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Evaluation of scanning 2D barcoded vaccines to improve data accuracy of vaccines administered

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ABSTRACT

Background and objective: Accurately recording vaccine lot number, expiration date, and product identifiers, in patient records is an important step in improving supply chain management and patient safety in the event of a recall. These data are being encoded on two-dimensional (2D) barcodes on most vaccine vials and syringes. Using electronic vaccine administration records, we evaluated the accuracy of lot number and expiration date entered using 2D barcode scanning compared to traditional manual or drop-down list entry methods.
Methods: We analyzed 128,573 electronic records of vaccines administered at 32 facilities. We compared the accuracy of records entered using 2D barcode scanning with those entered using traditional methods using chi-square tests and multilevel logistic regression.
Results: When 2D barcodes were scanned, lot number data accuracy was 1.8 percentage points higher (94.3–96.1%, $P < 0.001$) and expiration date data accuracy was 11 percentage points higher (84.8–95.8%, $P < 0.001$) compared with traditional methods. In multivariate analysis, lot number was more likely to be accurate (aOR = 1.75; 99% CI, 1.57–1.96) as was expiration date (aOR = 2.39; 99% CI, 2.12–2.68). When controlling for scanning and other factors, manufacturer, month vaccine was administered, and vaccine type were associated with variation in accuracy for both lot number and expiration date.
Conclusion: Two-dimensional barcode scanning shows promise for improving data accuracy of vaccine lot number and expiration date records. Adapting systems to further integrate with 2D barcoding could help increase adoption of 2D barcode scanning technology.

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1. Background and objectives

The National Childhood Vaccine Injury Act (NCVIA), passed in 1986, requires that healthcare providers record certain data, including lot number, for all vaccines administered [1]. The American Academy of Pediatrics and the Centers for Disease Control and Prevention (CDC) recommend also recording additional data elements, including expiration date [2,3]. Despite these requirements and recommendations, in 2011 only 60% of Immunization Information System (IIS) vaccination records for children younger than six years of age included the vaccine lot number [4]. Evidence suggests that vaccine data elements recorded in EMRs are not always recorded accurately [5–10]. Missing and inaccurate data may be due in part to the fact that providers read and interpret printed lot number and expiration date on vaccine vials

Abbreviations: 2D, two-dimensional; EMR, electronic medical record; FDA, U.S. Food and Drug Administration; IIS, Immunization Information System; NDC, National Drug Code/product identifier; VAERS, Vaccine Adverse Event Reporting System; VFC, Vaccines for Children.

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and then enter data manually into the electronic medical record (EMR).

Consistent and accurate documentation of vaccine lot number and expiration date in patient records is a first step in determining whether recalled or expired vaccines have been administered, identifying lots associated with adverse events for possible recall, and facilitating efficient and effective vaccine inventory management. In 2004, the U.S. Food and Drug Administration (FDA) passed a labeling rule requiring the placement of a machine-readable linear barcode containing the National Drug Code (NDC) on certain human drug and biological products, including vaccines, to reduce medication errors [11]. The NDC can be used to identify manufacturer (or labeler), vaccine product, and packaging; however, it cannot be used to determine lot number or expiration date [12]. Due to the importance of these additional data elements, the FDA published guidance in 2011 permitting vaccine manufacturers to request a waiver and replace linear barcodes with "alternative technology such as two dimensional symbology" capable of capturing additional data elements (Fig. 1) [13]. Two-dimensional vaccine barcodes encode NDC, lot number and expiration date, and as of July 2016, there were over 90 2D barcoded vaccines [14].

Theoretically, scanning 2D barcoded vaccines should increase the accuracy of vaccination records in EMRs, compared with manual data entry. However, the effect of 2D barcode scanning on vaccine data accuracy has not been widely studied [10,15,16]. In this evaluation, we assess the accuracy of lot number and expiration date in records entered via 2D barcode scanning compared with traditional data entry methods (e.g., drop down menu with jump capability, manual typing, or a combination of the two).

2. Methods

To recruit facilities, we contacted facilities that had expressed interest but were not enrolled in a previous CDC 2D vaccine barcode evaluation [17]. Additionally, we conducted targeted recruitment of other types of facilities (e.g., community vaccinators and pharmacies). We included facilities that: (1) were likely to use vaccines with 2D barcodes scheduled for distribution during the project period; (2) volunteered to scan 2D barcoded vaccines administered into their EMRs; (3) agreed to report de-identified EMR vaccine administration data for this evaluation; (4) used an EMR system to capture vaccine administration data that could be configured to input data using a 2D barcode scanner; and (5) agreed to use technology that allowed us to determine if the lot number and expiration date for a given vaccine administration was entered into the system with a 2D barcode scanner.

For each participating facility, we provided, installed, and configured corded, handheld image scanners with USB interface (i.e., 2D barcode scanners) to scan 2D barcoded vaccines to enter lot number and expiration date into EMRs. We conducted in-person staff training on use of scanners. Staff entered lot number and expiration date directly into EMRs using either 2D barcode scanning or traditional methods, depending on presence or absence of a 2D barcode; staff were encouraged, not required, to scan a 2D barcode if one was available. This evaluation was deemed to be public health practice and did not require IRB review.

	Linear Barcoded Vaccine Vial	2D Barcoded Vaccine Vial
Encoded Data	• National Drug Code (**NDC**) or Global Trade Item Number (GTIN)*	• GTIN • NDC • Expiration Date • Lot Number

Fig. 1. Either GTIN or NDC is encoded in a linear barcode. NDC is a unique 10-digit, 3-segment number that identifies labeler, product, and trade package size. GTIN (Global Trade Item Number) is a global product identification standard in which the NDC is encoded.

2.1. Data sources

We collected EMR data for all linear and 2D barcoded vaccines administered between July 1, 2014 and January 31, 2015. To determine whether scanning took place, we used a flag on records (native scan logs) or supporting text files (installed scan logs).[1] Some facilities employed an EMR system capable of tracking which vaccine records were entered into the system via a 2D barcode scanner (native scan log). Other facilities allowed us to install software to record data from the scanner into a separate text file to indicate whether a 2D barcode was scanned (installed scan log); to be considered scanned, the text file had to match an EMR record on lot number, time recorded, and date recorded. EMR vaccine administration records that did not match the text file across all three data points were considered entered via "traditional methods."

We determined whether lot number and expiration date entries were accurate by comparing data in the EMRs with a reference file containing 31,441 unique lot numbers. Lot numbers were compared to the reference file and considered accurate if a valid match was identified. The reference file was created from five sources: files from three manufacturers of 2D barcoded vaccines; records from the Vaccine for Children's (VFC) program; facility shipping manifests; facility inventory records; and Vaccine Adverse Events Reporting System (VAERS) data [18]. Manufacturer files and VFC data were supplemented by the other sources only if certain criteria were met (e.g., previously unidentified lot numbers had appeared at least three times in VAERS). Four of the five reference file sources included information from one year before start of this evaluation (July 2013) through January 2015; VFC records contained vaccines shipped from May 2014 to January 2015.

All facilities had EMR systems that automatically populated vaccine lot number by scanning the 2D barcode; however, not all EMRs could capture expiration date from the scan. When expiration date was populated from an inventory system or a prepopulated table, records were excluded from the analysis of expiration date. Expiration dates were considered accurate if the expiration date in the EMR was the same as the expiration date associated with the lot number in the reference file. Records were excluded from expiration date analysis if lot number was not accurate because expiration date could not then be verified or if the reference file did not include expiration date for that vaccine lot.

[1] Where facilities had existing EMRs capable of identifying which records were entered using a 2D scanner, we referred to those facilities as having native scan logs. At installed scan log facilities, the team had to install a text document to record vaccine information populated through 2D scanning and then match the text file records to the EMR data.