter additional information about the vaccine that is not accessible via reference tables or automatically populated by the EMR/IIS.

Note: Users should always verify vaccine information populated in their respective fields against information printed on the vaccine label to catch any label misprints or barcoding errors before the vaccine administration.

A-P-07: Reformat expiration date from the vaccine 2D barcode according to the default settings configured for the EMR/IIS.

The expiration date in the vaccine 2D barcode string is formatted YYMMDD. Before displaying the expiration date on the screen, it must be reformatted according to the user setting for the date configured in the EMR/IIS. Some vaccines may encode "00" as the day segment of the expiration date. Some vaccine manufacturers employ this practice when the vaccine does not include a day on the vaccine human readable expiration date. If the EMR/IIS identifies "00" as the day of the expiration date, the EMR/IIS should replace the "00" with the last date of the month noted in the expiration date.

A-P-08: Update mapping and reference data on a regular basis.

If the EMR/IIS leverages reference tables to look up and populate additional information about the vaccine, then these tables must be updated regularly to reflect modifications or additions of new

vaccine information. It is recommended that EMR/IIS vendors incorporate a reference data refresh process into their existing EMR/IIS update procedures to address this capability.

A-P-09: When the administration module is connected to an inventory module, decrement the inventory count according to the vaccine(s) administered.

If the administration module of the EMR/IIS is connected to an inventory module, then the EMR/IIS should automatically update the quantity in the inventory for the vaccine administered.

A-P-10: Administered vaccine data captured via scanner should have a 'scan confirmation' indicator.

Data that is captured via a scanner must be indicated in the database or data repository. This indicator should not be displayed on the screen to the users. This will allow confirmation that scanners are being used and will allow further analysis of that subset of data, if necessary.

To return to the section in the main document click here.

Alerts and Notifications

For each of the capabilities addressing alerts and notifications, EMR vendors may choose from different notification cues such as pop-up windows, visual indicators on the screen, and sound notifications according to the needs and specifications of the user.

A-AN-01: Notify users when a barcode is not identifiable.

When a scanned barcode is not identifiable according to GS1 standards for vaccine 2D barcodes, or the information contained in the barcode is not applicable to the screen in which it is scanned, the user must be notified of the barcode incompatibility.

A-AN-02: Warn users that an expired vaccine has been scanned.

When a vaccine is found to be expired at the time of administration, the user must be notified to take necessary follow-up actions.

A-AN-03: Validate the scanned vaccine against the patient medical record for accuracy.

The scanned vaccine must be validated against the patient record to ensure it is correct. To enhance patient safety, the validation can be made against closed-loop medication administration protocol that identifies the five rights of medication administration (i.e., right patient, right drug, right dose, right route, and right time) and/or a Clinical Decision Support System (CDSS) that indicates whether the vaccine is needed or contraindicated. A few examples of such validations are as follows:

- Validate if the vaccine is scheduled to be given to the patient on the day it is scanned
- Validate vaccine against vital signs and lab values
- Validate vaccine against age requirements for the vaccine
- Check if the patient is allergic to the vaccine

Note: Some of the validations could and should be performed earlier in the immunization workflow, such as when the vaccine is ordered for the patient. If not, then these validations should be performed at the time of scanning the 2D barcode during administration.

A-AN-04: When the administration module is connected to an inventory module, warn users if the vaccine is not present in the inventory.

If the administration module is connected to an inventory module, then the EMR/IIS must check to determine if the vaccine is present in the inventory and warn the user if it is not. The EMR/IIS must have the user enter the vaccine into the inventory before administering it.

A-AN-05: Warn users that a recalled vaccine has been scanned.

When a vaccine is found to be recalled during administration, the user must be notified and the EMR must provide steps to take necessary follow-up actions. The EMR must leverage the recalled vaccine reference table to check the vaccine against and notify the user accordingly.

To return to the section in the main document click .

5.3 Scenario 3 – Record VIS

The sections below detail the assumptions and considerations, process flow, and functional capabilities for recording VIS. To return to the section in the main document click here.

5.3.1 Assumptions and Considerations

When an EMR does not have the capability to generate VIS

Some EMR may have the functionality to select VIS based on the vaccine administered. When administering a vaccine, the appropriate VIS is printed and handed out to the patient. The EMR also updates the patient record with the VIS information, such as publication date. This functionality avoids the possibility of outdated VIS forms living in distant offices, and obviates the need for 2D barcode scanning of the forms. The functional capabilities in this scenario address EMR that do not have this functionality, and require health care professionals to manually select and print the VIS document to be given to the patient.

VIS is scanned before vaccine is administered

This scenario assumes that the VIS is given to the patient before the vaccine is administered. According to the National Childhood Vaccine Injury Act (42 U.S.C. §300aa-26), immunizers are required to provide patients a copy of the applicable VIS prior to vaccine administration. Scanning of the 2D barcode on the VIS is assumed to happen before the VIS is given to the patient.

User should verify scanned data elements

Users should always verify scanned data such as VIS document name and edition date displayed on the screen against the information printed on the VIS. This will help in identifying label misprints or barcode encoding errors before the vaccine is administered. In addition to the user performing the verification, the EMR should also have the necessary logic to verify barcode data to the extent possible.

To return to the section in the main document click here.

5.3.2 Recording VIS Process Flow
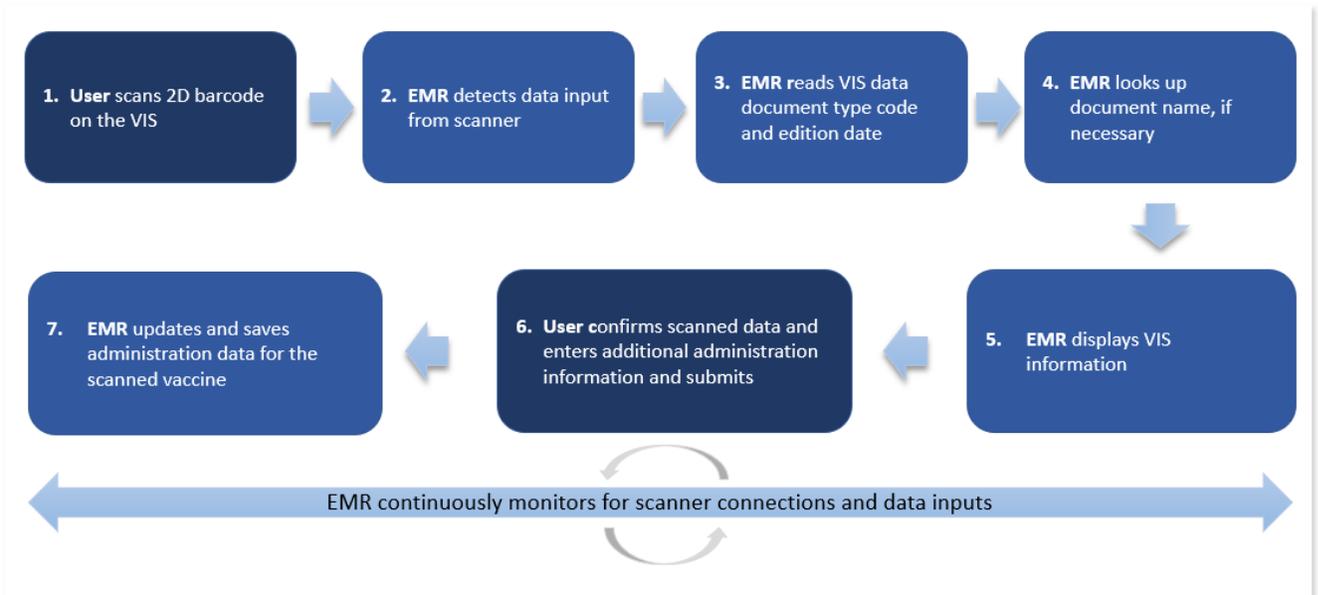
Figure 2: VIS Process Flow

The process flow depicted above for processing 2D barcodes for VIS is similar to Inventory and Administration. The difference in VIS scenario is the data elements in the VIS 2D barcode. Instead of GTIN/NDC, expiration date, and lot number, VIS 2D barcodes consist of the VIS document code and edition date.

Processing of 2D barcodes begins when the user scans the 2D barcode on the VIS before giving it to the patient. The scanner reads the barcode and transmits the barcode data string to the EMR for processing. As a prerequisite to this activity, a scanner must be connected to the computer and a connection between the EMR and the scanner must be established in order to receive and process data.

After receiving the data, the EMR reads the VIS document code and edition date in the VIS 2D barcode. The EMR uses this data to look up reference tables to access additional information about the VIS such as VIS document name and edition status. The VIS document data, along with the additional information looked up, are displayed on the EMR screen for the user to verify and confirm.

After confirmation, the user submits the record, which is then saved by the EMR.

To return to the section in the main document click .

5.3.3 Functional Capabilities Details

The sections below detail the functional capabilities for recording VIS. To return to the section in the main document click here.

Monitoring Functional Capabilities

As stated earlier in the document, the Monitoring functional capabilities are the same for the Inventory, Administration, and VIS scenarios. Refer to section 5.1.3 for details of Monitoring functional capabilities.

To return to the section in the main document click here.

Processing Functional Capabilities

V-P-01: Validate if the barcode is applicable to the EMR module

After the barcode is scanned and the EMR receives data from the scanner, the EMR/IIS must validate if the barcode data are valid and applicable to the current window or screen of the inventory module.

The EMR should check for the presence of Application Identifiers (AIs) to validate that the barcode conforms to GS1 standards. If the AIs are not present in the 2D barcode string, it is an indication that the barcode scanned is not a VIS document. Information about resource for the GS1 AIs can be found in Appendix C

Using the AIs, the EMR must then determine if the barcode applies to the current screen. This check is to differentiate vaccine barcodes from VIS barcodes and other barcodes that may be scanned. If data from the 2D barcode are not applicable to the EMR, the EMR should notify the user of the incompatibility.

V-P-02: Read the document code and edition date from the 2D barcode data string using application identifiers (AI) as defined by the GS1 general specifications.

Data contained within vaccine 2D barcodes are transmitted to the EMR as a series of characters. Using the AIs and the length of the data elements, as specified by GS1 standards, the EMR must read the VIS document code and edition date as separate data elements for processing.

V-P-03: Use scanned data elements, i.e., VIS document code and edition date, to look up additional information about the VIS.

Vaccine data other than the VIS document code and edition date must be looked up using reference data. Reference data may be stored in tables within the EMR or accessed via third-party sources. The reference tables map the VIS document code to associated information, including but not limited to, VIS document name and edition status. Utilizing mapping tables to look up additional information about the

VIS enhances the user experience and patient safety by reducing the time spent entering additional VIS information manually and by reducing the possibility of errors due to manual data entry.

V-P-04: Display the VIS document type, edition date, and other key data in the respective VIS fields.

Some EMR require a checkbox to confirm that the VIS was given to the patient while others require data entry in the EMR after a hard copy of the VIS has been given to the patient. If the EMR provides an option to scan a 2D barcode, the EMR must populate the VIS screen with scanned data elements such the VIS document code, edition date, and additional information (accessed via reference tables) into their respective fields automatically without user intervention.

V-P-05: Save original scanned values if providing an option to modify them.

If the EMR provides an option to modify the scanned values, the EMR should also store the original scanned values as they appear in the 2D barcode and ask the user to enter a reason for updating the scanned value.

V-P-06: Allow users to verify scanned data and manually enter additional VIS data.

EMR must allow users to verify scanned data and enter additional VIS information that cannot be automatically populated by the EMR.

Note: Users should always verify VIS information populated in their respective fields against information printed on the VIS to catch any label misprints or barcoding errors before the VIS is given to the patient.

V-P-07: Provide separate set of VIS fields to capture information for each VIS given.

There are instances where more than one vaccine is administered to a patient and a VIS (or set of VIS documents) is given to the patient for each vaccine administered. Additionally, in the case of combination or multi-component vaccines, a VIS for each of the vaccine components is given for the vaccine administered. For example, if the Hep A-Hep B vaccine is administered the provider may provide the Hepatitis A vaccine VIS and the Hepatitis B vaccine VIS. Conversely one of the VIS documents, the Multi Pediatric Vaccines VIS contains information related to the following vaccines: DTaP, Hib, Hepatitis B, Polio, and PCV13. This VIS could be used for any combination of these vaccines. In this case, one VIS document would suffice for multiple administered vaccines. The EMR must provide a set of VIS fields to capture information such as the VIS document name, document code, and edition date, etc., for each VIS document given to the patient. Stated another way, the EMR/IIS should allow for the capture of multiple VIS documents for a single injection. The number of VIS fields provided should correspond to the number of VIS documents that should be handed out, which may be higher than the number of injections given if combination or multi-component vaccines are included in the visit. In brief, one vaccine could give rise to multiple VIS documents and one VIS document, Multi Pediatric Vaccines VIS, is related to multiple vaccines.

V-P-08: Reformat edition date from the VIS barcode according to the default settings configured for the EMR.

The edition date in the vaccine 2D barcode string is formatted YYMMDD. Before displaying the edition date on the screen, it must be reformatted according to the user setting for the date configured in the EMR.

V-P-09: Update mapping and reference data on a regular basis.

If the EMR leverages reference tables to look up and populate additional information about the VIS, then these tables must be updated regularly to reflect modifications or additions of new VIS information. We recommend that EMR implementers incorporate a reference data refresh process into their existing EMR update procedures to address this capability.

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Alerts and Notifications

For each of the capabilities addressing alerts and notifications, EMR vendors may choose from different notification cues such as pop-up windows, visual indicators on the screen, and sound notifications according to the needs and specifications of the user.

V-AN-01: Notify users when a barcode is not identifiable.

When a scanned barcode is not identifiable according to GS1 standards for VIS 2D barcodes, or the information contained in the barcode is not applicable to the screen in which it is scanned, users must be notified of the barcode incompatibility.

V-AN-02: Notify users when a more recent VIS is available.

If a more recent version of the VIS document is available at the time of administration, notify the user before distributing the VIS document to the patient.

V-AN-03: Validate that the VIS matches the vaccine administered. Warn users if a discrepancy exists.

The VIS scanned must be validated against the vaccine administered to ensure that the correct VIS document is handed out to the patient. Notify the user of any discrepancy between the vaccine administered and the VIS document given to the patient.

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Appendices

Appendix A - Methods Used to Gather Requirements

The original methods used to gather the requirements for the functional capabilities guide are documented in this section. This section will continue to be updated based on ongoing engagement with stakeholders i.e. Prior pilot participants, EMR vendors, health systems, pharmacies, professional organizations, etc. in order to ensure the information provided within is current.

Pilots

In August 2011, the Food and Drug Administration (FDA) finalized guidance allowing vaccine manufacturers to apply for a waiver to the linear barcode rule, which opened the door for placing two-dimensional (2D) barcodes on unit of use (UoU) vaccine products. Two-dimensional barcodes can capture more data elements and occupy less space on the label than a linear barcode. Adding data elements such as lot number, expiration date, along with a NDC, would cause a linear barcode to outgrow the space available on many vaccine labels. This capability is valuable in the vaccine environment given that the product (vials/syringes) are small, the label spacing is limited, and the data requirements for vaccine administration are critical to patient records, registries, and related systems.

As a result, CDC contracted with Deloitte to conduct a pilot project to assess the impact of placing 2D barcodes on vaccine products and the ability to improve the accuracy and completeness of immunization records.

Concurrently, 2D barcodes were placed on vaccine information statements (VIS). VIS are distributed by providers to their patients prior to vaccine administration.

The first pilot data collection period commenced in August 2012 and ended in May 2013. Pilot participants included 10 immunization awardees, 220 immunizers (public and private), and two vaccine manufacturers. Data was collected from a second pilot conducted between July 2014 and January 2015; this pilot had 7 immunization awardees, 87 immunizers, and three vaccine manufacturers.

During each pilot, a workflow analysis was conducted at select sites to assess the impact of 2D barcoding at the point of immunization delivery and vaccine inventory entry. The purpose of these analyses was to develop a comprehensive view of each practice's immunization process and use this understanding to determine how 2D barcode utilization has impacted each practice's ability to accurately and efficiency manage vaccine inventory and administration.

Findings from the first pilot indicated that most EMR and IIS solutions were not yet designed to populate fields with information scanned from 2D barcoded vaccines, and few EMR or IIS solutions captured document type and edition date scanned from 2D barcoded VIS. There were relatively few 2D barcoded vaccines available at the time of this pilot and therefore opportunities to scan 2D barcodes to record vaccine data were limited.

In September 2013, the second pilot was conducted to expand the work of a previous pilot. In addition to an increase in products with 2D barcodes on the market, other settings, such as pharmacies, were becoming more commonplace for vaccine administration. These developments provided an opportunity to further understand the effects of introducing 2D barcode scanning on recording vaccine data. The 2013 pilot focused on three primary topics of interest: time savings, data quality, and user experience.

In January 2016, the third pilot was launched. This pilot continued to monitor 2D barcode adoption across the industry. Similarly, the 2016 pilot focused on the following primary topics of interest: the quality of vaccine data records, the time to enter vaccine data using scanning and non-scanning entry methods, how implementation of scanning occurred across sites within health system, and how staff experienced scanning.

Using observational data, survey data and data direct from the EMRs, these pilots demonstrated increased interest in the use of 2D barcodes and perceptions of time savings and improvements in data quality. Both were supported through quantitative data analytics. Despite these results, feedback still indicated that further adoption may not be achieved until 2D barcoding functionality is fully integrated into EMRs.

One-on-one Interviews

One-on-one interviews were conducted with EMR vendors to present and discuss three scenarios where 2D barcodes can be most useful.

In preparation for these discussions, the pilot team consolidated lessons learned during pilot implementation and workflow analysis site visits, and identified three scenarios in practice workflows where vaccine 2D barcodes had potential to improve practice efficiency and data completeness and accuracy. Those scenarios included recording vaccine inventory (Inventory), vaccine administration (Administration), and vaccine information statements (VIS).

To process vaccine 2D barcodes within each scenario, we asked solution architects to consider how and when to monitor barcode scanner connections and barcode data, process the barcode data, and provide users with associated alerts and notifications. We drafted a list of functional capabilities needed by EMR/IIS software to address these considerations for each scenario and shared with five EMR vendors during one-on-one interviews. CDC and a Deloitte Advisory Council of EMR and health care industry subject matter experts identified the EMR vendors to be consulted. The EMR vendors represented a combination of both hospital and ambulatory EMR applications in the marketplace.

For each scenario, we asked EMR vendors to describe their current state, answer questions on the capabilities proposed, and provide feedback on the draft practices. In addition, we asked vendors to comment on anticipated challenges to implementing such capabilities.

EMR 2D Barcode Functional Capability Open Forum (Forum)

We held the Forum in conjunction with the Healthcare Information Management Systems Society (HIMSS) annual conference and exhibition in New Orleans, Louisiana in 2013. The overall goal of the Forum was to share insights with EMR vendors on best practices and future state functionality needed to process vaccine 2D barcodes. The one-on-one EMR vendor interview feedback was incorporated into a functional capabilities report draft and was presented to Forum participants. Forum participants were asked for feedback on the Functional Capabilities list presented. Forum participants agreed with the majority of functional capabilities on the list.

Post Forum One-on-one Discussions

After the Forum, we conducted five additional one-on-one discussions to help further develop the Functional Capabilities list. Input from those discussions is reflected in this Functional Capabilities report along with the initial one-on-one interviews.

Ongoing discussion with Providers

Following the completion of the first pilot (2D), ongoing discussions and communications were held with providers, including pharmacies, via calls and interviews directly with the sites, discussion panels at conferences (e.g. American Pharmacists Association), and via surveys to gain an understanding of perception and need in functional capabilities of the electronic systems. Feedback was reviewed and incorporated based on frequency of notation and feasibility to be achieved within the systems.

Appendix B - Factors Influencing Implementation

During one-on-one Interviews, the Forum, and Post Forum one-on-one discussions, most EMR/IIS vendors indicated the following challenges and factors that they believe would influence implementing 2D barcode capability in their software.

- Customer demand – An increase in requests from immunization provider customers who want to take advantage of 2D barcodes on vaccines is a driving motivation for most EMR vendors to implement the capabilities. It was noted that the perception of the adoption of EMR by immunizers is still in its early stages. Scanner costs are a major factor that affect provider interest in requesting 2D barcode capabilities.
- Regulations –Meaningful Use requirements continue to be a high priority for most EMR vendors. Most EMR vendors have stated that time and resources are focused on implementing Meaningful Use requirements. Any similar initiatives will influence EMR vendor priorities when considering adopting 2D barcode capabilities.
- Current software capabilities – The capabilities within the current version of a provider's EMR software influence the level of changes required to bring the software up to 2D barcode capabilities. Some providers have customized solutions for their workflow, which creates a technical environment that makes upgrading the software capability challenging.
- Reference Data for NDC Mapping – There is limited public availability of NDC mapping data such as unit of sale to unit of use NDC, unformatted NDC (without dashes) to formatted NDC (with dashes) and NDC to manufacturer code. Data should exist in a format easy to download and process from a central location to EHR/IIS vendors influences the extent to which mapping tables can be leveraged to look up additional information about vaccines and reduce manual data entry.

Appendix C - 2D Barcode Standards

GS1 DataMatrix Symbology

GS1 DataMatrix is the 2D barcode type used on vaccine unit of use products and VIS documents. A detailed application guideline was prepared by the American Academy of Pediatrics (AAP) and GS1 US to assist the U.S. healthcare vaccine industry by providing the current best method for printing and scanning GS1 DataMatrix on vaccine packages for use at point-of-care. It is based on the GS1 General Specification and was developed using information obtained from members of the healthcare supply chain from manufacturers to immunizers.

Unit of Use: 2D Vaccine Barcode Data Structure

In this document, unit of use refers to the container (i.e., vial or syringe) that contains the vaccine and carries the label. This is also referred to as the primary packaging. The 2D barcodes placed on vaccine units of use and scanned into vaccine inventory and administration records contain three data elements: Global Trade Item Number (GTIN), expiration date, and lot number. Figure 4 displays an example of the 2D barcode data string encoded on vaccine units of use products. Figure 5 displays the National Drug Code (NDC) embedded in the GTIN. NDC is a unique, three-segment number which serves as a unique identifier for drugs.
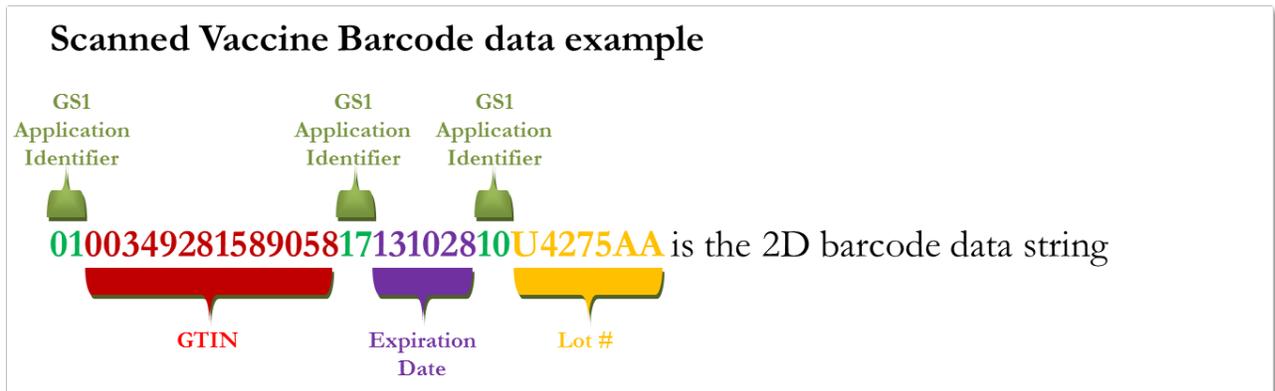

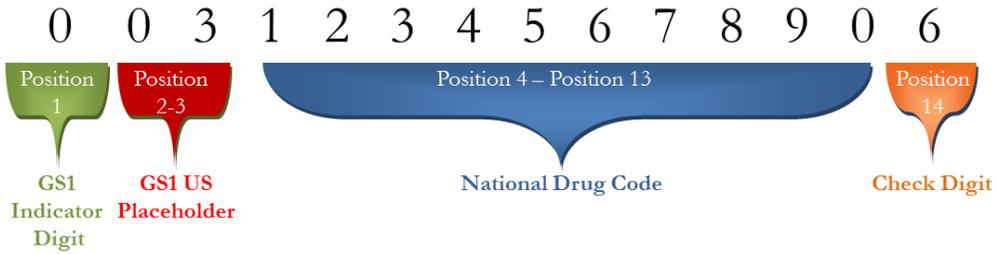*Figure 3: 2D Vaccine Barcode Data String - Contains the GTIN, expiration date, and lot number*

Figure 4: Global Trade Identification Number (GTIN) with embedded National Drug Code (NDC)

VIS 2D Barcode Data Structure

The 2D barcodes placed on VIS contain the VIS Global Document Type Identifier (GDTI) document code and the edition date. Figure 6 isplays the 2D barcode data string printed at the bottom of each VIS.

Figure 5: Global Document Type Identifier (GDTI) on VIS; Parentheses are for human-readable consumption and do not appear in the string

Unit of Sale: 2D Vaccine Barcode Structure – Drug Supply Chain Security Act (DSCSA)

Unit of sale refers to the immediate container or packaging that holds the unit of use. This is also referred to as secondary packaging. Title II of the Drug Quality and Security Act (DQSA), also referred to as the Drug Supply Chain Security Act (DSCSA), requires vaccine manufacturers to affix 2D barcodes to vaccine unit of sale packaging.

The 2D barcode required includes a standardized numerical identifier (SNI) in addition to the GTIN, expiration date, and lot number. Serialized 2D barcodes help enable product verification, which helps to identify potentially compromised vaccine products (i.e., recalled, contaminated, or counterfeit product) within the supply chain. Serial numbers are sometimes found within the 2D barcode on the unit of sale and need to be accounted for in the interpretation of the scan and configuration of scanner to health system; currently, serial numbers do not need to be recorded or monitored per guidance from the American Immunization Registry Association's Standards and Interoperability Steering Committee (SISC). An explanation of the data elements contained within the UoS barcode is shown in Figure 7 (from the February 27, 2017, AIRA/CDC Notice to the IIS Community: Serial Numbers in Unit of Sale 2D Barcodes).

Figure 6: Example of New UoS 2D Barcoded Vaccine Data String

The 2D barcode on unit of sale is expected to be used primarily in inventory management; for most systems, the inventory management module is a separate, but integrated, module to the patient vaccine

administration modules. For the purposes of this document, scanning the UoU 2D barcode is recommended for vaccine administration.

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Appendix D - Useful Resources

Below are useful reference resources:

- IIS: NDC Lookup Crosswalk

    http://www2a.cdc.gov/vaccines/iis/iisstandards/vaccines.asp?rpt=ndc

- Other Code Sets (e.g., CPT to CVX, Product Name to CVX, MVX, CPT to CVX, etc.)

    http://www.cdc.gov/vaccines/programs/iis/code-sets.html

- VIS Lookup Table

    https://www.cdc.gov/vaccines/programs/iis/code-sets/vis-barcode-lookup-table.html

- VIS Reference List

    http://www.cdc.gov/vaccines/hcp/vis/current-vis.html

- FDA's National Drug Code Directory

    http://www.fda.gov/drugs/informationondrugs/ucm142438.htm

- FDA's Recalls

    http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/Recalls/default.htm

Appendix E - References

1. Title II of DQSA, the Drug Supply Chain Security Act (DSCSA)

2. GS1 General Specifications

3. GS1 Healthcare Implementation Guideline

4. VIS

5. Bell C, Atkinson KM, Guerinet J, Wilson K, Feasibility and Limitations of Vaccine Two-Dimensional Barcoding Using Mobile Devices, J Med Internet Res 2016;18(6):e143