

EHR-IIS 2D Barcode Functional Capabilities Report

Version 1.3

Prepared for

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1 Change Log

Date	Version	Change
Jul 2013	1.0	a. Initial publication
Oct 2014	1.1	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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

2 Introduction

A primary goal of the Centers for Disease Control and Prevention's (CDC) two-dimensional (2D) vaccine barcode initiatives is to enhance the capacity for use of 2D vaccine barcodes to facilitate improved quality and timeliness of the capture and exchange of immunization-related information between immunization providers' Electronic Health Records (EHRs) and Immunization Information Systems (IISs). In 2010, 2D barcode piloting efforts confirmed that very few of the EHR software solutions used for immunization data currently have the ability to read and translate data from 2D vaccine barcodes. This lack of capability is due, in part, to the relatively new introduction of 2D barcodes to vaccines and Vaccine Information Statements (VIS).

Beyond the data exchange challenges, the 2D barcoding initiatives became a mechanism to draw attention to the benefits of 2D barcoding at provider sites. As a result, they have helped to initiate the adoption of the 2D barcodes by vaccine manufacturers, providers, and EHR/ IIS vendors. This report documents EHR/IIS 2D barcode functional capabilities as we understand them from the course of CDC 2D barcode initiatives. The content of this document is subject to change, and will be updated beyond the initial publication to reflect technological advancements and an evolving understanding of EHR/IIS 2D barcode capabilities.

3 Background

3.1 Pilot Overview

In August 2011, the Food and Drug Administration (FDA) finalized guidance¹ 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 product identifier, such as the National Drug Code (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 was conducted between July 2014 and January 2015; this pilot had 7 immunization awardees, 87 immunizers, and three vaccine manufacturers.

During the 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 efficiently manage vaccine inventory and administration.

Findings from the first pilot indicated that most EHR and IIS solutions are not yet designed to populate fields with information scanned from 2D barcoded vaccines, and few EHR or IIS solutions capture 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.

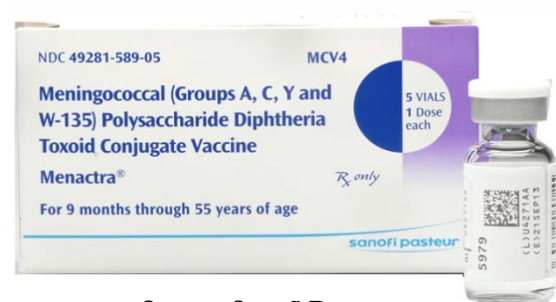
In September 2013, the second pilot was conducted to expand the work of a previous pilot. In addition to an increase in products with 2D barcodes on the market, other settings, such as pharmacies, were becoming more commonplace for vaccine administration. These developments provided an opportunity to 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.

Using observational data, survey data and data direct from the EHRs, this pilot 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 the health information systems.

¹ U.S. Department of Health and Human Services, U.S. Food and Drug Administration, Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research. *Guidance for Industry: Bar Code Label Requirements Questions and Answers*. August 2011. Web
<<http://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/UCM267392.pdf>>.

3.2 Vaccine Products

As of this document's publication date, four vaccine manufacturers are shipping most all of their U.S. products with 2D barcoded vaccine products on the unit of use presentations. This list will likely grow as industry adoption increases and more vaccine products enter the market. The list is updated as products are introduced and is maintained here: www.cdc.gov/vaccines/programs/iis/2d-vaccine-barcodes/.



Source: Sanofi Pasteur

3.3 Vaccine Information Statements (VIS)

Vaccine information statements (VIS) provide patients with needed 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 to scan the document code and edition date of a VIS into an EHR, IIS, or other electronic database. CDC expects to realize the following benefits when providers implement this new automated process³:

- Save time and gain efficiencies in immunization management
- Reduce the risk of data entry errors by scanning barcodes
- Improve accuracy resulting in improved safety for patients

The 2D barcoded VIS are available on the CDC website⁴ (www.cdc.gov/vaccines/hcp/vis/). As of publication, all VIS document currently contain 2D barcodes.

3.4 2D Barcode Standards

3.4.1 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 American Academy of Pediatrics (AAP) and GS1 US to assist the U.S. health care vaccine industry and provide 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 health care supply chain from manufacturers to immunizers. Information about these resource guides is available in Appendix D of this document.

3.4.2 Vaccine 2D Barcode Data Structure

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 1 displays an example of the 2D barcode data string encoded on vaccine units of use products. Figure 2 displays the National Drug Code (NDC) embedded in the GTIN. NDC is a unique, three-segment number which serves as a universal product identifier for drugs. In this document, GTIN and the NDC embedded in it are referred to

2 U.S. Department of Health and Human Services. *Vaccine Information Statements*. U.S. Center for Disease Control and Prevention: National Center for Immunization and Respiratory Diseases. March 2013. Web <<http://www.cdc.gov/vaccines/pubs/vis/>>.

3 GS1. *CDC Case Study "Better Immunization Management for Patient Safety."* GS1 US Healthcare. January 2013. Web <http://www.gs1us.org/gs1-us-library?Command=Core_Download&EntryId=272>.

4 U.S. Department of Health and Human Services. *Vaccine Information Statements*. U.S. Center for Disease Control and Prevention: National Center for Immunization and Respiratory Diseases. March 2013. Web <<http://www.cdc.gov/vaccines/pubs/vis/>>.

as the product identifier.

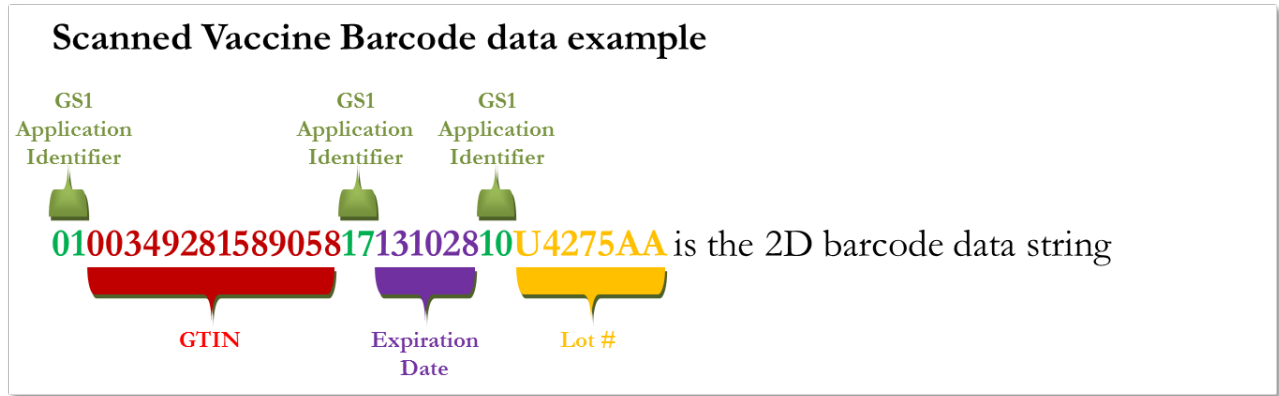


Figure 1: 2D Vaccine Barcode data string contains the GTIN, expiration, and lot number

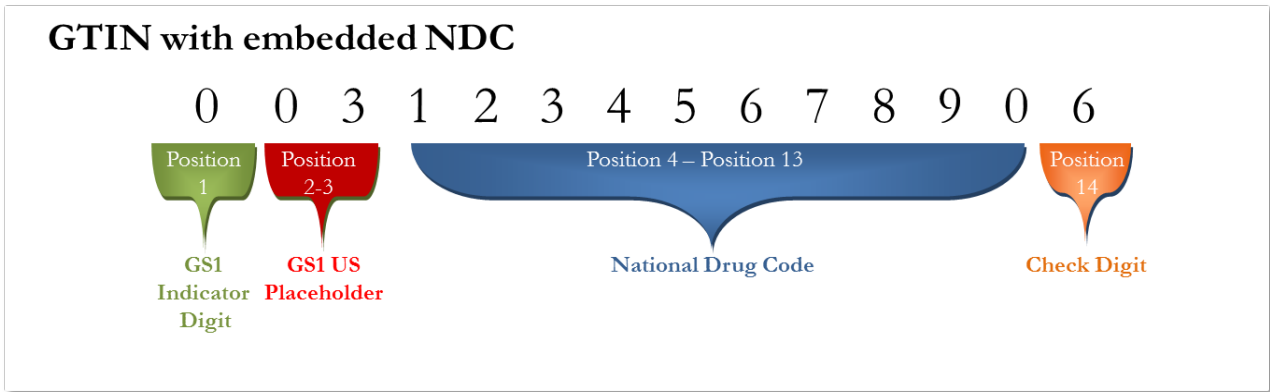


Figure 2: Global Trade Item Number with embedded National Drug Code

3.4.3 *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 3 displays the 2D barcode data string printed at the bottom of each VIS.

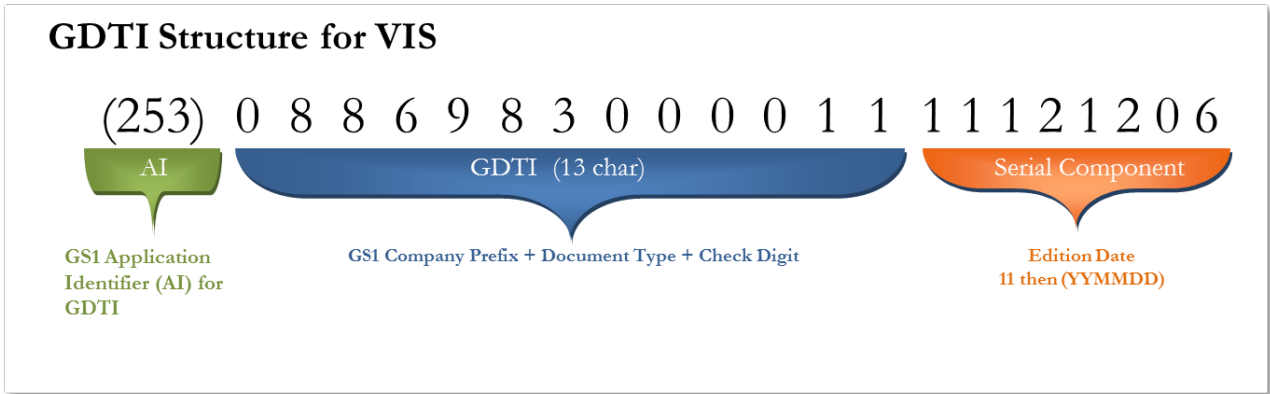


Figure 3: Global Document Type Identifier on VIS; note: parenthesis are for human readable consumption and do not appear in the string

3.4.4 *Primary Packaging and Secondary Packaging*

In this document, primary packaging⁵ refers to the container (i.e., vial or syringe) that contains the vaccine and carries the label. This is also referred to as the vaccine unit of use.

Secondary packaging⁶ or unit of sale refers to the immediate container or packaging that holds the primary packaging. A recently passed federal law⁶, 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 secondary packaging. Details on this Act can be found at:

www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/ucm20041041.htm. The 2D barcode required includes a standardized numerical identifier (SNI) in addition to the product identifier (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.



As of this document's publication date, GlaxoSmithKline (GSK) and Pfizer products contain 2D barcodes on secondary packaging. The 2D barcode on secondary packaging 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.

⁵ GS1 US. *American Academy of Pediatrics & GS1 Healthcare US Guideline for Suppliers*. February 2012. Web <http://www2.aap.org/immunization/pediatricians/pdf/barcoding_guidance_manufacturers_022212.pdf>

⁶ U.S. Food and Drug Administration. "Drug Supply Chain Security Act". www.cdc.gov/vaccines/programs/iis/2d-vaccine-barcodes/. The current report is an extension of the CDC 2D Barcode Pilot.

4 Goals and Objectives

The goal of the EHR/IIS Functionality report is to close the gap between the availability of 2D vaccine barcodes and their usage by identifying functional capabilities needed in EHR/IIS software solutions to capture and process 2D vaccine barcode data. CDC has posted the functional capabilities as guidance for EHR/IIS vendors interested in processing 2D barcodes placed on vaccine products and VIS. The objectives of this report are to connect with key stakeholders, gain buy-in on processing 2D vaccine barcodes, drive industry consensus, and to facilitate EHR/IIS development of 2D barcode scanning capabilities.

5 Approach

EHR/IIS input on the best practices and functional capabilities needed to process 2D barcodes on vaccines and VIS were identified using four basic approaches.

- One-on-one interviews with EHR vendors
- Open Forum review of draft functional capabilities with EHR vendors
- Post Forum one-on-one discussions to present draft functional capabilities to additional EHR vendors and state registries
- Ongoing discussions with provider community, including pharmacies

5.1 One-on-one Interviews

One-on-one interviews were conducted with EHR 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 2D vaccine barcodes had potential to improve practice efficiency and data completeness and accuracy. Those scenarios included recording vaccine inventory (Inventory), recording vaccine administration (Administration), and recording Vaccine Information Statements (VIS).

To process 2D vaccine 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 EHR/IIS software to address these considerations for each scenario and shared with five EHR vendors during one-on-one interviews. CDC and a Deloitte Advisory Council of EHR and health care industry subject matter experts identified the EHR vendors to be consulted. The EHR vendors represented a combination of both hospital and ambulatory EHR applications in the marketplace.

For each scenario, we asked EHR 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. For the one-on-one EHR vendor interview questions, refer to Appendix A.

5.2 EHR 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. The overall goal of the Forum was to share insights with EHR vendors on best practices and future state functionality needed to process 2D vaccine barcodes. The one-on-one EHR interview feedback was incorporated into a functional capabilities draft incorporating one-on-one EHR vendor interview feedback 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.

5.3 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.

5.4 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.

6 Functional Capabilities Overview

6.1 Scenarios and Classifications

Functional capabilities to process data in 2D barcodes were developed for three scenarios in the workflow of patient immunization:

- Scenario 1 - Record vaccine inventory (Inventory)
- Scenario 2 – Record vaccine administration (Administration)
- Scenario 3 – Record Vaccine Information Statements (VIS)
- Additional Considerations for Pharmacies

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

- Monitoring – State of readiness of an EHR/IIS to receive and process incoming data from a scanner
- Processing – Set of actions the EHR/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 EHR/IIS has received data from the scanner
- Alerts and Notifications – Warnings displayed to the users upon processing 2D barcodes

6.2 Similarities in Functional Capabilities

The functionality needed to monitor for 2D barcode input remains the same regardless of the scenario in which the 2D barcode is processed. To minimize repetition in this report, Monitoring functional capabilities are explained in detail only in the Inventory scenario. For Administration and VIS scenarios, Monitoring functional capabilities are replaced with a note for the reader to refer to the Monitoring functional capabilities in the Inventory scenario.

Similarities in the Processing and Alerts and Notifications classifications also exist across the three scenarios. These similarities exist because the functional capabilities needed by EHR/IIS to process 2D barcodes are very similar, with only slight scenario-specific variations required.

Unless otherwise noted, all functional capabilities outlined in Scenarios 1 – 3 should be addressed in pharmacy systems. Other considerations to be noted are discussed at the conclusion of Section 7.

7 Functional Capabilities

We divided the remainder of this section by scenario, providing the following information for each:

- Assumptions and considerations
- Process flow
- Functional Capabilities summary
- Functional Capabilities details

7.1 Scenario 1 - Record vaccine inventory (Inventory)

7.1.1 *Assumptions and Considerations*

2D barcodes on vaccine unit of use are scanned

Discussions with EHR/IIS vendors and information gained during the pilot revealed that most EHR/IIS solutions do not have a primary packaging (unit-of-use) NDC and secondary packaging NDC mapping feature built into their systems. Users currently open the secondary packaging to inventory vaccines at the unit of use level in order to use the 2D barcode. Scanning vaccines into inventory at any unit of use and unit of sale level, is not a common practice among immunization providers. To leverage 2D barcodes on vaccine unit of sale packaging, EHR/IISs 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.

Inventory scanning at the unit-of-sale is ideal but given the limited number of vaccines with a 2D barcode applied on the unit of sale packaging and the absence of unit of use to unit of sale packaging NDC relationships in most EHR/IIS, this scenario considers inventory scanning of 2D barcodes on the vaccine unit-of-use.

When 2D barcode on secondary packaging is scanned

In the event manufacturers place a 2D barcode on the vaccine unit of sale packaging and a 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 sale packaging. The primary difference will be the recording process. The EHR/IIS solution would apply the quantity of vaccines at the unit-of-use according to the quantity related to the NDC scanned on the vaccine unit –of-sale

When inventory module is absent or inventory is populated by staff

EHR/IIS may not always have an inventory module, or some providers may not have opted to purchase an optional inventory module with their EHR/IIS. As a result, the EHR/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 product identifier, 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 EHR/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.

7.1.2 *Inventory Process Flow*

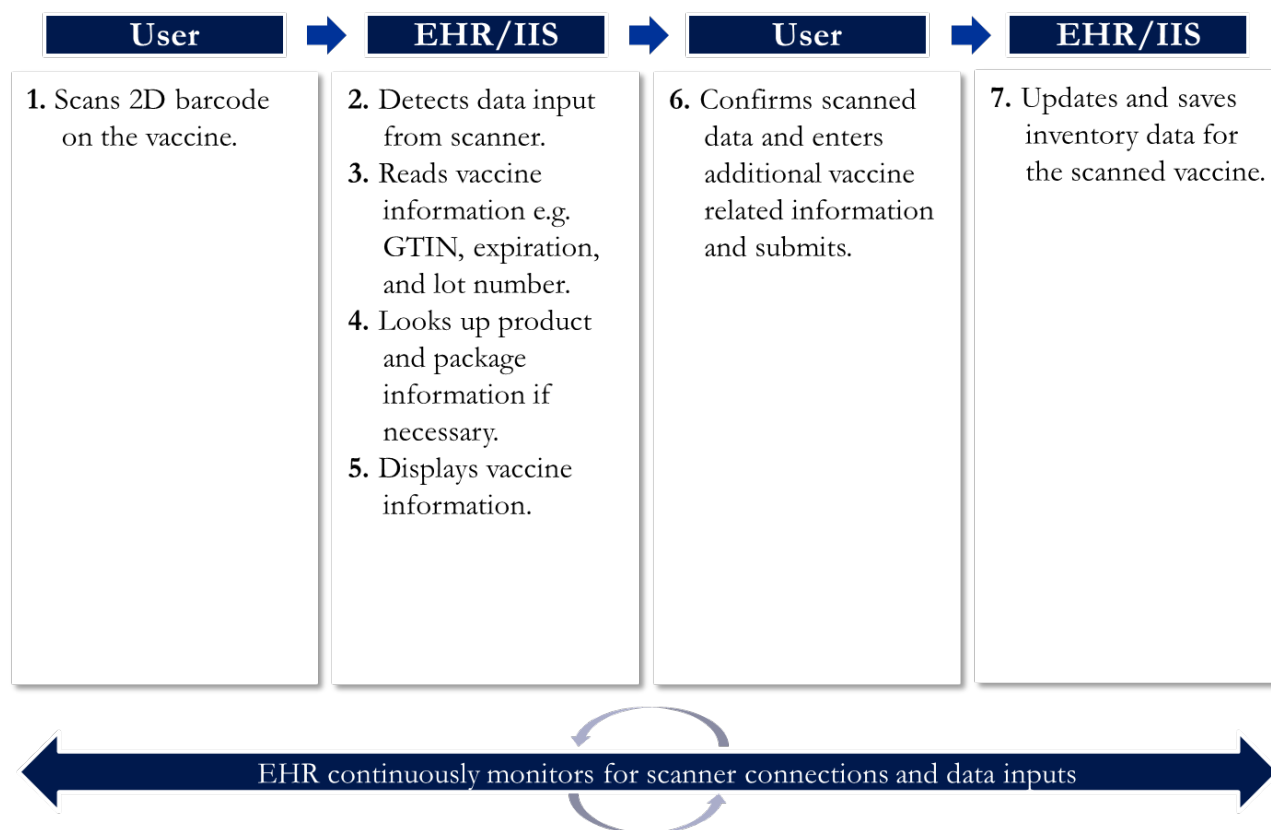


Figure 4: Process flow diagram logging vaccine units of use into inventory

In the inventory process flow depicted in Figure 4, processing of 2D barcodes begins with the receipt of new vaccine products and the user scans the 2D barcode on the vaccine unit of use. The scanner reads the barcode and transmits the barcode data string to the EHR/IIS for processing. As a prerequisite to this activity, a scanner must be connected to the computer and a connection between the EHR/IIS and the scanner must be established in order to receive and process data.

After receiving the data, the EHR/IIS reads the product identifier (GTIN), lot number, and expiration date found in the vaccine 2D barcode. The EHR/IIS 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 EHR/IIS can populate this information automatically. These tables are purchased files that the EHR vendor acquires and loads into the system. After looking up the product identifier, lot number, and expiration date, and supporting information, the EHR/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 of vaccine) automatically and submits the record, which is then saved by the EHR/IIS.

Table 1 Inventory EHR/IIS Interaction Table

Inventory - System Interaction Table	
User	EHR/IIS
Opens the inventory module	Readies to accept scanner data input
Scans 2D barcode from vaccine unit of use	Validates if the barcode is applicable to the current EHR/IIS module Reads GTIN, expiration date, and lot number Accesses mapping tables to look up additional product information Populates fields with vaccine information
Confirms data populated and enters quantity of vaccine and other inventory information	-
User submits the inventory record	Saves vaccine information to the inventory

7.1.3 Functional Capabilities Summary

This table lists functional capabilities needed by the EHR/IIS to process vaccine 2D barcode during vaccine inventory. Further explanation of each capability is provided in Section 7.1.4, Functional Capabilities Detail.

Table 2: Inventory Functional Capabilities Summary

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 EHR/IIS module
I-P-02	Processing	Read the GTIN, expiration date, and lot 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., product identifier, expiration date, and lot number) to look up other key data about the vaccine, such as manufacturer and product information (ie: product name or dose)
I-P-04	Processing	Display the product identifier, 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

ID	Functional Capability Classification	Functional Capability Description
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 EHR/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
I-AN-03	Alerts and Notifications	Warn users that a recalled vaccine has been scanned

7.1.4 *Functional Capabilities Details*

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 EHR/IIS must be capable of receiving and processing the data coming from the scanner. The EHR/IIS must monitor, detect, and establish a connection with the scanner attached to the computer. After a connection between the scanner and the EHR/IIS is established, the EHR/IIS must be able to detect incoming data from the scanner.

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, EHR/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, as 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 EHR/IIS must have a connection established and be able to accept data input from the scanner in the inventory module of the EHR/IIS where scanning is expected. Specifically, this refers to the EHR/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 EHR/IIS may choose to ignore the data input from the scanner.

Processing Functional Capabilities

I-P-01: Validate if the barcode is applicable to the EHR/IIS module.

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

The EHR/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 vaccine 2D barcode. Information about resources for the GS1 AIs can be found in Appendix D

Using the AIs, the EHR/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 EHR/IIS, the EHR/IIS should notify the user of the incompatibility.

I-P-02: Read the GTIN, 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 EHR/IIS as a series of characters. Using the AIs and the length of the data elements as specified by GS1 standards, the EHR/IIS must read GTIN, 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 EHR/IIS should read the entire lot number from the barcode data string. Some EHR/IIS leverage the initial characters of a lot number to direct the 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 EHR/IIS considers all active lots to identify a match and avoid inaccurate association of the scanned lot with an existing lot.

Note: Refer to Appendix D for resources on GS1 standards.

I-P-03: Use the scanned data elements, i.e., product identifier, 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 product identifier, lot number, and expiration date must be looked up using reference data. Reference data may be stored in tables within the EHR/IIS or accessed via third-party sources. The reference tables must provide a mapping of vaccine product identifiers 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.

Note: Refer to Appendix C for NDC mapping data currently available on the internet.

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

The EHR/IIS must populate scanned data elements such as product identifier, 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, EHR/IIS should provide an option to modify scanned values. If providing this option, the EHR/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 EHR/IIS tries to verify it against the inventory. The EHR/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.

EHR/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 EHR/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 2D vaccine barcode according to the default settings configured for the EHR/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 EHR/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 EHR/IIS identifies “00” as the day of the expiration date, the EHR/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 EHR/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 manufacture and product name) then these tables must be updated regularly to reflect modifications or additions of new vaccine information. We recommend that EHR/IIS vendors incorporate a reference data refresh process into their existing EHR/IIS update procedures to address this capability.

Alerts and Notifications

For each of the capabilities addressing alerts and notifications, EHR/IIS 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 EHR/IIS must allow the user to take the necessary follow-up actions. The EHR/IIS must leverage the recalled vaccine reference table to check the vaccine against and notify the user accordingly.

Note: Refer to Appendix C for information on recalled vaccines.

7.2 Scenario 2 – Record vaccine administration (Administration)

7.2.1 *Assumptions and Considerations*

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

The administration module of EHR/IIS may not be connected to an inventory module. 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 EHR/IIS to another and may not be referred to as the “inventory module.” In the Administration scenario, the term “inventory module” refers to the EHR/IIS component that maintains and tracks the quantity of vaccine available to the health care professional for administration.

User should verify scanned data elements

Users should always verify scanned data such as product identifier, 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 EHR/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.

7.2.2 Administration Process Flow

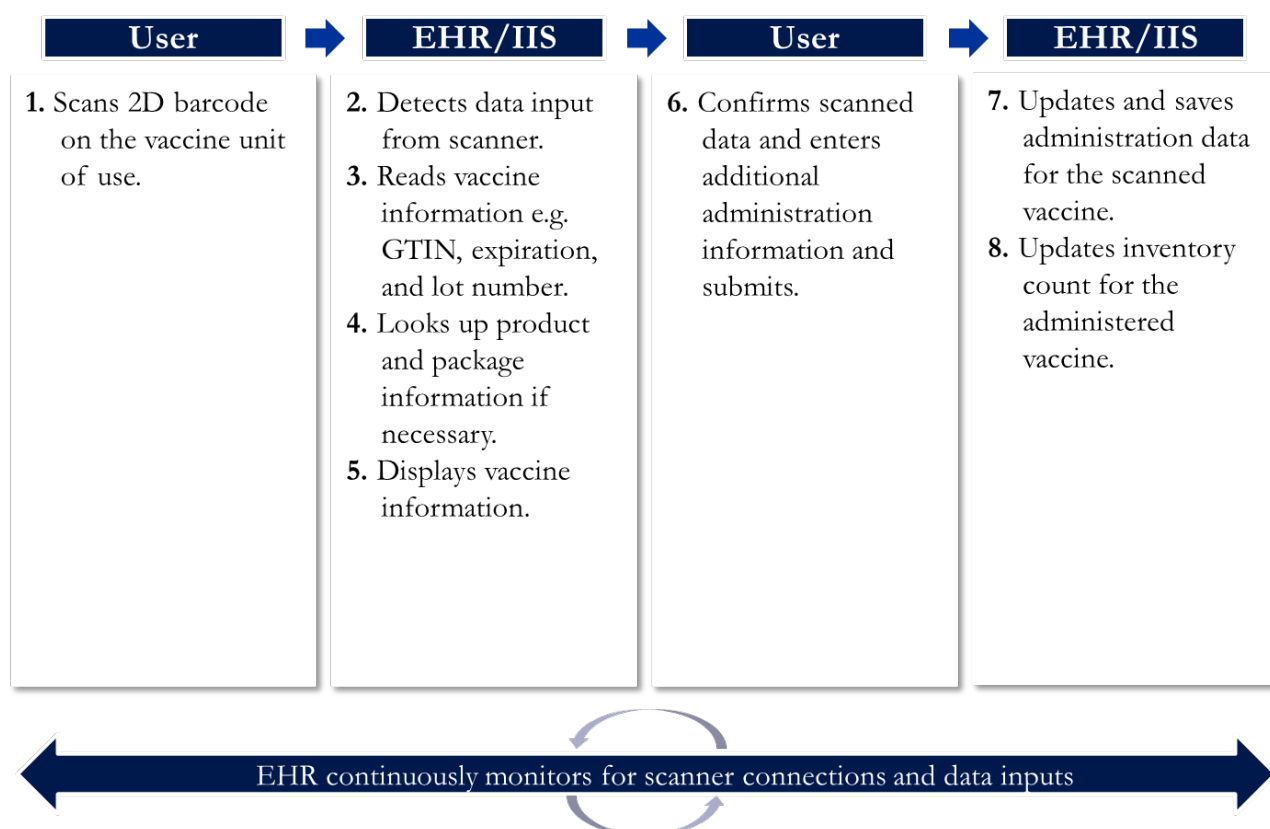


Figure 5: Process flow diagram administering vaccine

The process flow depicted in Figure 5 for processing 2D barcodes during administration is similar to the inventory scenario with two main differences:

1. The EHR/IIS must update the inventory module if it is connected to the administration module.
2. The EHR/IIS must 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 EHR/IIS for processing. As a prerequisite to this activity, a scanner must be connected to the computer and a connection between the EHR/IIS and the scanner must be established in order to receive and process data.

After receiving the data, the EHR/IIS reads the product identifier (GTIN), lot number, and expiration date found in the vaccine 2D barcode. The EHR/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 EHR/IIS can populate this information automatically. After looking up the product identifier, lot number, and expiration date, and supporting information, the EHR/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 EHR/IIS.

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

Table 3: Administration EHR/IIS Interaction Table

Administration - EHR/IIS Interaction Table	
User	System
Navigates to patient administration screen	Readies to accept scanner data input
Scans 2D barcode from vaccine unit of use	Reads GTIN, expiration date, and lot number Accesses mapping tables/inventory information to look up additional product information Populates fields with vaccine information
Confirms data populated and enters other administration information	-
User submits the administration record	Saves administration information to the EHR/IIS If applicable, updates vaccine quantity in inventory

7.2.3 Functional Capabilities Summary

This table lists functional capabilities needed by the EHR/IIS to process the vaccine 2D barcode during vaccine administration. Further explanation of each capability is provided in Section 7.2.4, Functional Capabilities Detail.

Table 4: Administration Functional Capabilities Summary

ID	Functional Capability Classification	Functional Capability Description
A-M-01	Monitoring	Monitor and establish connection with barcode scanner to receive 2D vaccine 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 EHR/IIS module.
A-P-02	Processing	Read the GTIN, expiration date, and lot number data elements from the 2D barcode data string using application identifiers (AI) as defined by the GS1 general specifications.
A-P-03a	Processing	If administration module is connected to an inventory module: <ul style="list-style-type: none"> • Validate barcode data against the product identifier, 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., product identifier, expiration date, and lot number) to look up additional information about the vaccine, such as manufacturer and other product information.

ID	Functional Capability Classification	Functional Capability Description
A-P-04	Processing	Display the product identifier, 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.
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 2D vaccine barcode according to the default settings configured for the EHR/IIS.
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.

7.2.4 *Functional Capabilities Details*

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 7.1.4 for details of Monitoring functional capabilities.

Processing Functional Capabilities

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

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

The EHR/IIS 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 D.

Using the AIs, the EHR/IIS 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 the 2D barcode are not applicable to the EHR/IIS, the EHR/IIS should notify the user of the incompatibility.

Note: There may be an instance where the EHR/IIS 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, 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 EHR/IIS as a series of characters. Using the AIs and the length of the data elements as specified by GS1 standards, the EHR/IIS must read GTIN, 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 EHR/IIS should read the entire lot number from the barcode data string. Some EHR/IIS leverage the initial characters of a lot number to direct the 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 EHR/IIS considers all active lots to identify a match and avoid inaccurate association of the scanned lot with an existing lot.

Note: Refer to Appendix D for resources on GS1 standards.

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

- **Validate barcode data against the product identifier, 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**

If the administration module is connected to an inventory module, the EHR/IIS must first check to determine if the scanned vaccine lot exists in inventory. To do this, the EHR/IIS validates the product identifier, 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 EHR/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.

Note: Refer to Appendix C for NDC mapping data currently available on the internet.

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

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

Note: Refer to Appendix D for NDC mapping data currently available on the internet.

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

The EHR/IIS must populate the Administration screen with scanned data elements such as product identifier, 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 EHR/IIS provides an option to modify the scanned values, the EHR/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.

EHR/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 EHR/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 2D vaccine barcode according to the default settings configured for the EHR/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 EHR/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 EHR/IIS identifies “00” as the day of the expiration date, the EHR/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 EHR/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 EHR/IIS vendors incorporate a reference data refresh process into their existing EHR/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 EHR/IIS is connected to an inventory module, then the EHR/IIS should automatically update the quantity in the inventory for the vaccine administered.

Please see section assumptions in section 7.1.1 that further describe the inventory management process.

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.

Alerts and Notifications

For each of the capabilities addressing alerts and notifications, EHR/IIS 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 EHR/IIS must check to determine if the vaccine is present in the inventory and warn the user if it is not. The EHR/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 EHR/IIS must provide steps to take necessary follow-up actions. The EHR/IIS must leverage the recalled vaccine reference table to check the vaccine against and notify the user accordingly.

Note: Refer to appendix D for a reference on recalled vaccines.

7.3 Scenario 3 – Record Vaccine Information Statements (VIS)

7.3.1 *Assumptions and Considerations*

When an EHR/IIS does not have the capability to generate VIS

Some EHR/IIS 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 EHR/IIS 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 EHR/IIS 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 EHR/IIS should also have the necessary logic to verify barcode data to the extent possible.

7.3.2 Recording VIS Process Flow

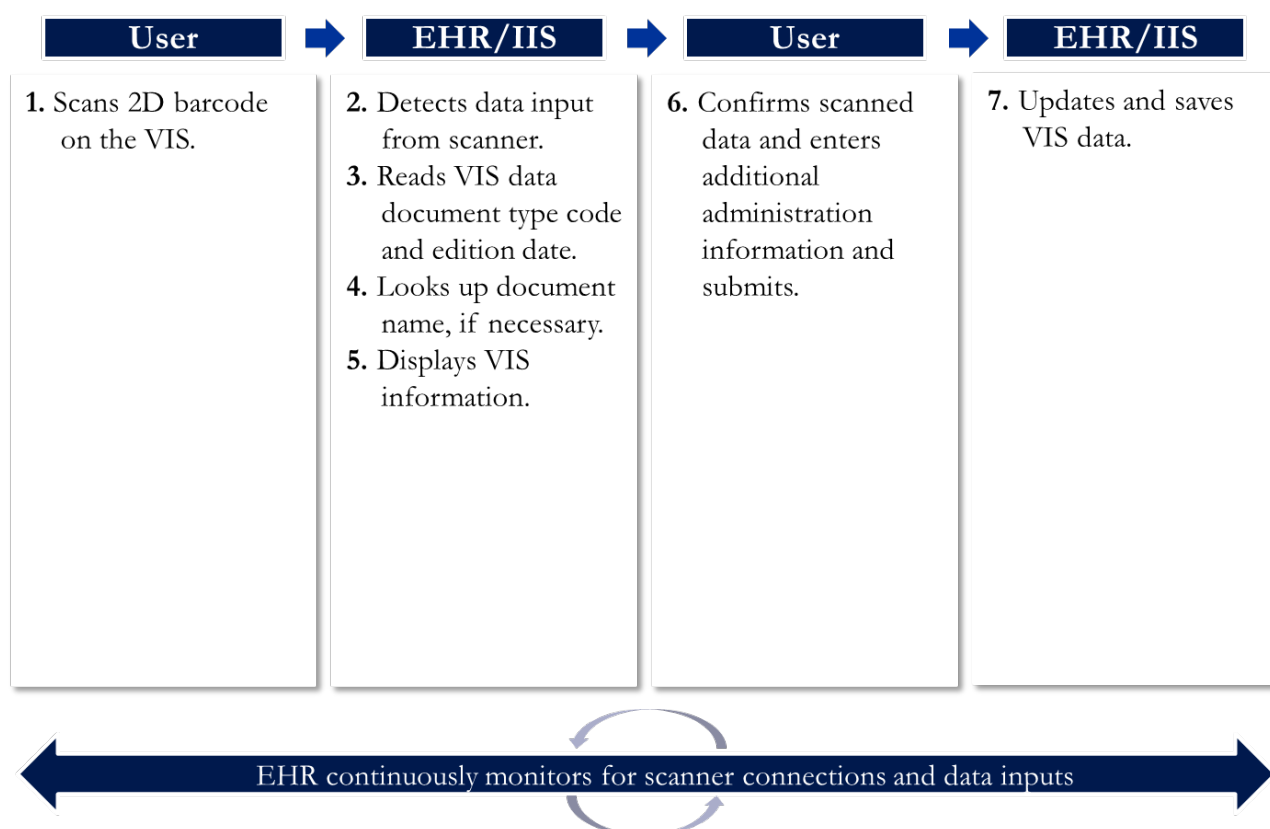


Figure 6: Process flow for recording VIS

The process flow depicted in Figure 6 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, 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 EHR/IIS for processing. As a prerequisite to this activity, a scanner must be connected to the computer and a connection between the EHR/IIS and the scanner must be established in order to receive and process data.

After receiving the data, the EHR/IIS reads the VIS document code and edition date in the VIS 2D barcode. The EHR/IIS 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 EHR/IIS screen for the user to verify and confirm.

After confirmation, the user submits the record, which is then saved by the EHR/IIS.

Table 5: VIS EHR/IIS Interaction Table

VIS - EHR/IIS Interaction Table	
User	EHR/IIS
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

VIS - EHR/IIS Interaction Table	
Confirms data populated and enters other information related to VIS	-
User submits the VIS record	Saves VIS information to the EHR/IIS

7.3.3 *Functional Capabilities Summary*

This table lists functional capabilities needed by the EHR/IIS to process VIS 2D barcodes during vaccine administration. Further explanation of each capability is provided in Section 7.3.4, Functional Capabilities Detail.

Table 6: VIS Functional Capabilities Scenario

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

ID	Functional Capability Classification	Functional Capability Description
V-AN-03	Alerts and Notifications	Validate that the VIS matches the vaccine administered. Warn users if a discrepancy exists.

7.3.4 *Functional Capabilities Details*

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 7.1.4 for details of Monitoring functional capabilities.

Processing Functional Capabilities

V-P-01: Validate if the barcode is applicable to the EHR/IIS module

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

The EHR/IIS 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 D.

Using the AIs, the EHR/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 EHR/IIS, the EHR/IIS 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 EHR/IIS as a series of characters. Using the AIs and the length of the data elements, as specified by GS1 standards, the EHR/IIS must read the VIS document code and edition date as separate data elements for processing.

Note: Refer to Appendix D for resources on GS1 standards.

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 EHR/IIS 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.

Note: Details about VIS reference tables can be found in Appendix C of this document.

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

The EHR/IIS 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 EHR/IIS provides an option to modify the scanned values, the EHR/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.

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

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

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 is given to the patient for each vaccine administered or, as in the case of combination vaccines, a VIS for each of the component vaccines is given for the each vaccines administered. The EHR/IIS 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 EHR/IIS must allow for the capture of multiple VIS for a single injection. The number of VIS fields provided should correspond to the number of VIS documents handed out.

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

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 EHR/IIS.

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

If the EHR/IIS 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 EHR/IIS implementers incorporate a reference data refresh process into their existing EHR/IIS update procedures to address this capability.

Alerts and Notifications

For each of the capabilities addressing alerts and notifications, EHR/IIS 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.

7.4 Additional Considerations for Pharmacies

As described in the introduction, pharmacy settings, both independent pharmacy and large retail, provided first hand feedback to challenges and considerations that must be taken into account for inventory and administration of vaccines in these unique settings. Beyond a clinical workflow, pharmacies have considerations for integration between point of sale, dispensing and order entry via their pharmacy management systems, or medication management systems. A description of these point of sale and order entry functions is out of scope for this document. As vaccine administrators, pharmacy systems should incorporate the same functional capabilities previously described in this document. Information on the same data items, as previously described, should be collected. The use of unstructured data, such as free text in notes fields, will not allow data to be messaged and transferred correctly.

8 Factors Influencing EHR/IIS Vendor Implementation of 2D Barcode Functionality

During One-on-one Interviews, the Forum, and Post Forum One-on-one Discussions, most EHR/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 EHR vendors to implement the capabilities. It was noted that the perception of the adoption of EHR by immunizers is still in its early stages. Scanner costs⁷ 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 EHR vendors. Most EHR vendors have stated that time and resources are focused on implementing Meaningful Use requirements. Any similar initiatives will influence EHR vendor priorities when considering adopting 2D barcode capabilities.
- Current software capabilities – The capabilities within the current version of a provider’s EHR 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 – 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.

⁷ RTI International. *Impact of a Two-Dimensional Barcode for Vaccine Production, Clinical Documentation, and Public Health Reporting and Tracking*. July 2012. Web <<http://www.cdc.gov/vaccines/programs/iis/activities/downloads/2d-barcode-trkg-rpt.pdf>>

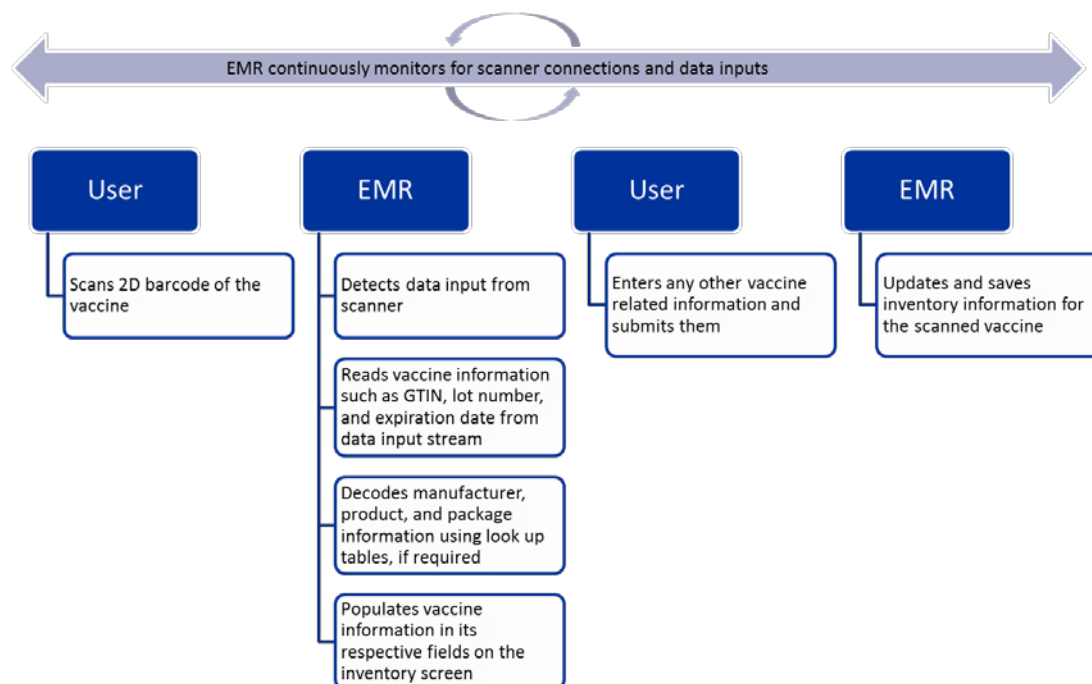
9 Appendices

Appendix A: Interview Guide

General 2D scanning questions

1. If you needed to implement 2D vaccine barcode functionality tomorrow, could you do it? What functional challenges would you encounter?
2. What priority level would you assign to incorporating these functional capabilities?
3. What would your timeline be to implement these functional capabilities?
4. What other concerns do you have or challenges do you face in adopting these capabilities?
5. Do you currently have any plans to implement 2D barcode scanning functionality in the future?

Use Case 1 – Inventory Vaccines



Inventory Vaccines - Process

6. What is your current state with respect to the process described?
7. From your point of view, what are the functional requirements to implement the process described? Please describe them in terms of the questions framed for this process.

Inventory Vaccines - Monitoring Functionality

1. At what point will the EMR begin monitoring for 2D barcodes read by scanners? Will monitoring begin automatically when launched or will users need to initiate the monitoring process?
 - a. Will the functional requirements be different if the scanner was corded versus wireless? How does this impact the workflow?
2. What will be monitored?
3. Will multiple scanner connections be supported, i.e., will the EMR listen for scanner connections when one is already connected?
4. Will the scanner connection status be displayed? If so, what details of the scanner connection will be displayed?
5. Will monitoring for 2D barcode/scanner input end automatically when the EMR is closed or will the user need to stop the monitoring process?

Inventory Vaccines - Scanning and Processing Functionality

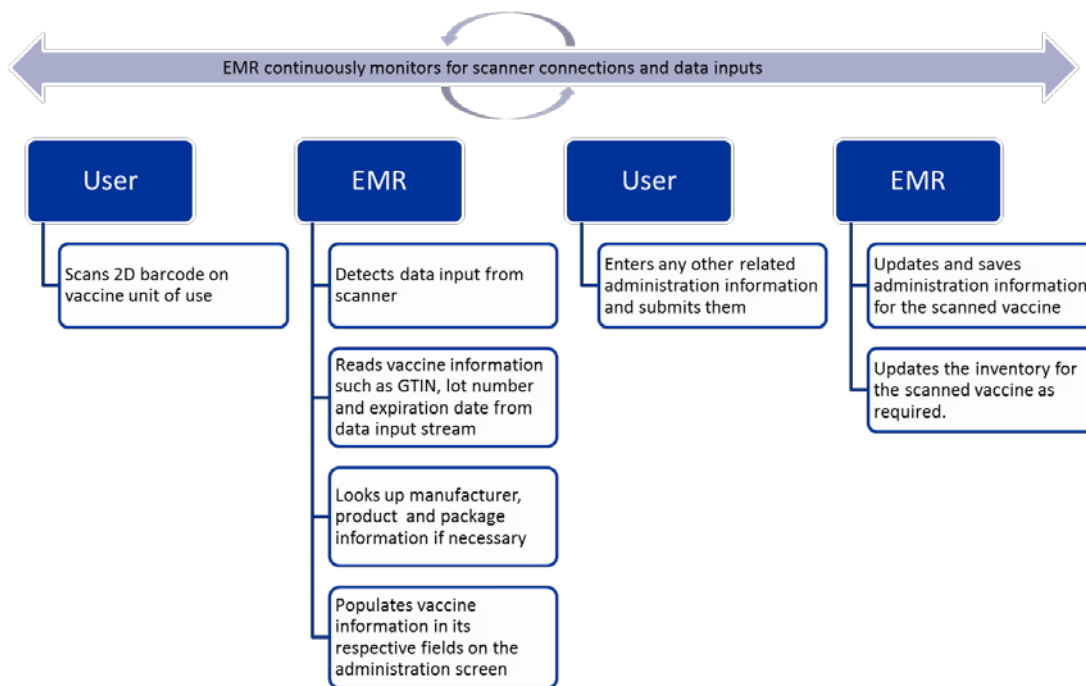
1. When data input is detected from scanner, what is the process to read the data input stream and to populate the respective fields?
2. Which data elements will be read from the 2D barcode scanner? All or only some of the available data elements?

3. After reading GTIN, lot number and expiration date, what information will be displayed on the inventory screen and how?
4. Will the data displayed on the screen be formatted in any way
5. If there are look up tables to look up vaccine related information, how will they be updated?
6. Will the EMR differentiate 2D barcode on carton versus 2D barcode on vaccine unit of use? If so, will the quantity information of the vaccine be recorded accordingly?

Inventory Vaccines - Alerts and Notifications

1. Will errors be detected and the user notified if an incorrect barcode or barcode type is scanned?
2. Will users be notified if they are not in the screen where scanning is expected?
3. Will users be notified if the scanned vaccine is expired?
4. Will users be able to override values populated by the scanner?

Use Case 2 – Administer Vaccines



Administer Vaccines - Process

1. What is your current state with respect to the process described?
2. From your point of view, what are the functional requirements to implement the process described? Please describe them in terms of the questions framed for this process.

Administer Vaccines – Monitoring Functionality

1. At what point will the EMR begin monitoring for 2D barcodes read by scanners? Will monitoring begin automatically when launched or will users need to initiate the monitoring process?
 - a. Will the functional requirements be different if the scanner was corded versus wireless? How does this impact the workflow?
2. What will be monitored?
3. Will multiple scanner connections be supported, i.e., will the EMR listen for scanner connections when one is already connected?
4. Will the scanner connection status be displayed? If so, what details of the scanner connection will be displayed?
5. Will monitoring for 2D barcode/scanner input end automatically when the EMR is closed or will the user need to stop the monitoring process?

Administer Vaccines – Scanning and Processing Functionality

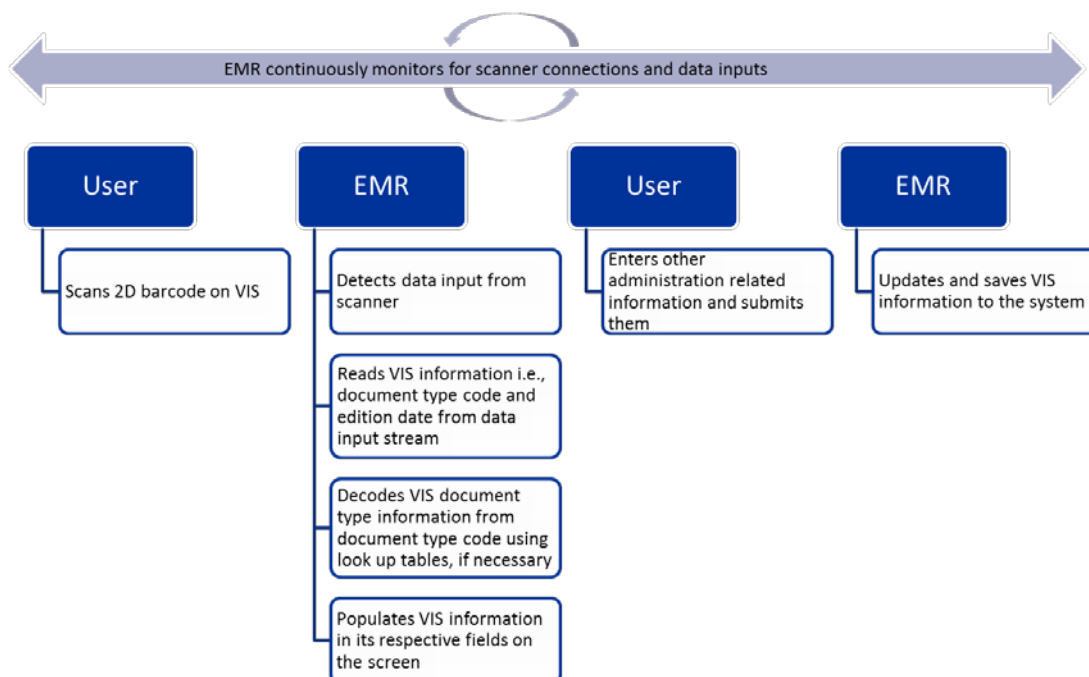
1. When data input is detected from scanner, what is the process to read the data input stream and to populate the respective fields?

2. Which data elements will be read from the 2D barcode scanner? All or only some of the available data elements?
3. After reading GTIN, lot number and expiration date, what information will be displayed on the inventory screen and how?
4. Will the data displayed on the screen be formatted in any way
5. If there are look up tables to look up vaccine related information, how will they be kept updated?
6. If the provider site uses both an inventory and an administration module, will the inventory count be updated automatically when a vaccine is administered?

Administer Vaccines – Alerts and Notifications

1. Will errors be detected and the user notified if an incorrect barcode or barcode type is scanned?
2. Will users be notified if they are not in the screen where scanning is expected?
3. Will users be notified if the scanned vaccine is expired?
4. Will users be able to override values populated by the scanner?
5. Will EMR validate that the vaccine matching the scanned vaccine data is correct for the patient and alert the user if it is not?

Use Case 3 – 2D Barcode on Vaccine Information Sheets (VIS)



VIS - Process

1. What is your current state with respect to the process described?
2. From your point of view, what are the functional requirements to implement the process described? Please describe them in terms of the questions framed for this process.

VIS – Monitoring Functionality

1. At what point will the EMR begin monitoring for 2D barcodes read by scanners? Will monitoring begin automatically when launched or will users need to initiate the monitoring process?
 - a. Will the functional requirements be different if the scanner was corded versus wireless? How does this impact the workflow?
2. What will be monitored?
3. Will multiple scanner connections be supported, i.e., will the EMR listen for scanner connections when one is already connected?
4. Will the scanner connection status be displayed? If so, what details of the scanner connection will be displayed?
5. Will monitoring for 2D barcode/scanner input end automatically when the EMR is closed or will the user need to stop the monitoring process?

VIS – Scanning and Processing Functionality

1. When data input is detected from scanner, what is the process to read the data input stream and to populate the respective fields?
2. Which data elements will be read from the 2D barcode scanner? All or only some of the available data elements?
3. After reading VIS document code and edition date, what information will be displayed on the inventory screen and how?
4. Will the data displayed on the screen be formatted in any way?
5. If there are look up tables to look up VIS related information, how will they be kept updated?

VIS – Alerts and Notifications

1. Will errors be detected and the user notified if an incorrect barcode or barcode type is scanned?
2. Will users be notified if they are not in the screen where scanning is expected?
3. Will users be notified if there is a more recent version of the VIS?
4. Will users be able to override values populated by the scanner?
5. Will EMR validate that the vaccine administered matches the VIS distributed and vice-versa and alert the user if it is not?

Appendix B: Consolidated Functional Capabilities Summary

Table 7: Consolidated Functional Capabilities Summary

#	Functional Capability	Scenario 1 - Inventory Vaccine	Scenario 2 - Administer Vaccine	Scenario 3 - VIS
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.	✓	✓	✓
Processing				
3	Validate if the barcode is applicable to the EHR/IIS module.	✓	✓	✓
4	Read the data elements present in the 2Dbarcode 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: <ul style="list-style-type: none"> • Validate barcode data against the product identifier, 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., product identifier, 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.			✓
12	Reformat date from the 2D barcode according to the default settings configured for the EHR/IIS.	✓	✓	✓

#	Functional Capability	Scenario 1 - Inventory Vaccine	Scenario 2 - Administer Vaccine	Scenario 3 - VIS
13	Update mapping and reference data on a regular basis.	✓	✓	✓
14	When the administration module is connected to an inventory module, decrement the inventory count according to the vaccine(s) administered.		✓	
Alerts and Notifications				
15	Notify users when a barcode is not identifiable.	✓	✓	✓
16	Warn users that an expired vaccine has been scanned.	✓	✓	
17	Validate the scanned vaccine against the patient medical record for accuracy.		✓	
18	When the administration module is connected to an inventory module, warn users if the vaccine is not present in the inventory.		✓	
19	Warn users that a recalled vaccine has been scanned.	✓	✓	
20	Notify user when a more recent VIS is available.			✓
21	Validate that the VIS matches the vaccine administered. Warn users if a discrepancy exists.			✓

Appendix C: Reference Data Resources

1. IIS: HL7 Standard Code Set - Mapping NDC to CVX and MVX
www2a.cdc.gov/vaccines/iis/iisstandards/vaccines.asp?rpt=ndc
2. Other Code Sets (e.g., CPT to CVX, Product Name to CVX, MVX, CPT to CVX, etc.)
www.cdc.gov/vaccines/programs/iis/code-sets.html
3. National Drug Code Directory
<http://www.fda.gov/drugs/informationondrugs/ucm142438.htm>
4. VIS lookup table
www.cdc.gov/vaccines/pubs/vis/vis-barcodes.htm#convert
5. FDA's recall and withdrawal website
<http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/Recalls/default.htm>
6. Code Sets and Mapping Tables
www.cdc.gov/vaccines/programs/iis/code-sets.html
7. VIS reference list
www.cdc.gov/vaccines/hcp/vis/current-vis.html

Appendix D: Resources for GS1 DataMatrix Symbology

1. American Academy of Pediatrics and GS1 Healthcare US Guideline for Suppliers: The Application of GS1 DataMatrix Barcodes to Vaccines for Point of Care
https://www.osehra.org/sites/default/files/barcoding_guidance_manufacturers_022212.pdf
2. GS1 General Specifications
<http://www.gs1us.org/resources/standards/standards-library/gs1-general-specifications>