

Implementation Pilot for Two-Dimensional (2D) Vaccine Barcode Utilization: Additional Workflow Analysis (WFA) Final Report

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Executive Summary

In 2011, CDC's Immunization Services Division within the National Center for Immunization and Respiratory Diseases (CDC/NCIRD/ISD) contracted with Deloitte Consulting (Deloitte) to conduct the *Implementation Pilot for Two-Dimensional (2D) Vaccine Barcode Utilization*. As part of that pilot project, Deloitte performed workflow analyses (WFAs) in a subset of practices to describe how the introduction of 2D barcoded vaccine scanning changed vaccination administration and inventory processes and affected the time it takes practitioners to record vaccine data (i.e., lot number, expiration date, and product identifier). Although valuable lessons were learned during these WFAs, the limited number of 2D barcoded vaccines available during the pilot project observation period¹ hindered the ability to develop a full understanding of the effect of 2D barcodes on recording data about vaccine administrations and vaccine inventory. As of May 2014, multiple 2D barcoded presentations of vaccines which were not available in the original pilot timeframe had come to market, therefore, Deloitte performed a second set of WFAs to answer the following questions:

- (1) In what ways, if any, does the use of 2D barcoded vaccines affect the workflow procedures associated with recording vaccine data as part of the vaccine administration and inventory processes?
- (2) Does the use of 2D barcodes to record vaccine data during the vaccine administration and inventory processes change the amount of time it takes to record vaccine data? If so:
 - a. What is the direction and magnitude of this change?
 - b. What factors contribute to the changes in recording time?
 - c. How do these time differences relate to modifications made in the recording procedures when using 2D barcode scanning?
- (3) What are staff opinions about the use of 2D barcode scanning to record vaccine data in their practice?
 - a. To what extent do staff report improvements in the use of 2D barcode scanning given the increase in 2D barcoded vaccines in their practice?
 - b. What has facilitated the continued use of 2D barcode scanning to record vaccine data in the practice and what challenges remain?

Methods

To be included in the current WFA, practices included in the original pilot had to meet the following inclusion criteria: (1) All above the 33rd percentile in estimated volume of 2D barcoded vaccines administered in their practice, (2) Continued use of 2D barcode scanners to record data for vaccines administered after the data collection phase of the pilot ended in March/April 2013, (3) Encountered 2D barcoded vaccines more frequently than once a month, and (4) Expressed an interest in participating in the

¹ By the end of the implementation period the majority of practices ($n=111$, 71%) received 2D barcoded Menactra; however, other 2D barcoded vaccines were infrequently received during the original pilot.

WFA. Our team screened the 217 practices from the original pilot project for their eligibility using existing data and requesting additional information via email or phone.

Ten practices were selected for inclusion in the current WFA, as well as one practice that served to pilot test the proposed WFA data collection procedures. One project team member conducted all WFA practice visits. This WFA consultant performed three data collection activities: (1) Observations of the vaccine-specific administration and inventory workflow processes including data entry, (2) Time measurements for each step in these workflow processes as well as specifically for entering vaccine data using 2D barcode scanning and traditional methods of data entry and, (3) Semi-structured interviews with practice staff with direct experience recording vaccine administration or vaccine inventory data with 2D barcode scanners .

The WFA consultant used the detailed notes and time measurements taken during observations of the entire workflow process within each practice (for vaccine administrations and vaccine inventory) to develop process maps. The analysis team reviewed these process maps and extracted information about how the workflow processes differed when linear barcoded vaccines or 2D barcoded vaccines were in use. We identified the steps in the workflow that were commonly added or omitted between and within practices when using vaccines with different types of barcodes. A member of the analysis team transcribed digital recordings of the interviews, extracted, and coded relevant text from each transcript in response to the third evaluation question noted above.

We analyzed time measurements using descriptive statistics, and then tested for differences between the average time to record vaccine administration data using 2D barcode scanning compared to traditional data entry methods within practices with a t-test. We used the Wilcoxon Signed-Rank Test to examine whether this difference was statistically significantly different at the aggregate practice level. Additionally, to account for the effects of potential confounding factors, we performed random intercept linear mixed effects analysis of the relationship between time to record vaccine data and barcode type. Due to the limited sample size, we used descriptive statistics to examine differences in the time to record vaccine data for inventory when using 2D barcode scanning relative to traditional data entry methods.

Results

The majority of WFA practices specialized in pediatrics ($n=6$, 60%), were small in size (five or fewer physicians) ($n=6$, 60%), and used 2D barcode scanners only to record vaccine administrations ($n=7$, 70%). Two of the 10 participating practices had an EMR that is 2D barcode capable². In over half of the WFA practices, approximately 26% to 50% of their vaccine supply is public purchase ($n=6$, 60%).

The workflow procedures associated with patient visits where one or more vaccines were administered were more likely than the processes associated with vaccine inventory to differ with the introduction of 2D barcode scanning. However, minimal changes occurred in this procedure for the 10 practices observed. All practices, with the exception of one, had 2D barcode scanners located at every data entry site in the practice. As a result, no changes beyond those associated with physically scanning the barcode occurred in

² 2D capable means an EHR can process the scan from a 2D barcode scanner (not configured using our configuration utility) to deposit the data into their system.

the overall workflow procedures when a 2D barcode vaccine was recorded. The WFA consultant observed three practices performing inventory data entry. In general, the procedures associated with recording vaccine inventory changed minimally in these three practices between the activities performed for recording data from linear barcoded vaccines and 2D barcoded vaccines—with the major difference being the use of a 2D barcode scanner.

Across all 10 practices, the average time to record vaccine administration data using 2D barcode scanning was 26.75 seconds and the average time to record vaccine administration data from a linear barcode using traditional methods was 28.47 seconds. This difference was not statistically significantly different³. The largest predictor of differences in time to record vaccine data in the random intercept linear mixed effects analysis was administering nurse—this explained 17% of the variation in time. Practice and vaccine type both individually explain 9% of the variability in time to record vaccine data.

For five practices, the average time to record data about vaccines administered was lower when using 2D barcode scanners than recording data from linear barcoded vaccines using traditional methods. For five practices, the average time to record data about vaccines administered increased. Mean differences between 2D barcode scanning and using the traditional method of data entry to record data for vaccines administered ranged between 16.68 seconds to -16.79 seconds. Only one practice experienced a statistically significant decrease in the average time to record data for vaccines administered, where the average time to record using traditional methods was 44.55 seconds ($SD=16.39$) and the average time to record using 2D barcode scanning was 27.76 seconds ($SD=16.39$).

Many individuals interviewed were not certain as to why their practice continued using 2D barcode scanning after the original pilot project came to a close ($n=13$ interviews of 26⁴). Interviewees who provided a specific answer about why their practice continued to scan 2D barcodes to record vaccine data most frequently noted a perceived increase, or potential for improved, accuracy of records ($n=11$ interviews). In 21 of 27 interviews, individuals conveyed that staff had noticed an increase in the number of vaccines with 2D barcodes since the pilot end date; however, opinions were mixed about the extent to which this increase had improved the process of using 2D barcode scanners to record vaccine data. The most frequent benefit of using 2D barcode scanning mentioned by interviewees was a perceived improvement in the accuracy of vaccine data. The most frequent challenge cited was difficulties with scanning barcodes and the level of inconsistency with which the scanning process actually works.

Conclusions and recommendations

This WFA provides some limited indications that 2D barcode scanning can save time when entering data about vaccines administered. The use of 2D barcode scanning in one of the 10 practices resulted in a

³ $V=344$, $p=0.437$

⁴ Interviews performed were semi-structured in nature. This format allowed the interviewer to adapt the interview as needed based upon the context. Therefore, in some instances all questions on the interview guide were not asked in every interview.

statistically significant decrease in average time to record vaccine data. We hypothesize that such differences may become more widespread when the practice of 2D barcode scanning to record vaccine data is common in health care practices and encourage future research once all vaccines are 2D barcoded. In the interim, there are several findings from this WFA that suggest steps that could improve the process of using 2D barcode scanning to record vaccine data in health care practices. Based upon these findings we recommend that:

1. Practices considering 2D scanning adoption should invest time up front to plan how 2D barcode scanning will work best with their operations to help determine the appropriate number and placement of scanners so as not to introduce operational impediments.
2. The CDC and FDA should collaborate with the manufactures to investigate the quality and consistency of the 2D barcode labeling. Consistent reports from interviewees that there is variability in the ease of scanning 2D barcodes by vaccine type warrants further investigations about the quality of 2D barcode labeling and the ability to consistently produce batches with labels that practitioners can easily scan.
3. The EMR software should be configured or set up to read the entire lot number which will prevent default selection by the system of lots with similar first characters. Solution vendors incorporating 2D barcode scanning of vaccines into their applications should read the entire lot number from the encoded data string.
4. Industry should further investigate inconsistencies of 2D barcode scanning. Non-specific, but frequent, concerns from interviewees about the inconsistency of 2D barcode scanning suggests that follow-up product evaluations that examine the possible root causes of these reported inconsistencies would be helpful. Such investigations might examine the comparative effectiveness of 2D barcode scanning using a variety of conditions, such as: (a) placement of the barcode in different locations on the label, (b) other quality features of barcodes (e.g., different background colors, ink used for 2D barcode), or (c) peel-off labels versus labels on vials or syringes.

1. Introduction

In 2011, CDC's Immunization Services Division within the National Center for Immunization and Respiratory Diseases (CDC/NCIRD/ISD) contracted with Deloitte Consulting (Deloitte) to conduct the *Implementation Pilot for Two-Dimensional (2D) Vaccine Barcode Utilization*. As part of that pilot project, Deloitte performed workflow analyses (WFAs) in a subset of practices to describe how the introduction of 2D barcoded vaccine scanning changed vaccination administration and inventory processes and affected the time it takes practitioners to record vaccine data (i.e., lot number, expiration date, and product identifier). Although valuable lessons were learned during these WFAs, the limited number of 2D barcoded vaccines available during the pilot project observation period⁵ hindered the ability to develop a full understanding of the effect of 2D barcodes on recording data about vaccine administrations and vaccine inventory.

As of May 2014, multiple 2D barcoded presentations of vaccines which were not available in the original pilot timeframe had come to market. This development provided an opportunity to examine the potential effects of 2D barcode scanning in an environment where 2D barcode vaccine volume has increased. As a result, Deloitte performed a second set of WFAs from June-July 2014 with a new subset of the 217 practices from the pilot project. In this report, we present the findings from this second WFA, specifically addressing the following questions:

- (1) In what ways, if any, does the use of 2D barcoded vaccines affect the workflow procedures associated with recording vaccine data as part of the vaccine administration and inventory processes?
- (2) Does the use of 2D barcodes to record vaccine data during the vaccine administration and inventory processes change the amount of time it takes to record vaccine data? If so:
 - a. What is the direction and magnitude of this change?
 - b. What factors contribute to the changes in recording time?
 - c. How do these time differences relate to modifications made in the recording procedures when using 2D barcode scanning?
- (3) What are staff opinions about the use of 2D barcode scanning to record vaccine data in their practice?
 - a. To what extent do staff report improvements in the use of 2D barcode scanning given the increase in 2D barcoded vaccines in their practice?
 - b. What has facilitated the continued use of 2D barcode scanning to record vaccine data in the practice and what challenges remain?

⁵ By the end of the implementation period the majority of practices ($n=111$, 71%) received 2D barcoded Menactra; however, other 2D barcoded vaccines were infrequently received during the original pilot.

2. Methodology

2.1. Selection of practices

The target number of practices for participation in this WFA was 10. To select practices for inclusion, we assessed several factors. The first factor of interest in this WFA was the anticipated volume of 2D barcoded vaccines administered by the practice. Our goal was to obtain participation from practices that likely administer the largest volume of 2D barcoded vaccines out of all practices that participated in the pilot project. Due to the timeline for the current WFA and the effort that would be involved in obtaining data from each pilot practice regarding the volume of 2D barcoded vaccines they administered in the months directly preceding this WFA, we leveraged existing data from the pilot project to generate an estimate of the possible 2D barcoded vaccine administration volume within each practice.

To estimate the volume of 2D barcoded vaccines administered, our team obtained the National Drug Code (NDC) from manufacturers for all 2D barcoded vaccines as of May 7, 2014. We then used the NDC to identify the brand and type of vaccines. Our team used the NDC, brand, manufacturer, and vaccine type to identify and label each vaccine administered in the pilot project Immunization Information Systems (IIS) data file as 2D barcoded or not. Seasonal vaccine products, specifically influenza vaccines, were excluded from this file since practices frequently change the manufacturers from which they order product between seasons. Subsequently, we ran a frequency distribution to group practices into three categories – low, medium, and high volumes of anticipated 2D barcoded vaccines administered. Practices at or below the 33rd percentile in anticipated volume based upon the number of 2D barcoded, non-influenza, vaccines they administered between November 2011 and March/April 2013 were categorized as low volume (range: 2 to 625 vaccines administered), those above the 33rd percentile and at or below the 66th percentile were categorized as medium volume (range: 628 to 1,919 vaccines administered), and those above the 66th percentile were categorized as high volume (range: 2,013 to 33,165 vaccines administered).

Subsequently, our team contacted practices assigned to the high or medium volume categories via email. This email included a brief description of the purpose and timing of the WFA, and asked for additional information from the practice to determine their eligibility for participation (Appendix A). Practices were eligible for inclusion if they reported:

1. Continued use of 2D barcode scanners to record data for vaccines administered after the pilot ended in March/April 2013
2. Encountering 2D barcoded vaccines more frequently than once a month
3. Interest in participating in the WFA

Members of our team placed at least one phone call to each of the practices that did not respond to the email as well as to practices that did respond and met the eligibility criteria. For practices meeting the eligibility criteria, we requested additional data about the practice including: (1) the name of their EMR, (2) the number of physicians in the practice, (3) the approximate percentage of vaccines that are private-purchase, (4) the approximate percentage of vaccines that are public-purchase, (5) when practice staff

typically record data about vaccines administered, and (6) where 2D barcode scanners used for recording vaccine administrations are located within the practice. The original intention of gathering this additional data was to provide further information helpful to selecting the practices for the WFA (e.g., obtain an even split of practices with 2D enabled EMR systems vs. non-2D enabled).

2.2. Data collection

One project team member conducted all WFA practice visits. Prior to the in-person visits, the WFA consultant met with the Deloitte team project manager and lead evaluator to become familiar with the current protocol, the specific data collection and documentation procedures, and who to contact in the event questions arose in the field. The WFA consultant also spoke with individuals who conducted WFAs for the original pilot to become familiar with the lessons they learned. The first WFA visit was used as a “pilot test” for the procedures outlined in the project protocol⁶. Following this initial pilot visit, the Deloitte lead evaluator, project manager, and WFA consultant discussed the feasibility of the protocol procedures and revised the data collection procedures to improve data documentation.

The consultant performed three data collection activities for the WFA: (1) Observations of the vaccine-specific administration and inventory workflow processes including data entry, (2) Time measurements for each step in these workflow processes as well as specifically for entering vaccine data and, (3) Interviews with practice staff. Each data collection activity is described in greater detail below.

2.2.1. Observations of vaccine-specific administration and inventory workflows

The WFA consultant performed observations of vaccine administration and vaccine inventory (where applicable) processes while on-site at each practice. For these observations the consultant shadowed at least two staff members⁷ while they performed the entire process associated with patient visits in which one or more vaccines were administered, and at least one individual while they performed the process involved with recording vaccine inventory data (where applicable). The process for selecting individuals to observe varied slightly by practice; however, the general rule followed by the WFA consultant was to observe all individuals who administered vaccines and were working during the days of the WFA visit. The WFA consultant typically did not observe individuals who noted they never personally use the 2D barcode scanners to record vaccine data.

For both the vaccine administration and vaccine inventory workflows, the WFA consultant documented each step in the workflow process for each observation instance and assigned a unique identifier code that represented both the observed staff member and the observation instance. Our team also gathered additional descriptive information for each observation instance (Table 1). In addition to these elements,

⁶ Since this practice was used as a pilot data collection effort a limited amount of data obtained is included in our analyses. Specifically, we included feedback obtained through staff interviews.

⁷ One exception to this process occurred at the WFA visit to practice 2299. There is only one nurse who administers vaccines in this office, therefore the WFA consultant observed only this individual. A medical assistant who does not administer vaccines on a typical day, but does so when the nurse is not in the office was asked to participate in mock scans.

the WFA consultant recorded the practice identification number, the name of the EMR used, and the traditional procedures used to record vaccine data (e.g., drop down, manual entry) for each practice visited.

Table 1. WFA data elements gathered during observations of workflow processes

Process Observed	Data Elements Collected
Vaccine Administration	<ul style="list-style-type: none"> • Unique identifier for staff member being observed • Number of vaccines administered to patient • Names of vaccines • Number of 2D barcoded vaccines administered to patient • Number of linear barcoded vaccines administered to patient • Name of the key step in the process under observation* • Length of time (in seconds) for the key steps in the process • When vaccine administration data were recorded (Before or after administration) • Physical location where vaccine data were entered into the EMR • Additional comments regarding process or WFA data collection
Vaccine Inventory	<ul style="list-style-type: none"> • Unique identifier for staff member being observed • Type of vaccine being recorded into inventory (linear or 2D) • Name of vaccine being recorded into inventory (e.g., Menactra) • Name of the step in the process • Length of time (in seconds) for the key steps in the process • Physical location where vaccine data were entered into inventory • Additional comments regarding process or WFA data collection
*General steps as defined by the consultant based on each site’s workflow process.	

2.2.2. Time measurements

The WFA consultant recorded time measurements associated with the four processes depicted in Table 2. Specifically, the consultant recorded times for each key step in the entire process associated with patient visits in which one or more vaccines were administered, and for the process involved with recording vaccine inventory data (where applicable). Additionally, the consultant recorded the time it took practitioners to enter data, either by scanning or traditional methods, for each vaccine that was administered to a patient or recorded for the purpose of vaccine inventory. The WFA consultant recorded times using *TimeStudy*,⁸ an application specifically designed for use in time and motion studies.

⁸Information about *TimeStudy* is provided at: <https://itunes.apple.com/us/app/timestudy-by-nuvizz/id504948284?mt=8>

Table 2. Processes for which time was measured with start and stop times

Process *	Observation start	Observation end
1. Vaccine inventory process	Retrieve vaccine from shipment box	Save vaccine inventory record in electronic system
2. Vaccine-specific patient visit	Review patient chart [†]	Save patient record in electronic system
3. Data entry for vaccine inventory	For 2D barcoded vaccines this included picking up the scanner. For linear barcoded vaccines this is entering the lot number and expiration date	Complete data entry of data element of interest in 2D barcode scanning—either lot number or expiration date
4. Data entry for vaccines administered	For 2D barcoded vaccines this included picking up the scanner. For linear barcoded vaccines this is entering the lot number and expiration date	Complete data entry of data element of interest in 2D barcode scanning—either lot number or expiration date

* Each process listed was timed for both 2D barcoded and linear barcoded vaccines. For the second process listed – “vaccine-specific patient visit”—practitioners often administered more than one vaccine. Therefore observations included those in which the practitioner administered only linear barcoded vaccines, only 2D barcoded vaccines, or a mixture of linear and 2D barcoded vaccines. [†]The start times for the vaccine-specific patient visit frequently varied as these depended upon the process employed within a given practice.

After observing the workflow process to garner a general understanding of the typical steps and procedures, the WFA consultant timed as many instances of vaccine administrations and vaccine inventory as possible with a goal of 30 observations each for both 2D barcode scanning and traditional methods in each participating practice. In small practices, the consultant attempted to capture times associated with all vaccine-specific patient visits that took place during the days of the WFA visit. In larger practices with more than one practitioner, the WFA consultant attempted to maximize the number of vaccine-specific patient visits observed while also spreading these observations across the practitioners, in an effort to obtain approximately the same number of observations per practitioner.

Table 3 provides an example of how time measures were recorded for each step of the workflow process associated with one vaccine-specific patient visit. The specific steps recorded in the first column varied by each observation instance however, consistent terminology for similar steps was used throughout the data collection effort. We used a similar procedure to document times associated with the steps involved in vaccine inventory.

Table 3. Example of time measurements of vaccine administration process

Step in Process*	Time (sec)
Patient counseling	5.21
Login	32.13
Data Entry	17.16
Walking	10.36
Wash hands	33.64
Vaccine Prep	59.28
Data Entry	9.11
Linear input	21.13
2D input	25.78

*The “2D input” step in this chart refers to the specific time it took to perform the steps specific only to 2D scanning: picking up the scanner, scanning the barcode for lot # and expiration date, and pressing the ‘scan’ button when necessary. The “linear input” steps refer to the specific steps that would be performed in the traditional method instead of the 2D scanning process—so either manually typing or selecting from a drop box the lot number and expiration date. The “Data Entry” step refers to the steps that are performed for both processes—such as typing or drop down selection of manufacturer, input location, etc. The WFA consultant wanted to single out the steps that are directly comparable to measure the differences for the two processes: linear vs. 2D.

When documenting the time associated with recording vaccine data elements for a single vaccine administered or entered into inventory, the WFA consultant also documented several variables of potential interest to the analysis (Table 4). Per the WFA protocol, our intention was to record 30 time measurements of the linear barcode recording process and 30 time measurements of the 2D barcode recording process in each location (administration and inventory) per facility (Table 5). In the event that 2D barcoded vaccines were not administered, or administered with limited frequency, during the date and time of the visit the WFA consultant requested practitioners engage in “mock” scanning procedures. Towards the end of the WFA visit, the WFA consultant reviewed the number of observations made and worked with those who she was observing to obtain time measures for mock procedures⁹. It should be noted, however, that three practices were uncomfortable with the mock scanning process and declined to participate due to concerns about the mock scans introducing data that might interfere with the inventory reconciliation and management process. The decision to engage in mock scanning was usually dependent on whether the EMR system easily allowed the staff to create a mock patient (which the EMR knew not to subtract the inventory for) or whether the staff could easily perform the process completely without saving the vaccine administration into the EMR.

Table 4. Variables recorded for instances of vaccine data entry (administration and inventory)

⁹ Detailed information about the mock data entry procedures are provided in the WFA protocol.

Variable	Description
Staff ID	Unique identifier for staff member observed
Vaccine Name	Name of the vaccine (e.g., Menactra)
Barcode Type	2D barcode or linear barcode
Procedure	Process observed—administration or inventory
Real or mock scan	Real or mock scan observed
Time (seconds)	Time in seconds that elapses between the instant when a staff member accesses the vaccine administration or vaccine inventory module in their electronic system to enter data until all data is entered for that vaccine.
Physical location where vaccine was recorded- administration	Location in practice where vaccine data was recorded. Options include: nurses station; refrigeration area/prep station; patient area/point of care; other
When vaccine administration data was recorded	Before or after vaccine was administered
Physical location where vaccine was recorded- inventory	Text based description
Comments	Any additional comments about the process observed or efforts to record information about the data entry process

Table 5. Proposed number of observations per process for data entry time measures

Process	Administration	Inventory
2D barcode scanning	30	30
Traditional method	30	30
<i>Total (practice- level)</i>	60	60

2.2.3. Staff Interviews

The WFA consultant conducted in-person, semi-structured interviews with a subset of staff at each practice. Specifically, this activity targeted performing interviews with three¹⁰ to five individuals who had direct experience recording vaccine administration or vaccine inventory (where applicable) data with 2D barcode scanners. Interviewees were selected for participation based upon their schedule availability, and in some practices, based upon the preference of the practice’s point of contact. On occasion we conducted interviews with a representative from information technology or a nurse manager who provided oversight to the medical staff depending upon what seemed most appropriate in the practice context. Given the busy nature of the practices, we ensured that no interviews exceeded 15 minutes in duration. The WFA consultant obtained permission to digitally record the interview. Our team transcribed the interviews prior to analysis. In the event that a digital recording was unavailable, the team used notes taken during the

¹⁰ These estimates assumed that the facility was large enough to have at least three individuals who were directly involved in recording vaccine administration or vaccine inventory data. In the event this assumption was violated we proposed to speak with all individuals who were involved in this process (i.e., one or two persons).

course of the interview in the analysis¹¹. The semi-structured interview guide used by the WFA consultant for these staff interviews is provided in Appendix B.

2.3. Data analysis

2.3.1. Comparison of vaccine-specific administration and inventory workflows

One primary question of interest in this evaluation is—“ In what ways, if any, does the use of 2D barcoded vaccines affect the workflow procedures associated with recording vaccine data as part of the vaccine administration and inventory processes?” The WFA consultant used the detailed notes and time measurements taken during observations of the entire workflow process within each practice (for vaccine administrations and vaccine inventory [where applicable]) to develop process maps. The analysis team reviewed these process maps and extracted information about how the workflow processes differed when linear barcoded vaccines or 2D barcoded vaccines were in use. We identified the steps in the workflow that were commonly added or omitted between practices when using vaccines with different types of barcodes and present these findings in the results section. We also report on unique changes to individual practice workflows. Appendix C includes process maps and detailed case descriptions for each practice.

2.3.2. Changes in amount of time to record vaccine data

Another central question of interest to this evaluation concerns whether or not using a 2D barcode scanner to record vaccine data is more or less expedient than entering data from vaccines without a 2D barcode – “Does the use of 2D barcodes to record vaccine data during the vaccine administration and inventory processes change the amount of time it takes to record vaccine data?” To address this question, the analysis team combined and manually cleaned the datasets created for each practice during the WFA visits and performed descriptive analyses¹² on the data to examine measures of central tendency, dispersion, and shape of the distribution. The team used these descriptive analyses to consider whether transformation procedures were needed for any of the key variables prior to producing regression models.

Since the underlying assumptions of the parametric t-test were not met, the analysis team used the non-parametric Wilcoxon Signed-Rank Test to examine whether differences existed between the time to record data using 2D barcode scanners compared to recording data using tradition methods in the aggregated practice data. Additionally, to account for the effects of potential confounding factors, we performed random intercept linear mixed effects analysis of the relationship between time to record vaccine data and barcode type. As fixed effects, we entered barcode and EMR into the model. As random effects, we had intercepts for vaccine name, staff ID and practice ID. To adhere to the model’s assumption of linearity in the outcome measure, time, we performed a log transformation of time to adjust for right skew in the time variable. The final model took the form of:

$$y (\text{Log of time}) = \beta_0 + \beta_1 * (2D \text{ barcoded}) + \beta_2 * (EMR) + v(\text{Vaccine}) + v(\text{Practice}) + v(\text{Nurse}) \varepsilon$$

¹¹ This situation only occurred for a portion of one interview; all others included a complete digital record.

¹² Included measures of central tendency (mean, median, and mode), dispersion (standard deviation), and shape (skew and kurtosis). Additionally we examined visual plots of data including histograms and boxplots.

2.3.3. Staff opinions about 2D barcode scanning

The final question of interest in this evaluation relates to the staff's opinions of using 2D barcode scanning to record vaccine data. As previously noted, the WFA consultant took detailed notes and digital recordings during the interviews. Prior to performing analysis of the interviews, a member of the analysis team transcribed each recording and extracted relevant text from each transcript that included opinions from staff regarding the following topics:

- Factors that facilitated the continued use of 2D barcode scanning to record vaccine data
- Challenges that remain in using 2D barcode scanning to record vaccine data
- Reported improvements in using 2D barcode scanning in a context where more vaccines are 2D barcoded than during the pilot project observation period
- Benefits of recording vaccine data using 2D barcode scanning as compared to other methods
- Drawbacks of recording vaccine data using 2D barcode scanning as compared to other methods

The analyst further examined these excerpts to identify additional themes within these categories (e.g., commonly held opinions about benefits).

3. Results

In this section we provide an overview of the characteristics of practices participating in the WFA as well as a summary of each of the evaluation questions posed for this WFA. We provide detailed, de-identified summaries for each practice visited as part of the WFA, in Appendix C.

3.1. Practice characteristics

Of the 217 practices that participated in the original pilot, we estimated that 145 would likely administer a high or medium volume of vaccines that were currently 2D barcoded. Each of these practices was contacted by our team—90 provided the majority of data requested and 55 did not provide a response to our request after multiple attempts. Of the 90 practices that provided data, 74 were determined ineligible based on the inclusion criteria described in Section 2. Of the 16 eligible practices, three were associated with a single facility in one state and grouped together as a single practice for the WFA. Another three were associated with a single local health department, with two of these practices available for a visit.

Our team successfully scheduled and performed WFA visits at 11 out of 13 eligible practices. One of the eligible practices was experiencing computer issues that were unlikely to be resolved as of the scheduled time for the WFA; so we excluded that practice. We were unable to accommodate the schedule for another practice—this practice had one individual user of the 2D barcode scanner and this person was unavailable at the time open on the WFA visit schedule. One of the 11 practices the WFA consultant visited served as a pilot for the procedures outlined in the protocol. This resulted in 10 practices where we conducted WFA visits.

An overview of the demographics for the 10 participating practices in the WFA is provided in Table 6. The majority of WFA practices specialized in pediatrics, were small in size (five or fewer physicians), used 2D barcode scanners only to record vaccine administrations, and had an EMR that is not 2D barcode capable¹³. In over half of the WFA practices, approximately 26% to 50% of their vaccine supply is public purchase.

Table 6. Characteristics of participating WFA practices

Characteristic	Frequency
Location of practice *	
Michigan	3
Washington	3
New York	2
Florida	1
New Jersey	1
Practice specialty	
Pediatrics	6
Public health department	3
Family practice	1
Number of physicians	
5 or fewer	6
6 to 15	3
16 or more	1
MEMR	
EPIC	3
Mitchell and McCormick [†]	2
Aprima	1
E-MDs	1
GE Centricity	1
Insight Netsmart	1
Sage Intergy	1
Estimated 2D barcode volume administered[‡]	
High (Range: 2,157 to 9,515 vaccines administered)	6
Medium (Range: 672 to 1,779 vaccines administered)	4
Process for which 2D scanning is used	
Vaccine Administrations	7
Vaccine Inventory	0
Both Processes	3
Percentage of public vaccines (approximate)	
0%-25%	1
26%-50%	6
51%-75%	1
76%-100%	2

¹³ 2D capable means an EHR can process the scan from a 2D barcode scanner (not configured using our configuration utility) to deposit the data into their system.

* Location of practice relates to the Immunization Awardee jurisdiction within which the practice resides. †2D barcode capable. ‡This represents the number of 2D barcoded vaccines (non-influenza) that would have been administered by the practice during the original pilot project time period (Nov 2011-March/April 2013) given which vaccines were 2D barcoded as of May 7, 2014).

3.2. Vaccine-specific administration and inventory workflows

The WFA consultant observed over one hundred vaccine-specific administration workflows from start to finish across the 10 participating practices. The smallest number of observations was six, the largest number was 20. Observations of the inventory process were only possible in two of the 10 participating practices, with six observations total (Table 7).

Table 7. Number of observations by process

Practice	Administration	Inventory
1187	15	5
2413	17	--
2133	8	--
2508	6	--
2091	8	1
2452	7	--
2299	11	--
2429	14	--
2168	20	--
2510	6	--
Total	112	6

3.2.1. Vaccine administration

The workflow processes associated with patient visits where one or more vaccines were administered were more likely than the processes associated with vaccine inventory to differ with the introduction of 2D barcode scanning. However, minimal changes occurred in this procedure for the 10 practices observed. All practices, with the exception of the pilot practice and Practice 2168, had 2D barcode scanners located at every data entry site in the practice. As a result, no changes beyond those associated with physically scanning the barcode occurred in the overall workflow procedures when a 2D barcode vaccine was recorded. In one location where 2D barcode scanners were not readily accessible at each recording station, staff reported in the interviews that they purposefully changed their regular workflow to accommodate the 2D barcode scanning observations for the WFA.

Only one of the observed practices incorporated the use of a portable tablet device to record data while in the patient room. The staff informed the WFA consultant that the tablet was unable to use the 2D barcode scanner because it was not configured to perform scanning and the only available 2D barcode scanners at this specific practice were located at the stationary nursing stations.

3.2.2. Vaccine inventory

The WFA consultant observed two practices performing inventory data entry because only those two incorporated the use of 2D barcode scanners into their normal inventory recording process. The practices used these inventory processes to keep an accurate count of vaccines in stock within the facility. Additionally, the data entered at inventory populates drop down menus in practices that have EMRs that make use of drop down menus to enter data (such as lot numbers, vaccine names, and vaccine manufacturers) when recording data about vaccines administered. The two practices where the inventory process was observed (Practice 2091 and Practice 2452) were affiliated with the same local health department where inventory was a centralized function.

In general, the procedures associated with recording vaccine inventory changed minimally in these three practices between the activities performed for recording data from linear barcoded vaccines and 2D barcoded vaccines—with the major difference being the use of a 2D barcode scanner. In the observed practices, the manual entry of lot number and expiration date was no longer necessary when a practitioner scanned a 2D barcode. Practitioners in practices 2091 and 2452 used the Vendor B EMR which required them to press a “scan” button prior to scanning the 2D barcode on each vaccine to activate the scanning capability in the EMR. This was recognized by nurses as a challenge when entering data for multiple vaccines administered to a single patient since it adds an extra step to the process for each vaccine entered. It did not, however, seem to present similar difficulties in recording vaccine inventory.

One of the practices observed (practice 1187), relocated the inventory process to a different location since the start of the pilot study as part of an internal initiative to improve efficiency; the addition of scanners was a step included in the update of this inventory process. The previous inventory recording process was done at the front desk where patients checked in. The same staff member still performs the inventory input; however, there is now a computer station with a scanner in the inventory storage room, and the vaccines are now either scanned or input traditionally in the storage room whenever a new shipment arrives. The staff member noted that this cuts down on the number of interruptions and therefore likely cuts down on the number of data errors made as a result of having to stop and return to the process several times.

We should also note that individuals performing data entry at inventory noted that they preferred to scan the 2D barcode located on the box over having to open the box and scan the individual vials. One practice noted that these lot numbers were initially different, but it was decided as an office policy to always use the box barcode instead.

3.3. Changes in amount of time to record vaccine data

One of the purposes of the WFA is to evaluate whether a statistically significant difference exists in the time it takes to record vaccine data from a 2D barcode compared to a linear barcode. As described in the methodology section, the WFA consultant obtained measurements of the time it took practitioners to record data for vaccines administered and vaccine inventory. Results for each of these processes are provided below.

3.3.1. Vaccine administration

The WFA consultant captured time measurements for 129 instances of recording data using 2D barcode scanning and 186 instances of recording data from linear barcoded vaccines using the practice’s traditional method of data entry. As seen in Table 8, few observations were of mock procedures.

Table 8. Number of time measurements for recording vaccine administration data *

Attribute	2D	Linear	Total
Real Scan	93	158	251
Mock Scan	36	28	64
Total Observations	129	186	315

* Observations performed in N=10 practices

The average time to record vaccine administration data using 2D barcode scanning was 26.75 seconds. The average time to record vaccine data from a linear barcode using traditional methods was 28.47 seconds. Thus, when data across all 10 practices were aggregated, we saw an improvement of 1.72 seconds when recording data with a 2D barcode scanner versus recording data from a linear barcoded vaccine using traditional methods.

We conducted a paired-sample t-test to examine whether the difference in the time it takes to record vaccine data by scanning a 2D barcode is a statistically significant improvement over the time it takes to record the same information using traditional data entry procedures with a linear barcoded vaccine. Our analysis revealed that the assumption of normal distribution was not met within the time to record vaccine data; therefore we selected the nonparametric paired sample Wilcoxon Signed-Rank Test which does not assume an underlying distribution of the paired differences. The results from this test indicate, that the average time it took to record vaccine data using 2D barcode scanning is not statistically significantly different than the time it takes to record vaccine data using traditional data entry procedures with a linear barcoded vaccine (Table 9).

Table 9. Results of Wilcoxon Signed-Rank Test

Barcode Type	Average Time (all data)	Difference	V *	P-Value
Linear	28.47	1.72	344	0.437
2D	26.75			

*V is the test statistic output for the Wilcoxon Signed-Rank Test. It is equal to the absolute value of the sum of signed ranks. This test was conducted using the R function Wilcox.test

Although there was not a statistically significant difference between the time to record vaccine data using a 2D barcode scanner relative to entering data using traditional methods when considering all of the practices together, there were several additional practice-specific factors that could affect recording time. These factors included EMR type, vaccine type, and idiosyncratic differences between nurses and differences between the practices. For instance, Figure 1 and Table 10 show there were substantial differences between practices in time to record vaccine data. The shortest average time to record vaccine data was 11

seconds. The longest average time to record vaccine data was 36 seconds. That is a 25-second difference in average time to record vaccine data regardless of the type of barcode on the vaccine. The shortest average time to record data from linear barcoded vaccines was 10 seconds with the longest being 44 seconds. The shortest average time to record data from 2D barcoded vaccines was 14 seconds with the longest being 39 seconds. Differences in average recording times for linear barcoded vaccines indicate there were unique differences between practices in scanning that should be considered when measuring changes in average time to record data from 2D barcoded vaccines. Variability in recording time was also present within practices—some practices had substantially more variation in recording times than others.

Figure 1. Time to record vaccine administration data by practice

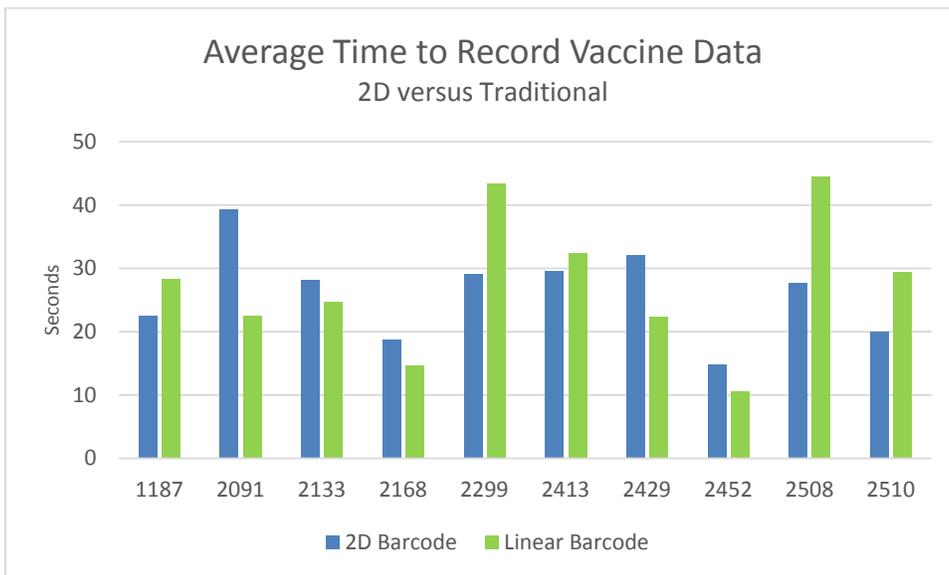


Table 10. Descriptive statistics of time to record vaccine data by practice

Practice ID	Observations	Overall Mean (SD)	2D Barcoded Mean (SD)	Linear Barcoded Mean (SD)	Mean Difference (2D-Linear)
1187	40	26.45 (9.84)	22.63 (9.15)	28.29 (9.78)	-5.66
2091	19	28.77 (18.27)	39.31 (22.87)	22.63 (12.22)	16.68
2133	21	26.00 (12.73)	28.16 (17.33)	24.66 (9.47)	3.5
2168	43	16.41 (6.97)	18.83 (7.11)	14.67 (6.46)	4.16
2299	25	35.45 (24.66)	29.15 (19.36)	43.46 (29.08)	-14.31
2413	40	31.52 (9.90)	29.58 (10.21)	32.46 (9.8)	-2.88
2429	31	27.05 (20.61)	32.08 (28.08)	22.34 (8.04)	9.74
2452	17	11.82 (4.01)	14.90 (4.26)	10.53 (3.26)	4.37
2508	63	36.02 (21.32)	27.76 (16.39)	44.55 (22.66)	-16.79*
2510	16	27.11 (9.33)	20.03 (3.22)	29.47 (9.57)	-9.44

*Difference between the mean time to record data from 2D barcoded vaccines and linear barcoded vaccines is statistically significant at a .05 level after Bonferroni adjustment (t=-3.36)

For five practices, the average time to record vaccine data was lower when using 2D barcode scanners than recording data from linear barcoded vaccines using traditional methods. For five practices, the average time to record vaccine data increased. As noted in the above table, these differences were not significant, with one exception. Those practices that saw improvement in time to record vaccine data with 2D barcode scanners versus traditional methods had higher than average time to record linear vaccines. One practice experienced a decrease of 14.31 seconds between traditional methods and 2D barcode scanning but they had an average time for traditional methods 15 seconds higher than the overall average of 28 seconds. Similarly, a practice that experienced a 16 second improvement from traditional methods to 2D barcode scanning had an average scanning time, however, the traditional method was 16 seconds higher than the overall average recording time using the traditional method. Practices that saw time to record vaccine data increase with 2D barcode scanning versus traditional methods from linear barcoded vaccines had lower than average time to record data from vaccines with linear barcodes. For instance, one practice that experienced a large increase in time to record data from 2D barcodes versus the traditional method had a traditional average time 6 seconds under the average recording time overall.

Although the EMR and general data entry procedures were similar between the two practices under the same local health department (practices 2091 and 2452), these practices had large differences in the average time to record vaccine data using 2D barcode scanning versus traditional methods. In both practices, it took practitioners longer to record vaccine data using 2D barcode scanners; however, this difference was appreciably larger for Practice 2091 (16.68 seconds compared to 4.37 seconds in Practice 2452). This difference was the result of two outlier observations where the Vendor B EMR system froze at

Practice 2091 when using a 2D barcode scanner¹⁴. However, when the Vendor B system¹⁵ did not freeze (Practice 2452), the average time to record a 2D barcoded vaccine was the smallest of any practice observed (14.90 seconds).

Practices where the largest decrease in time occurred when using 2D barcode scanners (Practice 2299 and Practice 2508) both manually entered lot number and expiration date (as opposed to using a drop down menu) in the absence of a 2D barcoded vaccine. In Practice 2299, the lot number which had to be manually typed into the system was case sensitive meaning that upper and lower case letters must match exactly to the lot number on the vaccine. This case sensitivity resulted in a more challenging data entry procedure. One practice (Practice 2429) had a relatively large standard deviation for recording vaccine data with 2D barcode scanners. All of the individuals observed at this practice were hired after the pilot observation period; variation in their exposure to scanning technologies prior to joining this practice may be one reason for the large variation in time to record vaccine data. Additionally, observations suggested that the practitioners at this location were not in the habit of using the 2D barcode scanners as part of their normal routine.

The largest predictor of differences in time to record vaccine data in the random intercept linear mixed effects analysis was the nurse administering the vaccines. Observations indicated that data entry times differed as a result of how practitioners entered data into the EMR—for example, whether they elected to use a mouse to move between data entry cells or tab between cells and whether they focused solely on entering data or engaged in other tasks while performing data entry. These differences explain 17% of the variation in time. Practice and vaccine type both individually explain 9% of the variability in time to record vaccine data. We anticipated that practice differences could arise due to a difference in recording processes, expectations, and staff in each practice.

We expected that vaccine name could affect time to record data due to differences in vaccine manufacturer and packaging. Vaccines that take substantially longer than average to record may indicate a packaging issue such as the barcode being placed in a hard-to-record location. The linear vaccine that took the longest to record was IPV with an average recording time of 57 seconds or two times the average recording time for linear vaccines. The 2D barcoded vaccine that took the longest to record was DTaP at an average of 33 seconds, compared to an overall 2D barcoded vaccine average of 26 seconds. Despite having the highest average, 33 seconds is a seven second improvement over the average time to record data for the linear barcoded DTaP vaccine. Among all the vaccines we observed that had both 2D barcode and linear barcode presentations, it took less time to record data using a 2D barcode scan than traditional procedures for data entry with linear barcoded vaccines.

¹⁴ Removal of the two outliers decreased the amount of time it took practitioners, on average, to record data using a 2D barcode scanner. The average 2D barcode scanning time dropped to 30.43 seconds (SD=20.89), resulting in an average difference of 7.81 seconds in recording time between 2D barcode scanning and entering data from a linear barcoded vaccine. This difference remained statistically insignificant (T=0.78, p=0.47).

¹⁵ It should be noted that although both practices used the Vendor B EMR they reside under the same health department system and therefore likely have in common other software and hardware. The EMR in use is only one of several factors that could relate to the freezing issues experienced within these practices.

Conducting the mixed model analysis allows for the examination of the net effects other variables (EMR, nurses, vaccine name, and practice) may have on the time it takes to record vaccine data when scanning a 2D barcode relative to entering data from a linear barcoded vaccine using traditional methods. The final analysis revealed that the use of a 2D barcode scanner is associated with a decrease of .89 seconds in time to scan vaccine data when the net effect of these other factors is included. Visual inspection of residual plots did not reveal any obvious deviations from homoscedasticity or normality indicating that the underlying assumptions of this statistical approach were met.

3.3.2. Vaccine inventory

There were only two practices where inventory processes were observed. Between these two practices the WFA consultant took 33 time measurements— nine at the first practice and 24 at the other practice (Table 11). The small number of observations did not afford us the opportunity to conduct inferential statistics for the inventory process, thus we present descriptive statistics only in this section.

Table 11. Number of time measurements for recording vaccine inventory data *

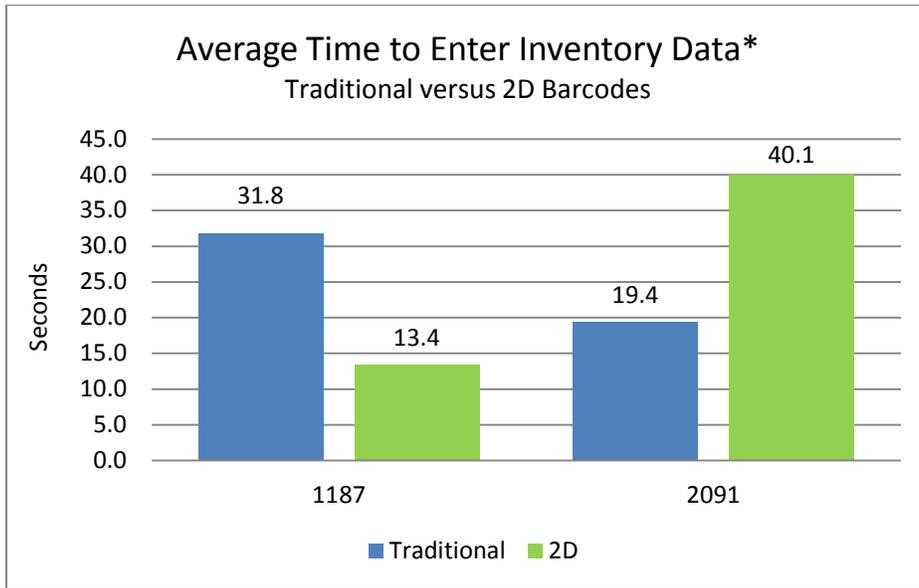
Attribute	2D	Linear	Total
Real Scan	11	13	24
Mock Scan	4	5	9
Total Observations	15	18	33

* Observations performed in N=2 practices. All mock scans occurred in one practice.

The overall average recording time for the nine observations in the first practice was 21.6 seconds. This practice did experience a drop in the average time to record vaccine inventory data from 31.8 seconds using their traditional method of data entry to 13.4 seconds using 2D barcode scanners. This is an 18 second improvement in average time to record vaccine inventory data¹⁶. The second practice had an overall average vaccine inventory recording time of 26.3 seconds. Unlike the first practice, this practice experienced an increase in average time to record vaccine data using 2D barcode scanners compared to their traditional method of data entry. The average time practitioners took in this practice to record inventory data using their traditional method of data entry was 19.4 seconds, while the average time they took to record vaccine inventory data using 2D barcode scanning was 40.1 seconds. This is an increase of 20.7 seconds using 2D barcode scanners versus their traditional data entry method (Figure 2).

¹⁶ Due to the low sample size there is no statistically sound method to determine if this is a statistically significant change.

Figure 2. Time to record vaccine inventory data by practice



* All observations of inventory data entry at practice 1187 were mock scans. No mock scans were observed at practice 2091.

3.4. Staff opinions about 2D barcode scanning

The WFA consultant obtained staff opinions about using 2D barcode scanning to record vaccine data through in-person semi-structured interviews while visiting each practice (See Appendix B). A total of 27 interviews were performed with 32 interviewees. The largest number of interviews the WFA consultant performed in any single practice was five (with six individuals). In two practices the WFA consultant interviewed one individual. Table 12 summarizes the number of interviewees and interviews performed by practice.

Table 12. Number of interviewees and interviews by practice

Practice	Number of interviewees*	Number of interviews
2091	3	3
2452	3	2
1464 [†]	3	3
2413	3	3
1187	6	5
2133	2	2
2510	2	2
2508	6	3
2299	1	1
2429	1	1
2168	2	2
TOTAL	32	27

*Some interviewees participated in the same interview. †Pilot practice for current 2D WFA.

Factors facilitating continued use of 2D

Interviewees who provided a specific answer about why their practice continued to scan 2D barcodes to record vaccine data most frequently noted a perceived increase, or potential for improved, accuracy of records ($n=11$ interviews¹⁷). Interviewees, although less frequently, also mentioned a perceived time savings from using the 2D barcode scanner to enter data ($n=3$). There was also a general sense among many who were interviewed that just being a part of the pilot helped to stimulate continued use ($n=6$)—for example, some of these interviewees noted that they were accustomed to using 2D barcode scanners since they did so during the pilot project observation period. Since they already had the equipment and didn't experience any serious issues using it, they simply continued on the same course. During one interview, it became apparent that a group of nurses at one practice were unaware that the pilot project observation period had come to a close.

In many interviews, the interviewee mentioned that they did not know why their practice continued to use 2D barcode scanning or that they were hazarding a guess about why this process was still in place ($n=13$ of 26 interviews where question was specifically addressed¹⁸). What is clear is that continued or sustained use of 2D barcode scanning in these practices was rarely, if ever, an intentional or planned act. None of the interviewees noted that there was a specific policy or procedure in place requiring staff to scan 2D barcoded vaccines. In one practice there was a sense from an interviewee that although there was not a formal policy in place that 2D barcode scanning was strongly recommended – “They don't have an option not to use it, so if it is there I want them using it”. However, this statement was tempered by two other interviewees who indicated that the practice was recommended or that they did it because of participation in the pilot. For other practices, there was the general sense from interviewees that scanning 2D barcodes was simply a continued practice and that individual staff were allowed to scan or not based upon their own preference.

Improvements given increase in 2D barcoded vaccines

During 21 of the 27 interviews (78%), interviewees conveyed that staff had noticed an increase in the number of vaccines with 2D barcodes since the pilot end date. In some of these instances, although the respondent was asked about 2D barcode volume since the end date, it was unclear what their referent period of time was. Some interviewees appear to have referred to the time since the pilot began rather than came to a close. Nevertheless, there was wide recognition that a greater number of 2D barcoded

¹⁷ All n 's listed for interview data in Section 3.4 represent the frequency of interviews in which a given theme was mentioned.

¹⁸ Interviews performed were semi-structured in nature. This format allowed the interviewer to adapt the interview as needed based upon the context. Therefore, in some instances all questions on the interview guide were not asked in every interview.”

vaccines were in the supply chain than in the past. Although we know that 52 presentations of 22 types of vaccines were available as of August 4, 2014, the interviews helped to confirm that 2D barcoded vaccines are making it through the supply chain and into some practices.

During two interviews respondents clearly used the March/April 2013 end date of the pilot project as their referent and noted that more 2D barcoded vaccines had not come out since this time, but did mention an increase during the course of the pilot project. Those responding ($n=4$) that they did not know if there was an increase in availability of the 2D barcodes in the supply chain had either stopped using the barcode scanners, did not administer vaccines very frequently, were new to the office, or were not responsible for administering vaccines (e.g., information technologist).

During the original 2D pilot project a large percentage of respondents ($n= 161, 77%$) to the second User Experience Survey indicated the fact that “only a small percentage of vaccines have 2D barcodes” presented a challenge to integrating 2D barcodes into their practice’s process for recording information for vaccine administration or inventory. Since additional vaccines are now in the supply chain with 2D barcodes, we inquired during the course of interviews as to whether (and how) this increase in the percentage of 2D barcoded vaccines in the practice affected their ability to use 2D barcode scanning to record vaccine data.

Responses to this interview question were mixed. Interviewees noting that there was an effect of the increase in 2D barcoded vaccines ($n=9$) often provided fairly general feedback about the process being easier or quicker. Other interviewees indicated that since there were more 2D barcoded vaccines, they became more efficient at scanning and were better able to integrate it into their routine. One interviewee commenting on her routine also called to attention the desire to have more 2D barcoded vaccines because now there is an extra step in the process—having to look to check if the vaccine is 2D barcoded or not. She pointed out that the more 2D barcodes there are, the more it became a part of her routine. Another interviewee noted that the increased flow of 2D barcoded vaccines resulted in her looking for the 2D barcode more frequently than she did in the past—increasing her behavior to see if a barcode was available. Another interviewee noted that there was a negative effect on her process—that more 2D barcoded vaccines slowed her down because the scanner did not read the 2D barcodes consistently; when she had to scan a few times per barcode it disrupted her normal process.

Multiple interviewees, however, specifically remarked that the increase in 2D barcoded vaccines did not affect their ability to use scanning to record vaccine data ($n=7$). Based upon our estimates of the current 2D barcode vaccine administration volume within the participating WFA practices—meaningful differences did not appear between practices where interviewees indicated that this increased volume has no effect and those where the interviewees reported the increased volume having a positive effect on their ability to use scanning to record vaccine data.

Reported benefits of 2D barcode scanning

Interviewees most frequently reported that the benefit of using 2D barcode scanning is improved accuracy of vaccine data ($n=18$). Many of the interviewees who noted this advantage specifically mentioned this benefit relative to accurate lot numbers. Some individuals specifically commented on the difficulties they

experienced when recording lot numbers manually. Specific examples of challenges recording lot numbers included having difficulties reading the small numbers associated with the lot and difficulties with distinguishing between characters that look very similar.

“...honestly, sometimes like when you get a row of 5 in a thing you actually have to count how many 5’s are there—it isn’t easy to pick it up because they are so small.”

“I do find it easier when it works, I like not having to look at the tiny little numbers and guess if it is a six or an eight but they are so small that I can’t tell which one is which. So I like that part of it.”

Interviewees also frequently mentioned ($n=7$) that scanning 2D barcodes was quicker than their traditional method of data entry or felt that not having to enter as much vaccine data by hand or drop down was a benefit.

Some interviewees in practices where scanning was used to record vaccine data at inventory also mentioned the benefit of having accurate lot numbers for the purpose of reconciliation. Several also noted that they enjoyed the addition of 2D barcodes to vaccine boxes, as it helped to make the scanning process easier at inventory.

“I think a week ago we typed in the wrong lot number for a vaccine we received in because it didn’t have the 2D barcode and once those are administered to our patients then when we find out after so many have been administered, someone notices ‘oh the wrong lot number was put in’ we have to take all of those immunizations out of the client’s records, fix the mistake we made, re-enter it into [the EMR] and then re-enter it into all of the client records. And it’s okay if it is like 5 but we have done 75 before and I’ve put the lot number and someone even double checked me. So scanning is good because it is accurate.”

“And they also put it on the outside of boxes. Glaxo does a lot with it on the outside which is nice, because you don’t have to open up the box. I still open up the box of the ones that don’t show, just to make sure because some of them still have the 2D on it without it being on the outside of the box. But that is the only thing that I would rather not do is open the box.”

Reported challenges and drawbacks of 2D barcode scanning

By far, the most frequent comment regarding the challenges of using 2D barcode scanning to record vaccine data related to difficulties scanning barcodes and the level of inconsistency with which the scanning process actually works. Many interviewees remarked that some vaccine types scanned easier than others. The influenza vaccine was mentioned by several interviewees working in different practices as difficult to scan. We are not aware, however, of which specific influenza vaccines these practices use. Some interviewees did not offer information about specific vaccines rather they described this challenge in general terms, noting that it sometimes took a long time to scan or after multiple attempts failed to scan.

Interviewee: "I think it is very easy, the only issue is some of the vaccines don't scan as well as the others". Interviewer: "Do you know which ones in particular?" Interviewee: "Hep A I think the barcode is too light and sometimes the influenza—influenza does not scan, hardly ever".

"...the only challenging I would say is some barcodes are not as easy to get to scan. I found that with the flu vaccine, they were very difficult to get. I would think that was the hardest. But for example, DTaP and the Menactra are very easy barcodes to use and Hepatitis A is a very easy barcode to use."

"...sometimes you are able to scan and sometimes the scanner doesn't work and by the time you get it to scan you could have entered the numbers in, you know, in less time."

A few individuals offered other challenges including having to remember to look to see if a vaccine is 2D barcoded, not having a mechanism for scanning multi-component vaccines, and still having to open some boxes to record vaccine inventory. Some individuals also noted a desire to have more information populate into their EMR about the vaccine when scanning a 2D barcode (such as vaccine name, manufacturer, NDC, as opposed to only populating lot number and expiration date). Analyses of user experience data collected during the pilot project observation period also highlighted this as a challenge, however, such functionality is a function of EMR capabilities. EMRs that are 2D capable are able to receive and process the data elements from scanning a 2D barcoded vaccine (i.e., lot number, expiration date, and product ID) to identify and input additional variables for the vaccine.

There were two challenges that arose in a subset of practices visited for the WFA. The first concerned the wrong lot number entering into an EMR when a 2D barcoded vaccine was scanned. This happened for two practices where the lot number is selected from a drop down list. It appears that lot numbers are selected in these EMR systems via an auto-populate feature which may inadvertently select the incorrect lot number based upon how the EMR selects a match. For example, if the configuration is set up to look for a match with the first three digits of a lot number and there are two lot numbers in the EMR system with the same first three digits, the wrong lot number could be selected by the EMR.

The diversity of EMR solutions observed in the pilot made implementation of a programmatic interface between the 2D barcode scanner and each EMR infeasible within the pilot timeline. Therefore, to enable scanners to work with EMRs for the pilot we used a configuration utility. The configuration utility enables the 2D barcode scanner to read the data into the correct fields in the EMR but does not modify the programmatic behavior of the EMR. If an EMR selects the lot number based on the first few lot characters keyed in and there are multiple lots in the system whose lot numbers begin with the same characters, scanning a 2D barcode results in the first match being selected. One interviewee noted that it was important to point out that as a result, 2D barcode scanning was not always a "fail-safe" method for entering the correct lot number.

A second issue noted by interviewees, and witnessed during the course of observations, was the freezing of the EMR system used in the practices located under the same local health department (Practice 2091 and

Practice 2452). Interviewees reported that the system would intermittently crash when using the 2D barcode scanner. While in Practice 2091 the WFA consultant observed this occurring in real time. During one 2D barcode scan, the influenza vaccine did not register a scan within 30 seconds. The EMR system subsequently froze and the nurse had to exit out of the EMR and start data entry over. The nurses at this practice noted that the system freezing is inconsistent—sometimes they can use the scanner for extensive periods without the system freezing. The system froze twice during the observations, both times when influenza vaccine was being administered.

4. Strengths and Limitations

There are several strengths and limitations associated with the WFA we present in this report. One of the strengths relates to the consistency and quality of data collection activities. Throughout the course of the entire WFA project, we incorporated multiple checkpoints to test and examine the quality of our data collection procedures. Prior to data collection, the WFA team’s project manager, evaluator, and WFA consultant met in person to review the data collection procedures and discuss any initial questions. Additionally, we used one practice visit as a pilot test to examine the proposed data collection activities in action to fully assess their feasibility. Following the pilot test, the WFA team regularly checked in via email and phone while the WFA consultant was in the field to identify any emergent issues in data collection and actively discuss next steps.

A related strength of the WFA concerns the type of data gathered and the specific procedures used. For example, the WFA consultant performed interviews with practice staff while on-site. During these interviews, individuals were asked to step away from their regular work to reflect specifically on the questions posed absent distractions. The WFA consultant digitally recorded these interviews to ensure that we fully captured the content and tone of interviews. Additionally, in the current WFA we opted to gather time measurement data for the main steps in the workflows performed in the participating practices. Such data helps to provide information about the context within which data entry about vaccines occurs, and can suggest the proportion of time out of the whole workflow process that is affected by procedures such as 2D barcode scanning.

The main limitation in this WFA concerns the selection of practices. As described in the methodology section, the practices participating in this WFA were not randomly selected from all practices that participated in the pilot project. As such, the practices that elected to participate may be more likely to have successfully integrated 2D barcoding into their workflows and have more positive opinions about their use than other practices from the pilot project. Additionally, we were unable to visit every practice that met the inclusion criteria because of the short time period available to perform data collection activities. Two practices experienced scheduling conflicts that our team could have accommodated with a longer data collection window.

Other limitations associated with the WFA include the number of data entry observations the WFA consultant was able to observe and the limited number of practices visited. Several practices visited do not specifically focus on administering vaccines, as such only a subset of patient visits relate to vaccinations.

Since the WFA visits did not occur during the “busy season” for vaccination such as the school season or influenza season, we were not able to observe as many data entry efforts as we originally targeted. When possible, the WFA consultant did work to obtain mock scans, however three practices did not participate in mock scanning due to staff concerns that the falsely entered data would result in issues around reconciliation of inventory.

Finally, we were unable to explore the specific differences in data entry among staff with respect to the data entry process. These differences made up much of the variability in the time to record vaccine data at administration; however, we did not obtain specific information about factors that may have contributed to these differences such as the work history or other demographics of each nurse performing data entry. We were, however, able to identify some sources of this variability between nurses as part of the detailed observations performed (discussed in Section 5).

5. Conclusions and Recommendations

The analyses we performed of time to record vaccine administration data indicated no statistically significant difference between the average time it took practitioners to record vaccine data using 2D barcode scanning compared to using their traditional method to record data from vaccines with a linear barcode (e.g., manual entry or selecting from a drop down menu). This finding is inconsistent with the results of the first WFA performed during the pilot observation period. In the initial WFA, we found that it took, on average, 3.6 seconds longer to record vaccine data using 2D barcode scanning than entering data using traditional procedures. This difference was statistically significant at $\alpha=.05$.

There are multiple potential reasons that we found no differences in data entry time between 2D barcode scanning and traditional procedures for recording data about vaccines administered. First, we noted a clear relationship between the percent of 2D barcoded vaccines and the time to record vaccine data in the initial WFA—with practices that had a higher percentage of 2D vaccine administration volume also generally having smaller data entry time. This could indicate that more exposure to 2D barcode scanning influences overall scanning time. Practices in the current study were exposed to 2D barcode scanning for longer than those in the initial WFA, and also experienced a recent increase in the number of 2D barcoded vaccines available. While we hesitate to state a direct relationship, it may be the case that as health care practitioners increase their level of comfort with 2D barcode scanning, the scan time will increasingly approach the manual/drop down entry time.

The majority of interviewees (78%) did note that they witnessed an increase in the number of vaccines with 2D barcodes since the pilot project¹⁹. However, interviewee perceptions were mixed regarding whether this increased volume affected their ability to record vaccine data. Some interviewees felt that this change made it easier or quicker to scan, others specifically pointed to an increase in efficiency as they got more

¹⁹ These interviewees were typically able to specifically name which vaccines were 2D barcoded during the pilot project observation time period and which ones were now 2D barcoded, indicating that an availability heuristic was unlikely to be occurring.

used to the practice and were better able to integrate it into their routine, and others did not feel the increase affected their ability to scan.

Second, practices in the current WFA that saw time to record data about vaccines administered increase with 2D barcode scanning versus traditional methods from linear barcoded vaccines had lower than average time to record data from vaccines with linear barcodes. For instance, one practice that experienced a large increase in time to record data from 2D barcodes versus the traditional method had a traditional average time 6 seconds under the average recording time overall for traditional methods. Third, the practices we included in the current WFA are different from those we included in the initial WFA. Since the current WFA does not include the same practices these findings are not directly comparable to the initial WFA—it is possible that underlying difference between the practices in the initial WFA and the practices in the current WFA drive the disparate findings. Fourth, different individuals recorded data for the initial WFA than for the current WFA. Small differences in recording procedures could also contribute to different findings.

Finally, there could be a unique uncaptured driving factor for why the findings from the current WFA differ from the findings of the initial WFA. Additional factors that may affect this relationship include a health practitioner's tenure, volume of vaccine administration, and workforce culture around 2D barcoded vaccines. For example, the mixed model presented in Section 3.3 estimated that "administering nurse" explains 17% of the variation in time to record vaccine data. Although we did not capture potential factors for these idiosyncratic differences in recording times using quantitative variables, the WFA consultant's qualitative observations suggested that the manner in which health care practitioners recorded vaccine data varied widely. Observations indicated that data entry times differed as a result of how practitioners entered data into the EMR—for example, whether they elected to use a mouse to move between data entry cells or tab between cells and whether they focused solely on entering data or engage in other tasks while performing data entry.

Several other findings from the current WFA warrant mention. First, for most practices, there were minimal changes to the workflows associated with entering data between linear and 2D barcoded vaccines. Information from the first workflow analysis and User Experience surveys conducted during the observation period of the pilot project indicated major disruptions in some practice's workflows with the introduction of 2D barcode scanning—with some practices having to physically retrieve a 2D barcode scanner from another room, shelf, or drawer to scan. In the current WFA, all practices (with the exception of one clinic and the pilot practice) had a 2D barcode scanner located at every data entry point in their practices. We hypothesize that the number and placement of scanners within these practices contributed, at least in a small way, to more frequent and continued use of 2D barcode scanning within the participating practices.

Additionally, findings from the interviews suggest that challenges remain for full integration of 2D barcode scanning into practice workflows. The primary challenge concerns the consistency with which 2D barcode scanning results in successfully registering data into the practice's EMR. Interviewees perceived differences in the ease with which scans registered from different 2D barcoded vaccines. They also noted general challenges with getting scans to register. In some cases, the interviewees noted that they would attempt to

scan a vaccine one or two times and then revert to their traditional method of data entry if the scan was unsuccessful. For some, however, this inconsistency resulted in no longer using the 2D barcode scanner.

In some practices (two observed by the WFA consultant), the EMR system allows a user to select a lot number from a drop-down menu and automatically advances the user to a lot number based on characters keyed by a user. Some interviewees who interfaced with such EMRs noted that 2D barcode scanning sometimes selected the incorrect lot number. This issue was a product of the way 2D barcode scanners interfaced with EMRs for the pilot project. The diversity of EMR solutions observed in the pilot made implementation of a programmatic interface between the 2D barcode scanner and each EMR infeasible within the pilot timeline. Therefore, to enable scanners to work with EMRs for the pilot we used a configuration utility. The configuration utility enables the 2D barcode scanner to read the data into the correct fields in the EMR but does not modify the programmatic behavior of the EMR. If an EMR selects the lot number based on the first few lot characters keyed in and there are multiple lots in the system whose lot numbers begin with the same characters, scanning a 2D barcode results in the first match being selected. One interviewee noted that it was important to point out that as a result, 2D barcode scanning was not always a “fail-safe” method for entering the correct lot number.

The majority of individuals interviewed continued to see the value in using 2D barcode scanners to record vaccine data. Several specifically pointed out the difficulties they have with correctly deciphering and hand-entering the lot number into their EMR and noted that 2D barcode scanning does improve accuracy by populating the correct lot number into the system. Additionally, one might infer that 2D barcode scanning can be readily adopted into the regular workflows of practices at least partially due to its acceptance among end users. None of the practices participating in this WFA had a policy in place requiring their staff to use the scanners, however, in several instances practitioners still elected to use 2D barcode scanning to record vaccine data.

Based upon the findings from this WFA we recommend that:

1. Practices considering 2D scanning adoption should invest time up front to plan how 2D barcode scanning will work best with their operations to help determine the appropriate number and placement of scanners so as not to introduce operational impediments.
2. The CDC and FDA should collaborate with the manufacturers to investigate the quality and consistency of the 2D barcode labeling. Consistent reports from interviewees that there is variability in the ease of scanning 2D barcodes by vaccine type warrants further investigations about the quality of 2D barcode labeling and the ability to consistently produce batches with labels that practitioners can easily scan.
3. The EMR software should be configured or set up to read the entire lot number which will prevent default selection by the system of lots with similar first characters. Solution vendors incorporating 2D barcode scanning of vaccines into their applications should read the entire lot number from the encoded data string.

4. Industry should further investigate inconsistencies of 2D barcode scanning. Non-specific, but frequent, concerns from interviewees about the inconsistency of 2D barcode scanning suggests that follow-up product evaluations that examine the possible root causes of these reported inconsistencies would be helpful. Such investigations might examine the comparative effectiveness of 2D barcode scanning using a variety of conditions, such as: (a) placement of the barcode in different locations on the label, (b) other quality features of barcodes (e.g., different background colors, ink used for 2D barcode), or (c) peel-off labels versus labels on vials or syringes.

This WFA provides some limited indications that 2D barcode scanning can save time when entering data about vaccines administered. We hypothesize that the time saving differences may become more widespread when the practice of 2D barcode scanning to record vaccine data is common in health care practices. Future research is needed once all vaccines are 2D barcoded.

Appendix A: Email Disseminated to Candidate Practices

From: support [<mailto:support@2dvaccineadoptionpilot.com>]

Sent: Date

To: Practice Point of Contact

Subject: 2D Vaccine Barcode Pilot - Work Flow Analysis

Dear {Point of Contact}-

Thank you for your participation in *CDC's Implementation Pilot for Two-Dimensional (2D) Vaccine Barcode Utilization*. Since the pilot, vaccine manufacturers have continued to affix 2D barcodes to their vaccine products. Many more vaccines currently have 2D barcodes—approximately 24 vaccines have 2D barcodes today as compared to the eight with barcodes during the original pilot. We are fortunate to have an opportunity to follow-up with a subset of practices who participated in the pilot project to learn more about the workflow associated with scanning 2D barcodes to record vaccine data now that more vaccines have 2D barcodes and are asking for your assistance in this effort.

Based upon the data we gathered during the pilot, we have identified your practice as a potential candidate for the upcoming workflow analysis (WFA) project. To determine if you are eligible for this project, we ask that you complete the following three questions. We would greatly appreciate answers to these questions even if you do not have an interest in participating. Practices not interested in participating will be screened out of the project and not contacted by our team.

1. Since the implementation pilot came to a close, has your practice continued 2D barcode scanning?
 Yes No

If yes to question 1, please answer the following:

2. During which of the following procedures do practice staff use 2D barcode scanners to record vaccine information?
 - a. Inventory: Yes No
 - b. Vaccine administration: Yes No
3. With what frequency do you typically encounter 2D barcoded vaccines?
 Daily
 Weekly
 Monthly
 Quarterly
 Other (Please describe: _____)
4. As part of the workflow analysis project, a member of our team will visit practices to observe the process of recording vaccine information and conduct brief interviews with up to five staff members

to learn about their experience scanning 2D barcoded vaccines. This visit will occur over the course of a regular workday and will be arranged at a time that is most convenient to participating practices in June 2014. Given this description, would your practice be interested in participating in the proposed WFA? Please note that responding “yes” in no way commits your practice to participation at this time.

Yes No

Thank you very much for your time, if you have indicated an interest in participating in the WFA a member of our team from Deloitte will contact you within the next week to inform you of your practice’s eligibility, ask some additional questions (if needed), and potentially schedule a WFA visit.

Thank you for your continued interest in 2D barcoding.

~ Deloitte Team

Appendix B: Interview Guide

Introduction:

Hello [name of interviewee], I am [name of interviewer] from Deloitte Consulting. Thank you for agreeing to participate in an interview. The purpose of this interview is to learn about your experience using 2D barcode scanning to record vaccine data since the pilot came to a close earlier this year. We will analyze the data you provide through this interview alongside interview data we obtain from staff from nine other practices that are participating in this project to identify and report out on common experiences.

The aggregate findings from these interviews will be used by the CDC and others interested in 2D barcoding of vaccines to better understand the experience of practitioners employing this technology. Although we may use quotes from this interview in our final report on this project, we will not associate your name with these quotes.

I will be taking detailed notes during our interview, however, to make sure I capture important points correctly I would like to also digitally record this conversation. Do I have your permission to record this interview? [If yes]- Thank you, if at any point in this interview you would like me to stop this recording please just let me know and I will do so.

Section 1: General information

- First, please tell why your practice elected to continue scanning 2D barcodes to record vaccine data.
- Beyond the items you just mentioned, were there other actions taken within or outside of your practice to help facilitate the continued use of 2D barcode scanning (e.g., policies requiring staff to use this process, recommended procedures by leadership, IIS policies)?
 - [If yes]- Please tell me about these actions.

Section 2: Personal use of 2D barcode scanning

Now I would like to ask you some questions about your experience using 2D barcode scanning to record vaccine data.

- First, please tell me a little about your experience using 2D barcode scanning to record vaccine data. To what extent do you find this activity to be easy or challenging? Why? What makes this challenging/easy? Please provide me with an example.
- Since the pilot came to a close in March 2014²⁰, would you say that you have seen more 2D barcoded vaccines? [If yes]- Please tell me more about the types of vaccines you have seen and the frequency with which you administer these vaccines.
- To what extent has the increased flow of vaccines affected your ability to use 2D barcode scanning to record vaccine administrations/inventory, if any? {probe for specifics and examples}

²⁰ Should have been March 2013. Frequently this exact language was not used in the course of interviews (due to the semi-structure nature) and therefore was unlikely to have affected interviewee responses.

Section 3: Benefits and drawbacks of using 2D barcode scanning

- What do you perceive to be the benefits of using 2D barcode scanning to record vaccine administration/inventory data? {probe for specific examples of these benefits in their practice}
- What do you feel are some of the drawbacks of using 2D barcode scanning to record vaccine administration/inventory data that you haven't already mentioned during our conversation? {probe for any implications}

Section 4: Close-out

- Those are all of the questions I have for you.
- Are there any items we have discussed that you would like to elaborate on further? [If yes]- which ones? {ask for elaboration if needed}
- What other items do you think would be helpful for us to know about the experience of using 2D barcode scanning to record vaccine data that we haven't covered, if any?

Thank you very much for your time. Do you have any questions for me before we end our interview?

Appendix C: Practice Summaries

Practice ID: 1187

Practice Attributes		
	Practice Type	Public Health Department
	Practice Size (# of physicians)	5 or fewer
	EMR System	Vendor F
	Estimated 2D vaccine administration volume	3953- High
	Estimated % public vaccines	33%
	Process observed	Administration and Inventory

Overall Workflow Process

Practice 1187 administers vaccines in nurse working stations that are set up in two separate patient care areas with 2D barcode scanners. There are laptops set up as the computers for these working stations, however, these laptops remained stationary during observations with the 2D barcode scanners attached to the laptops for the entire duration of the visit.

The nurses always entered or scanned vaccine data before administering vaccines. While talking to the nursing manager, she noted there was a study done on-site previously that determined that order of operations was the most effective and efficient way to capture vaccine administration data with the least amount of errors. Four different nurses were observed during the visit—they comprise all of the nurses that use the 2D barcode scanners in this practice. There is an IT representative that rotates through all of the different practices in the county and is available to answer any IT related questions. He was on-site during the WFA visit, participated in all of the interviews, provided the WFA consultant a tour of the facility, and was the key point of contact prior to and during the visit.

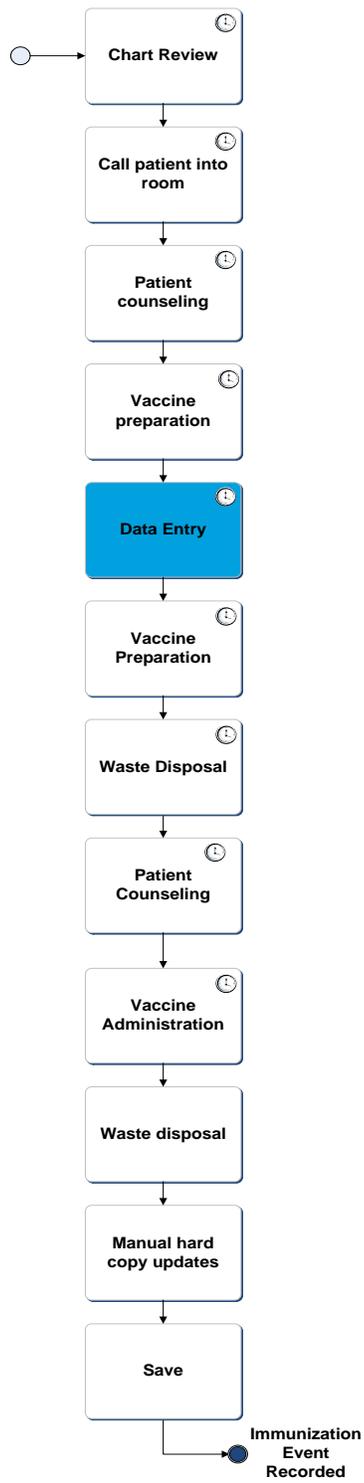
A refrigerator with approximately one-day's supply of vaccines is located in a refrigeration preparation room next to the patient care rooms/nursing stations. A much larger refrigeration area, containing four large-scale refrigerators, is located at the back of the facility. Staff referred to this location as the "storage room" since it is the physical location where they store the remaining vaccines on-site. During the day of the visit, the varicella vaccine supply was only located in the storage room given a refrigeration issue in the preparation room. There is usually an additional smaller refrigerator in the preparation room where these are stored, but the refrigerator was not working on the days of observations.

Administration process

The WFA consultant observed four individuals performing vaccine administration procedures while at this practice. These were all of the nurses that were administering vaccines on the days of observations. The typical steps during administration started with staff at the front desk preparing patient information and providing the applicable VIS statements to the patient's parents. The nurse then calls the patient to the patient room where the nurse reviews each vaccine and the potential side effects, verifies the patient's information, and reviews the vaccine schedule. Following this interaction with the patient, the nurse retrieves the vaccines to prepare—either from the refrigeration preparation room (which is between twenty and forty yards away from the patient rooms) or the storage room in the back of the building (during this visit nurses had to retrieve varicella from this location).

Once the nurse returns to the patient room, they wash their hands, prepare the vaccine(s), and enter data into the practice's EMR while sitting at the nurse's station located in the patient room. Multiple data elements have drop down functionality in the EMR which pulls possible response options from the inventory records. 2D barcode scanners used at administration in this practice are configured to capture the lot number and expiration date. Vaccine data elements are saved once after the nurse enters data about all vaccines administered. After saving the data, the nurse completes any remaining vaccine preparation steps (such as gathering Band-Aids, alcohol swabs, etc.) and administers the vaccine(s). The nurse then updates the hard copy patient chart and writes updates on a yellow information sheet to give to the patient's parents for their records.

Figure C-1. Overall vaccine administration process



The average time to perform all steps in the process depicted in Figure C-1 was 186.91 seconds (SD=89.11). The longest step in the process on average was vaccine administration whereas the shortest step was logging into the EMR. Table C-1 provides the average length of time for each step as well as the standard deviation associated with each of these steps. Table C-1 shows the steps captured for all observations; Figure C-1 shows the WFA of the most common steps that create the normal process for vaccine administration at this location.

Table C-1. Average time to perform steps* in vaccine administration workflow

	Observations	Mean	Standard Deviation
2D input	17	20.79	8.87
Call Patient into room	5	40.76	29.42302
Chart Review	8	34.79	25.43955
Data Entry	23	17.91	18.84738
Linear input	31	27.14	10.96769
Login to EMR	45	12.72	15.05072
Patient Counseling	26	64.17	71.55357
Vaccine Admin	3	89.00	54.10967
Vaccine Prep	20	74.77	57.59485
VIS Statement gathering	2	64.20	69.08295
Walking	26	31.28	35.92996
Wash Hands	10	24.80	5.702507
Waste Disposal	4	31.13	22.64557

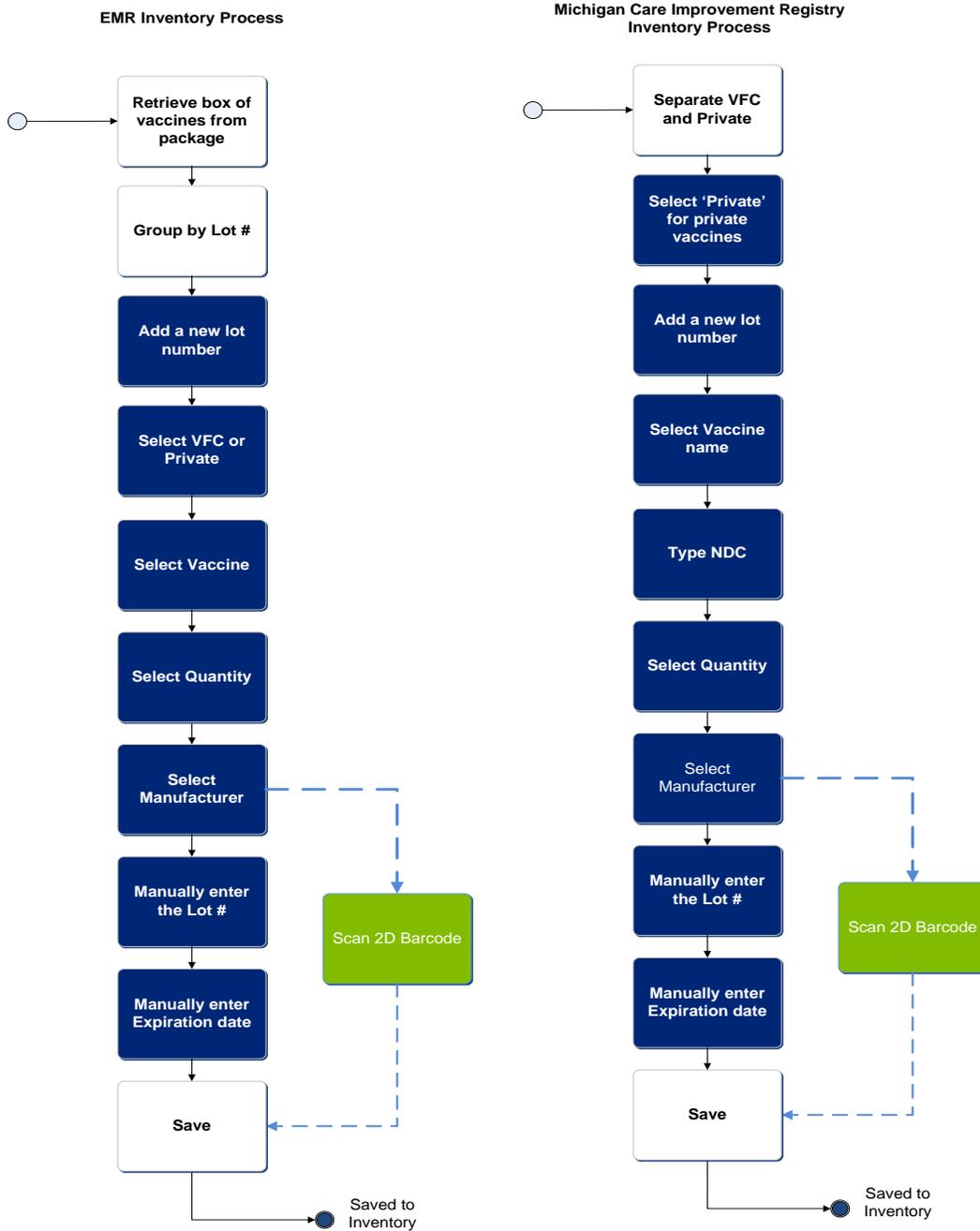
*The “2D input” step in this chart refers to the specific time it took to perform the steps specific only to 2D scanning: picking up the scanner, scanning the barcode for lot # and expiration date, and pressing the ‘scan’ button when necessary. The “linear input” steps refer to the specific steps that would be performed in the traditional method instead of the 2D scanning process—so either manually typing or selecting from a drop box the lot number and expiration date. The “Data Entry” step refers to the steps that are performed for both processes—such as typing or drop down selection of manufacturer, input location, etc. The WFA consultant wanted to single out the steps that are directly comparable to measure the differences for the two processes: linear vs. 2D.

Inventory process

One individual, the front desk representative, is responsible for recording vaccine inventory data and was observed during the visit. Each time the practice receives a new shipment, she retrieves the boxes of vaccines from the shipping package and organizes the vaccines received by lot number and private versus public in a storage room located at the back of the office prior to scanning. She then enters data into both the EMR and the Michigan Care Improvement Registry (MCIR) state tracking system at a computer located in the back room.

She first enters data into the EMR and subsequently enters data for all private vaccines into MCIR. Data for VFC vaccines is already included in MCIR (by the state) therefore it does not need to be entered by the practice. After data entry is complete, she puts the vaccine boxes back in the fridge and files the packing slip at the front desk clerical station.

Figure C-2. Overall vaccine inventory process



Blue fill indicates a data entry process step

The average time to perform all steps in the process depicted in Figure C-2 is 38.61 seconds (SD=9.73). There was one person observed for the inventory process. The longest step in the process on average was recording of data from a linear barcoded vaccine whereas the shortest step was retrieving the packing slip. Table C-2 provides the average length of time for each key step as well as the standard deviation associated with each of these steps.

Table C-2. Average time to perform key steps* in vaccine inventory workflow

	Observations	Average*	Standard Deviation
2D input	8	8.400135	4.449885
Linear input	4	22.00558	12.15877
Data Entry	15	11.73131	11.28233
Retrieve Packing Slip	6	6.099342	5.174005

*The “2D input” step in this chart refers to the specific time it took to perform the steps specific only to 2D scanning: picking up the scanner, scanning the barcode for lot # and expiration date, and pressing the ‘scan’ button when necessary. The “linear input” steps refer to the specific steps that would be performed in the traditional method instead of the 2D scanning process—so either manually typing or selecting from a drop box the lot number and expiration date. The “Data Entry” step refers to the steps that are performed for both processes—such as typing or drop down selection of manufacturer, input location, etc. The WFA consultant wanted to single out the steps that are directly comparable to measure the differences for the two processes: linear vs. 2D.

Data Entry Process & Time Measurements

The same EMR is used for inventory and administration, and several comments were made throughout the day that the combination of both processes made sense to the nurses and that the two processes tie together nicely. The lot numbers were populated into the EMR during the inventory process, so that they automatically populate the drop down menu options available when entering vaccine administration data. The general procedure for entering vaccine inventory and administration data is described below and depicted in Figures C-3 and C-4.

The general process for entering vaccine inventory data involves:

- Entering data into the EMR by...
 - Selecting Private or VFC vaccine from drop down menu
 - Selecting vaccine name from drop down menu
 - Selecting vaccine manufacturer from drop down menu
 - Manually entering quantity
 - Entering lot number and expiration date: For vaccines with a linear barcode this data is manually entered, for 2D barcoded vaccines this data is scanned into the system
 - Saving the record after each vaccine’s data is entered
- Entering data into MCIR by...
 - Selecting ‘Private’ from a drop down menu
 - Double checking for duplicate lot numbers
 - Entering vaccine name, manufacturer, lot number, NDC, number of doses, current date, and expiration date. Vaccine name and manufacturer are available in a drop down menu. NDC, number of doses, and current date are manually entered for all vaccine barcode types (i.e., linear or 2D). For 2D barcoded vaccines lot number and expiration date are input from the scan.
 - Saving vaccine data after entering each individual vaccine,

The general process for entering data about vaccine administrations into the EMR includes:

- A person from the front desk prepares patient information and gives VIS Statements to patient

- Nurse calls patient and escorts them to the patient room
- Nurse goes over each vaccine and details/side effects of the vaccine with the patient and verifies patient information and vaccine schedule
- Nurse walks to the nurses room to get vaccines and for vaccine preparation
 - Some of the vaccines required the nurse to walk to the supply room; one example was the varicella vaccine (Note: this is usually kept in the nurses room but the freezer is not working today)
- Walks back to patient room and washes hands
- Vaccine preparation
- Data entry into the EMR (Select drop downs for linear: vaccine name, lot number, manufacturer, expiration date, administration location. If scan for 2D: lot number and expiration date populate, but select remaining from drop downs.)
- Vaccine preparation and patient counseling at the same time-prepping for side effects/what to expect, (Note: prepping vaccines in patient area in front of patient)
- Vaccine administration in patient room
- Waste disposal
- Update the patient chart/information manually on hard copy of vaccine records
- Meet with parents to give information

The process for entering a linear barcoded vaccine involves nurses selecting the correct lot number from a drop down menu. Vaccine data is saved at the end, and multiple vaccines can be entered in a list format before saving. The nurses generally knew which vaccines had 2D barcodes based on manufacturer based on memory and frequency of administration, but did not organize in a particular way during the administration process. There is an auto-populate feature in the EMR that automatically populates the lot number if there is only one lot number in the inventory, so if there was only one lot number, no scanning or selection of dropdowns was necessary. The NDC number is tied to the lot number during inventory, so it was not necessary to input again during the administration process.

Figure C-3. Vaccine administration data capture process

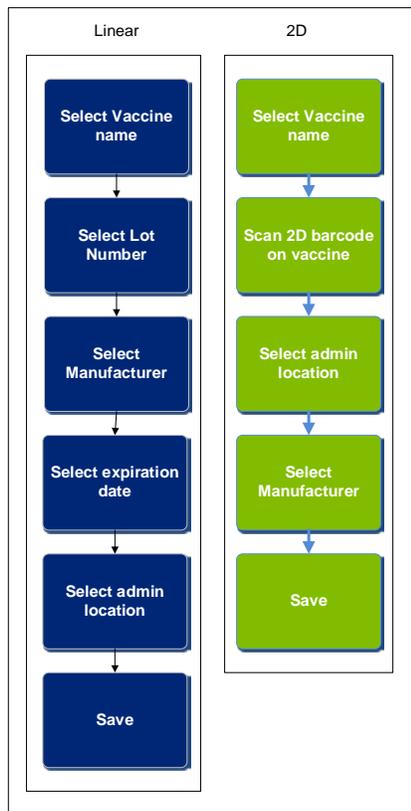
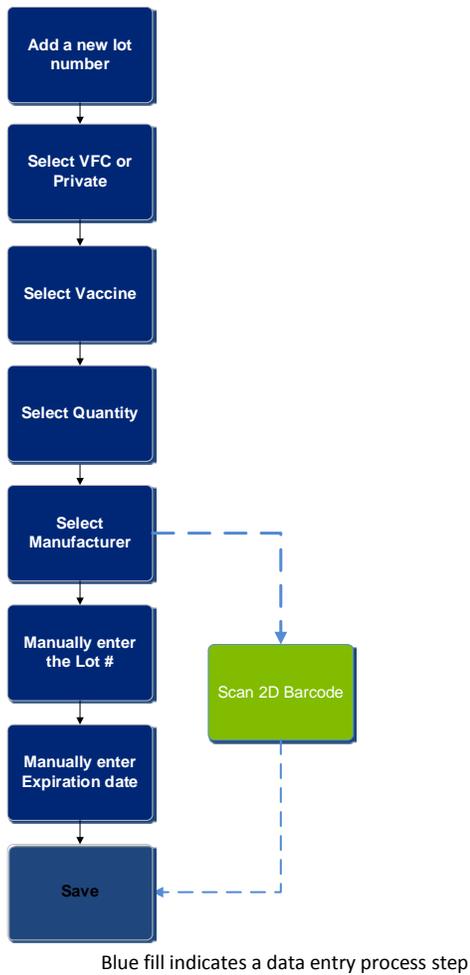


Figure C-4. Vaccine inventory data capture process



The WFA consultant recorded 40 time measurements of the vaccine administration data entry process at this practice for the four individuals observed. Twenty seven time measurements were taken for data entry using 2D barcode scanners and 13 measurements were recorded for linear barcoded vaccines. On average, it took 5.66 seconds less for nurses to enter vaccine administration data using 2D barcode scanners (Mean=22.63, SD=9.15) than it did for them to manually enter data from vaccines with a linear barcode (Mean=28.29, SD=9.78).

12 time measurements were taken of the vaccine inventory data entry process at this practice for the one individual observed. 8 time measurements were taken for data entry using 2D barcode scanners and 4 measurements were recorded for linear barcoded vaccines. On average, it took 18.35 seconds less for the front desk staff member to enter vaccine administration data using 2D barcode scanners (Mean = 13.4, SD =5.41) than it did for them to manually enter data from vaccines with a linear barcode (Mean = 31.75, SD=11.87).

Figure C-5. Time to record vaccine administration data by barcode type

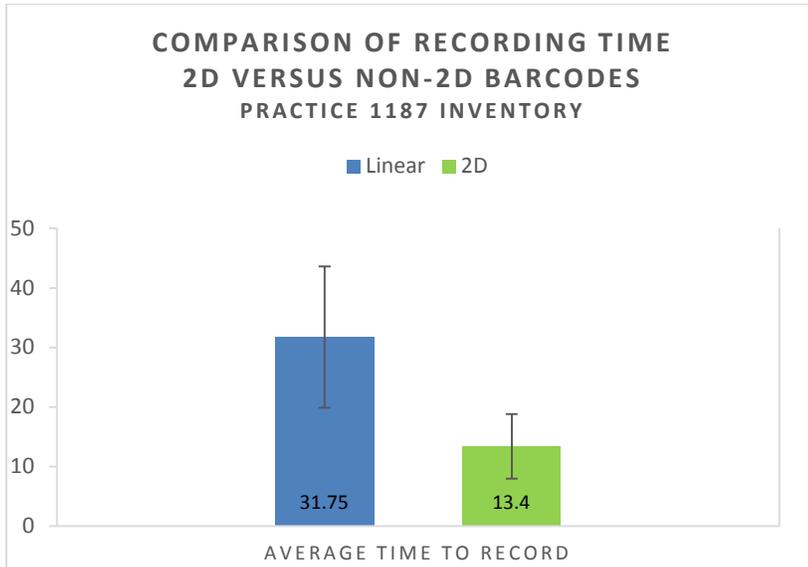
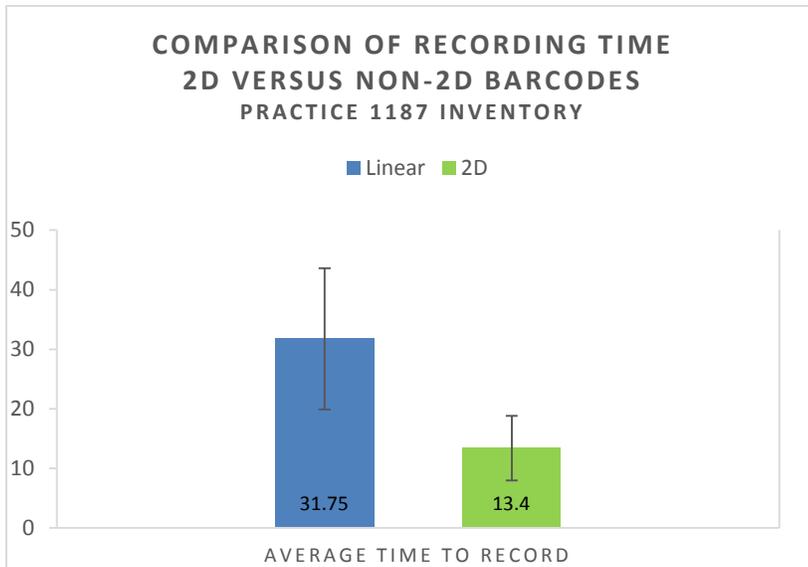


Figure C-6. Time to record vaccine inventory data by barcode type



Other observations

There was no written or formal policy at this location requiring staff to use the scanners, but the practice of using 2D barcode scanning to record vaccine data was heavily engrained in the organizational culture. The leadership at this practice supported using 2D barcode scanning, and continuously encouraged use of the scanners by pointing out the current and future benefits to the nurses. In response to asking if policies are in place, the Nursing Manager said, "There are not policies yet, but those will come now that we have it in place and we are using it and it is improving. At first they really did struggle with it, some of the codes weren't as clear, the labels weren't as dark so it was hard to pick it up but the staff told me that is improving. So now we are going to continue to use it, especially since the inventory balances nicely. So we

are going to continue to use it, so now we put policies and procedures in place. They don't have an option not to use it, so if it is there I want them using it. "

This practice appeared to use the scanners more frequently than any other practice observed for the WFA. The two nurses that were very positive regarding the use of 2D barcode scanners appeared to use them whenever possible. However, it should be noted that there was a recognition among staff that some of the nurses were hesitant to use the barcode scanners at first and that there was a learning curve before they were comfortable using the scanners. Staff noted that initially, the use of the scanners interrupted the normal routine however, it was noted that having a key information technology contact who could address issues as they arose was helpful.

The nurses mentioned that more vaccines were currently 2D barcoded than during the pilot project—during the pilot project observation period the clinic only had Menactra vaccines with 2D barcodes and now they estimate that 50% of the vaccines have 2D barcodes. One of the nurses mentioned, "The benefit is that in case there was ever a recall you would know that it was in there correctly, you would be getting a hold of everyone who had received that vaccine-which is the whole purpose behind entering the lot numbers."

Some issues with the specific vaccines were noted by multiple nurses during the interviews and throughout the day. The influenza vaccine was singled out as the one that was the most challenging to scan. Nurses reported that all of the 2D barcodes on a curved surface (syringe) are the most difficult to scan. Also, some noted that Menactra is sometimes printed partially off of the label, and these were not able to be read by the scanner. However, this seemed to be a batch issue, because the newer shipments of Menactra do not have this issue.

HepA, DTaP, and Polio consistently have 2D barcodes in this practice. HepA and DTaP were recognized as being the easiest to scan. Nurses noted that they currently have to look at each vaccine to see if there is a 2D barcode available and that they believe the process will be faster and easier when all vaccines are 2D barcoded. Two nurses reported that they really liked the 2D barcode scanners and spoke very highly of them; one nurse did not think it helped the process and had trouble getting the scanners to quickly scan so did not think it saved time or effort—"if you have multiple vaccines that is a challenge in the clinic room. From a nursing standpoint in the clinic I see no advantages to the 2D scanning barcode because we already find the lot number in a drop box. So we find the lot number and then we scan it so it is an extra step for us in the clinic room."

Practice ID: 2091

Practice Attributes		
	Practice Type	Public Health Department
	Practice Size (# of physicians)	5 or fewer
	EMR System	Vendor B
	Estimated 2D vaccine administration volume	6295 -High
	Estimated % public vaccines	50%
	Process observed	Administration and Inventory

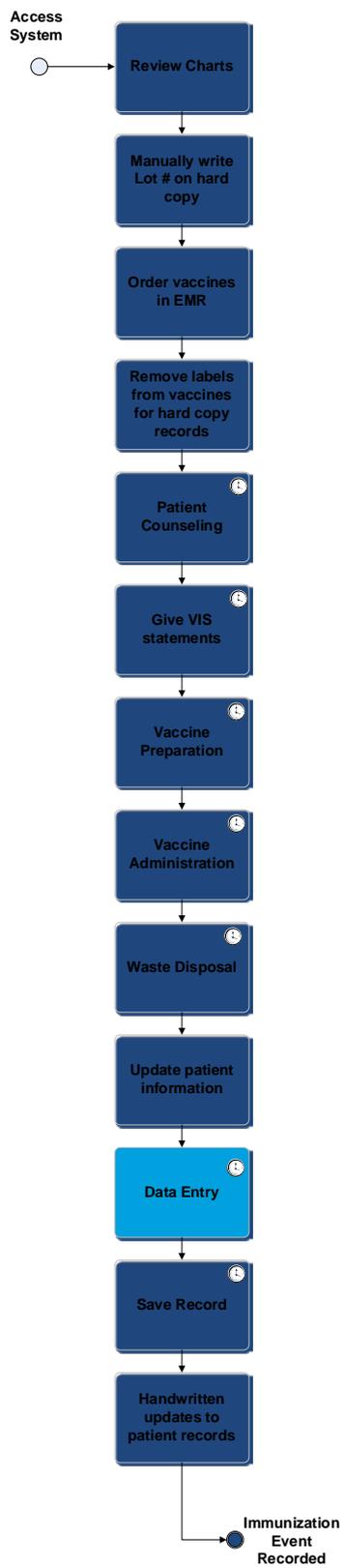
Overall Workflow Processes

Practice 2091 is one of two practices visited in the same local county health department (the other is practice 2452). Each patient room has a nursing station inside the room that includes a desktop computer with a barcode scanner attached. Each nurse is assigned to work in a single patient room. This practice keeps both electronic and hard copies of patient records. Notes are taken on the hard copy of the patient record while visiting with the patient and entered in the computer later in the workflow process. Labels from vaccines are removed from the vials and adhered to the hard copy record.

Administration Process

There are six nurses in this practice, four of which were observed for the administration process during the WFA. All nurses scheduled to work during the WFA were observed. The administration process begins with the nurse reviewing the patient information and charts. The nurse then retrieves the vaccine(s) from the refrigerator, brings the vaccines to the nursing station, and writes the names of the vaccines and lot numbers on the hard copy patient record. If the vaccine has a removable label, the nurse removes the label and attaches it to the hard copy patient record. Next, the nurse orders the vaccines through EMR system. Subsequently, the nurse calls the patient into the patient room, reviews the patient information with the family, provides the appropriate VIS statements, and performs patient counseling. Next, the nurse performs the vaccine preparation activities, administers the vaccine, disposes of waste, and updates information in the EMR. Finally, the nurse provides an updated immunization card to the parents for their records.

Figure C-7. Overall vaccine administration process



The average time to perform all steps in the process depicted in Figure C-7 was 264 seconds (SD=160). The longest step in the process on average was calling the patient whereas the shortest step was logging into the electronic system. Table C-3 provides the average length of time for each step as well as the standard deviation associated with each of these steps.

Table C-3. Average time to perform key steps* in vaccine administration workflow

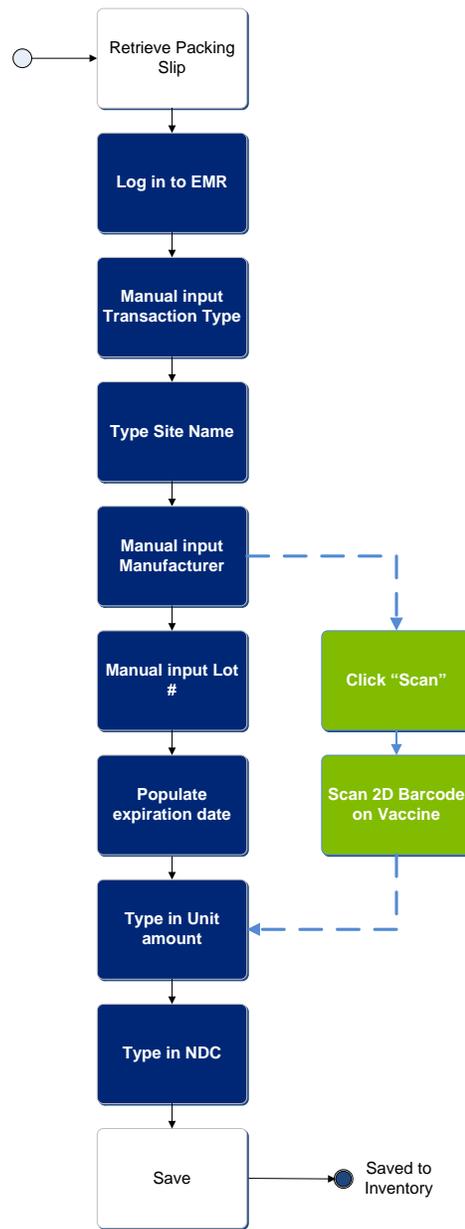
	Observations	Mean	Standard Deviation
2D input	13	26.37	20.20
Chart Review	10	41.92	61.09
Data Entry	8	22.03	13.50
Linear input	15	23.37	16.43
Login	28	16.41	21.37
Vaccine Admin	11	74.04	91.06
Patient counseling	6	73.47	74.52
Waste Disposal	7	19.56	16.13
VIS Statement	5	51.36	43.39
Call Patient	3	279.63	457.37
Vaccine Prep	7	65.97	68.26

*The “2D input” step in this chart refers to the specific time it took to perform the steps specific only to 2D scanning: picking up the scanner, scanning the barcode for lot # and expiration date, and pressing the ‘scan’ button when necessary. The “linear input” steps refer to the specific steps that would be performed in the traditional method instead of the 2D scanning process—so either manually typing or selecting from a drop box the lot number and expiration date. The “Data Entry” step refers to the steps that are performed for both processes—such as typing or drop down selection of manufacturer, input location, etc. The WFA consultant wanted to single out the steps that are directly comparable to measure the differences for the two processes: linear vs. 2D.

Inventory Process

The inventory process is performed centrally for all practices associated with the local county health department. Data is entered once a month by two Biological Clerks and always takes place at the receiving desk. Data is entered directly into the EMR. As a general procedure, when the lot number on the box is different from the lot number on the vial the clerks input the box lot number. One clerk was observed during the WFA.

Figure C-8. Overall vaccine inventory process



Blue fill indicates a data entry process step

The average time to perform all steps in the process depicted in Figure C-8 was 191 seconds (SD=186.8)²¹. The longest step in the process on average was entering 2D barcoded vaccine data whereas the shortest step was entering other data. As seen in Table C-3, the standard deviation associated with the longest step is

²¹The average and standard deviation are based upon observations of the full inventory process for four times.

very high. This is because the clerk observed used the 2D barcode scanner until it registered the data in the EMR—in some instances this took three or four tries before the data registered in the system. The normal process would have been to try once or twice and then revert to manual entry of the data. If the scan had worked the first time in each instance, this average time would be noticeably shorter. Table C-4 provides the average length of time for each step as well as the standard deviation associated with each of these steps.

Table C-4. Average time to perform key steps* in vaccine inventory workflow

	Observations ²²	Average	Standard
2D input	11	40.0848	55.1664
Linear input	13	19.44525	7.897434
Enter Data	2	3.900254	0
Retrieve Packing Slip	4	16.03948	10.61519

*The “2D input” step in this chart refers to the specific time it took to perform the steps specific only to 2D scanning: picking up the scanner, scanning the barcode for lot # and expiration date, and pressing the ‘scan’ button when necessary. The “linear input” steps refer to the specific steps that would be performed in the traditional method instead of the 2D scanning process—so either manually typing or selecting from a drop box the lot number and expiration date. The “Data Entry” step refers to the steps that are performed for both processes—such as typing or drop down selection of manufacturer, input location, etc. The WFA consultant wanted to single out the steps that are directly comparable to measure the differences for the two processes: linear vs. 2D.

Data Entry Process & Time Measurements

This practice uses one of the few EMRs that are 2D barcode enabled, as such upon scanning a 2D barcode the information encoded on the barcode (lot number, expiration date, and product identifier) are entered into the record along with several other data elements specific to the vaccine scanned.

The typical process used for recording data about vaccine inventory includes:

- Log in to EMR
- Type an “R” into the Transaction Type field to indicate the vaccine is from ‘Receiving’
- For linear barcoded vaccines...
 - Type in the practice name for the destination location and enter the lot number
 - Select manufacturer from a drop down menu.
 - Type the expiration date, amount of units and NDC
- For 2D barcode scan...
 - Press “scan” icon on the screen
 - Scan 2D barcoded vaccine – populates the expiration date and lot number; if the date is ever entered incorrectly, the date must be selected from the calendar view to continue. She will then type in the amount of units and NDC.

²² In some of the processes observed the individual entered more than one vaccine into inventory (2D or linear) and for some of the processes observed the individual did not have to enter additional data.

The EMR links the vaccine information entered during inventory to pull vaccine information such as lot number, vaccine name, and NDC from input during the inventory scanning process. This is used to populate the drop down menus. If the lot number is already in the system, it will populate everything except for the units.

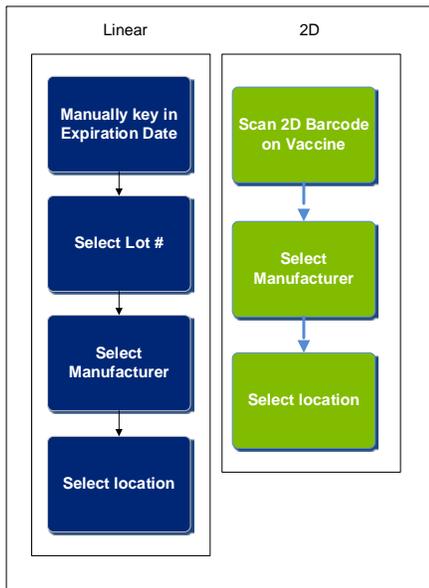
To record data about vaccines administered the nurse...

- Logs into EMR
- For linear barcoded vaccines...
 - Select lot number, expiration date, manufacturer, vaccine location from drop down menus that are pre-populated from the inventory process.
- For 2D barcode scan...
 - Presses the 'scan' button icon on the screen
 - Scans a single 2D barcoded vaccine – which inputs the lot number and expiration date. The vaccine name is pulled from when the vaccines were previously ordered, and the manufacturer and location is selected with pre-populated drop down menus that are pre-populated from the inventory input.
 - Repeat above process for each 2D barcoded vaccine administered

After data for all vaccines has been entered the information is saved. The typical process used for recording data about vaccine inventory includes:

- Log in to EMR
- Type an "R" into the Transaction Type field to indicate the vaccine is from 'Receiving'
- For linear barcoded vaccines...
 - Type in the practice name for the destination location and enter the lot number
 - Select manufacturer from a drop down menu.
- For 2D barcode scan...
 - Press "scan" icon on the screen
 - Scan 2D barcoded vaccine – populates the expiration date, and if the date is ever entered incorrectly, the date must be selected from the calendar view to continue. She will then type in the amount of units and NDC. If the lot number is already in the system, it will populate everything except for the units.

Figure C-9. Vaccine administration data capture process



Nineteen time measurements were taken of the vaccine administration data entry process at this practice for the 4 individuals observed. Twelve time measurements were taken for data entry using 2D barcode scanners and seven measurements were recorded for linear barcoded vaccines. On average, it took 16.68 more seconds for nurses to enter vaccine administration data using 2D barcode scanners (Mean=39.31, SD =22.87) than it did for them to manually enter data from vaccines with a linear barcode (Mean = 22.63, SD=12.22).

Figure C-10. Vaccine inventory data capture process



Twenty-four time measurements were taken of the vaccine inventory data entry process at this practice for the one individual observed. Thirteen time measurements were taken for data entry using 2D barcode scanners and 11 measurements were recorded for linear barcoded vaccines. On average, it took 20.63 more seconds for nurses to enter vaccine administration data using 2D barcode scanners (Mean=40.08, SD =55.17) than it did for them to manually enter data from vaccines with a linear barcode (Mean =19.45, SD=7.90).

Figure C-11. Comparison of time to record vaccine administration by barcode type

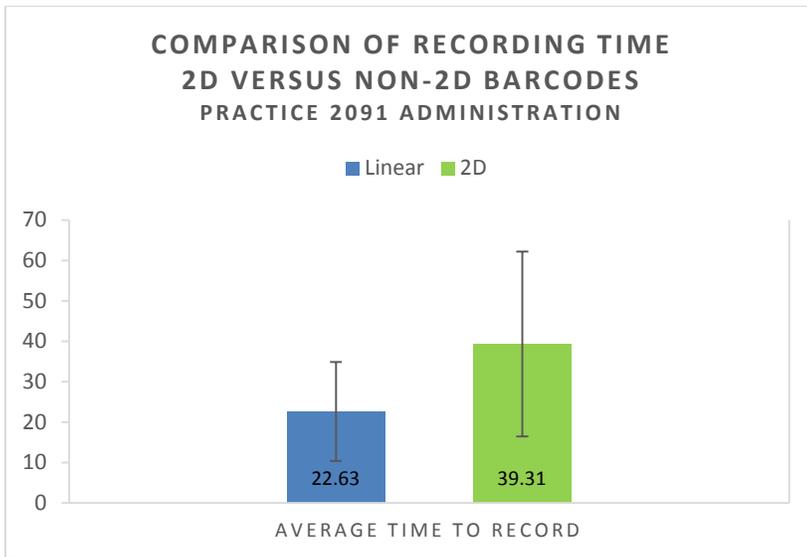
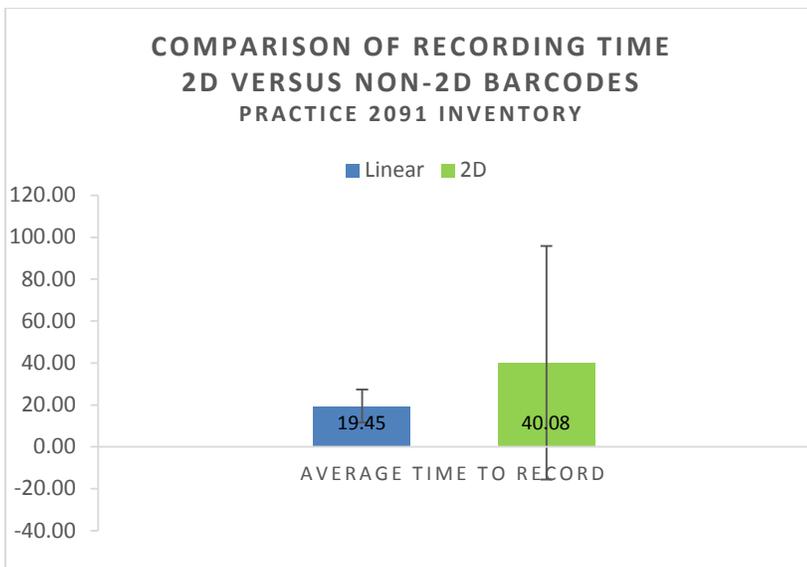


Figure C-12. Comparison of time to record vaccine inventory by barcode type



Other observations

Accuracy was noted as being the greatest advantage to using 2D barcodes scanners. One individual working on inventory provided an example of such benefits, “I think a week ago we typed in the wrong lot number for a vaccine we received in because it didn’t have the 2D barcode and once those are administered to our patients then when we find out after so many have been administered, someone notices ‘oh the wrong lot number was put in’ we have to take all of those immunizations out of the client’s records, fix the mistake we made, re-enter it into [EMR name] and then re-enter it into all of the client records. And it’s okay if it is like

5 but we have done 75 before - and I've put the lot number and someone even double checked me. So scanning is good because it is accurate.”

Nurses reported a similar issue to what was experienced at the other practice observed in this local county health department with respect to the EMR system freezing up with the use of 2D barcode scanners. An episode of the system freezing was seen during the WFA visit. During one scan the flu vaccine did not register a scan within 30 seconds. The EMR system subsequently froze and the nurse had to exit out of the EMR and start data entry over. The nurses noted that the system freezing is inconsistent—sometimes they can use the scanner for extensive periods without the system freezing. The flu vaccine froze the system twice during the observations.

The nurses mentioned being nervous about the possibility of the system freezing and this nervousness affected how they elected to use the scanners. For instance, one nurse mentioned avoiding the use of 2D barcode scanners when their patient is a crying baby. Additionally, nurses always scanned the vaccines with 2D barcodes first in the process so that if the system froze during the process it would not adversely affect the inventory numbers (lot numbers are pulled from the inventory).

Staff noted that some shipments of the same vaccines have 2D barcodes and some do not. Examples include HepA, Pediarix, and the different Flu vaccines administered in this practice. Nurses also mentioned that having to think to look for the 2D barcode was a challenge and decreased the frequency with which they use the scanner. They noted that if all of the vaccines were 2D barcoded, this would eliminate confusion, and potentially increase the frequency of use.

Practice ID: 2133

Practice Attributes		
	Practice Type	Pediatrics
	Practice Size (# of physicians)	5 or fewer
	EMR System	Vendor D
	Estimated 2D vaccine administration volume	2688- High
	Estimated % public vaccines	100%
	Process observed	Administration

Overall Workflow Processes

Practice 2133 has three barcode scanners located at three nursing stations. Two of these nursing stations are located central the patient rooms and the third is in the refrigeration room/prep area. The preparation area is directly to the right of the refrigerator.

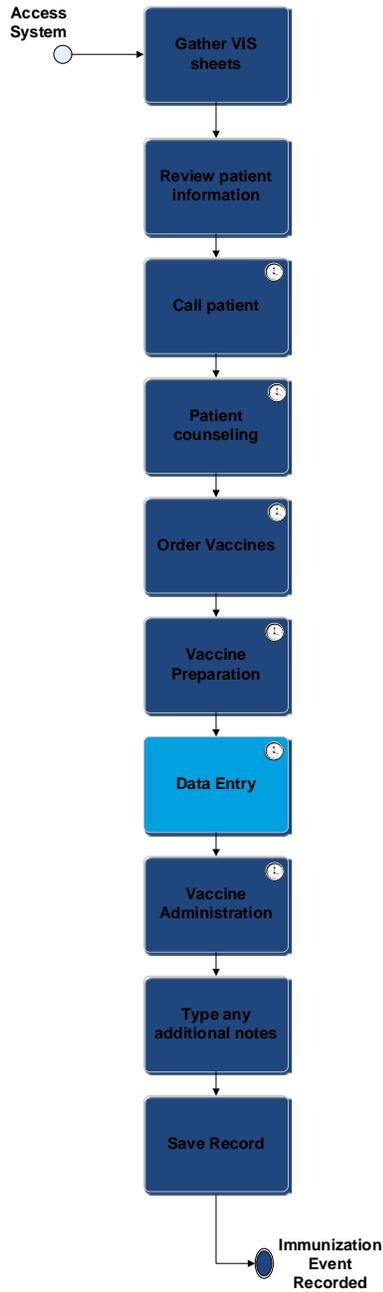
Two nurses were observed at this location. These are the two nurses that use the scanners on a regular basis. There was a college nursing student in training shadowing one of the nurses during the visit²³. All vaccinations? were observed unless there was overlap between the two nurses.

The vaccine administration process²⁴ begins when the nurse obtains VIS sheets and pulls up the patient's information on the computer in the exam room. A system alerts the nurses' station that the patient is present and the nurse proceeds to the waiting area to call the patient to the exam room where they review the patient information and cover general wellness topics. During this visit the nurse updates the patient's information and general vaccine information in the EMR at a computer located in the exam room. The nurse then reviews wellness questions, updates the patient chart, and takes measurements (e.g., weight). Following the visit with the nurse, the patient sees the physician who tells the nurse which vaccine(s) are approved for the patient. The nurse retrieves the vaccine(s) from the refrigeration room, writes down the patient's information on the syringes, prepares the vaccines (in the preparation area), and enters data about the vaccine into the EMR at the nurses station located outside of the exam room.

²³ This differed from other practices, therefore interpretation of overall workflow times should take into account the time it takes to explain a procedure, etc. to the trainee.

²⁴ Due to office policies, observations were not made in the room with the patients at this facility, so the "vaccine administration" was timed as when the nurse went into the room after inputting the information. Because this facility input the information "before administration" the steps in the data capture process were observed at the nurse's station prior to vaccine administration.

Figure C-13. Overall vaccine administration process



The average time to perform all steps in the process depicted in Figure C-26 was 109.83 seconds (SD=62.34). The longest step in the process on average was vaccine administration whereas the shortest step was login. Table C-5 provides the average length of time for each step as well as the standard deviation associated with each of these steps.

Table C-5. Average time to perform key steps* in vaccine administration workflow

	Observations	Mean	Standard Deviation
2D input	9	27.14	16.49765
Chart Review	1	16.20	
Data Entry	7	11.29	10.23495
Linear input	14	23.19	10.63652
Login	18	4.23	3.034865
Vaccine Admin	2	210.54	297.1116
Vaccine Prep	7	132.22	72.22315
Walking	7	12.73	2.437497

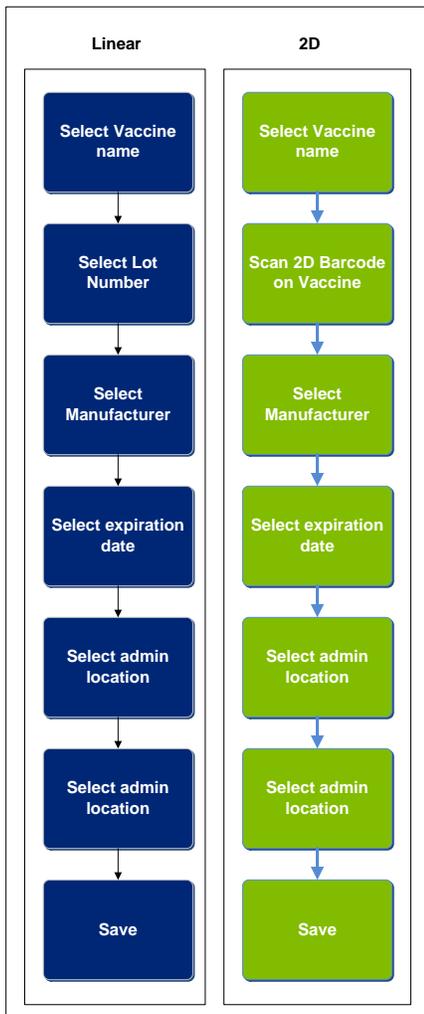
*The “2D input” step in this chart refers to the specific time it took to perform the steps specific only to 2D scanning: picking up the scanner, scanning the barcode for lot # and expiration date, and pressing the ‘scan’ button when necessary. The “linear input” steps refer to the specific steps that would be performed in the traditional method instead of the 2D scanning process—so either manually typing or selecting from a drop box the lot number and expiration date. The “Data Entry” step refers to the steps that are performed for both processes—such as typing or drop down selection of manufacturer, input location, etc. The WFA consultant wanted to single out the steps that are directly comparable to measure the differences for the two processes: linear vs. 2D.

Data Entry Process & Time Measurements

The first time point at which the nurses access the EMR is to enter a standard set of data during the patient examination. A standard list of questions regarding patient information is displayed in the EMR in survey format. During the patient visit, the nurse asks this set of questions and enters the data using a series of drop down menus.

The data entry process specifically related to vaccines administered begins after the physician leaves the patient room and tells the nurse which vaccines should be administered. When entering data about linear barcoded vaccines the nurse selects the vaccine name, lot number, manufacturer, administration location, expiration date, and clinic location using drop down menus. When entering data about 2D barcoded vaccines, the nurse scans the 2D barcode and the lot number is entered into the EMR. After the lot number is entered, the nurse must select the vaccine name, manufacturer, administration location, expiration date, and clinic location using drop down menus. For both types of vaccines, the nurse completes the data entry process by manually typing any additional notes and saves the record after entering each vaccine.

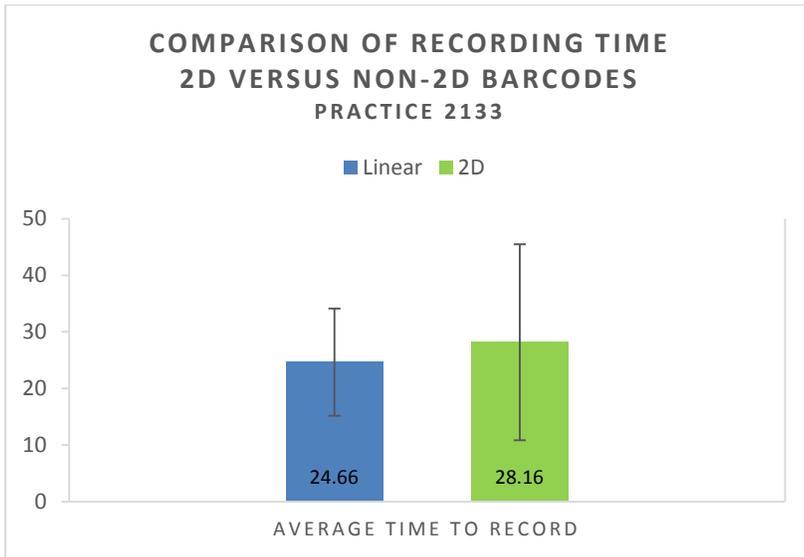
Figure C-14. Vaccine administration data capture process



The WFA consultant recorded 21 time measurements of the vaccine administration data entry process at this practice for the 2 individuals observed. Thirteen time measurements were taken for data entry using 2D barcode scanners and 8 measurements were recorded for linear barcoded vaccines. On average, it took 3.5 seconds longer for nurses to enter vaccine administration data using 2D barcode scanners (Mean =28.16, SD =17.33) than it did for them to enter data from vaccines with a linear barcode (Mean = 24.66, SD=9.47).²⁵

²⁵ Due to the anonymity of data collection we do not have a nurse specific identifier to assess what, in any, effect the student nurse may have had on the time to record vaccine data at this location. The student nurse was not observed as part of the study; she was also observing the process for learning purposes.

Figure C-15. Time to record vaccine administration data by barcode type



Other observations

There are no formal policies at this practice requiring nurses to use the 2D barcode scanners, however, the leadership and physicians encourage use of the scanners because they perceive it increases the accuracy of lot numbers. Nurses mentioned some inconsistencies with scanning that presented challenges— inconsistency in one scanner’s performance and some variability between the ease with which they were able to scan different types of vaccines.

Two scanners were used at this location, but one of the barcode scanners was not scanning as consistently as the other. When cleaned with an alcohol swab, it seemed to work more effectively. During the interviews, one of the nurses mentioned that some vaccines do not scan as well as others and noted difficulties scanning the HepA and influenza vaccines. Nurses noted that some shipments of vaccines have 2D barcodes and some do not. The vaccines nurses recognize as consistently having 2D barcodes are: Pentacel, DTaP, HepA, Pediarix, and Menactra.

It should be noted that due to scheduling challenges, the WFA consultant visited this practice during its least busy days – Tuesday and Wednesday.

Practice ID: 2168

Practice Attributes		
	Practice Type	Pediatrics
	Practice Size (# of physicians)	6 to 15
	EMR System	Vendor G
	Estimated 2D vaccine administration volume	2517- High
	Estimated % public vaccines	40%
	Process observed	Administration

Overall Workflow Processes

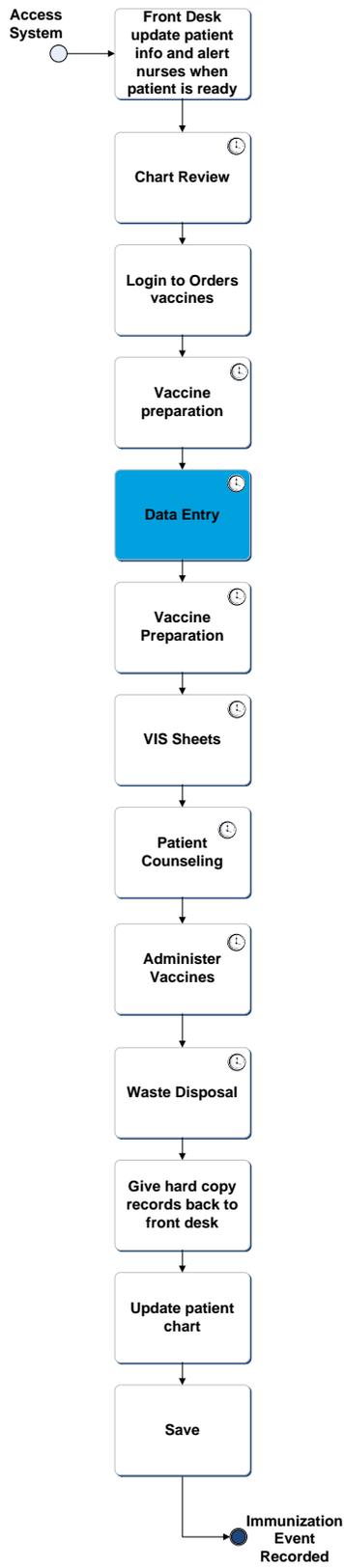
At Practice 2168, the preparation rooms are located on the opposite ends of the building with six patient rooms surrounding each. A nursing station with a computer and 2D barcode scanner were set up in both refrigeration preparation areas. Both nursing stations had desktop computers with scanners attached that were within five feet of the refrigerator; there was a portable tablet used at this location also, but there was no scanner attached to the tablet. The inventory process was not observed because 2D scanners are not involved in that process.

Six different nurses were observed during the vaccine administration process. Ten different nurses rotate through this office; all six that were working at this practice during the two days were observed. Each of the nurses has received training on the 2D barcoding process; however nurses can choose whether regular use is helpful. The primary contact was the nursing supervisor, and she was included in the six observed in the study.

The typical vaccine administration process²⁶ started with the nurse administering the vaccines speaking with the physician to determine which vaccines will be ordered. While in the room with the patient, the physician places an order for the vaccines. Once this order is placed, the nurse receives an alert on the computer to retrieve the vaccine(s). The nurse enters data about the vaccine(s) into the EMR after retrieving them from the refrigeration preparation area. Nurses always enter vaccine data before administration in this practice. Several of the nurses grouped the vaccines based on whether there was a 2D barcode on the vaccine or not prior to recording the vaccine data. After the vaccine data is saved in the EMR, the nurse prepares the vaccine(s) while in the refrigeration area. In addition, the nurse writes information about the vaccines on hard copy of daily office vaccine data sheet. After disposing of waste from the vaccine preparation, the nurse obtained the appropriate VIS sheets and rubber gloves when exiting the refrigeration room on the way to the patient room where the nurse administered vaccines.

²⁶ Observations related to patient engagement (e.g., patient counseling and the vaccine administration) were not observed at this practice. The WFA consultant was allowed to view processes that took place in the refrigeration preparation and nursing station areas.

Figure C-16. Overall vaccine administration process



The average time to perform all steps in the process depicted in Figure C-23 was 194.13 seconds (SD=210.61). The longest steps in the process on average were patient counseling and vaccine administration whereas the shortest step was waste disposal. Table C-6 provides the average length of time for each step as well as the standard deviation associated with each of these steps.

Table C-6. Average time to perform key steps* in vaccine administration workflow

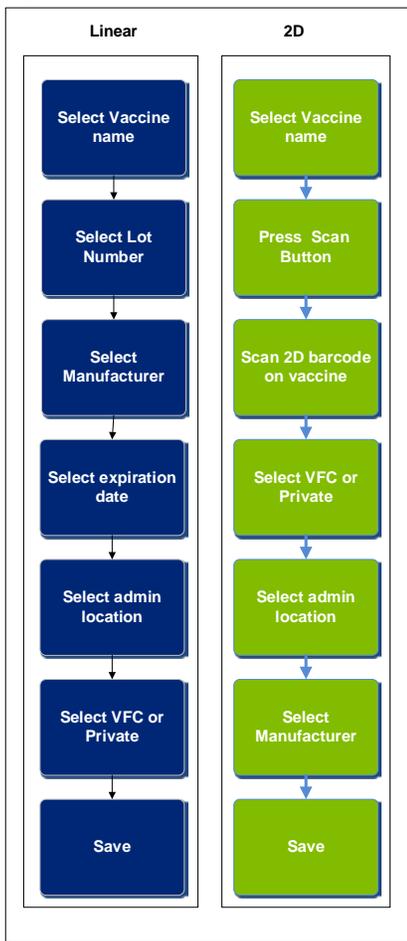
	Observations	Mean	Standard Deviation
2D input	19	15.85	9.31
Chart Review	31	36.92	58.26
Data Entry	6	27.88	14.37
Linear input	38	14.19	6.89
Login to EMR	30	5.67	5.63
Vaccine Admin Patient Counseling	5	147.39	162.93
Waste Disposal	5	5.59	3.34
Vaccine Prep	29	59.46	46.78
VIS Statement	6	33.62	32.84
Walking	3	49.63	64.71

*The “2D input” step in this chart refers to the specific time it took to perform the steps specific only to 2D scanning: picking up the scanner, scanning the barcode for lot # and expiration date, and pressing the ‘scan’ button when necessary. The “linear input” steps refer to the specific steps that would be performed in the traditional method instead of the 2D scanning process—so either manually typing or selecting from a drop box the lot number and expiration date. The “Data Entry” step refers to the steps that are performed for both processes—such as typing or drop down selection of manufacturer, input location, etc. The WFA consultant wanted to single out the steps that are directly comparable to measure the differences for the two processes: linear vs. 2D.

Data Entry Process & Time Measurements

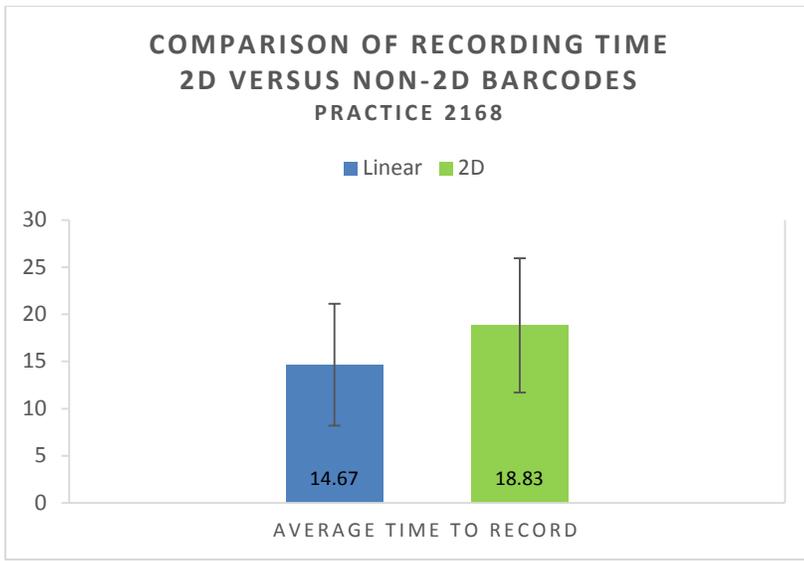
Most of the information about a vaccine administered is pulled into the patient record from the inventory record, therefore, the manual typing in this system was minimal irrespective of whether a linear or 2D barcoded vaccine was recorded. In all cases, the ‘auto-complete’ function of the lot number field pulled from the last lot number that was entered for that vaccine in the system. When recording about a vaccine with a linear barcode, the nurse manually types in the vaccine lot number and expiration date. For the 2D process, the nurse scans the 2D barcode to record the lot number and expiration date. After the lot number and expiration date are in the system, all other information is pulled from the inventory record, with the exception of the vaccine manufacturer which the nurse must select from a drop down list. The nurse verifies that the data in the record is correct and saves the record. Right after the nurse enters the vaccine data into the EMR, they were required to separately enter the vaccines in the State Registry system.

Figure C-17. Vaccine administration data capture process



The WFA consultant recorded 43 time measurements of the vaccine administration data entry process at this practice for the 6 individuals observed. Twenty five time measurements were taken for data entry using 2D barcode scanners and 18 measurements were recorded for linear barcoded vaccines. On average, it took 4.16 seconds longer for nurses to enter vaccine administration data using 2D barcode scanners (Mean = 18.83, SD =7.11) than it did for them to manually enter data from vaccines with a linear barcode (Mean = 14.67, SD=6.46).

Figure C-18. Time to record vaccine administration data by barcode type



Other Observations

Individuals in this practice generally thought that the greatest benefit of using 2D barcode scanners was that it eliminated human error of inputting lot numbers. The scanners were provided for use, but not required—nurses could use them or not as they chose.

Nurses identified several challenges in recording vaccine data. First, the nurses noted that the Prevnar and Flu vaccines were the most difficult to scan. Additionally, some of the scanners perceived as easier to use than others. Nurses also noted frustrations with having to look to see if a 2D barcode is on each vaccine and noted that they would be more likely to use 2D barcode scanning if on a regular basis if all vaccines had them. One of the nurses stated that she is bothered by the red light on the scanner because she feels it is blinding, so she prefers not to use it; she also stated that she thinks it takes too long to scan sometimes. A notable benefit identified by staff from this practice was not having to decipher numbers in the lot numbers so they could type them into the EMR—one nurse provided a specific example of it being difficult to tell the difference between a six and eight in some of the lot numbers.

“If it worked all of the time, I don’t see that there would be a drawback. Because it is quick, it is efficient, you have no errors. I think it is fantastic. But it doesn’t work all of the time.”

Practice ID: 2299

Practice Attributes		
	Practice Type	Pediatrics
	Practice Size (# of physicians)	5 or fewer
	EMR System	Vendor C (different from Pilot EMR)
	Estimated 2D vaccine administration volume	672- Medium
	Estimated % public vaccines	40%
	Process observed	Administration

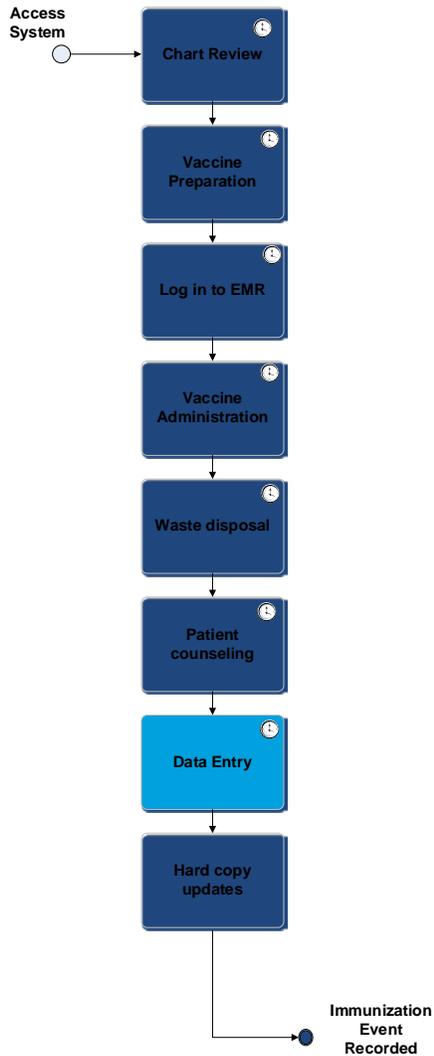
Overall Workflow Process

Practice 2299 is small in size and is currently set up to use 2D barcode scanning to record vaccines administered. The practice configuration enables lot number and expiration date to scan into the EMR. The practice comprises one patient room, with a refrigeration and preparation station in a room located across the hall. There is one nurse's station in the practice which is set up directly to the left of the refrigerator. This is the only nurse's station and the only barcoding scanner observed at this location. There are two additional scanners kept on-site, but only one of them is used on a consistent basis. The other two are for back-ups and to use on very busy days.

Two individuals were observed while at this practice. One nurse is primarily responsible for administering vaccines in this practice and therefore regularly uses the 2D barcode scanner to record vaccine administration data. The second individual observed (a Medical Assistant), administers vaccines when the main nurse is out of the office, and therefore has an opportunity to use the 2D barcode scanner.

The general workflow associated with vaccine administration begins with the patient visiting with the physician who subsequently places an order for the vaccines. The nurse then retrieves the patient's information on the computer and reviews their chart for insurance information and immunization records. The nurse also reviews paper copies of records if needed. Subsequently the nurse pulls the vaccines ordered by the physician from the refrigerator and separates the vaccine vials or syringes into groups arranged by private and public vaccines. She then inputs the information into the EMR system by tabbing across and manually typing: vaccine name, manufacturer, expiration date, lot #, practice, location, administrator's initials; private vs. public; and saves after all vaccines have been entered. After the data entry portion of the process, the nurse updates the hard copy patient chart with vaccines given and the date. Data entry of vaccine information always occurred prior to vaccine administration. In the final stages of the visit the nurse calls the patient into the room, administers the vaccines, cleans up, and conducts patient counseling. Figure C-19 depicts this overall workflow process for the administration process.

Figure C-19. Overall Administration Process



The average time to perform all steps in the process depicted in Figure C-19 was 229.24 seconds (SD=448.44). The longest step in the process on average was vaccine administration whereas the shortest step was Login. Table C-7 provides the average length of time for each step as well as the standard deviation associated with each of these steps.

Table C-7. Average time to perform key steps* in vaccine administration workflow

	Observations	Mean	Standard Deviation
2D scanning	14	27.97	19.67
Chart Review	10	21.32	15.51
Data Entry	12	27.25	16.84
Linear input	12	50.85	33.52
Login	14	5.62	7.57
Vaccine Admin	3	455.19	505.59
Patient counseling	1	287.43	
Waste Disposal	2	8.08	0.70
Vaccine Prep	8	46.22	31.51

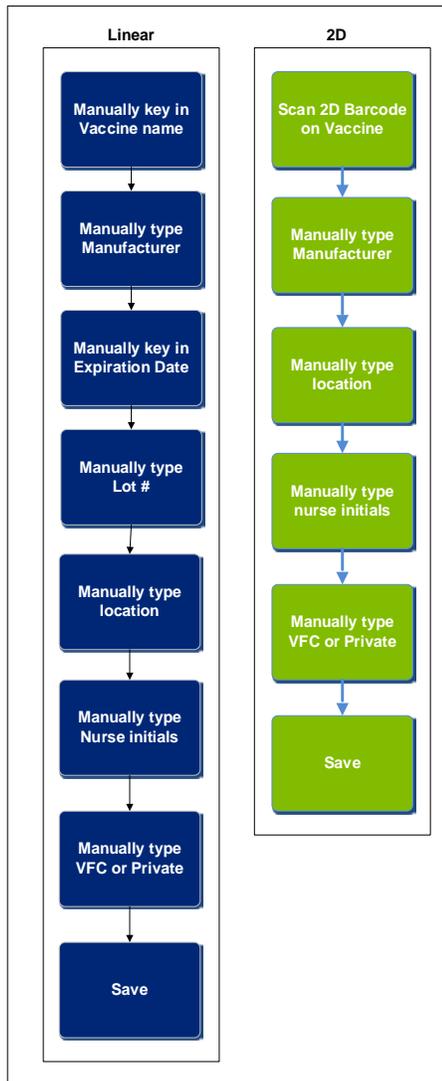
*The “2D input” step in this chart refers to the specific time it took to perform the steps specific only to 2D scanning: picking up the scanner, scanning the barcode for lot # and expiration date, and pressing the ‘scan’ button when necessary. The “linear input” steps refer to the specific steps that would be performed in the traditional method instead of the 2D scanning process—so either manually typing or selecting from a drop box the lot number and expiration date. The “Data Entry” step refers to the steps that are performed for both processes—such as typing or drop down selection of manufacturer, input location, etc. The WFA consultant wanted to single out the steps that are directly comparable to measure the differences for the two processes: linear vs. 2D.

Data Entry Process & Time Measurements

During the pilot observation period, this practice used a different EMR than the current one and was configured to scan at both inventory and administration. Since this time, the practice changed their EMR system; the practice currently is unable to use with 2D barcode scanners to record inventory.

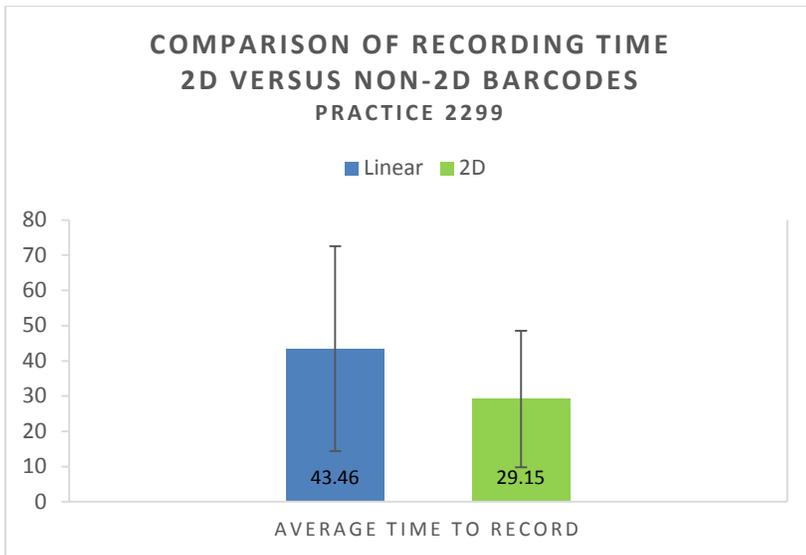
The EMR has a separate screen that is automatically viewed by the end-user to enter vaccine information. The data entry fields in the EMR are entered manually (i.e., no drop-down functionality). Each data entry field is set-up to auto-populate words that are typed frequently. Observations of the process indicated that this was easy to follow and only required a couple of letters because of the auto-populate feature—as the nurse tabbed between fields quickly. In the case of linear barcoded vaccines, the lot number was manually entered—this was noticeably the longest step in the data entry process. When the 2D barcode scanner was used, the nurse simply scanned the 2D barcode when the lot number field was reached while tabbing across. This automatically populated the next field—the expiration date. Figure C-20 depicts the primary steps in the data entry process for linear and 2D barcoded vaccines.

Figure C-20. Vaccine administration data capture process



Twenty-five time measurements were taken at this practice for the two individuals observed. Eleven time measurements were taken for data entry using 2D barcode scanners and 14 measurements were recorded for linear barcoded vaccines which were manually entered. On average, it took 14.31 fewer seconds for the nurses to enter vaccine administration data using 2D barcode scanners (Mean = 29.15, SD = 19.36) than it did for them to manually enter data from vaccines with a linear barcode (Mean = 43.46, SD=29.08).

Figure C-21. Time to record vaccine administration data by barcode type



Other observations

This is a long-standing health care practice. The newest person on the staff (who was the one mainly observed) has been employed at the practice for nine years whereas two individuals who staff the front desk and the physician have been here for over 20 years. These individuals on some occasions have cared for up to four generations of patients; they know their patients well. It is a family-like atmosphere.

Only one of the nurses in this practice uses the 2D barcode scanner on a regular basis—she is the only practitioner who regularly administers vaccines in this practice. She was very positive about the technology—it is clear that she really likes it and talks very positively about it to the others in the office.

“I like the fact that it is convenient, you just tap where the lot # goes, you scan it, and there is less typing so there are less errors. That is what I like about it. My experience is great.”

Feedback throughout the day by staff at this location indicated that there were no issues with the scanner operating. The nurse who primarily uses the 2D barcode scanner noted that she wished the barcode pulled more information than just the lot number and expiration date and remarked that even populating the manufacturer name it would save a lot of time. The flu vaccine was noted as the slowest to scan; the HepA, DTaP, and Menactra vaccines were noted as being “easy to scan.” The nurse noted that she liked that the barcode scans pick up the case sensitivity, because the Vendor C EMR requires the lot numbers to be case sensitive.

Practice ID: 2413

Practice Attributes		
	Practice Type	Pediatrics
	Practice Size (# of physicians)	5 or fewer
	EMR System	Vendor A
	Estimated 2D vaccine administration volume	3613/High
	Estimated % public vaccines	30%
	Process observed	Administration

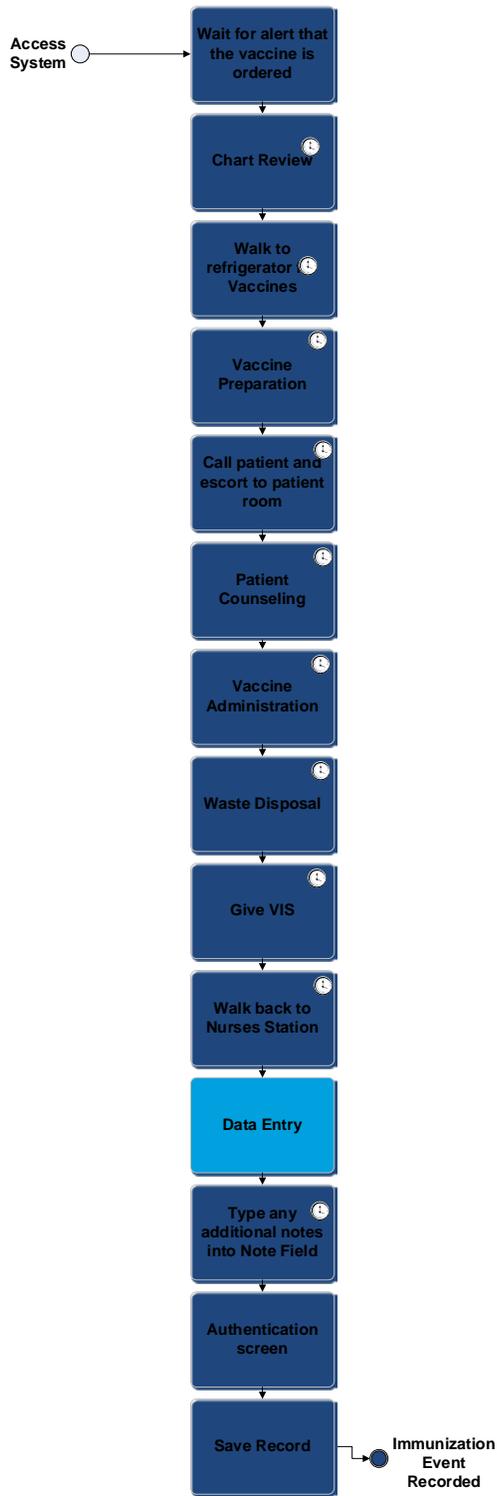
Overall Workflow Processes

Practice 2413 has eight nursing stations. Five of these stations are located in a room with the refrigeration and preparation area, the other three stations are located in a separate room. Each nurse has her own designated area with a computer, preparation space, and a 2D barcode scanner. Nurses prepare vaccines and enter the vaccine administration data at the nursing station to which they are specifically assigned. Generally, five nurses are on duty, therefore some of the stations are available and used by floating staff who call patients to set up appointments and give patient's results or updates.

All nurses staffed to work during the WFA visit were observed, therefore a total of five nurses were observed. The leadership at this office was very positive about the use of 2D barcode scanners, and all of the nurses adopted them into their normal routine.

The vaccine administration process was initiated when a nurse saw a 'blue dot' next to the patient information list available in the EMR. This blue dot appears when the physician orders a vaccine while in the patient room and alerts the nurse that a vaccine is needed. Typically, the nurse would update the patient record in the EMR at this time and retrieve the vaccine(s) from the refrigerator. The nurses used the vaccine preparation area to group the vaccines by barcode type (2D or linear). The 2D barcodes were usually done first to save time. Although nurses determined whether they would enter vaccine information prior to or after administering a vaccine, they most frequently entered this data prior to administration. After entering the vaccine data, the nurse prepared the vaccine(s) at their respective nursing station and entered the patient care area once the physician visit was complete. Once in the room, the nurse answered questions from the patient's parents, verified the patient's date of birth, and administered the vaccine(s). Following vaccine administration, the nurse disposed of any waste, and reviewed the respective VIS statements with the parents.

Figure C-22. Overall vaccine administration process



The average time to perform all steps in the process depicted in Figure C-22 was 309 seconds (SD=282). The longest step in the process on average was Chart Review whereas the shortest step was Login. Table C-8 provides the average length of time for each step as well as the standard deviation associated with each of these steps.

Table C-8. Average time to perform key steps* in vaccine administration workflow

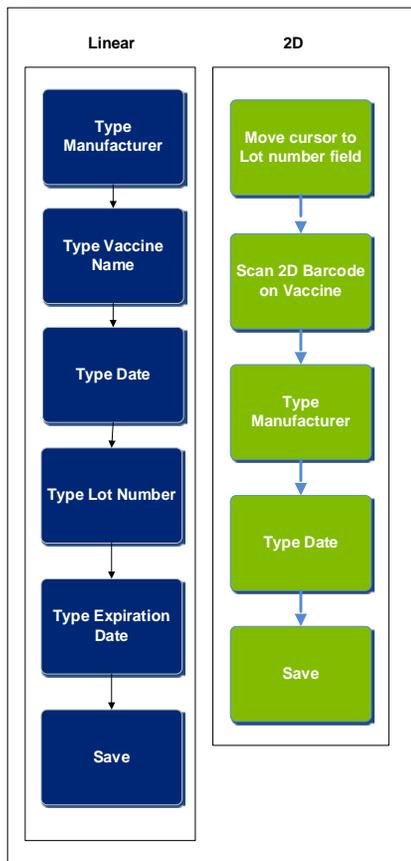
	Observations	Mean	Standard Deviation
2D input	16	29.15	13.02821
Call Patient	3	78.21	35.97192
Chart Review	12	79.65	120.3064
Data Entry	28	15.40	23.55034
Linear input	30	30.95	10.6209
Login to EMR	51	8.16	5.651279
Patient Counseling	23	46.44	85.37094
Vaccine Admin	20	48.01	26.32805
Vaccine Prep	37	66.42	66.58643
VIS Statement	27	27.80	52.11368
Walking	34	30.25	46.37036
Waste Disposal	20	16.39	10.79679

*The “2D input” step in this chart refers to the specific time it took to perform the steps specific only to 2D scanning: picking up the scanner, scanning the barcode for lot # and expiration date, and pressing the ‘scan’ button when necessary. The “linear input” steps refer to the specific steps that would be performed in the traditional method instead of the 2D scanning process—so either manually typing or selecting from a drop box the lot number and expiration date. The “Data Entry” step refers to the steps that are performed for both processes—such as typing or drop down selection of manufacturer, input location, etc. The WFA consultant wanted to single out the steps that are directly comparable to measure the differences for the two processes: linear vs. 2D.

Data Entry Process & Time Measurements

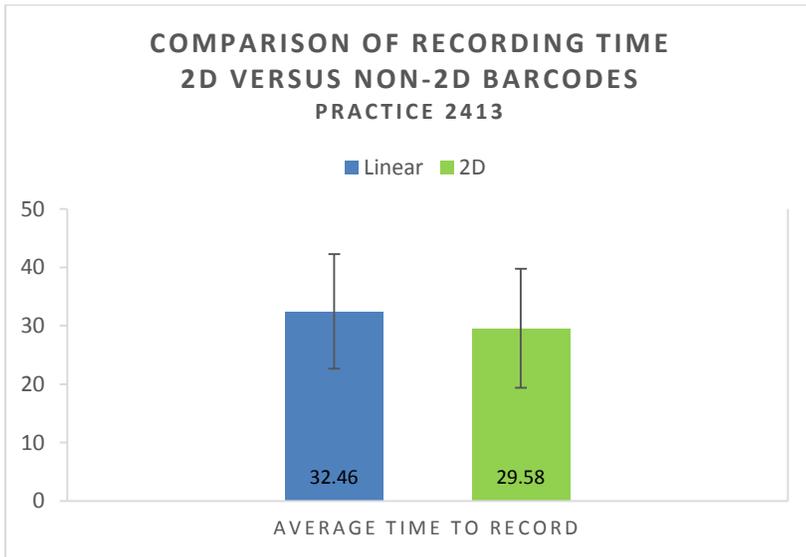
As previously noted, Vendor A is used in this practice. To enter vaccine administration data for vaccines with a linear barcode, the nurse logs into the EMR and manually enters all data elements. The 2D barcoding scan is initiated immediately when input screen is pulled up. For 2D barcoded vaccines, the nurse scans the lot number and expiration date and manually enters all remaining data elements. After the nurse enters all of the vaccine data, they enter information into an authentication screen and then save.

Figure C-23. Vaccine administration data capture process



The WFA consultant took 40 time measurements of the vaccine administration data entry process at this practice for the 5 individuals observed. Twenty-seven time measurements were taken for data entry using 2D barcode scanners and 13 measurements were recorded for linear barcoded vaccines. On average, it took 2.88 fewer seconds for nurses to enter vaccine administration data using 2D barcode scanners (Mean = 29.58, SD =10.21) than it did for them to manually enter data from vaccines with a linear barcode (Mean = 32.46, SD= 9.8).

Figure C-24. Comparison of time to record vaccine data by barcode type



Other observations

The clinic is in a small town and the patients consistently visit the clinic for all types of appointments. The nursing manager mentioned that the Pediatric Department was often recognized throughout the local health system as being a ‘best in class’ area. Most of the nurses offered very positive feedback about the use of 2D barcode scanners. They felt that the scanners worked easily and that use of the scanners increased the accuracy of the lot numbers entered. A common theme was that nurses preferred to use the scanners because it eliminated the need to read very small lot numbers. One individual offered a specific example—noting that sometimes there are five zeroes in a row in a lot number and it can be easy to miss one when manually recording this data.

The most common challenge noted by the nurses was the wait time associated with the scanner reading the barcode. Nurses noted that individual syringes were the least consistent to scan. Additionally, staff noted that not all lots of the same vaccine have the 2D barcodes; some shipments have them and some do not—indicating that the supply of 2D barcoded vaccines may still be inconsistent in the supply chain.

There was no formal policy in place at this practice requiring staff to use the 2D barcode scanners. However, the leadership encouraged the use of the scanners on a regular basis. Nurses in this practice appeared to be very collaborative—they often helped each other mid-process. This is one possible reason why 2D barcode scanning was accepted among all of the nurses.

A printed list of which vaccines had 2D barcodes was kept by one of the lead nurses, but was not distributed. This was mainly because it was dependent on shipments whether the vaccines had barcodes, so this list changes frequently. The nurse with the list sat close to the refrigerator so it was easy to check the list when retrieving the vaccines. The 2D barcode scanners only captured the Lot number and expiration date, so each

entry still manually entered any notes and the publication date of the VIS. There was a 'cheat sheet' of these expiration dates at each station.

Practice ID: 2429

Practice Attributes		
	Practice Type	Pediatrics
	Practice Size (# of physicians)	5 or fewer
	EMR System	Vendor E
	Estimated 2D vaccine administration volume	1779- Medium
	Estimated % public vaccines	25%
	Process observed	Administration

Overall Workflow Processes

Practice 2429 has two nurse stations that include a desktop computer with 2D barcode scanners attached. These nurse stations are located in the refrigerator preparation room that is centrally located to the six patient rooms in this practice. Everyone working in this practice, which includes approximately 10 people (including front-desk staff), has access to the 2D barcode scanners. Although nurses are responsible for administering vaccines, other individuals in the practice enter data about vaccines administered into the EMR.

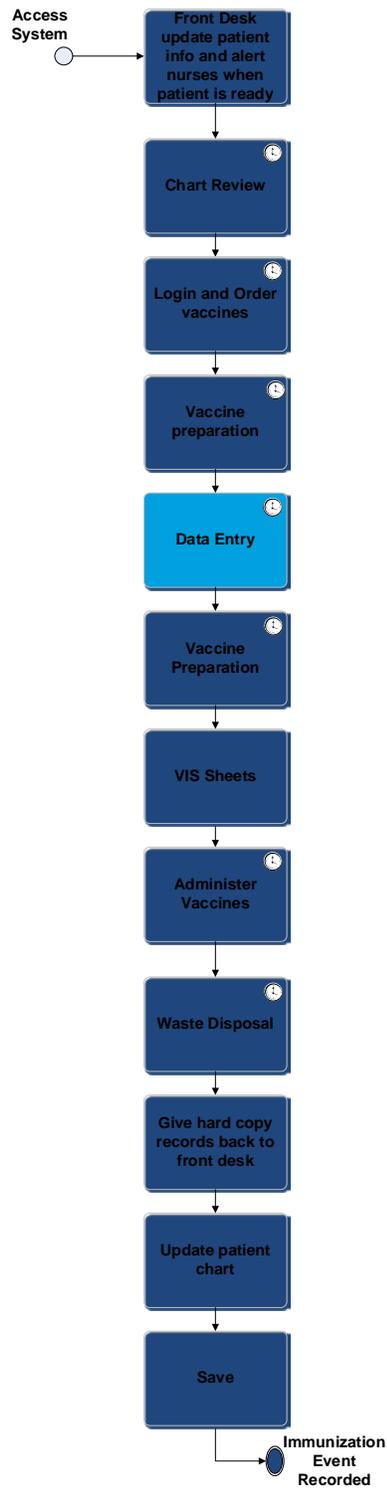
Five nurses were observed at this location—this comprises all nurses who used the 2D barcode scanners and were administering vaccines during the WFA visit. At the beginning of the visit, and whenever a new nurse started working, the WFA consultant requested to be informed about when vaccines were to be administered.

The vaccine administration process²⁷ typically started when the front desk staff updated a sheet containing patient information which they subsequently brought to a window in the nurse’s room. When a new patient was available, the front desk person said “chart” to alert the nurses. At this time, the nurse took the patient information sheet to the nurse’s station and accessed the patient’s information in the EMR. While in the EMR, the nurse ordered the vaccine(s), reviewed the patient information to verify past records, and entered additional information as needed about the activities planned for the current day’s appointment (e.g., eye exam, blood work). Subsequently, the nurse retrieved the vaccine(s) from the refrigerator and entered vaccine data into the EMR. Data about vaccines was always entered prior to administering the vaccine in the practice.

²⁷Observations related to patient engagement (e.g., patient counseling and the vaccine administration) were not observed at this practice. The WFA consultant was allowed to view processes that took place in the vaccine preparation area and during data entry.

After entering the vaccine data, the nurse completed vaccine preparation activities (e.g., ready band aids, open alcohol swabs) and gathered the appropriate VIS sheets on the way on the way to the patient room. When in the exam room, the nurse administered the vaccine(s). Following vaccine administration, the nurse returns the patient record to front desk and logs back on to a computer in the nurse's station to update the patient chart noting that the vaccines were given and updating patient information/vitals captured during the visit (e.g., height, weight, and blood work).

Figure C-25. Overall process for vaccine administration



The average time to perform all steps in the process depicted in Figure C-25 was 281.13 seconds (SD=248.79). The longest step in the process on average was patient counseling whereas the shortest step

was logging into the EMR. Table C-9 provides the average length of time for each step as well as the standard deviation associated with each of these steps.

Table C-9. Average time to perform key steps* in vaccine administration workflow

	Observations	Mean	Standard Deviation
2D inputs	11	37.64	31.12
Chart Review	7	31.62	37.16
Data Entry	14	36.96	28.40
Linear inputs	15	19.26	9.81
Login to EMR	16	10.31	7.83
Vaccine Admin	6	168.23	155.63
Patient Counseling	1	547.56	
Waste Disposal	1	43.49	
Vaccine Prep	17	102.80	215.62
Order shots	2	21.45	10.38
Walking	2	49.28	32.07
Handwritten Notes	2	10.47	5.60

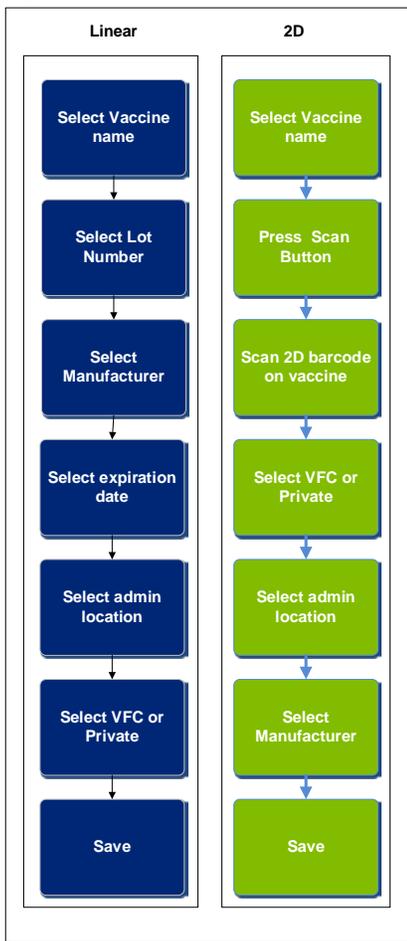
*The “2D input” step in this chart refers to the specific time it took to perform the steps specific only to 2D scanning: picking up the scanner, scanning the barcode for lot # and expiration date, and pressing the ‘scan’ button when necessary. The “linear input” steps refer to the specific steps that would be performed in the traditional method instead of the 2D scanning process—so either manually typing or selecting from a drop box the lot number and expiration date. The “Data Entry” step refers to the steps that are performed for both processes—such as typing or drop down selection of manufacturer, input location, etc. The WFA consultant wanted to single out the steps that are directly comparable to measure the differences for the two processes: linear vs. 2D.

Data Entry Process & Time Measurements

Staff entered all data about a vaccine into a central box located in the middle of the screen by selecting values from drop down boxes. For linear barcoded vaccines this involved selecting the vaccine’s lot number²⁸, expiration date, manufacturer, VFC status (VFC or not), and vaccine administration location. The procedure for entering data about 2D barcoded vaccines differs slightly. Staff must press a ‘scan’ button before using the scanners for each vaccine administered. Scanning the 2D barcode enters the lot number and expiration date into the EMR. The staff member saves the vaccine record after entering data for each vaccine administered.

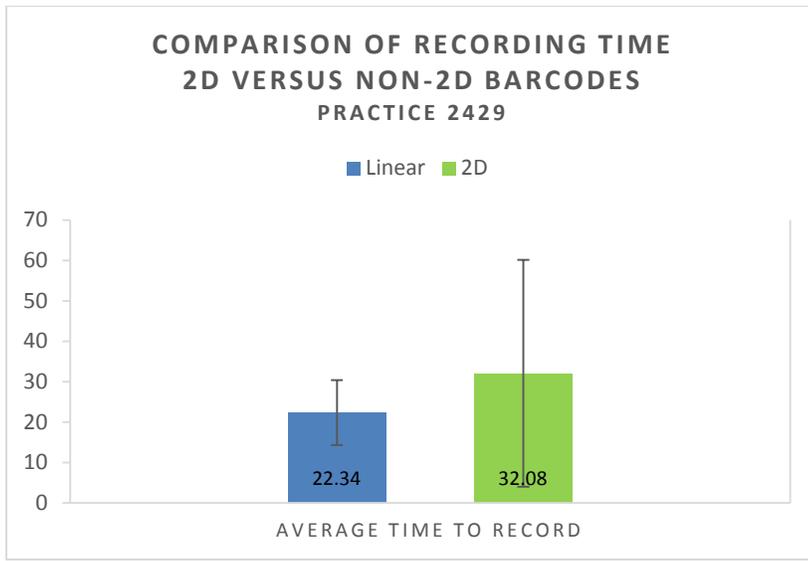
²⁸ Lot numbers are pre-entered into the system during the inventory process.

Figure C-26. Vaccine administration data capture process



The WFA consultant recorded 31 time measurements were taken of the vaccine administration data entry process at this practice for the 5 individuals observed. Sixteen time measurements were taken for data entry using 2D barcode scanners and 15 measurements were recorded for linear barcoded vaccines. On average, it took 9.74 seconds longer for nurses to enter vaccine administration data using 2D barcode scanners (Mean = 32.08, SD =28.08) than it did for them to manually enter data from vaccines with a linear barcode (Mean = 22.34, SD= 8.04).

Figure C-27. Time to record vaccine administration data by barcode type



Other observations

This is a pediatric practice that sees patients for many types of medical visits other than vaccine administration. This is a very busy practice with several doctors ($n=5$) and up to 10 nurses present in the office at a time. During the WFA most patient appointments were for procedures other than vaccinations.

There were five nurses observed during the WFA, however, most of these individuals reported that they do not use the 2D barcode scanners on a regular basis because they perceive it is easier to enter vaccine data manually, particularly when the lot numbers are already loaded as part of the inventory process. None of the nurses observed worked in this practice during the pilot project observation period. One individual, who was employed in this practice during the pilot project observation period, was on vacation during the WFA. Staff noted that she is the one that likes 2D barcode scanning the best and uses it the most frequently.

“Flu season it was especially nice because it had a peel off label and could stick it to the billing sheet and scan it later. It seems easier because it is not rounded.”

Nurses noted that if scanning the 2D barcode resulted in all of the vaccine data populating into the EMR that this process would be very helpful and save a lot of time. The nurses also mentioned that a lot number is “randomly chosen” when using a 2D barcode scanner. This is likely due to an auto-complete configuration in the EMR that matches the scanned lot number with the first few digits of lot numbers loaded in at inventory (instead of matching the entire lot number). Nurses are concerned that scanning a 2D barcode may result in an incorrect entry and therefore double check the entry regularly—causing an extra step in the data entry process.

Nurses appreciated the peel-off labels on the flu vaccine. One noted that it was helpful to adhere the peel off label to the billing sheet so it could be scanned later. More than one nurse remarked that it seemed

easier to scan a 2D barcode from labels that they peeled off—mentioning difficulties scanning barcodes on a rounded surface. One nurse also mentioned that Pentacel seemed easier to scan than Varivax.

Practice ID: 2452

Practice Attributes		
	Practice Type	Public Health Department
	Practice Size (# of physicians)	5 or fewer
	EMR System	Vendor B
	Estimated 2D vaccine administration volume	6295 -High
	Estimated % public vaccines	50%
	Process observed	Administration and Inventory

Overall Workflow Processes

Practice 2452 is one of two practices visited in a local county health department in Michigan during the WFA; the second facility is Practice 2091. There are minor differences between the workflow processes at these two practices—the primary difference relates to vaccine administration, namely the location of exam rooms. At the practice described in the current case study, all exam rooms are located on the same hallway whereas in Practice 2091 the rooms are distributed more broadly throughout the facility. Otherwise the procedures used at these sister practices are very similar for recording vaccine administration and are exactly the same for recording vaccine inventory. The WFA consultant did observe both administration and inventory data entry procedures for this practice, however, given that inventory procedures are performed by exactly the same individuals observed for practice 2091 inventory findings are not repeated here.

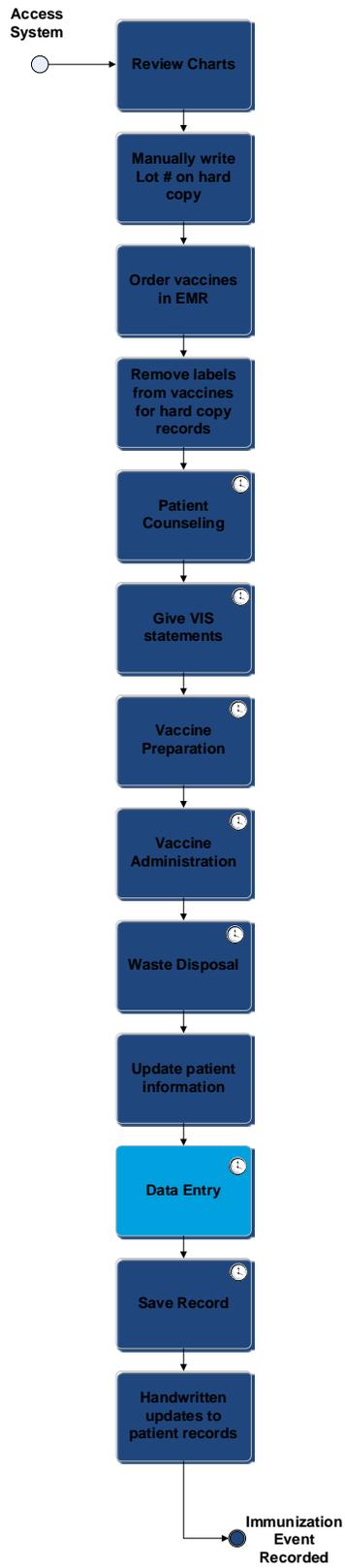
Administration Process

Four nurses were observed through the vaccine administration process during this visit. Five nurses use the barcode scanners in this practice, however, only four were present during observations. The vaccine administration process begins with the nurse reviewing the patient information and charts. The nurse then retrieves the vaccine(s) from the refrigerator and returns to the nursing station to write down the names of the vaccines and lot numbers on the hard copy patient record. If the vaccine has a removable label, the nurse adheres the label to the hard copy patient record. Next, the nurse orders the vaccines via the EMR system. After the nurse places this order, she calls the patient into the exam room, reviews the patient's information with the family, provides the relevant VIS statements, and performs patient counseling. Vaccine preparation then takes place, followed by vaccine administration, and waste disposal. The nurse then updates information into the EMR. Nurses, however, can elect to input in the vaccine data either before or after administration. The Nurse Manager noted that she prefers to input vaccine data before administration occurs, because this procedure affords the opportunity to ensure the correct vaccine is administered by double checking the lot numbers match. As a final step in this process, the nurse provides an updated (handwritten) immunization card to the patient's parents for their records.

Most of the nurses left the barcode scanner on the stand when recording vaccine administrations. Some, however, have the scanner physically taped to a desk because they found that the specific angle allows

them to scan the barcode much easier and want to keep the exact specifications for future scans. When administering a group of vaccines—some 2D barcoded and some linear barcoded—the nurses would typically enter data for the 2D barcoded vaccines first. Multiple instances occurred where the EMR system would freeze when recording 2D barcoded vaccines, when this occurred, nurses noted that all vaccine data entered prior to the system freezing was lost.

Figure C-28. Overall vaccine administration process



The average time to perform all steps in the process depicted in Figure C-28 was 30.35 seconds (SD=23.99). The longest step in the process on average was Vaccine preparation whereas the shortest step was Logging into the EMR. Table C-10 provides the average length of time for each step as well as the standard deviation associated with each of these steps.

Table C-10. Average time to perform key steps* in vaccine administration workflow

	Observations	Mean	Standard Deviation
2D input	4	14.61	4.86
Chart Review	2	9.68	11.03
Data Entry	2	8.61	8.54
Linear input	15	9.50	3.91
Login	15	7.20	10.17
Vaccine Prep	1	23.82	

*The “2D input” step in this chart refers to the specific time it took to perform the steps specific only to 2D scanning: picking up the scanner, scanning the barcode for lot # and expiration date, and pressing the ‘scan’ button when necessary. The “linear input” steps refer to the specific steps that would be performed in the traditional method instead of the 2D scanning process—so either manually typing or selecting from a drop box the lot number and expiration date. The “Data Entry” step refers to the steps that are performed for both processes—such as typing or drop down selection of manufacturer, input location, etc. The WFA consultant wanted to single out the steps that are directly comparable to measure the differences for the two processes: linear vs. 2D.

Inventory Process

Please refer to description provided for Practice 2091.

Data Entry Process & Time Measurements

This practice uses one of the few EMRs that are 2D barcode enabled, as such upon scanning a 2D barcode the information encoded on the barcode (lot number, expiration date, and product identifier) are entered into the record along with several other data elements specific to the vaccine scanned.

The typical process used for recording data about vaccine inventory includes:

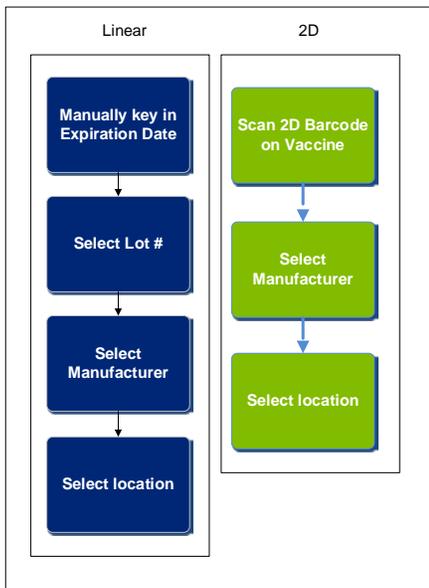
- Log in to EMR
- Type an “R” into the Transaction Type field to indicate the vaccine is from ‘Receiving’
- For linear barcoded vaccines...
 - Type in the practice name for the destination location and enter the lot number
 - Select manufacturer from a drop down menu.
 - Type the expiration date, amount of units and NDC
- For 2D barcode scan...
 - Press “scan” icon on the screen
 - Scan 2D barcoded vaccine – populates the expiration date and lot number; if the date is ever entered incorrectly, the date must be selected from the calendar view to continue. She will then type in the amount of units and NDC.

- The EMR links the vaccine information entered during inventory to pull vaccine information such as lot number, vaccine name, and NDC from input during the inventory scanning process. This is used to populate the drop down menus. If the lot number is already in the system, it will populate everything except for the units.

To record data about vaccines administered the nurse...

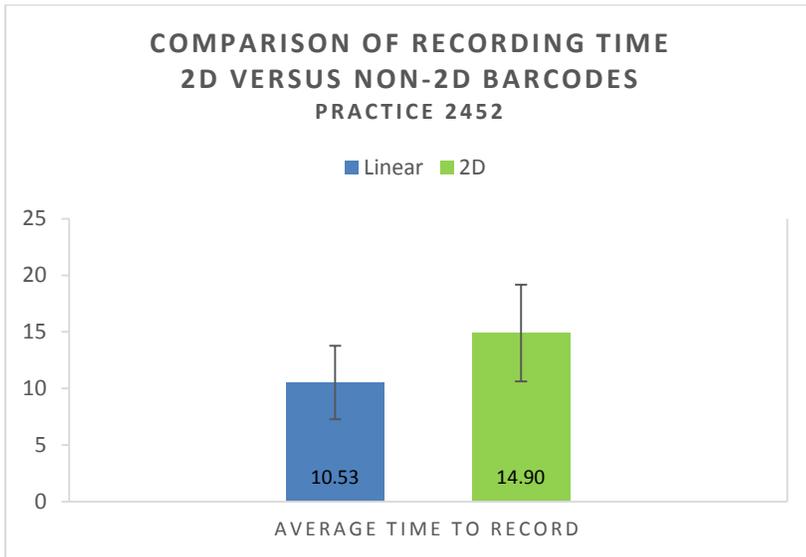
- Logs into EMR
- For linear barcoded vaccines...
 - Select lot number, expiration date, manufacturer, vaccine location from drop down menus that are pre-populated from the inventory process.
- For 2D barcode scan...
 - Presses the 'scan' button icon on the screen
 - Scans a single 2D barcoded vaccine – which inputs the lot number and expiration date. The vaccine name is pulled from when the vaccines were previously ordered, and the manufacturer and location is selected with drop down menus that are pre-populated from the inventory input.
 - Repeat above process for each 2D barcoded vaccine administered
 - After data for all vaccines has been entered the information is saved

Figure C-29. Vaccine Administration data capture process



Please refer to Practice 2091 case for information regarding the process used for entering vaccine inventory data.

Figure C-30. Time to record vaccine administration data by barcode type



Other Observations

Two main challenges staff at this practice consistently reported include – (1) having to press “scan” before scanning the 2D barcode on each vaccine and (2) a system freezing issue when using 2D barcode scanners. In order for the EMR to read the 2D barcode, the nurse had to press the “scan” button before each vaccine was scanned. Staff indicated that this added a step to the data recording process and noted that it would greatly increase the time of the process even if the “scan” button only had to be pressed once (not before each vaccine).

Perhaps the most pressing complaint from staff was that the scanners cause the system to freeze intermittently. If nothing was recognized by the scanner within a time frame (approximately 30 seconds), the system would freeze which requires the user to go into Task Manager (or hit CTRL+ALT+Delete), close the program, and then restart. During this process any previously entered vaccine data is lost. Inventory interview suggested that one out of four generally scans on the first try. This freezing issue occurs when recording data about vaccine inventory and vaccine administrations. Such issues may have been particularly frustrating for this location, since staff noted that they are able to enter information manually very quickly into the EMR—the WFA consultant observed data entry times as quick as 6 seconds for recording linear barcoded vaccines.

“I can definitely see the potential in the barcodes, and I think it is an excellent idea in theory. I’m not sure if it is the scanners or our computer system, but the execution currently is not ideal. I can see this being something really great in the future once the kinks get worked out, the 2D barcode holds more information and the system stops freezing. The lot numbers are really small and hard to read, so I like that it takes away the risk of keying it in wrong.”

The staff in this practice were focused on making the 2D barcode scanners work consistently—they indicated that the 2D barcode scanners seem very “sensitive” and/or “picky” because the nurses have to hold it exactly right for the barcodes to pick up. Staff tried multiple approaches to increase the probability of the barcodes scanning on the first try. In an effort to ensure appropriate alignment of the 2D barcode scanners they have used the following techniques: duct taped the scanner to a desk so that it maintains a consistent orientation and located a scanner so it aligns with a solid surface instead of a desktop (the desktop has a wood grain pattern on it and the scanners try to pick up that surface).

“I have it aimed towards my sharps container because it is solid. I find that when it is against this textured desk it is always flickering, the light is very wide, and I can scan when it is like that. I tried moving it, so it would be more conducive but I was having problems so I just found that it being up against something solid makes it happier as you might like to say.”

“I have to put it down so it is half on the table and half on a stack of copier paper and then I run it up along the side of the wall. If I move the scanner just a little bit then I sometimes will have a harder time scanning it. A lot of people will do it up against here (the side of the computer) or up against the wall. Once you find your position, then it is great. If someone moves it then it is like “oh my god”—if we had a bigger area that we can just go “boom” and it scans, that would be fantastic. It is kind of a narrow margin.”

Staff also made some observations about specific vaccines. For instance, they singled out Flu-T as the 2D barcoded vaccine that worked best with the scanner. In at least two interviews the following vaccines were identified as consistently having 2D barcodes: Pediarix, DTap, Flu, HepA. They also noted that removing the labels from syringes tended to make it easier to scan the 2D barcode. Practitioners felt that the difficulty scanning was related to the curvature of the syringes.

Practice ID: 2508

Practice Attributes		
	Practice Type	Family Practice
	Practice Size (# of physicians)	6 to 15
	EMR System	Vendor A
	Estimated 2D vaccine administration volume	1613-Medium
	Estimated % public vaccines	100%
	Process observed	Administration

Overall Workflow Process

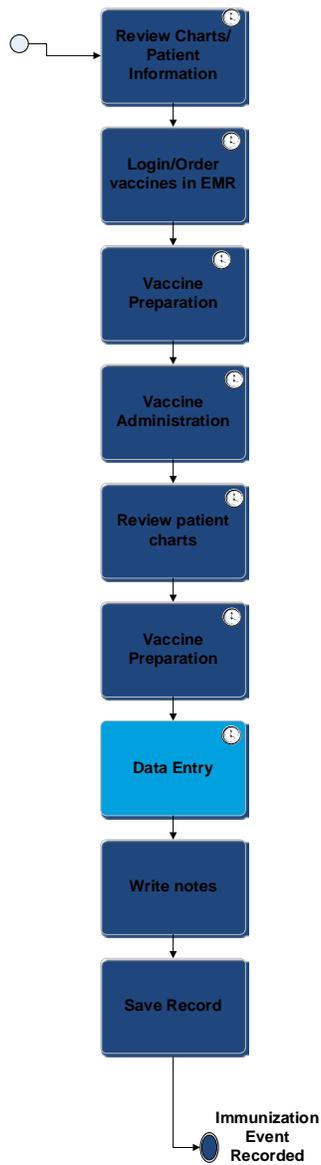
Practice 2508 is a multi-purpose practice (family practice, walk-in clinic, emergency care, and pediatrics were all in the same building). The practice comprises three floors, on which there are nurses seeing patients. Nurses working on the first floor were selected for observations since this is where the majority of vaccines are administered in the practice (i.e., many appointments for newborns). Nurses working on the second floor were also interviewed for the WFA, but were not observed during vaccine administration.

There are four nurse's stations located on the first floor—each station has a 2D barcode scanner and a desktop computer. The station is at the entry of the patient care area and there are eight patient rooms surrounding the nurse station area. There are five workstations on the second floor with barcode scanners, but only two stations had scanners. Responses to the initial requests for information about the practice during recruitment indicated that the facility used the scanners for inventory, however, while visiting the practice the WFA consultant was informed that that recording vaccine inventory with 2D barcode scanners was not part of the normal procedures.

Vaccine administration procedures varied greatly between nurses at this practice. There were two aspects of the process that always occurred—(1) a physician always visited the patient before the nurse and subsequently informed the nurse about what vaccine(s) to administer and (2) the nurses always entered vaccine data after administration. Four different nurses were observed for the WFA. Two of the nurses used the 2D barcode scanners on a regular basis, one noted that she used the scanner sometimes, and the other said she never used the scanners but tried it since it was part of the WFA to observe.

The vaccine administration process began with the nurse reviewing the patient chart and patient information. The nurse then orders the vaccine(s); nurses used a container to carry vaccines into the patient room and the vaccines are labeled and separated into different standardized portions of the container to help with confusion and entering data. After she prepares the vaccines, administers the vaccines in the patient area, she walks back to nurse's station to pull up patient chart in the EMR, enters the vaccine information including the date with notes, and saves the record. Nurses are required to order the vaccines from inventory before entering data about them into the system—some nurses order the vaccines before administration and some do it at the same time as inputting the information.

Figure C-31. Overall administration process



The average time to perform all steps in the process depicted in Figure C-31 was 256.58 seconds (SD=178.61). The longest step in the process on average was vaccine administration whereas the shortest step was data entry. Table C-11 provides the average length of time for each step as well as the standard deviation associated with each of these steps.

Table C-11. Average time to perform key steps* in vaccine administration workflow

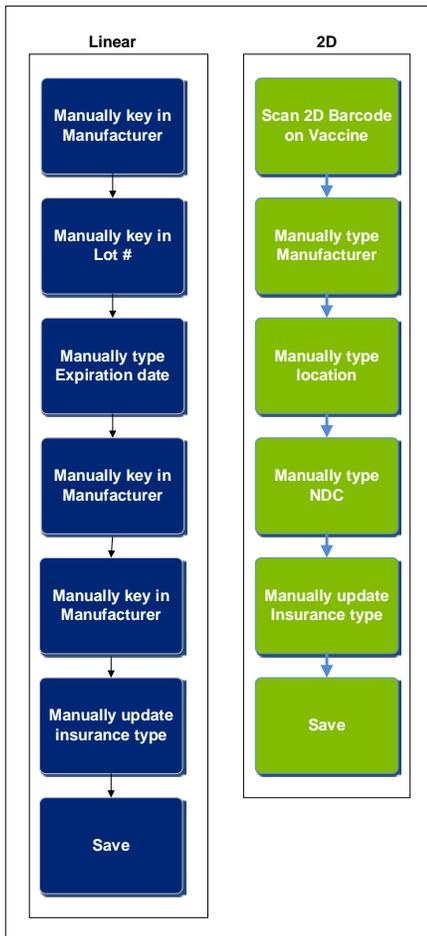
	Observations	Mean	Standard Deviation
2D	10	42.19	22.67395
Chart Review	7	45.24	37.38789
Data Entry	7	26.50	27.29573
Linear	16	42.07	26.66739
Login	29	70.16	190.5879
Vaccine Admin	5	248.59	304.3082
Patient counseling	6	84.14	156.2082

*The “2D input” step in this chart refers to the specific time it took to perform the steps specific only to 2D scanning: picking up the scanner, scanning the barcode for lot # and expiration date, and pressing the ‘scan’ button when necessary. The “linear input” steps refer to the specific steps that would be performed in the traditional method instead of the 2D scanning process—so either manually typing or selecting from a drop box the lot number and expiration date. The “Data Entry” step refers to the steps that are performed for both processes—such as typing or drop down selection of manufacturer, input location, etc. The WFA consultant wanted to single out the steps that are directly comparable to measure the differences for the two processes: linear vs. 2D.

Data Entry Process & Time Measurements

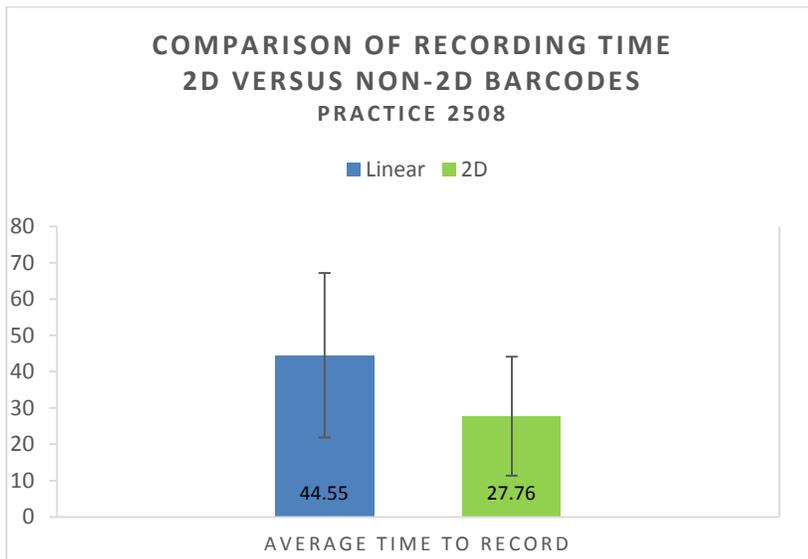
As previously noted, this practice uses Vendor A EMR. The configuration of this practice’s EMR required the nurses to manually type all data about vaccines as there are no drop down menus included in this system. Data about vaccines was always entered after administration and in the case of linear barcoded vaccines consisted of manually typing the vaccine manufacturer, lot number (2D scans would capture), expiration date (2D scans would capture), the NDC number, input practice, and insurance information. When scanning in a 2D barcoded vaccine the only difference was that lot number and expiration date were scanned into the system nurses entered all other data manually. After entering all of the data, the nurse saved the record once all vaccines were entered.

Figure C-32. Vaccine Administration data capture process



The WFA consultant recorded 63 time measurements of the vaccine administration data entry process at this practice for the 4 individuals observed. Thirty-one time measurements were taken for data entry using 2D barcode scanners and 32 measurements were recorded for linear barcoded vaccines. On average, it took 16.79 fewer seconds for nurses to enter vaccine administration data using 2D barcode scanners (Mean =27.76, SD =16.39) than it did for them to enter data from vaccines with a linear barcode (Mean = 44.55, SD=22.66).

Figure C-33. Time to record vaccine administration data by barcode type



Other observations

This practice does not have formal policies requiring the use of 2D barcode scanners to record vaccine data. Additionally, nurses expressed that they were not generally informed about the scanners. Some of the newer employees did not seem aware that it was an option to use 2D barcode scanners.

One of the nurses noted that she used the 2D barcode scanner as a paper weight, because it only scans in the lot number and expiration date and does not scan in the National Drug Code (NDC) number. The NDC number is lengthy and nurses in this practice are required to type it into the system manually. Another nurse noted that she would get frustrated with process if the scanner did not read information right away and would switch to manually typing.

It should be noted that patient flow was somewhat slower than normal during the days of the WFA visit. However, the WFA consultant was able to get permission to conduct mock scans and worked with the nurses to perform these to increase the number of observations.

Practice ID: 2510

Practice Attributes		
	Practice Type	Pediatrics
	Practice Size (# of physicians)	16 or more
	EMR System	Vendor A
	Estimated 2D vaccine administration volume	938 - Medium
	Estimated % public vaccines	100%
	Process observed	Administration

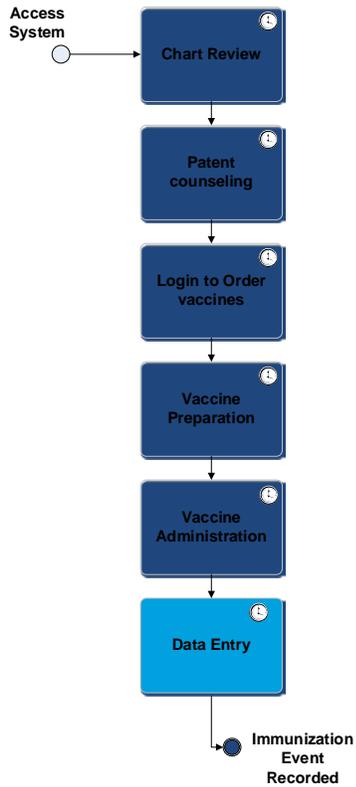
Overall Workflow Processes

Practice 2510 has five nursing stations. These stations are adjacent to each other and situated across from the work rooms. Each nursing station is equipped with a 2D barcode scanner. There is also a scanner set up in the Nursing Manager's office attached to her computer. Only four out of the six 2D barcode scanners worked at the time of observations—staff placed post-it notes on the scanners that are not operable.

Five nurses use the 2D barcode scanners in this practice, three of these nurses were observed for the WFA. The three nurses were chosen based on schedule. The vaccine administration process²⁹ in this practice started with the physician handing the nurse the patient information chart after visiting the patient and informing the nurse as to which vaccine(s) need to be administered. The nurse then walked from the nursing station (located outside of the exam room) to the refrigeration room/preparation station to prepare the vaccine(s). Subsequently, the nurse walked back to the exam room and administered the vaccine(s). Following the vaccine administration, the nurse logged into the EMR on the computer located at the nursing station, reviewed the patient's information and entered data about the vaccines administered. Whether nurses elected to use the 2D barcode scanner on a regular basis depended on whether there was a working 2D barcode scanner at the nursing station where they were working. Nurses always entered vaccine data after administration.

²⁹ Due to office policies, the WFA consultant was unable to observe activities in the patient area or able to be present during patient interactions. Observations were therefore limited to what took place at the nurses' station. The time measured as 'Vaccine Prep' is assumed as the entire time in preparation area, and 'Vaccine Administration' for the entire time in the room with the patient.

Figure C-34. Overall vaccine administration process



The average time to perform all steps in the process depicted in Figure C-34 was 185.91 seconds (SD=117.77). The longest step in the process on average was vaccine administration whereas the shortest step was logging in. Table C-12 provides the average length of time for each step as well as the standard deviation associated with each of these steps.

Table C-12. Average time to perform key steps* in vaccine administration workflow

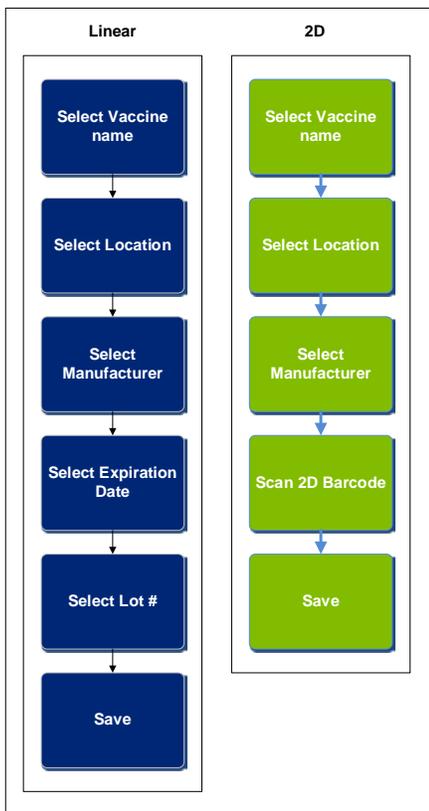
	Observations	Mean	Standard Deviation
2D input	1	19.28	
Chart Review	8	24.03	34.08
Data Entry	3	22.48	15.83
Linear input	8	27.49	12.25
Login	7	7.01	5.79
Vaccine Admin	4	208.68	296.62
Patient Counseling	1	3.58	
Waste Disposal	1	12.14	
Vaccine Prep	3	167.54	74.54
Walking	3	8.48	2.44

*The “2D input” step in this chart refers to the specific time it took to perform the steps specific only to 2D scanning: picking up the scanner, scanning the barcode for lot # and expiration date, and pressing the ‘scan’ button when necessary. The “linear input” steps refer to the specific steps that would be performed in the traditional method instead of the 2D scanning process—so either manually typing or selecting from a drop box the lot number and expiration date. The “Data Entry” step refers to the steps that are performed for both processes—such as typing or drop down selection of manufacturer, input location, etc. The WFA consultant wanted to single out the steps that are directly comparable to measure the differences for the two processes: linear vs. 2D.

Data Entry Process & Time Measurements

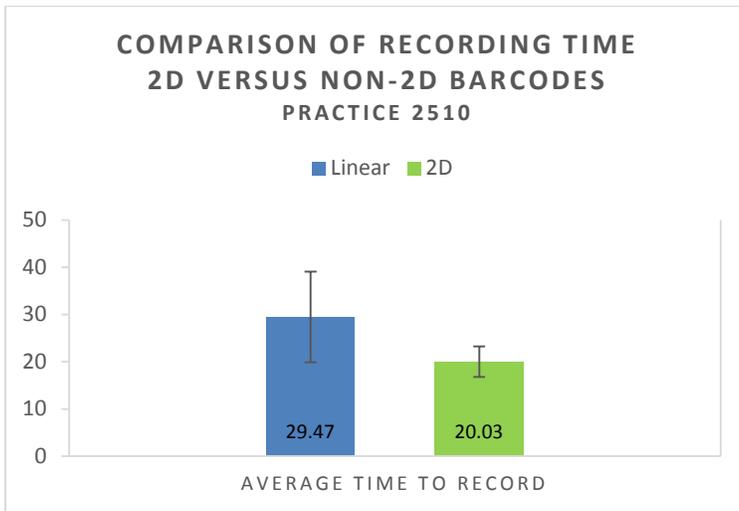
For vaccines with a linear barcode, the nurse enters the following data using drop down menus and then saves the record—vaccine name, input location, manufacturer, expiration date, and lot number. Minimal differences exist between entering data for linear barcoded vaccines and 2D barcoded vaccines. When entering data for 2D barcoded vaccines, the nurse picks up the barcode scanner after they select the manufacturer from the drop down menu. They then scan the barcode which populates the expiration date and lot number. All other data entry fields are selected from the respective drop down menus and the record is saved after each vaccine entry.

Figure C-35. Vaccine administration data capture process



The WFA consultant recorded 16 time measurements of the vaccine administration data entry process at this practice for the 3 individuals observed. Four time measurements were taken for data entry using 2D barcode scanners and 12 measurements were recorded for linear barcoded vaccines. On average, it took 9.44 seconds less seconds for nurses to enter vaccine administration data using 2D barcode scanners (Mean =20.03, SD =3.22) than it did for them to enter data from vaccines with a linear barcode (Mean = 29.47, SD=9.57).

Figure C-36. Time to record vaccine administration data by barcode type



Other observations

Both nurses who the WFA consultant interviewed during the visited mentioned accuracy as the biggest benefit of using the 2D barcode scanners. However, some challenges to using the scanners were noted. As already mentioned, some of the scanners at this practice were inoperable. For those scanners that did work, at least one nurse noted that sometimes the scanners work, and sometimes they don't. One nurse specifically stated, "Sometimes you are able to scan and sometimes the scanner doesn't work and by the time you get it to scan you could have entered the numbers in, you know, in less time."

Another challenge noted by one of the nurses related to multi-dose vials. The nurse mentioned that the polio and influenza (for children 3 and over) are multi-component vials and they cannot scan both vials into the EMR. As a result they have to type at least one of the numbers into the EMR. She noted they are unable to keep an empty vial on the desk for reference because the lot number may have changed. The nurse suggested that there should be a way to copy the barcode, or have labels on the boxes that can be used to scan for the multi-vials.

It should be noted that the time spent performing observations was truncated at this practice due to logistical issues in gaining access to practice processes.