

Guidance for Practitioners



Implementing Automated Identification of Vaccine Products (AIVP) or Two Dimensional (2D) Barcode Scanning Technology in the Clinical Practice Setting

(Document date: 11/17/16. This document will be revised as new information about implementation is learned. Please email immunize@aap.org with any additional questions you would like addressed in this document.)

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I. Introduction

Barcoding Terminology

- **GTIN** (Global Trade Item Number): This 14-digit unique identifier is assigned by the manufacturer, and includes the manufacturer name, a 10-digit NDC code, and vaccine name.
- **NDC** (National Drug Code): A unique 10-digit, 3-segment number. It is a universal product identifier for human drugs in the United States (including vaccine products).
- **Linear barcoding**: A linear barcode contains the information provided by the GTIN, previously it was the information provided by the NDC.
- **2-Dimensional barcoding**: A 2D barcode contains the GTIN as well as lot number and expiration date.
- **Primary packaging**: The unit of use, i.e., layer of packaging in immediate contact with the product. For vaccines, this is usually a vial or syringe.
- **Secondary packaging**: The saleable unit, most often the carton, of the vaccine

The History of 2D Barcoding

It has been more than four years since the initial 2D barcoding guidance was developed by the American Academy of Pediatrics (AAP) and Centers for Disease Control and Prevention (CDC). The majority of pediatric vaccines now have 2D barcodes on their primary packaging (vial or syringe).

- **From 2004 to 2011**, only linear barcodes were printed on vaccine vials and syringes.
- **Effective November, 2011**, the FDA finalized their guidance, allowing manufacturers to add 2D barcodes to vaccine vials and syringes. (Any subsequent label change must be approved by the FDA.)
- **As of August, 2016**
 - GlaxoSmithKline, Merck, Sanofi, and Wyeth/Pfizer vaccine products have 2D barcoding on their **primary vaccine packaging** (vials and syringes).
 - GlaxoSmithKline and Wyeth/Pfizer products also have 2D barcoding on their **secondary vaccine packaging** (box that holds unit of use). (The box 2D barcode is not always the same as the one on the vial or syringe. For example, there may be different NDC codes and different lot numbers – in the case of multi-component vaccines – on the box and the vial[s].)
 - Vaccine Information Statement (VIS) sheets also have 2D barcodes. Information contained within these codes includes the name and edition date of the VIS.
- **Effective November, 2017**, Title II of the Drug Quality and Security Act (DQSA), also referred to as the Drug Supply Chain Security Act (DSCSA), will require *all* vaccine manufacturers to apply 2D barcodes to vaccine secondary packaging. The required 2D barcode includes a standardized numerical identifier (SNI) in addition to the product identifier (GTIN), expiration date, and lot number.

2016 AAP Survey

To gauge current usage and interest in 2D barcoding technology, the CDC and AAP conducted a survey of pediatric office leaders early in 2016. The web link to the survey was very widely distributed through AAP committees and email lists. Respondents had to not be using 2D barcode scanning already. The following results were obtained from that survey.

- 77% “strongly agreed” that both the accuracy of entering vaccine information, and efficiency of entering vaccine information would improve, if 2D barcode technology were utilized.

- Almost 56% of respondents rated their interest in having a barcode scanner system as 10 out of 10 (10=extremely interested, 0=completely uninterested). Another 31% ranked their interest between 6 and 9.
- 87.5% of respondents said that their interest in barcoding would increase if there was evidence that use of barcode scanning commonly reduced the number of errors in vaccine documentation.
- Initial cost of EHR software interface was listed as the biggest barrier for adoption, with the cost of the scanner being the second biggest barrier.

II. Benefits of 2D Barcoding

Using 2D barcoding technology can benefit both patients and practices. The following are possible patient and practice benefits.

Patient Benefits

- **Improved patient safety.**
- **Reduced administration errors.** When using 2D barcode technology, with a properly designed software system, a scanned vaccine should match the ordered vaccine. (HepA isn't confused with HepB, for example.)
- **Better documentation.** Using 2D barcoding technology ensures that the proper vaccine identifiers (name, lot number, expiration date) are recorded on the patient's record.
- **Expired vaccine identified.** With a properly designed software system, an alert could be triggered when an expired vaccine is scanned.
- **Other vaccine problems identified.** Serialized 2D barcodes enable product verification, which helps to identify potentially compromised vaccine products (i.e., recalled, contaminated, or counterfeit product) within the supply chain.
- **Better reporting.** 2D barcoding technology ensures that the proper vaccine identifiers will be reported to the VAERS system. Manually entered data has been proven to be problematic, as lot numbers are often transcribed erroneously. These errors make it nearly impossible to accurately detect problematic lots or patterns.

Practice Benefits

- **Improved practice efficiency.** Using 2D barcoding technology saves time. One simple scan enters data automatically. Entering data manually takes much longer, and, because it runs the risk of human error in the recording process, requires double checks. In some situations, manual entry needs to be recorded in multiple places (e.g., patient's medical record, state registry) for the same patient, increasing both staff time and risk of error.
- **Appropriate vaccine inventory.** 2D barcode scanning systems can interact with an inventory module. By using these, practices are able to have an electronic account of actual inventory, which allows them to order "just in time," and keep "just the right amount" of vaccine on hand. Having less inventory reduces potential monetary losses due to mechanical failure, natural disaster, power outage, or human error. New 2D barcodes on the box can help offices with inventory tracking even more readily than the barcode on the vial or syringe.

- **Improved billing accuracy.** Using an electronic system, as opposed to a manual system, increases revenue by capturing all vaccines given, and making sure charges are generated for all vaccines given.
- **State registry benefits and perks.** When, and if, the state registries offer direct scanning, practices without an EHR (or those whose EHR doesn't upload information to the state registry) could benefit from the use of 2D barcode scanning by directly scanning the vaccine information into the state registry.

III. Three Practice Uses – Possible Workflows

Inventory Control

As noted above, using 2D barcode scanning with an electronic inventory module can help practices with inventory control. A practice can have “real time” information about what it has in stock, which allows more appropriate volume of inventory “on hand.” (Assuming that all vaccines removed from the refrigerator or freezer are scanned.) It also aids in reconciliation (i.e., comparing inventory to doses for which a bill was generated), which is important when we want to be sure every vaccine that is given is billed for.

With an EHR:

1. When vaccine is delivered to the office, enter the related data into the vaccine inventory module of the EHR.
2. Select the name/type of the vaccine for which information needs to be populated. (For example, a Hep B vaccine could be either Recombivax HB or Engerix-B).
3. Scan the 2D barcode from either the vial/syringe, or the box. Confirm that the vaccine manufacturer, vaccine name, lot number and expiration date have populated correctly. Note: For the sake of a consistent workflow, until all manufacturers include 2D coding on the box (secondary packaging), it may be preferable for staff to scan the vial or syringe (primary packaging).
4. At certain intervals, reconcile the actual physical vaccine count with the vaccine products billed.

Without an EHR:

1. Inventory control *may* be possible through a Practice Management System (PMS).
2. When a vaccine is administered, scan the 2D barcode into the PMS.
3. At certain intervals, reconcile the actual physical vaccine count with the vaccine products billed.

Clinical Vaccination Workflows

Schedules can be reviewed in advance and the patient’s vaccine needs determined. This could be done in various ways, including the use of a vaccine logic system, also known as clinical decision support. This may be in the EHR, or the state registry. In most cases, this will occur at the beginning of each day. The parent/patient is presented with the corresponding VIS sheet(s) for any vaccines the patient is scheduled to receive at that visit. Staff can scan the 2D barcode on the VIS into the patient chart, if the office chooses to use this method of documentation. (Some EHRs have VIS information programmed into their system, which may be easier to use.) Parents can then review these and discuss any questions or concerns with the physician or nurse.

With an EHR

1. The provider orders the vaccine(s) to be administered through the EHR.
2. The EHR automatically checks the order against the patient's record, for verification of need, using vaccine logic (clinical decision support). Appropriate EHR vaccine logic ensures minimum time intervals and minimum age are appropriate, and notifies the ordering provider of any discrepancy.
3. Staff receives the order and obtains the vial/syringe.
4. Staff "opens the order" for each vaccine ordered. Ideally, these should be separate and discrete orders, and fields. The staff member scans the vial/syringe and ensures it is the correct vaccine by matching it to its specific order. Performing the scan within the patient's chart enters the immunization information into the patient's permanent record and allows it to be uploaded to the registry. Administering staff documents site and route of each vaccine given. Once scanned, administered, and recorded, the dose is then automatically subtracted from the practice's inventory.
5. Vaccine product and administration fees are then billed electronically through the EHR/PMS.

Without an EHR:

1. The provider orders the vaccine(s) to be administered.
2. Staff receives the order, verifies the need by checking the patient record, obtains, and prepares the vial/syringe.
3. Staff scans the vial/syringe to determine that it is the correct vaccine.
4. Scanning automatically documents the information included within the 2D barcode and uploads charges to the PMS where the patient's identifying information (name, date-of-birth, account number) is entered.
5. Staff scans the 2D barcode for the VIS given.
6. Staff records site, volume, and route of administration.
7. Scanning automatically subtracts vaccine dose from the PMS module, if one exists.

Administrative/Clerical Processes

Registry or IIS Data Upload:

Depending on the state registry or IIS and the EHR/PMS, this should happen automatically, at regularly scheduled intervals. For those registries that will not accept information from an EHR and/or PMS, log into the registry and the patient's record. Scan each vaccine administered. *It should be noted that, at this time, we are aware of ~6 state registries having direct-scan capability.* They include: Michigan, Mississippi, Nebraska, New York State, Oregon and Wisconsin.

Separation of VFC and Privately Purchased Vaccines:

Currently, there is no way to discern between VFC and privately funded vaccines through electronic means, including the use of 2D barcoding technology. Vaccine manufacturers continue to supply product from the same lot to both private offices and federal programs. The only way to determine the difference is by manually entering them into the system, upon arrival in the office.

Partial use of 2D Barcodes:

As of May, 2016, only Flumist and Novartis flu-vaccine products lack a 2D barcode. Thus, offices that use these vaccines need systems with the capability of interpreting both 2D and linear barcoding. This necessitates having the capacity to allow manual data entry for these vaccines. In November 2017 2D barcoding will be required on the secondary packaging of all vaccines making this a moot issue (see above discussion on DSCSA).

IV. Choosing a Barcode Scanner

When choosing a barcode scanner, the most important things to consider are:

1. Product compatibility with both your hardware and software (EHR and/or registry)
2. Ability to read and translate 2D barcodes
3. Staff preference – if the scanner isn't user friendly for the staff, it won't get used
4. Choose a scanner that is of medical-device quality and “disinfectant ready.” Nearly all scanners labeled as a “healthcare scanner” have this feature.
5. Discuss software configurability and compatibility with both your EHR vendor and registry or IIS.

Four Types of Scanners

Corded. These have been the more commonly used scanners, to date.

Pros: less expensive; get their power from the computer they are plugged into; all data processing and decoding is done on the computer

Cons: Because they are corded, they need to be physically attached to a computer via a USB or serial port. In a busy office with a central vaccine dispensing area this could be problematic, as many vaccine administrators would each need a computer and scanner, or would need to share.

Cordless. These are also commonly used, and function similarly to the corded ones. Instead of being tethered to a computer, however, these communicate via Bluetooth signal. Data processing and decoding still occurs on the computer, but staff have the freedom to scan further from the base.

Pros: increased flexibility and mobility

Cons: higher cost than corded; independent power needs (since it isn't connected directly to a computer); each cordless device needs to be paired with a specific computer and it must not switch to another computer, if the other computer happens to be closer in distance

Wi-Fi with built in processing support. These scanners are mostly used in mobile applications, where access to a computer is not possible, or practical. Most function independently and have their own operating system.

Pros: they are independent of a computer

Cons: even more expensive than cordless; may require custom programming to communicate with the EHR

Refrigerator units with built in scanning devices and software. These are relative newcomers to the field. The scanner is integrated into the unit itself.

Pros: one-stop shop for not only scanning, but storage and handling

Cons: high monthly lease fee; small in capacity; designed to handle the average vaccine supply for a practice with 2-3 providers; currently limited to only reading 2D barcodes from secondary packaging

V. Getting the Scanner to “Work”

Scanners, have software that will decode the 2D barcode into a “string of numbers”. Once this string of numbers is available, tables are available to translate the information into the appropriate data needed to document GTIN, lot number, and expiration date. The [CDC has developed a comprehensive site](#) to help EHR vendors perform these functions (Functional Capabilities Report).

VI. Overcoming Hurdles

Despite 2D barcoding being introduced to vaccines in late 2011, uptake has been very slow. This appears to be multifactorial.

Manufacturer hurdles: Barcodes on secondary packaging

As of November 2017 manufacturers will be required to place 2D barcodes on the secondary packaging. Differences between manufacturers currently create inconsistency in practice workflow. Under current circumstances, scanning the vial or syringe offers the most consistency for using 2D barcodes, but a difficulty with this has been identified. Studies conducted by Deloitte and summarized in CDC’s [Summary Report: Reporting for the Adoption Strategies for 2D Barcode Project](#) concluded that many scanners (both machine and people) seemed to have difficulty scanning from the curved surfaces of the vials and syringes. While the 2D code from the secondary packaging is different from the 2D code from the primary packaging, the information needed for vaccine documentation is still the same. Getting a readable code onto the secondary packaging before November 2017 would be helpful in increasing uptake of 2D barcode scanning at the practice level.

EHR hurdles

All EHR companies that primarily serve hospital-based systems have incorporated 2D barcoding, as there are many items, in addition to vaccines, that 2D barcoding can be used to document. These include patient name, supplies, and medications. However, few ambulatory EHR vendors have incorporated 2D barcoding for vaccination into their systems. Their reasons are likely varied, but include lack of end user request for the technology, and small percentage of clients who vaccinate a large number of patients (i.e., pediatricians aren't a big part of their client population). There have also been concerns raised by practices whose vendors do offer the technology regarding safety, lack of checks and balances, high cost of implementation, and user-unfriendliness.

Practice hurdles

Practices want to utilize barcoding, but, without the consistency from manufacturers and EHR vendors, they are hesitant to jump in. As noted above, [surveys conducted by Deloitte](#) confirmed practices had difficulty scanning from curved vials and syringes. The same surveys revealed practices didn't like the inconsistency in workflow, due to some vaccines having the 2D code on the primary packaging alone, others having the 2D code on both the primary and secondary packaging, and others having no 2D code. Because scanning vials and syringes has been proven to be problematic, this must be corrected. This could be done with a better 2D code on the vial or syringe, with a 2D code on the secondary packaging, or with a better scanner. Some survey respondents abandoned using the 2D barcoding system due to its inefficiencies and because of frustration. In the 2016 AAP survey, two issues were considered major or moderate barriers by more than half of respondents: initial purchase of software required for EHR interface (71%) and initial purchase of barcode scanners (61%).