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Joseph F. Durbin

SECONDARY DATA ANALYSIS OF THE TWO-DIMENSIONAL (2D) BARCODING VACCINE PILOT STUDY

BY

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Secondary Data Analysis of the Two-Dimensional (2D) Barcoding Vaccine Pilot Study

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An abstract of
A Thesis submitted to the Faculty of the
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2014

Abstract

Secondary Data Analysis
of the Two-Dimensional (2D)
Barcoding Vaccine Pilot Study

BY

Joseph F. Durbin

2D barcoding use for vaccination administration in the U.S. health delivery system has gained gradual recognition as a viable way to improve completeness and accuracy of immunization records. Recording vaccination data has been a requirement since the passage of the National Childhood Vaccine Injury Act of 1986. Historically, records have had sub-optimal results with only 60% of reported vaccinations in Immunization Information Systems (IIS) having complete lot numbers.

This thesis project performed a secondary data analysis on data from the CDC/Deloitte Consulting 2011-2012 Implementation Pilot for Two-Dimensional (2D) Vaccine Barcode Utilization. The pilot provided 2D scanners to 217 public, private, and pharmacy immunizers to evaluate the impact of 2D barcoding on electronic medical records (EMR) and IIS records.

This thesis project cleaned, standardized, and analyzed two separate de-identified datasets – EMR and IIS – with 1,346,837 and 1,687,366 vaccination records respectively. The results of the analysis of pre- versus post-implementation of 2D scanning in EMR data showed 1) increases in average completeness -- 4.2% in lot number data (93.3% versus 97.5%); 9.9% in expiration

dates (86.0% versus 95.9%)-- and increases in average accuracy – 5.2% in lot numbers (91.0% versus 96.2%), and a 12.8% in expiration date (79.8% versus 92.5%); 2) the public practices had greater data quality than private sites (i.e., 3.2% and 6.4% greater completeness for lot number and expiration dates respectively; and 4.7% and 12.6% greater accuracy for lot number and expiration results respectively); and 3) the private practices had greater improvement of completeness and accuracy from pre- to post-implementation than the public sites indicating that private sites may have more room for improvement.

The impact of a fully integrated EMR with 2D barcoding if expanded out to the entire U.S. population could translate into millions of more complete and accurate vaccination records. For example of the 19.2 million vaccinated children < 6, there could be 2,457,600 more with accurate expiration dates. Patient safety could benefit from 2D barcoding by improving consistency with the Vaccine Adverse Event Reporting System (VAERS), reducing errors to free up more time for patient care, and contributing to greater accuracy in the event of vaccine safety recalls.

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Most importantly, I owe my deepest gratitude to my wife Jean for being my rock of encouragement. Your work and passion inspire me and I hope that my mark on the public health landscape is a sliver of yours. Thank you for supporting me to meet the target, holding down the fort, giving me sage advice, and loving me through the end.

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Chapter 1 - Introduction

1.1. Introduction and rationale

Context

Although there have been concerns about vaccine safety associated with smallpox vaccine during the early 19th century(Severyn, 1995), the modern history of vaccine fears about safety dates back to the late-1970's and early 1980's. During the early 1980's controversy about the alleged role of whole cell pertussis vaccine, administered to infants and young children along with diphtheria and tetanus toxoids (DTP), in causing brain damage led to an exponential increase in law suits filed against vaccine manufacturers. Some of the allegations related to beliefs there were "hot lots" of vaccine which caused higher rates of reactions than other lots. Although subsequent reviews by the Institute of Medicine (IOM) did not support a role for DTP in brain damage, parental concerns about vaccine-caused adverse events led to passage of the National Childhood Vaccine Injury Act of 1986 to compensate families of children injured by vaccines (Freed, Katz, & Clark, 1996). In addition, for vaccines in the Vaccine Injury Table, the Act required healthcare providers to record each vaccination administered to any person in order to be able to identify accurately the lot number, type, and presentation ("National Childhood Vaccine Injury Act," 1986). Although the Centers for Disease Control and Prevention (CDC) has not documented that there has been any causal associations between adverse events related to specific lots of vaccines, it is still very important to be able to track administration of vaccines

accurately and completely[1] (2011).since this problem could occur in the future (Centers for Disease Control and Prevention, 2011).

Background

The U.S. Food and Drug Administration (FDA) has regulatory authority over all vaccines produced and distributed in the United States including labeling specification of individual vaccines (U.S. Food and Drug Administration, 2012).

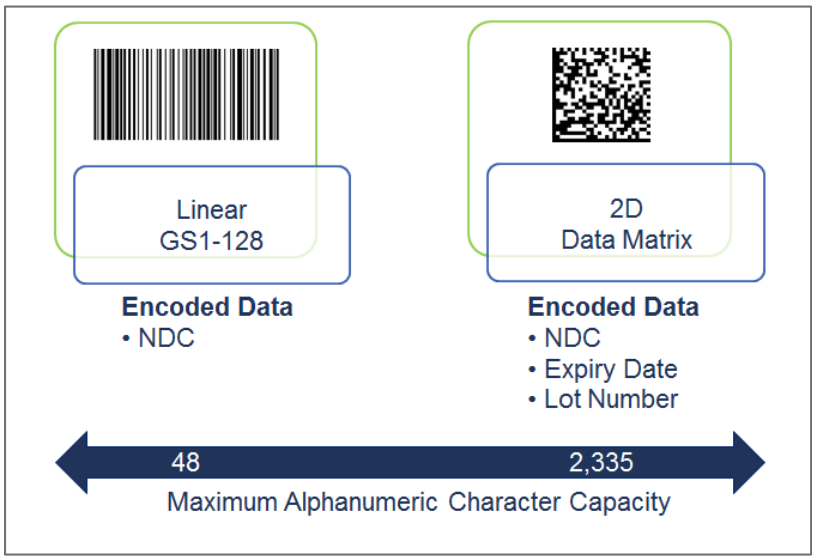

Figure 1. Differences in size and contents between linear and data matrix barcodes (Gerlach & Robinson, 2014).

Until 2011, only linear (1-dimensional) barcodes were used and mandated on all vaccines in the U.S. (U.S. Food and Drug Administration, 2011). This type of barcode only contained a small amount of the information that needed to be recorded in patients' charts when administering the vaccine (i.e., the National Drug Code). [2] Two-dimensional (2D) data matrix barcode technology

[1] For the 2D Vaccine Barcode Pilot and this thesis project, completeness and accuracy of data are defined as follows: Data (i.e., either lot # or expiration date variable/field) is complete when the vaccine record is not blank. Data is accurate when 1) the data element is complete and, 2) it matches a predetermined reference dataset. More details will be provided in Section 3.3, Procedures in the Methods section.

[2] GS1 is the non-for-profit organization that coordinates the barcoding standards for several industries. GS1-128 refers to the standard kind of data and data format that vaccine manufacturers have adopted; this standard has both linear and 2D barcode symbologies (GS1 US, 2014). The National Drug Code (NDC) is a unique identifying

(think small squares similar to those read by QR readers of smartphones) is now available that provides significantly more information in machine-readable format than the traditional linear barcodes (think UPC labels at the grocery store) in a smaller amount of space (Deloitte Corporation, 2013). For vaccines, this additional information provides the lot number and expiration date in machine readable format allowing for more reliable recording and storage of information for potential safety recalls. See Figure 1 above for a graphical depiction of 1D versus 2D barcodes (graphics courtesy of CDC).

Until the passage of a rule change in August 2011, only the linear 1D barcode was allowed on the vaccine product label (U.S. Food and Drug Administration, 2011). Some stakeholders in the immunization community made a strong push to allow and promote 2D barcoding usage for vaccinations. The American Academy of Pediatrics (AAP) released a guideline for practitioners for 2D barcoding (American Academy of Pediatrics, 2011) citing the benefits of use of 2D barcodes:

- Patient Safety can be improved by ensuring checks and balances of proper vaccines. By replacing manual record-keeping with electronic records enhanced by 2D technology, practices can reduce the chances of incorrect administration errors or duplicate vaccinations.
- Practice efficiency can be increased with electronic systems enhanced by 2D barcoding. Accurate inventory records and controls can be used for just-in-time inventories reducing potential waste. 2D barcoding can reduce documentation time.

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number assigned by the Food and Drug Administration (FDA) that specifies a manufacturer's brand and presentation of a pharmaceutical product including but not limited to vaccines (Fierro et al., 2014).

More accurate electronic records could help decrease missed billings. Vaccines for Children program reporting could be made easier through the development of a more accurate lot number control system.

- Integrated electronic systems can potentially reduce duplicate data entry.

The Public Health Agency of Canada (PHAC) made recommendations in 2010 to use 2D data matrix barcodes to increase accuracy and completeness of immunization data in their registries (Public Health Agency of Canada, 2010).

A study out of Canada showed the effectiveness and acceptance of 2D barcode readers by users during an influenza pilot test. Efficiency, defined as time taken to enter the data, was better than using the manual-entry paper, but not as fast as electronic drop-down entry[3]. User perceptions regarding barcode scanners were mostly favorable, but 61% of persons with systems that used drop-down menu technology did not see the benefit of 2D barcode scanners (Pereira, et al., 2012).

Known relationships between barcoding and Electronic Medical Record (EMR) usage

A Taiwan study compared nurses using a paper-based medication record system to those using a barcode medication administration system. The results showed that use of barcode medication technology allowed nurses to spend more time with patients instead of time spent on

[3] Some electronic systems have the ability to present choices of data via a drop-menu menu that can be selected with mouse clicks instead of manually entering (or scanning) the information. For example, in an EMR an immunizer may populate vaccination administration from a menu list of lot numbers that were previously entered during inventory.

medication documentation, activities (HUANG & LEE, 2011). In 2011 – 2012 Research Triangle Institute (RTI) performed a study for CDC to gauge the engagement, knowledge, attitudes, and beliefs of the immunization stakeholder community about the impacts of 2D barcoding on the manufacturing and clinical administration of vaccines. RTI performed semi-structured targeted interviews and surveyed immunizer practices. The surveyed primary care providers indicated that the most important factors in the acceptance and adoption of the 2D scanner technology included increased accuracy of records and efficiency gains in the recording/documentation process. The RTI study also found that the most common technical support needed was training on how to use the software, helping to integrate the scanner information into EMR's, and determining how best to select and install 2D scanners. At least 84% of the surveyed physician offices had plans to implement an EMR by the end of 2015 (RTI International for CDC, 2012). Using an electronic system (e.g., an EMR or Immunization Information System (IIS)) is necessary for 2D barcode usage. With the rapid adoption of EMR's in the immunizer community, the environment is ready for 2D barcode usage.

Implementation Pilot for 2D Vaccine Barcode Utilization

In 2011, CDC contracted with Deloitte Consulting [4] to manage the logistics of an *Implementation Pilot for 2D Vaccine Barcode Utilization*. This pilot recruited the following stakeholders to participate in the pilot: two vaccine manufacturers that were placing 2D barcodes

[4] For disclosure, Joseph Durbin actively participated in the 2D Vaccine Barcode Pilot with its project inception, scanner installation, training, data collection of some sites, and post-pilot collaboration. Mr. Durbin did not perform any post-pilot data analysis for the CDC contract.

directly on the vials; 10 immunization grantees (i.e., nine states and one city[5]) to provide IIS data; and, 241 participating immunizing practices[6]. Prior to the pilot, none of the practices were using 2D barcoding technology. In conducting the pilot, the Deloitte team of staff (hereafter called the "pilot team") provided all the practices with 2D scanners, training on how to use them, and continuing installation/implementation support as an intervention to evaluate and assess the extent to which 2D barcode scanning positively or negatively affected the data quality of vaccine records (i.e., lot number, expiration date, and product identifier) of the practice EMR and immunization grantee IIS. Data were collected from each practice pre- and post-implementation as well as on 2D barcoded and non-2D barcoded vaccines during the pilot (Fierro et al., 2014). These data were the basis of this thesis project.

1.2. Problem statement

Documenting vaccine administration has been mandated since the passage of the National Childhood Vaccine Injury Act of 1986 ("National Childhood Vaccine Injury Act," 1986). However, without the ability to read vaccine data directly in a machine readable way, the required information (i.e., lot number and product information) must be entered by hand and the records, therefore, are potentially prone to errors (Institute of Medicine, 2000). Historically, according to the Vaccine Adverse Event Reporting System (VAERS) (managed by the CDC) data, up to 20% of vaccinations have incomplete information (Centers for Disease Control and

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[5] These included Alaska, Florida, Iowa, Michigan, New Jersey, New York, New York City, Oregon, Washington, and Wyoming.

[6] Of the 241 practices that agreed to start the pilot, only 217 actually participated. Five of these dropped out before completing the pilot. See Chapter 3 – Methodology – for selection criteria.

Prevention, 2013). Additionally, up to 45% of Immunization Information System (IIS) lot number data are incomplete (Cardemil, Pabst, & Gerlach, 2013). Although the reasons for the incomplete VAERS and IIS records is not known, adding 2D barcoding into electronic systems should strengthen the quality of data making the reported immunization records more complete. Accuracy of immunization records has also been a historical issue. A UCLA study found that at least 10% of vaccine records had inaccurate data(Wilton & Pennisi, 1994). Another study of the MEDMARX database showed that of all immunization errors 10% were related to "transcribing/documenting" errors (Bundy, Shore, Morlock, & Miller, 2009). Scanning 2D barcodes directly into the patient record or other electronic system offers a potential solution to this problem by cutting out some of the human error part of vaccine administration documentation into the EMR or IIS. This thesis will analyze available data from the 2D Vaccine Barcode Pilot to establish if there is a measured difference between 2D and non-2D vaccination records and if differences exist between private provider and public clinic sites.

1.3. Theoretical Framework

Key Concepts of 2D Barcoding for Vaccinations

There are several barriers to adoption and utilization of the 2D Barcode technology. A summary is outlined below in *Table 1*.

Some of the barriers to the adoption 2D barcode scanning within vaccine immunizers include:

- Cost of investing in the barcode scanners and integrating into new or existing systems.
- Limitations on the number of vaccines with 2D barcodes available to practices (i.e., few types and limited quantities) (Gaddis, 2013).

- Having EMR issues preventing 2D integration (e.g., incompatibilities with barcode scanners, or no dedicated fields for lot number or expiration date), not having an electronic system to record data, or not having proper technical support or technical knowledge to integrate 2D barcoding with their systems (O'Connor et al., 2012).
- Training requirements for clinical and technical staff (O'Connor et al., 2012).
- Needing a different process for legacy (i.e., linear 1D barcoded) or non-barcoded vaccines (Laroche & Diniz, 2012).
- Using alternative technology such as drop-down menu use for populating vaccine information (Pereira, et al., 2012).

Some of the facilitators to adoption of 2D barcoding technologies include:

- The drive for greater data quality, patient safety, and quality of care (Douglas & Larrabee, 2003).
- Full integration of 2D barcoding with the practice EMR system. This would provide better data within the EMR and would provide a better user experience by easing or consolidating some of the steps in the documentation process (Deloitte Corporation, 2014).
- Efficiency of saving time if the practice is using an EMR system that has full integration of 2D barcoding (Deloitte Corporation, 2014).

Table 1. Summary of Facilitators and Barriers for Full Utilization of 2D Barcode Technology for Vaccinations

Facilitators	Barriers
• Quest for Greater Patient Quality • Quest for Greater Patient Safety • Quest for Better EMR Data & EMR User Experience • Quest for Time Saving Efficiency	• Cost • Limited 2D Vaccines • EMR Compatibility • Training burden • Different processes for Linear & 2D • Alternative Technology/Solution

1.4. Purpose statement

The purpose of this thesis is to determine the level of accuracy and completeness[7] of immunization records from the data collected during the 2D Vaccine Barcode Pilot. The primary aim is to show if a correlation exists between usage of the 2D technology and higher data quality. A secondary aim is to show if the clinical delivery venue (i.e., public versus private) was associated with a difference in the results of data quality of 2D or non-2D vaccination records.

1.5. Research questions

Question 1 - Use of 2D Technology

Question: Of the participating 2D Vaccine Barcode Pilot clinics, do the vaccinations given using 2D technology have a higher level of accuracy and completeness than those not using the technology?

[7] Complete is when the data element was present in data; Accurate is when data element was complete and matched the reference table. See the definition of terms (Section 1.7) and methodology (Section 3.3) for details.

Hypothesis: The level of accuracy and completeness of the vaccination records using 2D technology will have a higher level of accuracy and completeness than those vaccinations recorded without the technology.

Question 2 - Public versus Private Clinic Delivery Site

Question: Of the data collected during the Pilot, is there a higher level of accuracy and completeness in those vaccines that were delivered in a public clinic site (i.e., those clinics such as public health departments or Federally Qualified Health Centers (FQHC)) compared to those administered from private clinics?

Hypothesis: The records from public delivery sites will have a greater level of accuracy and completeness than private delivery sites.

1.6. Significance statement

This analysis will give insight into the potential level of improvement in recording of data by integrating 2D Barcoding Technology into clinics' electronic medical records. By showing the use of the technology improves data quality in medical records, FDA, CDC, State and Local Health Departments, AAP, American Immunization Registry Association (AIRA), American Medical Informatics Association (AMIA), and other health organizations could potentially endorse and promote the use of the technology by clinicians and immunizers. If proven successful, the use of 2D barcoding could improve overall data quality, and improve consistency in information gathered in VAERS reports and IIS records (Kennedy, 2013). Increasing accuracy and consistency in records from the onset of vaccination administration documentation could lead to less administrative time resulting in less time spent fixing errors, ultimately saving immunizers time and money (O'Connor et al., 2013). More importantly, the utilization of 2D barcode technology for vaccinations could facilitate greater accuracy in adverse event

monitoring in VAERS by automatically including lot number and expiry information in records. Likewise, in the event of a safety-related vaccine recall, 2D barcoding could facilitate greater accuracy in the FDA's program of vaccine safety monitoring (Iskander, Miller, & Chen, 2004).

1.7. Definition of terms

2D – The term Two Dimensional (2D) refers to the data matrix barcoding symbology (i.e., the system and arrangement standard of symbols for barcoding) that is used to place the encoded lot number, product identifier, and expiration date encoded as a barcode directly on the vial or syringe.

Accuracy – For this thesis project, accuracy is a data quality measure of the pilot vaccinations. An accurate data element (i.e., either lot number or expiration date) of a record must be complete (see below) and match a value in the reference dataset. Note, in the Deloitte 2D Vaccine Pilot, the variable was called "Accurate & Complete." See Section 3.3 for a full definition.

Completeness – For this thesis project, completeness is a data quality measure of the pilot vaccinations. Being complete for a data element is defined as data not being missing. If a particular field was systematically not recorded or reported for all cases (i.e., the field was always missing for that practice), the record was excluded before being analyzed to determine completeness.

EMR – Electronic Medical Records are used by providers as electronic patient records. For this thesis, EMR will be used for either an Electronic Medical Record or an Electronic Health Record (EHR). Although the two terms are often used interchangeably, EMR's are the digital version of patient charts that are kept in the physician's office. EHR's, a newer concept

than EMR's, are designed to capture all of the same data as an EMR but goes beyond that. EHR's are designed to be transportable and move with the patient (Garrett, 2011).

IIS – Immunization Information System. These are the electronic immunization registries run by the 64 state, city, or jurisdiction grantees of the Section 317 Grant. IIS collect all vaccination records within that particular jurisdiction. For this thesis only ten IIS's participated.

Provider – These were both public, private, and commercial (i.e., pharmacy) practices that administered vaccinations during the pilot.

Public – The delivery site of the vaccines were either "public" or "private" referring to the affiliation of the health care provider administering the vaccine. A public practice was either a health department or clinic such as a Federally Qualified Health Center (FQHC) that obtained the majority of its operating funds from governmental or public sources. Private practices were for-profit, not-for-profit, or commercial (i.e., pharmacy) entities.

Chapter 2 – Review of Literature

2.1. Introduction

This chapter will review the relevant literature surrounding 2D barcoding for vaccines and immunizations. The review of literature will show the previous studies that point to the need for a greater level of accuracy and completeness of records among immunizations. And, this review will give a history of events, studies, and occurrences that led to the need for the 2D Vaccine Barcode Pilot upon which this thesis is based.

2.2. Need for More Accurate and Complete Vaccine Records

The National Childhood Vaccine Injury Act of 1986 was a comprehensive law that outlined remedies and compensation for injuries and deaths associated with vaccines through the National Vaccine Injury Compensation Program.-This act has also required that all health care providers administering immunizations record the vaccine manufacturer and lot number of each vaccine and ensure proper recording and storing in each patient's medical record. This act and corresponding task force for safer childhood vaccines put emphasis on the need for accurate recording of immunization records.

A study performed at UCLA's Children's Health Center looked at 4040 patient encounters (2098 patient records) to evaluate the accuracy of the immunization records transcribed into the computer-based tracking system. The records of the children whose immunizations were determined to be not up to date were transcribed from hand-written charts to electronic records (n=458). These transcribed records were analyzed to determine the level of accuracy and completeness of the electronic records compared to the original hand-written records. The results showed a transcription error rate of at least 10.2% (214 of 2098 records had

at least one error) (Wilton & Pennisi, 1994). The significance of this study showed that hand-entry alone of data into computer systems can be greatly flawed.

Ortega and colleagues performed a population-based study looking at vaccination data comparing parental vaccination cards to a computer-based immunization registry record system in Delaware. They analyzed the records of children born between 1991 and 1993 and created a gold standard "composite" dataset for the group by combining the data from the registry with information from the immunization records. They found that 59.8% of the two sets of data were in agreement with each other. The computer system was 78.1% sensitive (i.e., predictive of the composite) to the gold standard composite dataset opposed to the parental records being only 54.9% sensitive. The researchers found that the "results indicate that a comprehensive computer-based record system, with adequate provider participation and proper data management, can be more reliable than parental vaccination cards (Ortega et al., 1997)."

CDC uses the Vaccine Adverse Event Reporting System (VAERS) as a surveillance system to track reports of negative health events that are temporally related to the administration of a vaccine. VAERS is used to track "increased number or types of reported adverse events" in order to improve patient safety. The vaccine lot numbers are used as an important identifier in the monitoring of vaccines. "FDA medical officers evaluate reporting rates of adverse events by lot, as needed, looking for unexpected patterns[8]. (Zhou et al., 2003)" Therefore, it is imperative to have an accurate lot number in order to accurately record and track lot-specific adverse effects.

Bundy, et al performed a study of 607 patient vaccination errors in the MEDMARX database, an anonymous voluntary internet-based repository of adverse drug reactions and

[8] Note, in the history of tracking lots, this type of lot-specific event has not lead to a recall.

medical errors, to analyze the related causes. The study found that of the five types of error categories (i.e., the wrong vaccine, wrong time, wrong dose, wrong route, and wrong patient), the wrong vaccine was the most common mistake with 75% of the errors found. These errors were due to look-alike or sound-alike vaccines (e.g., Infanrix, Kinrix, or Havrix). The authors cite that the use of barcoding as a potential fix for some of these issues, especially mistakes from similar packaging (Bundy et al., 2009).

In addition, the American Academy of Pediatrics recommends recording the expiration date in the patient's medical record (Pickering, Baker, D, & Long, 2012). CDC reported in their annual progress report on the status of Immunization Information Systems (IIS) that 40% of the records for lot numbers were incomplete (Cardemil et al., 2013). According to unpublished CDC data, nearly twenty percent of VAERS reports had missing lot number data (Centers for Disease Control and Prevention, 2013).

A Canadian study compared the electronic immunization data (vaccine name, lot number, and expiration date) of patients using barcode scanning versus those using manual methods. There were significantly fewer errors in the barcode-scanned data: 6 errors out of 346 vaccinations (1.7%) compared to zero (0%) barcoded errors, better results than drop-down menu use; and 19 errors out of 341 (5.6%) compared to zero (0%) barcoded errors better than manually typing (Pereira et al., 2014).

In a Canadian feasibility study of 2D barcode usage for inventory workflow in mass immunization clinics, the researchers found that barcode scanning was a workable method for entering vaccination records into their electronic system. The results of a survey of those using the barcode scanner showed 74% of users were satisfied with the method, 84% thought it would improve patient safety, and 77% thought it would improve accuracy (Pereira et al., 2012).

In summary, these previous studies show the need for a more accurate, complete, and automated method of recording vaccination data. The usage of 2D barcode technology can be a feasible solution.

2.3. History of 2D Barcode Use with Vaccines

Although the first commercial use of a barcode dated back to 1974 when a pack of chewing gum was scanned at a supermarket, the health industry has been much more slow to adopt the technology (GS1 US, 2013). This section outlines the relevant history of the adoption of 2D barcodes for vaccines.

1997 Vaccine Identification Standards Initiative (VISI)

In 1997, CDC's Immunization Safety Office organized the Vaccine Identification Standards Initiative (VISI) to bring together stakeholders to improve the overall safety of vaccinations through improvement of the accuracy, efficiency, and convenience of transferal of data to either paper charts or computerized records (Kennedy, 2013). VISI set guidelines for peel-off labels containing both human readable and barcoded forms of standardized data (i.e., lot number, expiration date, type, brand, and manufacturer of the vaccine) (Chen, Pool, Takahashi, Weniger, & Patel, 2001). Due to the FDA rule requiring linear barcodes (FDA regulations described in detail in this section below), the VISI full recommendations were not fully implemented across all manufacturers (O'Connor et al., 2012). The VISI initiative was still an important first step in laying the groundwork for 2D barcoding.

2001 HIMSS Recommendation

In a 2001 report by the Healthcare Information and Management Systems Society (HIMSS), the author states that the implementation of barcoding in health care at the unit-of-use

had been stymied by lack of Government mandate on the manufacturers to apply the barcodes, the expense of the providers in buying the costly scanner equipment, and the lack of a market need for software vendors. Despite these barriers, the HIMSS report states that the use of point-of-care, unit-of-use bar code should be supported to reduce medical errors and improve productivity (Simpson, 2001).

2003 FDA Requires Linear Barcodes

In March 2003, FDA released a final rule that required pharmaceutical manufacturers to include a linear barcode that included the drug's NDC on the unit-of-use of each product. This would allow providers to electronically scan each drug and to "verify that the right drug, in the right dose and right route of administration, is being given to the right patient at the right time (U.S. Food and Drug Administration, 2004)." The questions and answers to this rule, which were reaffirmed in February 2004 and in October 2006 by FDA, indicated that adding the lot number and expiration date to the bar code requirement via an alternative symbology (i.e., using a different kind or type of barcode) other than linear would not be cost effective (U.S. Food and Drug Administration, 2006). This rule followed behind the 1999 IOM report that cited among other issues in the U.S. healthcare, there were major safety problems in administration of drugs (Institute of Medicine, 2000).

FDA and AAP

In January 2009, the American Academy of Pediatrics (AAP) convened a meeting of industry stakeholders including vaccine manufacturers, providers, FDA, and CDC to further discuss the usefulness, effectiveness, and need of 2D barcodes for vaccines. Prior to this meeting, FDA questioned the feasibility of implementing 2D barcodes and therefore, did not require or allow anything but a linear barcode. AAP argued that due to the lowered costs and significant

advancement of the barcoding technology, the higher adoption rate of electronic health records by providers, and the increased complexity of the entire vaccine system it was time to transition to 2D barcodes for vaccines (American Academy of Pediatrics, 2009). In January 2010, AAP made a presentation to FDA recommending a change in the FDA rule to allow different barcode labeling that would permit 2D barcodes (Kennedy, 2013). And, in February 2010, AAP and the FDA met with the global product identification standards organization GS1 to formalize recommended guidance for vaccine manufacturers using GS1 standards for 2D barcoding on vaccines (O'Connor et al., 2012).

August 2011 - FDA Barcode Rule Change Allowing 2D Barcodes

In August 2011, the FDA released guidance to industry on the acceptable format of barcodes on drugs, especially vaccines. FDA stated in the answer to question 12 of the guidance that linear barcodes were still required but a manufacturer could request a waiver that would allow the substitution for 2D barcodes on the unit of use that would encode lot number and expiration date in addition to the product identifier (U.S. Food and Drug Administration, 2011). This guidance made certain that manufacturers were allowed to print 2D barcodes directly on vials or syringes, a move that would pave the way to greater usage of the technology.

October 2010 - CDC Feasibility Study: Impact of Transition to 2D Barcodes

Research Triangle Institute International (RTI) began a feasibility study funded by CDC that explored the impact that 2D barcodes had on the immunization system in the United States including effects on the manufacturers' production, the clinical documentation, and the reporting of vaccinations in the public health system. RTI performed stakeholder engagement activities to gauge the knowledge, attitudes, and beliefs of the potential impact of 2D barcoding. They performed prospective economic analyses. And, they analyzed data exchange and information

technology standards to evaluate the feasibility of implementing the technology needed for 2D barcoding (O'Connor et al., 2012). Their findings showed that using 2D barcodes could lead to a potential reduction in documentation time by 36-39 seconds per dose. Survey results indicated that “60% of pediatric practices, 54% of family medicine practices, and 39% of health departments would use the 2D barcode with more indicating they would do so if they also used electronic health records (O'Connor et al., 2013).” And, the economic analysis that included both manufacturer and provider costs predicted a $310 - $334 million net cost benefit between 2011 and 2023. The benefit-to-cost ratio was calculated to be between 2.7 and 2.8; meaning for every dollar spent on barcoding $2.70 to $2.80 of benefits would be realized. A recommendation was also made by RTI to perform a more extensive pilot implementation 2D barcoding in the clinical environment (O'Connor et al., 2013).

2D Vaccine Barcode Pilot Study

In September 2011, Deloitte Consulting was awarded a contract by CDC to perform a pilot with the following objectives: a) Assist providers in implementing and integrating technology for electronically reading 2D barcoded vaccines; b) Assess the challenges along the full implementation life cycle from vaccine production to administration to data capture; c) Evaluate the overall usage of 2D barcodes via the user experience surveys, as well as workflow and time and motion studies; d) Glean lessons learned and any best practices; e) Assess whether full usage of 2D barcode scanning of vaccines effect the completeness and accuracy of patient records within the EMR’s or IIS’s; and f) Fully apply 2D barcodes on the Vaccine Information

Statements (VIS)[9] (Kennedy, 2013). Two vaccine manufacturers participated in the pilot providing a total of eight different vaccines with 2D barcodes. There were 217 separate immunizers (145 private practices, one commercial[10] pharmacy, and 71 public practices) across 10 jurisdictions (i.e., 9 states and 1 city). Details on the recruitment criteria are given in more detail in the Chapter 3 – Methodology in Section 3.2 below. The data collection for the pilot ran from August 2012 through May 2013 (Kennedy, 2013). This study collected data that were used as the basis for this thesis.

2.4. Summary of current problem and study relevance

This chapter has reviewed the available literature of the need for a greater level of accuracy and completeness of vaccination records. From the early years of little or no electronic record to the advent of barcoding, the chapter reviewed the history of electronic capture and requirements for barcodes. From the history of 2D barcodes on vaccines, the literature showed how both the industry and technology matured to the point of FDA acceptance of the 2D barcodes today. All of the literature highlights the progression of studies and information that has led to the utilization of 2D barcodes. Yet, there are still many missing details in the body of knowledge of 2D barcodes for vaccines. It is unknown how much improvement in data quality of

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[9] Adding barcodes to VIS statements was a separate distinct portion of the Deloitte contract was unrelated to the pilot and evaluation project.

[10] The 2D Vaccine Barcode Pilot attempted to target other commercial entities such as mass vaccinators, but there was only one pharmacy that participated. For the rest of this thesis, “commercial” has been referred as “commercial pharmacy.”

vaccination records, if any, that 2D barcoding will have. Hence, this analysis is being conducted to help answer some of those questions. .

Chapter 3 – Methodology

3.1. Introduction

This study is a secondary data analysis of the 2D Vaccine Barcode Pilot conducted by the Deloitte Corporation for the Centers for Disease Control and Prevention (CDC) in 2012 to 2013. The objectives of the pilot were the following:

1. Measure the effect of 2D barcoding on vaccination data,
2. Evaluate the use of 2D barcodes,
3. Compile EMR and IIS 2D barcode scanning functionality to determine compatibility of scanners within individual types and brands of systems,
4. Document best practices and lessons learned,
5. Evaluate the impact on the supply chain of applying 2D barcodes on secondary packaging, and
6. Establish practical methodology for 2D barcodes on Vaccine Information Statements (VIS), (Gerlach & Robinson, 2014).

Objectives one through four were relevant to this thesis. The pilot provided 2D barcode scanners to each of the pilot participants, none of whom previously utilized any barcode scanning for immunizations. The implementation of a 2D barcode scanning process was the primary intervention. The outcome of interest was the determination if vaccine administration

data quality (completeness and accuracy of the lot number and expiration date data[11]) improved during the pilot.

Members of the Deloitte data team provided a de-identified dataset for analysis of this thesis project. Since the original pilot data contained no personally-identifiable information and the thesis project dataset was further de-identified, this project constituted a non-human subjects research project. A phone conversation with the Emory Institutional Review Board (IRB) confirmed that IRB approval was not necessary.

3.2. Population and sample

This section describes the characteristics of total pilot participants as well as the subset sample available for this Thesis secondary analysis.

Total Pilot Sample

The pilot study had 241 enrolled immunization providers but due to attrition only 217 participated for the duration of the pilot (Fierro et al., 2014). These providers all reported to one of 10 participating grantees: nine states (Alaska, Florida, Iowa, Michigan, New Jersey, New York, Oregon, Wyoming, and Washington) and one city (New York City). Each of the ten participating state/city public health departments provided Immunization Information System (IIS) records for each of the pilot providers with available records. The participating providers comprised 145 private practices, 71 public health departments, and 1 commercial pharmacy (Gerlach & Robinson, 2014).

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[11] "Complete" is defined as the data element (i.e., lot number or expiration date) was not missing in the data; "Accurate" is defined as the data element was complete and matched a result in the "source of truth" reference table. See the full definition of accurate and complete in Section 3.3 for details.

The provider sample was selected out of convenience through an extensive recruiting process with the following criteria for participation:

1. Each provider had to actively utilize either an EMR or IIS to document vaccinations;
2. The providers had to report data to their state or local IIS;
3. The providers' computer systems and EMR/IIS systems had to be compatible with the 2D barcode scanners;
4. The providers had to plan to carry at least one of two known 2D barcoded vaccines (i.e., Sanofi Menactra, or Sanofi Pediatric DT) during the pilot period;
5. The providers had to have utilized no barcode scanners prior to the pilot;
6. And, the providers had to agree to use the scanners during the pilot period, and cooperate with the delivery of data for all administered vaccinations as required by the pilot protocol.

Thesis Sample

The dataset made available for this secondary data analysis has been cleaned and completely de-identified of any practice-specific information with the exception of the following attributes:

- Provider ID
- Grantee (i.e., state or city of association)
- Specialty
- Number of physicians
- Practice type (i.e., public, private, or commercial pharmacy)

All other attributes were generic or were non-specific that would not identify the practice. Although the pilot data were already de-identified of any personally identifiable information, these thesis-level data were further de-identified.

Of the total possible sample of 217 providers, only 165 practices were able to provide EMR data due to technical limitations with their EMR, insufficient time or resources, or other constraints. However, five sites dropped out of the pilot before submitting the final data required leaving a total of 160 total providers for EMR data. Data from 211 providers were made available by their IIS[12]. The pilot data represented a total of about 1.7 million vaccination records for the EMR data and about 2.0 million records for IIS data. After data were filtered to remove vaccination dates that were outside of the pilot range and to remove products labeled as vaccine names that were not really vaccinations (e.g., “PPD test” or “Medroxyprogesterone”), the total vaccination numbers dropped to about 1.4 million EMR and 1.7 million IIS records (Deloitte Corporation, 2014). Table 2 below provides a summary of the key data about the practices and vaccination attributes.

[12] All of the practice sites in the EMR dataset were present in the IIS data except for one (1).

Table 2. Key data summary (Deloitte Corporation, 2014)

	EMR	**IIS**
Total Vaccinations	1,346,837	1,687,366
Unique Practices	160	211
Unique Vaccines*	69	68
Unique Lot Numbers†	8,330	9,479
Unique Expiration Dates‡	1,436	1,077

* Calculated after extensive standardization such as removal of non-vaccines (e.g., TB tests). Complete list of vaccines can be found in ***Appendix 1***.
† Standardized to remove text that was intentionally added (e.g., "P" for private, or manufacturer name). Spaces or other characters that were unintentionally added were left unchanged.
‡ Includes erroneous dates (e.g., a typo of 3013 instead of 2013) if the vaccination date and vaccine name were valid. However, during quality analysis this date would have been marked as inaccurate.

3.3. Procedures

Pilot Study Procedures

During the recruitment and enrollment of each of the immunizers into the pilot, the pilot team collected characteristic information about each provider via an online survey and subsequent recruiting phone calls. This information included practice size, practice type (i.e., sector such as private, public, or commercial pharmacy), practice specialty (e.g., pediatrics or internal medicine), IIS reporting model (how data was transferred to the IIS), vaccination

utilization (i.e., brand, type, and presentation[13] of all vaccines in stock and planned to be purchased during the pilot) (Fierro et al., 2014). These pilot characteristic data were stored in a centralized database portal.

Data were collected by pilot team in three phases: baseline data, which were pre-pilot data prior to the installation of barcode scanners; learning data, which was collected approximately half-way through the pilot period; and maturity data, which were collected at the end of pilot. The pilot team gathered data for each pilot provider from four sources[14]:

1. Inventory data from the clinics providing the lot number, expiration date, and quantities of each clinic's vaccine,
2. Shipping manifests/receipts showing the same inventory data,
3. The clinic's EMR showing details of each vaccination administration during the pilot, and
4. Data received from each of the clinic's state/city Immunization Information System (IIS).

Table 3 below outlines the schedule when the data were collected from the clinics. The compiled study datasets contained the same variables for the EMR and IIS datasets.

[13] The presentation of a vaccine is the dose-level container such as prefilled syringe, single dose vial, or multi dose vial,

[14] Some sites were unable to provide all data due to limitations of information availability, time, or technical capability.

Table 3. Summary of data sources, collection times, and methods (Deloitte Corporation, 2014).

Data Source	Baseline Data	Learning Data	Maturity Data
EMR Records (Clinics) IIS Vaccination Report (State/City)	Vaccination dates from 11/2/2011 to 3/15/2012	Vaccination dates from 4/1/2012 to 12/15/2012	Vaccination dates from 12/1/2012 to 4/15/2013
Shipping Manifest (Clinics) Shipping Reports (McKesson)	Receipts from 11/1/2011 to 2/29/2012	Receipts from 4/1/2012 to 11/30/2012	Receipts from 12/1/2012 to 3/31/2013
Vaccine Inventory Balance Report (Clinics) IIS Inventory Records (State/City)	Balance of Vaccines as of: • 11/1/2011 • 2/29/2012 • Date of installation	Balance of vaccines as of 11/30/2012	Balance of vaccines as of 3/31/2013
Data Collection Method (Clinics)---->	Collected at time of initial provider site visit/installation	Paper documents collected by mail, EMR extract via FTP on 12/15/2012	Paper documents collect by mail, EMR extract via FTP on 5/15/2013
Data Collection Method (State/City & McKesson[15])------>	Electronic dataset via FTP 8/1/2012	Electronic dataset via FTP 12/15/2012	Electronic dataset via FTP 5/15/2012

Definition of Completeness and Accuracy

Each vaccination record contained separate data elements for lot number, expiration date, and product code. This thesis project only analyzed results for lot number and expiration date because product code information was not able to be directly inserted into the EMR/ISS with the 2D barcode reader. Completeness and accuracy was determined individually for lot number and expiration date (e.g., within the same record, lot number could be complete but not accurate; or,

[15] McKesson is the national vendor contracted to distribute all Vaccine for Children (VFC) vaccines for all providers in the U.S.

lot number could be complete and accurate, but expiration date could have a different value) (Deloitte Corporation, 2014). Figure 2 below gives a graphical depiction of how completeness and accuracy was determined.

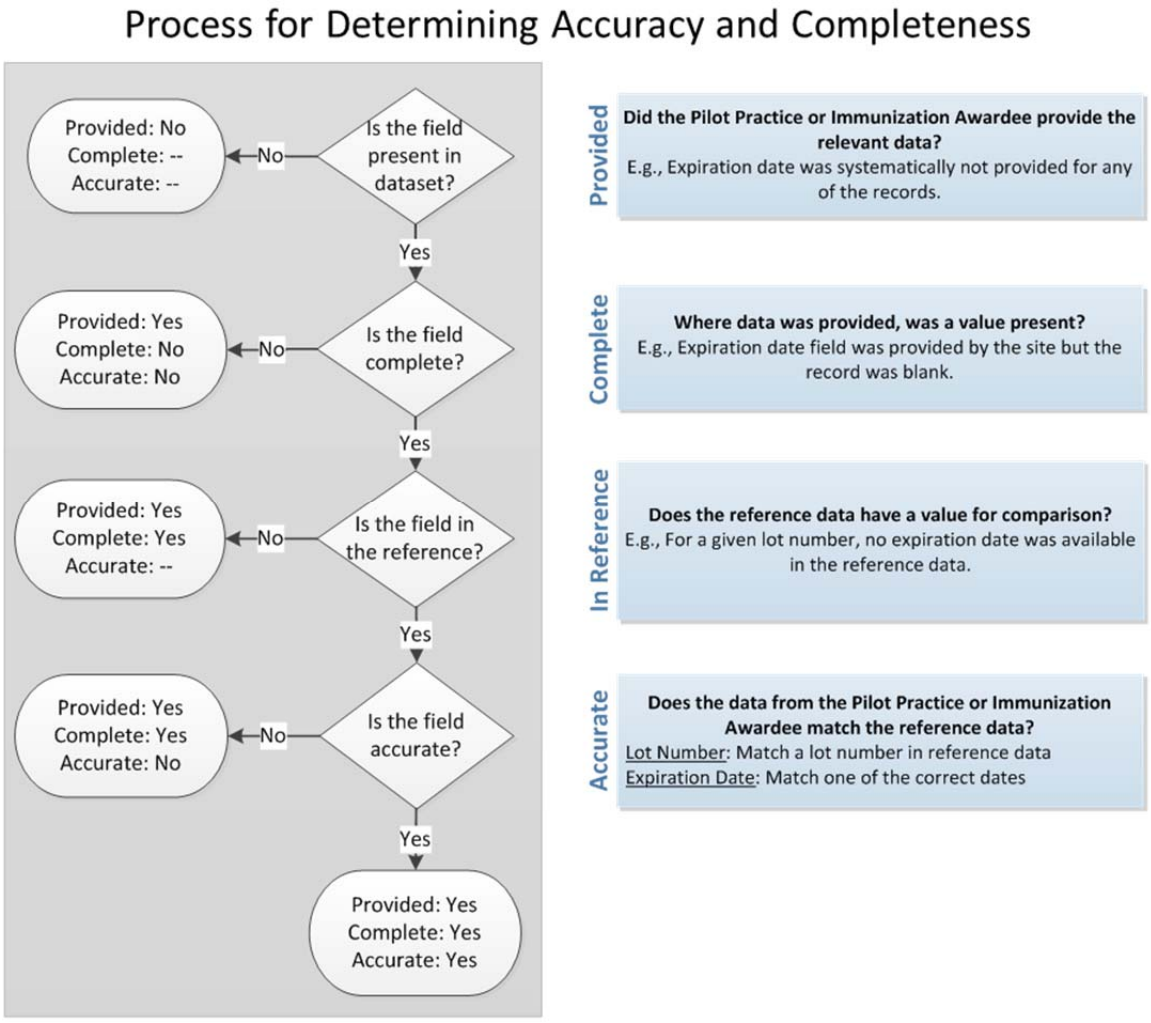

Figure 2. Determination of Complete and Accurate. Adapted from Deloitte's 2014 Final Report (Deloitte Corporation, 2014).

Completeness was evaluated simply by analyzing the presence of data within each record. If the record had a value present for a particular data element (i.e., either lot number or expiration date) in question, that data element was complete. Missing values were marked as incomplete. Note, if a particular field was systematically not provided by the particular practice

the record was marked as “not provided” and therefore not evaluated as complete or accurate (Deloitte Corporation, 2014).

Determining accuracy of the two data elements (i.e., lot number and expiration date) for each vaccination involved a two-step process. First, the record must have been complete (i.e., not missing). Second, the field must match a separate reference dataset that was considered the “source of truth.” (See the “Reference Dataset” discussion in the next section for how this reference dataset was constructed.) Looking at individual records, a determination for accuracy was made separately for each data element (Deloitte Corporation, 2014). Lot number and expiration date are separate variables within the same record and are evaluated separately for accuracy and completeness. However, expiration date accuracy is contingent upon the determination of a complete and accurate lot number, because without one there is no way to properly look up the appropriate value in the reference dataset.

The pilot team calculated three data quality elements for each of the three data fields (i.e., lot number, expiration date, and product code). These data quality elements included completeness, accuracy, and accuracy & complete. The pilot team defined the difference between “accurate” and “accurate & complete” as the following: “A field (e.g., Expiration Date) marked as ‘accurate and complete’ has data present from the provider, has reference data available to check it against, and matches between the provider data and reference data. This metric was always equal to or lower than accuracy since “accurate” excluded records that were not complete(Deloitte Corporation, 2014).“ The distinction between the two values was very confusing so this thesis project only used their accurate & complete variable as the “accurate” value throughout the analysis.

Reference Dataset

In order to make a determination of accuracy for each data field the pilot team needed to create a reference dataset to act as the "source of truth." Five sources of information were collected to compile this master reference dataset (Deloitte Corporation, 2014):

1. *Shipping Manifests* from pilot sites – Invoices or shipping registers from the vaccine distributor that listed the quantities of the contents by lot number, expiration date, and product name.
2. *Vaccine Inventories* from pilot sites – Separate listing of information from inventory.
3. *Manufacturer Data* – Information directly from the two manufacturers (i.e., Sanofi Pasteur and Glaxo Smith Kline (GSK)) of 2D barcoded lot numbers.
4. *McKesson Vaccine Data* – Data on vaccines that were sent including some private stock and all VFC vaccines.
5. *VAERS Data* – Data were reviewed during the pilot period. If two or more VAERS MedAlerts contained the same lot number, that lot number was included as valid.

All information was reviewed and standardized to ensure consistency. Figure 3 below illustrates these reference data sources (Deloitte Corporation, 2014).

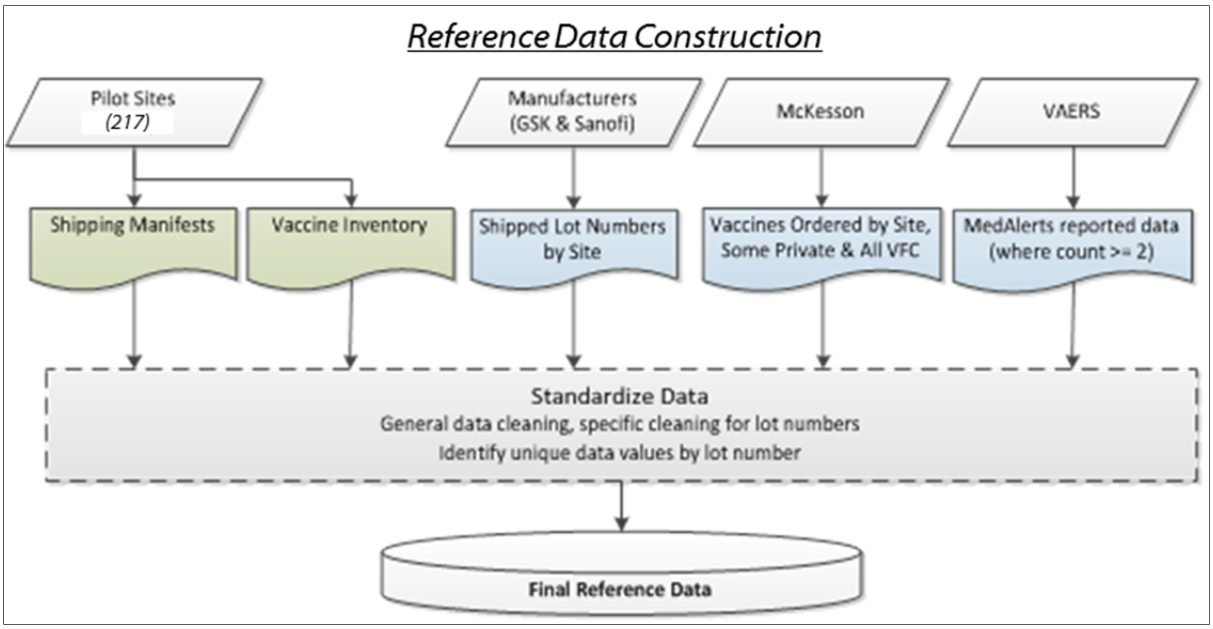

Figure 3. Data sources for reference data. Adapted from Deloitte's 2014 Final Report (Deloitte Corporation, 2014).

In order to evaluate the effect of 2D barcoding on vaccination record keeping, one must be able to measure or estimate how often the 2D barcode scanners were used in comparison to being enter via other methods (e.g., manual entry or drop-down menus). As described in Section 3.5 below, a major limitation of the pilot study was the inability to document at the record or vaccination level when a scanner was used. To overcome this limitation, the pilot team used two user experience surveys to approximate the use of 2D scanners by each practice. These two surveys were obtained from provider administrators, physicians, nurses, and medical assistant staff to gauge the level of participation and utility of the 2D barcode scanners. They used the surveys to approximate the percentage of the 2D barcoded vaccines administered that had been scanned instead of entered manually (Deloitte Corporation, 2014). This percentage was used to establish an average amount of time the 2D scanning was completed.

3.4. Plans for data analysis

Two sets of de-identified data were provided by the pilot data team for this thesis analysis. The first was a primary set of data with 47 variables (see ***Appendix 2*** for full list) as two CSV files (one for EMR and one for IIS data). These data were imported into IBM SPSS Statistics (version 19, IBM Corporation, Chicago), which was the software package used for all analyses. A key variable, "provider_type," used to determine public or private provider type was missing. A second de-identified table was provided with the missing variable association with the 217 providers. A Vlookup function was performed within Excel (version 2010, Microsoft Corporation, Seattle) and the provider_ type variable was merged into the existing datasets.

A new categorical variable was created called "PrePilot"[16] based on the associated barcode scanner install date. All vaccinations prior to this date were considered to occur during pre-pilot implementation and therefore would not have had the opportunity to scan 2D barcodes. A Pre/Post analysis using this variable was key for several analyses.

Descriptive statistics (including frequency and percentages) were calculated for the following: practices, 2D-barcoded vaccines, vaccinations, and lot number and expiration date data quality (complete and accurate[17]). The data were analyzed by a number of variables

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[16] The pilot team used a different variable "Scanner_Install" to determine pre- and post-pilot calculations. In comparing the newly-created PrePilot variable to this Scanner_Install variable using the EMR dataset, there were 26,171 out of the 1,313,463 records that differed between the pilot team results and this thesis analysis. The difference in overall analysis results (See Chapter 4) resulted in less than a 0.1% change in the final findings.

[17] "Complete" is defined as the data element (i.e., lot number or expiration date) was not missing in data; "Accurate" is defined as the data element was complete and matched a result in the "source of truth" reference table. See the full definition of accurate and complete in Section 3.3 for details.

primarily 2D versus non-2D vaccines, pre- versus post-implementation, and public versus private delivery site.

All analyses were performed separately on each of the two datasets: EMR data and IIS data. Although the analysis tables were provided for both datasets, the summary of results, discussion, and conclusions focused primarily on the EMR data. This approach provided a streamlined focus on just one set of figures and tables and was less confusing to the reader. As described in the limitations below in Section 3.5, the EMR dataset consisted of more robust and reliable data. Focusing on EMR data may be more interesting to the broader immunizing community. Major differences between the EMR and IIS datasets were notated as appropriate.

3.5. Limitations and delimitations

Limitations

Since this was a secondary data analysis, this thesis project had no control over the design and execution of the data being gathered. Since it was a quasi-experimental study of a population chosen out of convenience under a pilot with a tight budget, there was not a true control group. This limitation was overcome by comparing pre- and post-implementation vaccination and comparing 2D and non-2D barcodes.

The biggest limitation of the pilot data was the inability to definitively determine which vaccinations were documented using the scanner and which ones were completed manually (i.e., hand-entered or documented via drop-down menu). The pilot data team attempted to overcome this by deriving a complex way of inferring the information – the “Scan Effect”. (Fierro et al., 2014) A more precise way of determining 2D scanning usage could have been calculated/recorded if tracking software were available on the pilot practice client computers, or if that EMR natively captured the information at the record level.

Some key attributes of the data were missing that prevented some robust and potentially useful analysis. For example, the dates of the data extract for each site were not recorded. This information would have been valuable in analyzing if there was a difference in data quality at the beginning compared to the end of the reporting period. Also, public (e.g., Vaccines for Children (VFC) or other vaccines marked as public by practices)) versus privately-purchased vaccines had over 60% missing (i.e., unknown) data. For the EMR data, there were 391,202 publicly-purchased vaccines, 146,053 privately-purchased vaccines, and 822,381 unknown purchase source. This was another missed opportunity for comparison.

There were inconsistencies with the IIS dataset that made that data less reliable than the EMR dataset. Each grantee gave the pilot team data from their corresponding IIS in a prescribed standard format. However, it was unclear about how to interpret the origin of missing data for some attributes. Some data attributes were missing for a particular practice but it was not clear if those were real omissions by the practices during vaccine administration, if they were reporting errors, or if those were attributes collected internally but not reported to the IIS. There was much more clarity in the EMR dataset as those data were delivered individually to the pilot team (Deloitte Corporation, 2014).

This thesis project has a limitation of the depth of analysis completed on the available data. There were opportunities to perform multiple logistical regression analysis or other multivariate analysis to account for potential confounding such as those performed by the pilot team. See Section 5.5 Recommendations for examples of more detailed analyses.

Delimitations

In order to keep this thesis focused, the analyses will not include some variables or attributes such as the comparison of vaccination by the type of EMR (i.e., fully 2D integrated

versus not) or by provider size (i.e., small, medium, and large). These data were available and will make excellent future analyses.

Chapter 4 – Results

4.1. Introduction

This study performed a secondary data analysis of two separate datasets obtained during the 2D Vaccine Barcode Pilot study: EMR data and IIS data. Results tables of the analysis for both datasets are presented in section 4.5. This section will focus primarily on the EMR dataset for two reasons: 1) the results will be simplified by focusing on just one set of figures and tables, and 2) the EMR dataset consisted of more robust and reliable data (see conclusions in Chapter 5 for more discussion).

This chapter will provide a description of study population group including details on the practices and vaccinations; results of the analysis by each of the two stated hypotheses; additional findings; a summary of the results; and, the data tables for both the EMR and IIS datasets.

Description of Practices and Vaccinations

The EMR data were provided directly from each individual site participating in the pilot as an electronic extract or print-out directly from their EMR. Of the original 217 practices enrolled in the pilot, only 165 practices submitted EMR data of any kind due to issues with creating and submitting the data. Of these 165, five sites dropped out before completing the pilot and were excluded from analysis. Data from 160 practices were analyzed.

The pilot team requested the same variables for the same participating practices to comprise the IIS dataset. Since IIS data were received directly from the participating 10 grantees, the pilot team did not rely on individual practices to submit data and therefore, more sites were included than in the EMR data. Of the original 217 practices enrolled, IIS-specific data were

received for 216. After removing the five dropped sites there were a total of 211 practices analyzed with the IIS data.

Table 4 (EMR Data: Total Numbers of Practices by Vaccine) provides a distribution of participating practices that administered 2D-bacoded vaccines. There were eight vaccines that had a 2D barcode at some point during the pilot period. Due to a lack of available distribution or to the timing of the pilot, the 2D versions of some of these vaccines types were not present frequently or at all for some sites. For example, 2D barcoded Tenivac did not make the inventories of any of the sites. Looking at the pre-pilot vaccine inventories, only three 2D vaccines were available to practices: Adacel, Menactra, and Pediatric DT in the EMR data; Daptacel, Havrix, and Menactra in the IIS data. During the pilot, the practices had seven types of 2D vaccines. Menactra was the most common with 106 practices having 2D vaccines for the EMR data, and 165 practices for the IIS data. For the remaining analyses the comparisons included all of these “2D Barcoded” vaccines versus “Non-2D” vaccines.

Table 5 (EMR Data: Public and Private Practices by Vaccine) shows the distribution of the practices with 2D vaccines by public and private practice types. Although there were approximately 60% fewer Public Practices (n=46) than Private Practices (n=114), there were 82,756 more vaccinations given by Public Practices (n=454,284) than by Private Practices (n=537,040) during the pilot implementation.

Figure 4 below summarized the quantities of total vaccines by EMR and IIS dataset. The five practices that dropped out resulted in 12,799 EMR vaccinations and 40,532 IIS vaccinations that were not considered from analysis. Each dataset had instances of some missing values (i.e., practices systematically either did not record or did not report that field): 33,374 and 108,039 missing lot numbers for EMR and IIS respectively; and 163,235 and 339,115 missing expiration

dates respectively. For the EMR data (original n=1,359,636 vaccinations), the total valid counts for analysis for lot number and expiration date were 1,313,463 and 1,183,602 vaccinations respectively. For IIS data (original n=1,727,898), the respective valid totals are 1,579,327 and 1,348,251.

	EMR Dataset	IIS Dataset
All Vaccinations Records	**1,359,636**	**1,727,898**
Dropped Out	-12,799	-40,532
Lot # Missing	-33,374	-108,039
Lot # Total Valid	**1,326,262**	**1,579,327**
Expiration Date Missing	-163,235	-339,115
Expiration Date Total Valid	**1,196,061**	**1,348,251**

Figure 4. Summary of total valid vaccinations and missing data by EMR and IIS Datasets.

See Table 6 (EMR Data: Total Number of Vaccinations by Practice Delivery Site (Public versus Private) During the Pilot Implementation) for details including a break out of the number of vaccinations by 2D and non-2D vaccine type. There were substantially fewer 2D vaccines than non-2D vaccines available during the pilot period by a factor of over six to one (i.e., there were 60,461 total confirmed 2D-barcoded vaccinations and 401,030 non-2D vaccinations).

4.2. Findings

Use of 2D Technology

This section will show the results of the analysis evaluating the Question 1 hypothesis measuring the level of completeness and accuracy of the patient records for the data elements of lot number and expiration date for those instances using 2D barcoding technology when recording vaccination information compared to the vaccinations recorded without the technology. As described in more detail in Section 3.3 of the Methodology, completeness and accuracy are measurements of the independent variables lot number and expiration date. A

variable is marked “complete” when it is not missing from the record. Accuracy for the independent variable is determined by two factors: 1) The data element must be complete, and 2) The data element must match the reference dataset (i.e., “source of truth”). It is possible for one vaccination record entry to have a complete and accurate lot number, but have a complete and inaccurate expiration date. The first method of analysis presents the differences in data quality between pre- and post-implementation (i.e., with and without barcode scanning capacity). (See Table 7 (EMR Data: Data Quality by Total and Barcode Type (2D/Non-2D) Vaccinations)). Lot number and expiration date were separate independent data variables. The average results of the pre- and post-implementation comparison of the EMR data is shown in Figure 5. For all vaccinations, on average lot number records in the practices’ EMR data were 4.2% more complete (i.e., 93.3% versus 97.5%) and 5.2% more accurate (i.e., 91.0% versus 96.2%) post-implementation using the 2D scanners than pre-implementation. Expiration dates were on average 9.9% more complete (i.e., 86.0% versus 95.9%) and 12.8% more accurate (i.e., 79.8% versus 92.5%).

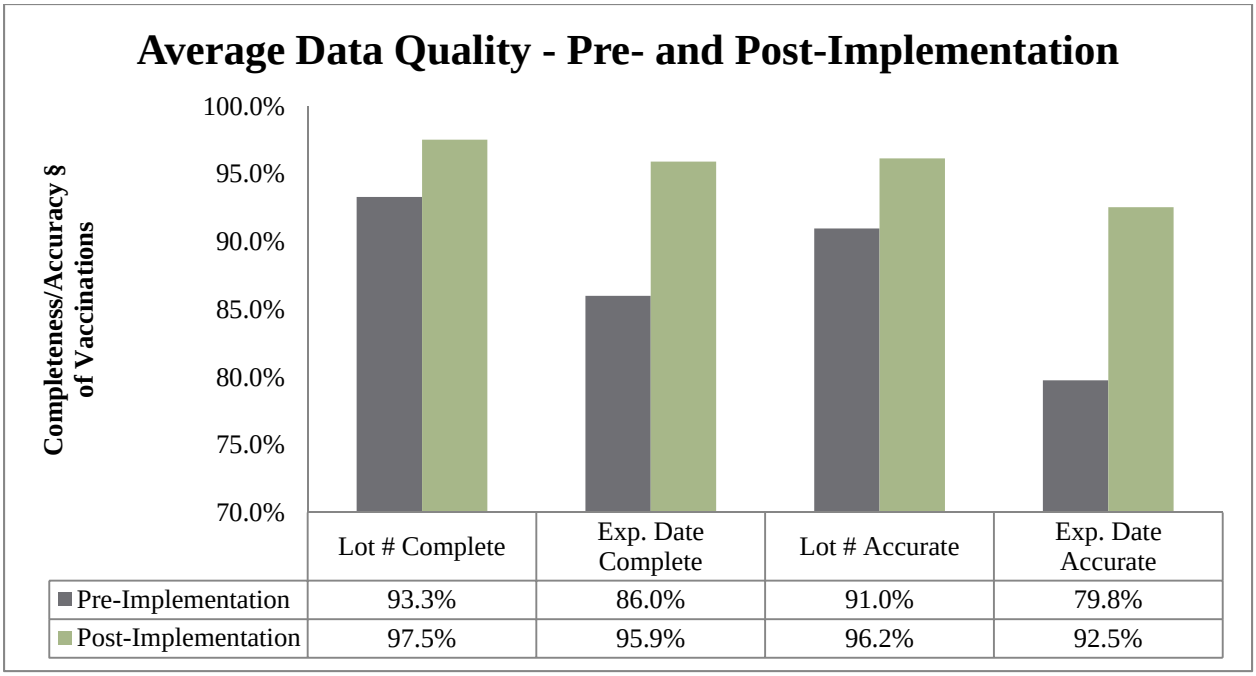
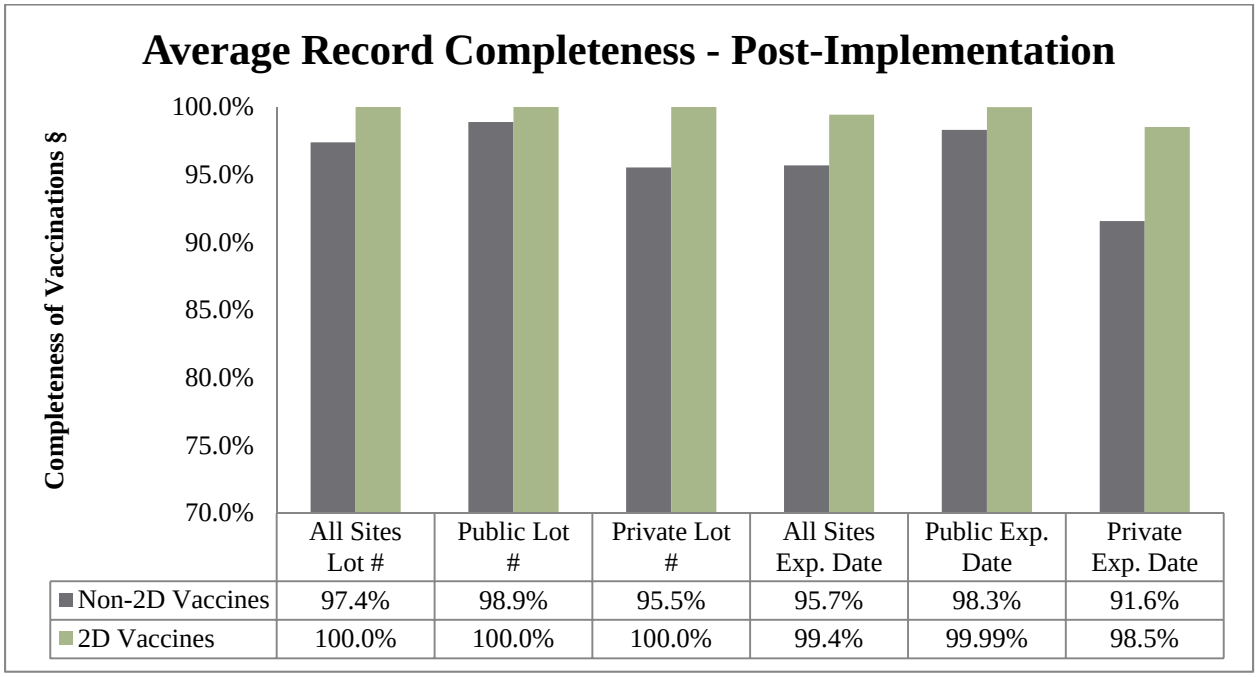


Figure 5. EMR Data – Average Data Quality of All Vaccinations in EMR dataset Pre-Implementation (lot number n=343,202; expiration date n= 307,040) and Post-Implementation (lot number n=970,261; expiration date n= 876,562). See Table 7 for details.
§ Complete = data element was present in data; Accurate = data element was complete and matched the reference table.

Regarding the IIS dataset, the overall analysis for the use of 2D technology on data quality produced mixed results. Comparing the pre- and post-implementation data quality, there was an increase in completeness (78.2% for pre- versus 92.7% for post-implementation) and accuracy (75.2% versus 88.0%) of the lot number data, but there was a decrease in both completeness (79.4% for pre- versus 68.9% post-implementation) and accuracy (76.4% versus 66.0%) of the expiration dates during the post-implementation. Detailed IIS data results for average pre- and post-implementation data quality are shown in Table 8 and the topic is discussed further in Chapter 5.

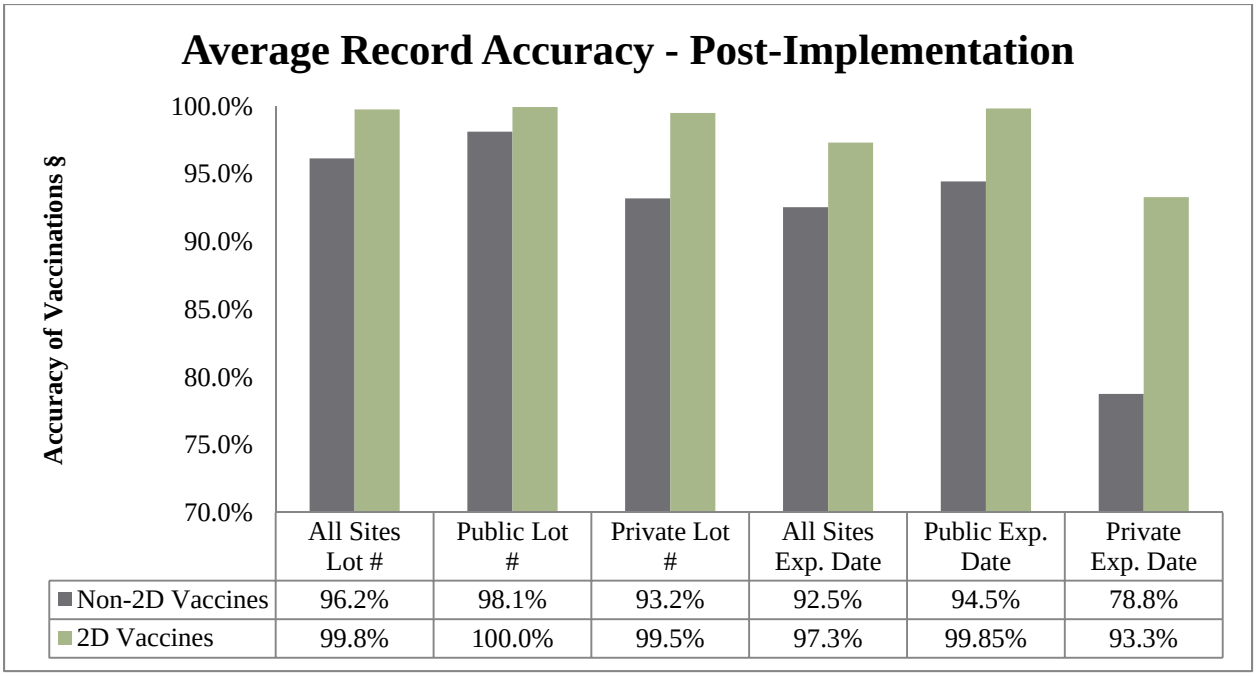
The second method used to determine how 2D technology affected data quality was to compare the 2D barcoded vaccines with the non-2D vaccines during the post-implementation period during the pilot. Vaccinators did not have the opportunity to use the barcode scanners for

non-2D barcoded vaccines. These were entered either manually or via a drop-down menu choice. Figure 6 and Figure 7 below provide the 2D versus non-2D analysis of completeness and accuracy respectively. Looking at the "All Sites" comparison, the results indicate that the 2D vaccines had greater data quality than non-2D vaccines: 2.6% (97.4% non-2D versus 100% 2D) greater lot number completeness and 4.8% (95.7% non-2D versus 99.4% 2D) greater expiration date completeness.



	All Sites Lot #	Public Lot #	Private Lot #	All Sites Exp. Date	Public Exp. Date	Private Exp. Date
Non-2D Vaccines	97.4%	98.9%	95.5%	95.7%	98.3%	91.6%
2D Vaccines	100.0%	100.0%	100.0%	99.4%	99.99%	98.5%

Figure 6. EMR Data – Average Vaccination Record Completeness of 2D and non-2D Vaccines Post-Implementation. (Lot #: All Sites Non-2D n=909,800; All Sites 2D n=60,461. Exp. Date: All Sites Non-2D n=819,617; All Sites 2D n=56,945.) See Table 9 for details.
§ Complete = data element was present in data.



	All Sites Lot #	Public Lot #	Private Lot #	All Sites Exp. Date	Public Exp. Date	Private Exp. Date
Non-2D Vaccines	96.2%	98.1%	93.2%	92.5%	94.5%	78.8%
2D Vaccines	99.8%	100.0%	99.5%	97.3%	99.85%	93.3%

Figure 7. EMR Data – Average Vaccination Record Accuracy of 2D and non-2D Vaccines Post-Implementation. (Lot #: All Sites Non-2D n=909,800; All Sites 2D n=60,461. Exp. Date: All Sites Non-2D n=819,617; All Sites 2D n=56,945.) See Table 9 for further details.
§ Accurate = data element was complete and matched the reference table.

When comparing 2D and non-2D metrics, the IIS dataset showed similar results in three out of four categories. Lot number completeness, lot number accuracy, and expiration accuracy all had higher numbers in the 2D vaccinations, but expiration date completeness was slightly lower in 2D. Table 10 gives further details of that IIS data analysis.

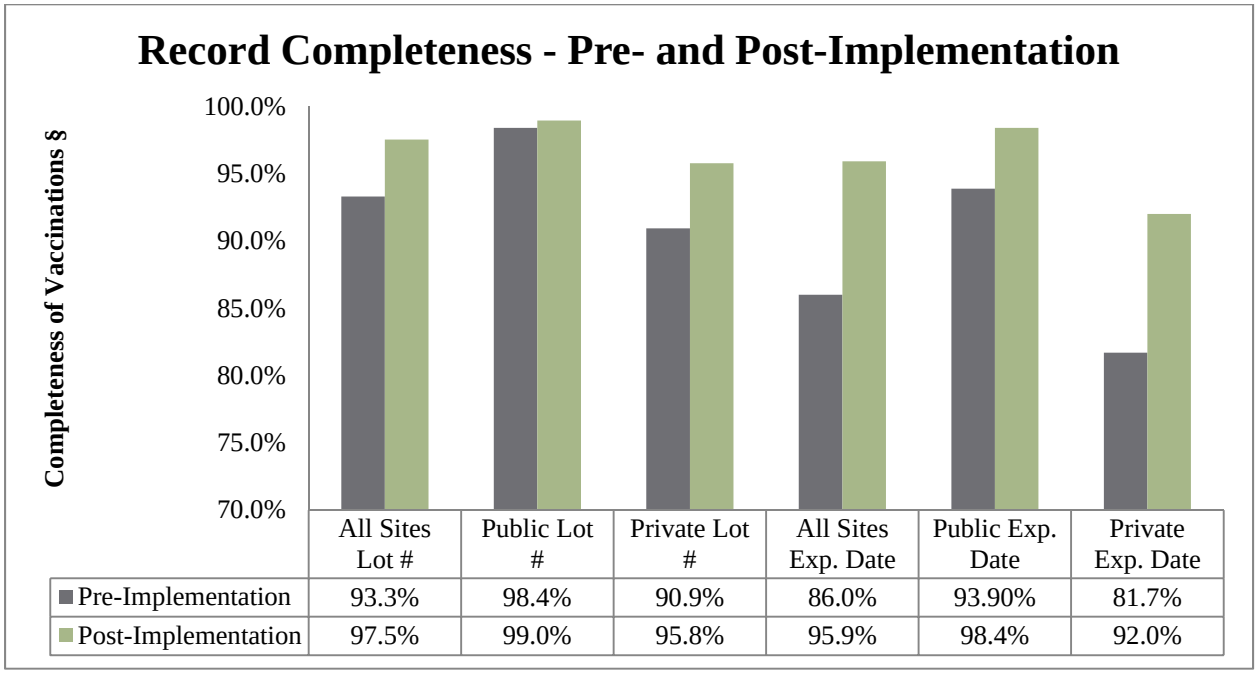
Public versus Private Clinic Delivery Site

Hypothesis 2 stated that the public clinic delivery sites (i.e., Public Health Departments or FQHC's) would have a greater level of data quality than the private sites. The first type of analysis compares the data quality during the pilot (i.e., post-implementation) between the public and private sites. Figure 6 (Vaccine Record Completeness - Post-Implementation) above shows that the 2D lot number completeness was the same at 100% for both private and public sites. The

levels of completeness were greater in the public sites for the non-2D lot number (3.4% greater (98.9% public versus 95.5% private)) as well as 2D expiration date (6.7% greater(98.3% versus 91.6%)) and the non-2D expiration date (1.5% greater (99.99% versus 98.5%)) metrics compared to private sites. Figure 7 (Vaccine Record Accuracy - Post-Implementation) above shows similar differences with the accuracy levels between public and private sites. Notable differences include a 15.7% (94.5% public versus 78.8% private) and 6.5% (99.6% versus 93.3%) higher accuracy rates in the expiration dates respectively of the non-2D and 2D vaccines of the public sites compared to the private ones. Table 11 breaks out the results of Data Quality by 2D Barcoded and Delivery site post-implementation. The IIS dataset showed similar results as the EMR data – public sites showed greater completeness and accuracy for both lot numbers and expiration dates (see Table 10 for details of the IIS data).

The second aspect of analyzing differences between public and private sites was to compare the results pre- and post-implementation. The public sites had greater data quality both before and after the pilot implementation across all four data elements. Figure 6 (Record Completeness - Pre- and Post-Implementation) below shows that public sites have higher completeness numbers across both metrics: 3.2% higher (99.0% public versus 95.8% private) for lot numbers and 6.4% higher (98.4% public versus 92.0% private) for expiration dates in post-implementation, compared to pre-implementation. Figure 8 (Record Accuracy – Pre- and Post-Implementation) below shows similarly higher accuracy numbers for public sites: 4.7% higher (98.3% public versus 93.6% private) for lot numbers and 12.6% higher (97.3% public versus 84.8% private) for expiration dates. EMR data details for data quality for pre- and post-implementation are found in Tables 12, 13, and 14. The IIS data revealed similar results showing

public sites as being more complete and more accurate both pre- and post-implementation. IIS details can be found in Tables 15, 16, and 17.



	All Sites Lot #	Public Lot #	Private Lot #	All Sites Exp. Date	Public Exp. Date	Private Exp. Date
Pre-Implementation	93.3%	98.4%	90.9%	86.0%	93.90%	81.7%
Post-Implementation	97.5%	99.0%	95.8%	95.9%	98.4%	92.0%

Figure 8. EMR Data -- Record Completeness Pre- and Post-Implementation for lot number and expiration date data. Public lot # n=107,080 (pre) and n=531,472 (post); Private lot # n=213,181 (pre) and n=414,994 (post); Public exp. date n=101,863 (pre) and n=526,775 (post); Private exp. date n=162,226 (pre) and n=314,090 (post). See Tables 11, 12, and 13 for additional details.
§ Complete = data element was present in data.

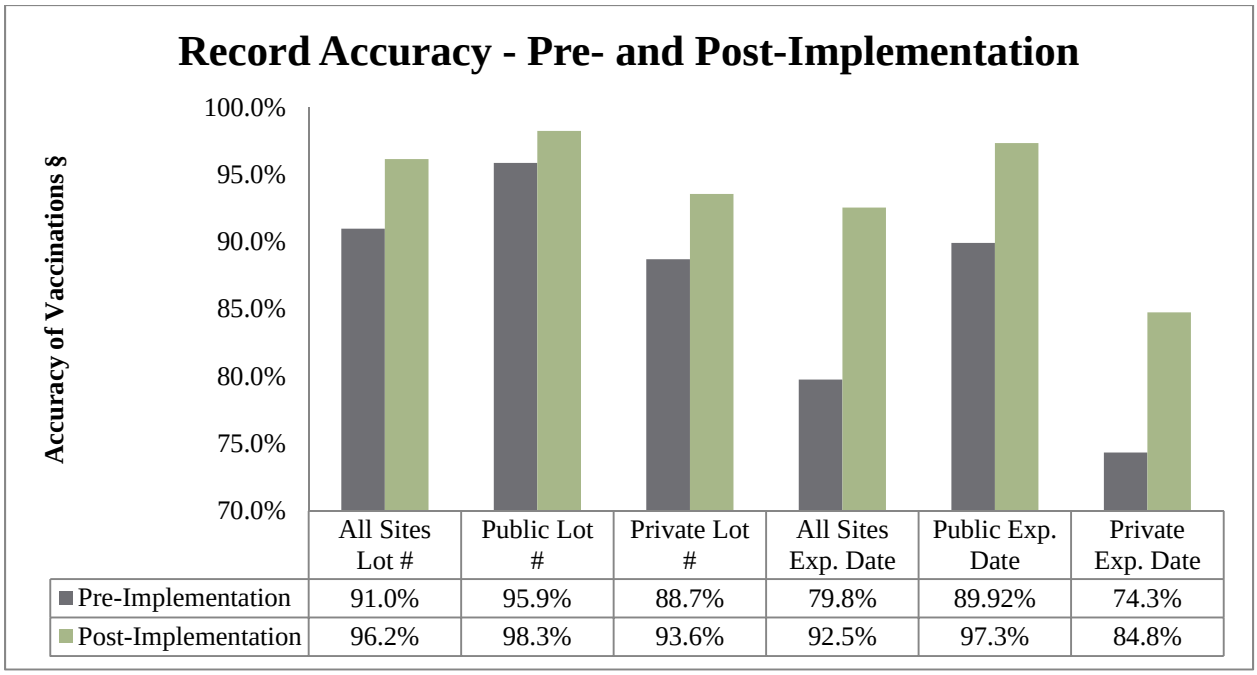


Figure 9. EMR Data -- Record Accuracy Pre- and Post-Implementation for lot number and expiration date data. Public lot # n=104,310 (pre) and n=527,655 (post); Private lot# n=207,926 (pre) and n=405,360 (post); Public exp. date n=89,713 (pre) and n=507,465 (post); Private exp. date n=138,899 (pre) and n=272,050 (post). See Tables 11, 12, and 13 for additional details.
§ Accurate = data element was complete and matched the reference table.

4.3. Other findings

Private Site Improvements Pre- and Post-Implementation

Although the public sites had higher average completeness and accuracy of data records as outlined in the previous section, the private sites had greater improvement from pre- to post-implementation of 2D barcode scanners. As shown in Figure 6 above, the public lot number completeness improved from pre- (98.4% complete) to post-implementation (99.0% complete) by 0.6% whereas the private lot number completeness improved by 4.8% (90.9% pre- versus 95.8% post-implementation). Thus, the improvement was 4.2% greater in the private versus public clinics. Similarly, as Figure 7 above shows, the public sites' accuracy of lot numbers improved from pre- (95.9% accurate) to post-implementation (98.3% accurate) by 2.4% compared to the 4.9% (88.7% pre- versus 93.6% post-implementation) increase in private site lot

number accuracy. Thus, the lot number accuracy improvement was 2.5% greater in the private versus public clinics. The private sites' expiration dates had a 5.8% greater improvement in completeness (i.e., public sites increased 4.5% (93.9% pre- to 98.4% post-implementation); private sites increased 10.3% (81.7% pre- to 92.0% post)) than the public sites. The private sites' expiration dates had a 3.0% greater improvement in accuracy (i.e., public sites increased 7.4% (89.9% pre- to 97.3% post-implementation); private sites increased 10.4% (74.3% pre- to 84.8% post)) than the public sites. The IIS data (see Tables 15, 16, and 17) showed a similar greater improvement in the lot number completeness and accuracy, but not with expiration date.

Pre- versus Post-Implementation Results

As described in the sections above the findings showed an improvement of completeness and accuracy in the lot number and expiration date data in the post-implementation. Looking solely at the pre-implementation data (see Tables 7 for EMR), the completeness (lot number at 93.3% complete, expiration date 86.0% complete) and accuracy (lot number 91.0% accurate, expiration date 79.8% accurate) were at a high level for this pilot study population.

4.4. Summary

The results can be summarized in three parts. First, although IIS data is inconclusive and inconsistent, the EMR data showed a greater level of completeness and accuracy of the sites using the 2D technology for recording vaccination information. Second, public delivery sites had greater data quality than private sites. Third, private practices experienced an overall greater level of improvement from pre- to post-implementation. Additionally, a noteworthy finding was that the records started in pre-implementation of 2D barcoding at a high level of completeness and accuracy.

4.5. Data Tables

Table 4. EMR Data: Total Numbers of Practices by Vaccine

	2D Barcoded Vaccines *			Non-2D Barcoded Vaccines **			
Vaccine Type[18]	# Practices using these vaccines	# Practices Pre-Pilot	# Practices During Pilot	# Practices using these vaccines	# Practices Pre-Pilot	# Practices During Pilot	All Practices
Adacel vials	45	1	45	133	123	89	134
Daptacel vials	43	0	43	116	97	87	117
Fluzone unit-dose vials (2012)	45	0	45	151	139	113	151
Havrix Adult unit-dose vials	22	0	22	150	137	109	150
IPOL multi-dose vials	34	0	34	146	133	111	146
Menactra unit-dose vials	106	54	101	149	138	106	154
Pediatric DT unit-dose vials	5	1	4	87	71	54	87
Tenivac vials	0	0	0	45	5	45	45

* These include only LOT # that contained 2D barcodes. ** Includes the vaccines of this type without 2D barcodes.

[18] The non-brand name vaccine types: Adacel is Tdap; Daptacel is DTaP; Fluzone is influenza; Havrix is Hepatitis A; IPOL is polio; Menactra is Meningococcal; Pediatric DT is Pediatric Diphtheria and Tetanus; Tenivac is Diphtheria-Tetanus. (Centers for Disease Control and Prevention, 2014).

Table 5. EMR Data: Public and Private Practices by Vaccine

	Public Practices (n=46)			Private Practices (n=114)			
2D Barcoded Vaccines *	# Practices using these vaccines	# Practices Pre-Pilot	# Practices During Pilot	# Practices using these vaccines	# Practices Pre-Pilot	# Practices During Pilot	Total
Adacel vials	5	0	5	40	1	40	45
Daptacel vials	7	0	7	36	0	36	43
Fluzone unit-dose vials (2012)	14	0	14	31	0	31	45
Havrix Adult unit-dose vials	10	0	10	12	0	12	22
IPOL multi-dose vials	7	0	7	27	0	27	34
Menactra unit-dose vials	32	10	32	74	44	69	106
Pediatric DT unit-dose vials	4	1	3	1	0	1	5
Tenivac vials	0	0	0	0	0	0	0
Non-2D-barcoded Vaccines **	46	43	36	114	108	82	160

* These include only LOT # that contained 2D barcode

** Includes all non-2D vaccines including the non-2D listed above.

Table 6. EMR Data: Total Number of Vaccinations by Practice Delivery Site (Public versus Private) During the Pilot Implementation

	2D-Barcoded Vaccines *			Non-2D Barcoded Vaccines **		
	Delivery Site †			Delivery Site †		
Practices	Private (n=74)	Public (n=36)	Total (n=110) ‡	Private (n=82)	Public (n=36)	Total (n=118) ‡
Adacel vials	3,066	446	3,512	11,039	6,047	17,086
Daptacel vials	5,298	1,016	6,314	5,959	1,295	7,254
Fluzone unit-dose vials-2012	4,683	16,457	21,140	77,699	164,330	242,029
Havrix Adult unit-dose vials	125	2,137	2,262	22,756	34,222	56,978
IPOL multi-dose vials	1,453	64	1,517	7,426	2,745	10,171
Menactra unit-dose vials	10,748	14,944	25,692	5,333	8,448	13,781
Pediatric DT unit-dose vials	3	21	24	184	51,474	51,658
Tenivac vials	0	0	0	484	1,589	2,073
Total Vaccinations	25,376	35,085	60,461	130,880	270,150	401,030

	Delivery Site †		
Practices	Private (n=81)	Public (n=36)	Total (n=117) ‡
Total of Other Vaccine Types ††	298,028	231,805	529,833
Total of All Vaccinations	454,284	537,040	991,324

* These include only LOT # that contained 2D barcode during the pilot.

** Includes the vaccines of this type without 2D barcodes.

† Private (includes 1 pharmacy) or Public practices by total # of vaccinations for both pre- and post-pilot.

†† Total vaccinations of all other vaccine types not listed above. Number of vaccines: Private (n=55) and Public (n= 52) and Total (n= 56).

‡ Note, one provider (case #1758) only gave data on the vaccines that were possibly 2D barcoded, thus there were 117 total sites instead of 118. For the 2D-Barcoded Vaccine total, only 110 sites of the 118 had any 2D vaccines.

Table 7. EMR Data: Data Quality by Total and Barcode Type (2D/Non-2D) Vaccinations

All Sites		Pre-Implementation **			Post-Implementation			Pre-Implementation **				Post-Implementation		
			Complete §			Complete §			Accurate §				Accurate §	
Lot Number	*n* =	Pre-I n=	n	%	Post-I n=	n	%	Pre-I n=	n		%	Post-I n=	n	%
Total Vaccinations	1,313,463	343,202	320,261	93.3%	970,261	946,466	97.5%	343,202	312,236		91.0%	970,261	933,015	96.2%
2D Barcoded *	61,567	1,106	1,106	100.0%	60,461	60,461	100.0%	1,106	1,088		98.4%	60,461	60,323	99.8%
Non-2D Barcoded	1,251,896	342,096	319,155	93.3%	909,800	886,005	97.4%	342,096	311,148		91.0%	909,800	872,692	95.9%
Expiration Date	*n* =	Pre-I n= †	n	%	Post-I n=	n	%	Pre-I n= †	n		%	Post-I n= †	n	%
Total Vaccinations	1,183,602	307,040	264,089	86.0%	876,562	840,865	95.9%	286,600	228,612		79.8%	842,273	779,515	92.5%
2D Barcoded *	57,972	1,027	1,021	99.4%	56,945	56,619	99.4%	1,027	962		93.7%	56,942	55,426	97.3%
Non-2D Barcoded	1,125,630	306,013	263,068	86.0%	819,617	784,246	95.7%	285,573	227,650		79.4%	785,331	724,089	92.2%

* 2D-Barcoded Vaccines include Adacel, Daptacel, Fluzone, Havrix, IPOL, Menactra, Pediatric DT, and Tenivac that contain a 2D barcode.

** Includes 2D and Non-2D barcoded vaccines. None of the pre-implementation (in grey) vaccinations used 2D scanners. Numbers for relative comparison only.

† These totals differ between "complete" and "accurate" because of more missing records.

§ Complete was measured by the presence of data in either the lot number or expiration date fields; Accurate is measured separately for lot number or expiration date: first, the field must have been complete and second, it must have matched the reference table “source of truth.”

Table 8. IIS Data: Data Quality by Total and Barcode Type (2D/Non-2D) Vaccinations

All Sites		Pre-Implementation **			Post-Implementation			Pre-Implementation **			Post-Implementation		
			Complete §			Complete §			Accurate §			Accurate §	
Lot Number	*n* =	Pre-I n=	n	%	Post-I n=	n	%	Pre-I n=	n	%	Post-I n=	n	%
Total Vaccinations	1,579,327	448,655	350,903	78.2%	1,130,672	1,047,574	92.7%	448,655	337,394	75.2%	1,130,672	995,140	88.0%
2D Barcoded *	50,454	1,270	1,270	100.0%	49,184	49,184	100.0%	1,270	1,192	93.9%	49,184	48,160	97.9%
Non-2D Barcoded	1,528,873	447,385	349,633	78.2%	1,081,488	998,390	92.3%	447,385	336,202	75.1%	1,081,488	946,980	87.6%
Expiration Date	*n* =	Pre-I n= †	n	%	Post-I n=	n	%	Pre-I n= †	n	%	Post-I n= †	n	%
Total Vaccinations	1,348,251	360,010	285,984	79.4%	988,241	680,962	68.9%	335,530	256,482	76.4%	936,735	618,526	66.0%
2D Barcoded *	43,060	1,133	920	81.2%	41,927	28,149	67.1%	1,133	910	80.3%	41,927	27,737	66.2%
Non-2D Barcoded	1,305,191	358,877	285,064	79.4%	946,314	652,813	69.0%	334,397	255,572	76.4%	894,808	590,789	66.0%

* 2D-Barcoded Vaccines include Adacel, Daptacel, Fluzone, Havrix, IPOL, Menactra, Pediatric DT, and Tenivac that contain a 2D barcode.

** Includes 2D and Non-2D barcoded vaccines. None of the pre-implementation vaccinations use 2D scanners. Numbers are shown for relative comparison only.

† These totals differ between "complete" and "accurate" because fewer expiration dates were provided.

§ Complete was measured by the presence of data in either the lot number or expiration date fields; Accurate is measured separately for lot number or expiration date: first, the field must have been complete and second, it must have matched the reference table “source of truth.”

Table 9. EMR Data: Data Quality by Total and Delivery Site (Public/Private) Vaccinations

		Pre-Implementation **			Post-Implementation			Pre-Implementation **				Post-Implementation			
			Complete §			Complete §			Accurate §				Accurate §		
Lot Number	*n* =	Pre-I n=	n	%	Post-I n=	n	%	Pre-I n=	n		%	Post-I n=	n	%	
Total Vaccinations	1,313,463	343,202	320,261	93.3%	970,261	946,466	97.5%	343,202	312,236		91.0%	970,261	933,015	96.2%	
Public *	645,848	108,808	107,080	98.4%	537,040	531,472	99.0%	108,808	104,310		95.9%	537,040	527,655	98.3%	
Private	667,615	234,394	213,181	90.9%	433,221	414,994	95.8%	234,394	207,926		88.7%	433,221	405,360	93.6%	
Expiration Date	*n* =	Pre-I n=	n	%	Post-I n=	n	%	Pre-I n=	n		%	Post-I n=	n	%	
Total Vaccinations	1,183,602	307,040	264,089	86.0%	876,562	840,865	95.9%	286,600	228,612		79.8%	842,273	779,515	92.5%	
Public *	643,698	108,484	101,863	93.9%	535,214	526,775	98.4%	99,765	89,713		89.9%	521,319	507,465	97.3%	
Private	539,904	198,556	162,226	81.7%	341,348	314,090	92.0%	186,835	138,899		74.3%	320,954	272,050	84.8%	†

* Public sites were Public Health Department clinics. Private included both private practices and 1 commercial pharmacy site.

** Includes 2D and Non-2D barcoded vaccines.

† Private Vaccines with Expiration Date provided was 341,348. Of these only 320,954 could be verified as accurate or inaccurate due to missing data.

§ Complete was measured by the presence of data in either the lot number or expiration date fields; Accurate is measured separately for lot number or expiration date: first, the field must have been complete and second, it must have matched the reference table “source of truth.”

Table 10. IIS Data: Data Quality by 2D Barcoded and Delivery Site (Public/Private) Vaccinations - Post-Implementation

Post-Implementation		Complete §						Accurate §					
			2D Vaccines			Non-2D Vaccines			2D Vaccines			Non-2D Vaccines	
Lot Number	*n* =	2D n=	2D Comp. n=	%	Non-2D n=	Non-2D Comp. n=	%	2D n=	2D Accur. n=	%	Non-2D n=	Non-2D Accur. n=	%
Total Vaccinations	1,130,672	49,184	49,184	100.0%	1,081,488	998,390	92.3%	49,184	48,160	97.9%	1,081,488	946,980	88.0%
Public *	233,318	13,001	13,001	100.0%	220,317	216,666	98.3%	13,001	12,960	99.68%	220,317	211,746	96.1%
Private	897,354	36,183	36,183	100.0%	861,171	781,724	90.8%	36,183	35,200	97.3%	861,171	735,234	85.4%
Expiration Date	*n* =	2D n=	n	%	Non-2D n=	n	%	2D n=	2D Accur. n=	%	Non-2D n=	Non-2D Accur. n=	%
Total Vaccinations	988,241	41,927	28,149	67.1%	946,314	652,813	69.0%	41,927	27,737	66.2%	946,314	590,789	66.0%
Public *	215,410	12,271	12,087	98.5%	203,139	192,774	94.9%	12,271	12,059	98.3%	203,139	180,134	88.7%
Private	772,831	29,656	16,062	54.2%	743,175	460,039	61.9%	29,656	15,678	52.9%	743,175	410,655	55.3%

* Public sites were Public Health Department clinics. Private included both private practices and 1 commercial pharmacy site.

** Includes 2D and Non-2D barcoded vaccines.

§ Complete was measured by the presence of data in either the lot number or expiration date fields; Accurate is measured separately for lot number or expiration date: first, the field must have been complete and second, it must have matched the reference table “source of truth.”

Table 11. EMR Data: Data Quality by 2D Barcoded and Delivery Site (Public/Private) Vaccinations - Post-Implementation

Post-Implementation		Complete §						Accurate §						
			2D Vaccines			Non-2D Vaccines			2D Vaccines				Non-2D Vaccines	
Lot Number	*n* =	2D n=	2D Comp. n=	%	Non-2D n=	Non-2D Comp. n=	%	2D n=	2D Accur. n=		%	Non-2D n=	Non-2D Accur. n=	%
Total Vaccinations	970,261	60,461	60,461	100.0%	909,800	886,005	97.4%	60,461	60,323		99.8%	909,800	872,692	96.2%
Public *	537,040	35,085	35,085	100.0%	501,955	496,387	98.9%	35,085	35,069		99.95%	501,955	492,586	98.1%
Private	433,221	25,376	25,376	100.0%	407,845	389,618	95.5%	25,376	25,254		99.5%	407,845	380,106	93.2%
Expiration Date	*n* =	2D n=	n	%	Non-2D n=	n	%	2D n=	2D Accur. n=		%	Non-2D n=	Non-2D Accur. n=	%
Total Vaccinations	876,562	56,945	56,619	99.4%	819,617	784,246	95.7%	56,945	55,426		97.3%	819,617	724,089	92.5%
Public *	535,214	35,072	35,069	99.99%	500,142	491,706	98.3%	35,072	35,019		99.8%	500,142	472,446	94.5%
Private	341,348	21,873	21,550	98.5%	319,475	292,540	91.6%	21,873	20,407		93.3%	319,475	251,643	78.8%

* Public sites were Public Health Department clinics. Private included both private practices and 1 commercial pharmacy site.

** Includes 2D and Non-2D barcoded vaccines.

§ Complete was measured by the presence of data in either the lot number or expiration date fields; Accurate is measured separately for lot number or expiration date: first, the field must have been complete and second, it must have matched the reference table “source of truth.”

Table 12. EMR Data: Lot Number Data Quality of 2D Vaccines by Pre- and Post-Implementation -- All Sites

All Sites		Pre-Implementation **			Post-Implementation			Pre-Implementation **				Post-Implementation		
			Complete §			Complete §			Accurate §				Accurate §	
Lot Number	*n* =	Pre-I n=	n	%	Post-I n=	n	%	Pre-I n=	n		%	Post-I n=	n	%
Total Vaccinations	1,313,463	343,202	320,261	93.3%	970,261	946,466	97.5%	343,202	312,236		91.0%	970,261	933,015	96.2%
2D Barcoded *	61,567	1,106	1,106	100.0%	60,461	60,461	100.0%	1,106	1,088		98.4%	60,461	60,323	99.8%
Non-2D Barcoded	1,251,896	342,096	319,155	93.3%	909,800	886,005	97.4%	342,096	311,148		91.0%	909,800	872,692	95.9%
Expiration Date	*n* =	Pre-I n= †	n	%	Post-I n=	n	%	Pre-I n= †	n		%	Post-I n= †	n	%
Total Vaccinations	1,183,602	307,040	264,089	86.0%	876,562	840,865	95.9%	286,600	228,612		79.8%	842,273	779,515	92.5%
2D Barcoded *	57,972	1,027	1,021	99.4%	56,945	56,619	99.4%	1,027	962		93.7%	56,942	55,426	97.3%
Non-2D Barcoded	1,125,630	306,013	263,068	86.0%	819,617	784,246	95.7%	286,600	227,650		79.4%	785,331	724,089	92.2%

* 2D-Barcoded Vaccines include Adacel, Daptacel, Fluzone, Havrix, IPOL, Menactra, Pediatric DT, and Tenivac that contain a 2D barcode.

** Includes 2D and Non-2D barcoded vaccines. None of the pre-implementation (in grey) vaccinations used 2D scanners. Numbers for relative comparison only.

† These totals differ between "complete" and "accurate" because of more missing records.

§ Complete was measured by the presence of data in either the lot number or expiration date fields; Accurate is measured separately for lot number or expiration date: first, the field must have been complete and second, it must have matched the reference table “source of truth.”

Table 13. EMR Data: Lot Number Data Quality of 2D Vaccines by Pre- and Post-Implementation -- Public Sites

Public Sites		Pre-Implementation **			Post-Implementation			Pre-Implementation **				Post-Implementation		
			Complete §			Complete §			Accurate §				Accurate §	
Lot Number	*n =*	Pre-I n=	n	%	Post-I n=	n	%	Pre-I n=	n		%	Post-I n=	n	%
Total Vaccinations	645,848	108,808	107,080	98.4%	537,040	531,472	99.0%	108,808	104,310		95.9%	537,040	527,655	98.3%
2D Barcoded *	35,218	133	133	100.0%	35,085	35,085	100.0%	133	133		100.0%	35,085	35,069	100.0%
Non-2D Barcoded	610,630	108,675	106,947	98.4%	501,955	496,387	98.9%	108,675	104,177		95.9%	501,955	492,586	98.1%
Expiration Date	*n =*	Pre-I n= †	n	%	Post-I n=	n	%	Pre-I n= †	n		%	Post-I n= †	n	%
Total Vaccinations	643,698	108,484	101,863	93.9%	535,214	526,775	98.4%	99,765	89,713		89.9%	521,319	507,465	97.3%
2D Barcoded *	35,204	132	132	100.0%	35,072	35,069	100.0%	132	131		99.2%	35,072	35,019	99.8%
Non-2D Barcoded	608,494	108,352	101,731	93.9%	500,142	491,706	98.3%	99,633	89,582		89.9%	486,247	472,446	97.2%

* 2D-Barcoded Vaccines include Adacel, Daptacel, Fluzone, Havrix, IPOL, Menactra, Pediatric DT, and Tenivac that contain a 2D barcode.

** Includes 2D and Non-2D barcoded vaccines. None of the pre-implementation (in grey) vaccinations used 2D scanners. Numbers for relative comparison only.

† These totals differ between "complete" and "accurate" because of more missing records.

§ Complete was measured by the presence of data in either the lot number or expiration date fields; Accurate is measured separately for lot number or expiration date: first, the field must have been complete and second, it must have matched the reference table “source of truth.”

Table 14. EMR Data: Expiration Date Data Quality of 2D Vaccines by Pre- and Post-Implementation -- Private Sites

Private Sites		Pre-Implementation **			Post-Implementation			Pre-Implementation **				Post-Implementation		
			Complete §			Complete §			Accurate §				Accurate §	
Lot Number	*n* =	Pre-I n=	n	%	Post-I n=	n	%	Pre-I n=	n		%	Post-I n=	n	%
Total Vaccinations	667,615	234,394	213,181	90.9%	433,221	414,994	95.8%	234,394	207,926		88.7%	433,221	405,360	93.6%
2D Barcoded *	26,349	973	973	100.0%	25,376	25,376	100.0%	973	955		98.2%	25,376	25,254	99.5%
Non-2D Barcoded	641,266	233,421	212,208	90.9%	407,845	389,618	95.5%	233,421	206,971		88.7%	407,845	380,106	93.2%
Expiration Date	*n* =	Pre-I n= †	n	%	Post-I n=	n	%	Pre-I n= †	n		%	Post-I n= †	n	%
Total Vaccinations	539,904	198,556	162,226	81.7%	341,348	314,090	92.0%	186,835	138,899		74.3%	320,954	272,050	84.8%
2D Barcoded *	22,768	895	889	99.3%	21,873	21,550	98.5%	895	831		92.8%	21,870	20,407	93.3%
Non-2D Barcoded	517,136	197,661	161,337	81.6%	319,475	292,540	91.6%	185,940	138,068		74.3%	299,084	251,643	84.1%

* 2D-Barcoded Vaccines include Adacel, Daptacel, Fluzone, Havrix, IPOL, Menactra, Pediatric DT, and Tenivac that contain a 2D barcode.

** Includes 2D and Non-2D barcoded vaccines. None of the pre-implementation (in grey) vaccinations used 2D scanners. Numbers for relative comparison only.

† These totals differ between "complete" and "accurate" because of more missing records.

§ Complete was measured by the presence of data in either the lot number or expiration date fields; Accurate is measured separately for lot number or expiration date: first, the field must have been complete and second, it must have matched the reference table “source of truth.”

Table 15. IIS Data: Lot Number Data Quality of 2D Vaccines by Pre- and Post-Implementation -- All Sites

All Sites		Pre-Implementation **			Post-Implementation			Pre-Implementation **			Post-Implementation		
			Complete §			Complete §			Accurate §			Accurate §	
Lot Number	*n =*	Pre-I n=	n	%	Post-I n=	n	%	Pre-I n=	n	%	Post-I n=	n	%
Total Vaccinations	1,579,327	448,655	350,903	78.2%	1,130,672	1,047,574	92.7%	448,655	337,394	75.2%	1,130,672	995,140	88.0%
2D Barcoded *	50,454	1,270	1,270	100.0%	49,184	49,184	100.0%	1,270	1,192	93.9%	49,184	48,160	97.9%
Non-2D Barcoded	1,528,873	447,385	349,633	78.2%	1,081,488	998,390	92.3%	447,385	336,202	75.1%	1,081,488	946,980	87.6%
Expiration Date	*n =*	Pre-I n= †	n	%	Post-I n=	n	%	Pre-I n= †	n	%	Post-I n= †	n	%
Total Vaccinations	1,348,251	360,010	285,984	79.4%	988,241	680,962	68.9%	335,530	256,482	76.4%	936,735	618,526	66.0%
2D Barcoded *	43,060	1,133	920	81.2%	41,927	28,149	67.1%	1,133	910	80.3%	41,927	27,737	66.2%
Non-2D Barcoded	1,305,191	358,877	285,064	79.4%	946,314	652,813	69.0%	334,397	255,572	76.4%	894,808	590,789	66.0%

* 2D-Barcoded Vaccines include Adacel, Daptacel, Fluzone, Havrix, IPOL, Menactra, Pediatric DT, and Tenivac that contain a 2D barcode.

** Includes 2D and Non-2D barcoded vaccines. None of the pre-implementation vaccinations use 2D scanners. Numbers are shown for relative comparison only.

† These totals differ between "complete" and "accurate" because of more missing records.

§ Complete was measured by the presence of data in either the lot number or expiration date fields; Accurate is measured separately for lot number or expiration date: first, the field must have been complete and second, it must have matched the reference table “source of truth.”

Table 16. IIS Data: Lot Number Data Quality of 2D Vaccines by Pre- and Post-Implementation -- Public Sites

Public Sites		Pre-Implementation **			Post-Implementation			Pre-Implementation **			Post-Implementation		
			Complete §			Complete §			Accurate §			Accurate §	
Lot Number	*n* =	Pre-I n=	n	%	Post-I n=	n	%	Pre-I n=	n	%	Post-I n=	n	%
Total Vaccinations	354,025	120,707	102,298	84.7%	233,318	229,667	98.4%	120,707	101,132	83.8%	233,318	224,706	96.3%
2D Barcoded *	13,166	165	165	100.0%	13,001	13,001	100.0%	165	165	100.0%	13,001	12,960	99.7%
Non-2D Barcoded	340,859	120,542	102,133	84.7%	220,317	216,666	98.3%	120,542	100,967	83.8%	220,317	211,746	96.1%
Expiration Date	*n* =	Pre-I n= †	n	%	Post-I n=	n	%	Pre-I n= †	n	%	Post-I n= †	n	%
Total Vaccinations	318,325	102,915	95,175	92.5%	215,410	204,861	95.1%	97,377	87,589	89.9%	205,537	192,193	93.5%
2D Barcoded *	12,436	165	147	89.1%	12,271	12,087	98.5%	165	147	89.1%	12,271	12,059	98.3%
Non-2D Barcoded	305,889	102,750	95,028	92.5%	203,139	192,774	94.9%	97,212	87,442	89.9%	193,266	180,134	93.2%

* 2D-Barcoded Vaccines include Adacel, Daptacel, Fluzone, Havrix, IPOL, Menactra, Pediatric DT, and Tenivac that contain a 2D barcode.

** Includes 2D and Non-2D barcoded vaccines. None of the pre-implementation vaccinations use 2D scanners. Numbers are shown for relative comparison only.

† These totals differ between "complete" and "accurate" because of more missing records.

§ Complete was measured by the presence of data in either the lot number or expiration date fields; Accurate is measured separately for lot number or expiration date: first, the field must have been complete and second, it must have matched the reference table “source of truth.”

Table 17. IIS Data: Lot Number Data Quality of 2D Vaccines by Pre- and Post-Implementation -- Private Sites

Private Sites		Pre-Implementation **			Post-Implementation			Pre-Implementation **			Post-Implementation		
			Complete §			Complete §			Accurate §			Accurate §	
Lot Number	*n* =	Pre-I n=	n	%	Post-I n=	n	%	Pre-I n=	n	%	Post-I n=	n	%
Total Vaccinations	1,225,302	327,948	248,605	75.8%	897,354	817,907	91.1%	327,948	236,262	72.0%	897,354	770,434	85.9%
2D Barcoded *	37,288	1,105	1,105	100.0%	36,183	36,183	100.0%	1,105	1,027	92.9%	36,183	35,200	97.3%
Non-2D Barcoded	1,188,014	326,843	247,500	75.7%	861,171	781,724	90.8%	326,843	235,235	72.0%	861,171	735,234	85.4%
Expiration Date	*n* =	Pre-I n= †	n	%	Post-I n=	n	%	Pre-I n= †	n	%	Post-I n= †	n	%
Total Vaccinations	1,029,926	257,095	190,809	74.2%	772,831	476,101	61.6%	238,153	168,893	70.9%	731,198	426,333	58.3%
2D Barcoded *	30,624	968	773	79.9%	29,656	16,062	54.2%	968	763	78.8%	29,656	15,678	52.9%
Non-2D Barcoded	999,302	256,127	190,036	74.2%	743,175	460,039	61.9%	237,185	168,130	70.9%	701,542	410,655	58.5%

* 2D-Barcoded Vaccines include Adacel, Daptacel, Fluzone, Havrix, IPOL, Menactra, Pediatric DT, and Tenivac that contain a 2D barcode.

** Includes 2D and Non-2D barcoded vaccines. None of the pre-implementation vaccinations use 2D scanners. Numbers are shown for relative comparison only.

† These totals differ between "complete" and "accurate" because of more missing records. And, there were fewer records with the "accurate" variable available.

§ Complete was measured by the presence of data in either the lot number or expiration date fields; Accurate is measured separately for lot number or expiration date: first, the field must have been complete and second, it must have matched the reference table “source of truth.”

Additional IIS Data Tables

For reference, Tables 18, 19, 20, and 21 below give additional details about the IIS Dataset findings.

Table 18. IIS Data: Total Numbers of Practices by Vaccine

	2D Barcoded Vaccines *			Non-2D Barcoded Vaccines **			
	# Practices using these vaccines	# Practices Pre-Pilot	# Practices During Pilot	# Practices using these vaccines	# Practices Pre-Pilot	# Practices During Pilot	All Practices
Adacel vials	71	0	71	163	123	148	165
Daptacel vials	77	1	77	141	97	136	141
Fluzone unit-dose vials (2012)	82	0	82	188	139	185	188
Havrix Adult unit-dose vials	29	1	29	208	137	202	208
IPOL multi-dose vials	53	0	53	198	133	192	198
Menactra unit-dose vials	165	54	164	184	138	172	189
Pediatric DT unit-dose vials	4	0	4	93	71	77	93
Tenivac vials	0	0	0	58	5	58	58

* These include only LOT # that contained 2D barcode

** Includes the vaccines of this type without 2D barcodes.

Table 19. IIS Data: Public and Private Practices by Vaccine

	Public Practices (n=45)			Private Practices (n=166)			
2D Barcoded Vaccines *	# Practices using these vaccines	# Practices Pre-Pilot	# Practices During Pilot	# Practices using these vaccines	# Practices Pre-Pilot	# Practices During Pilot	Total
Adacel vials	8	0	8	63	0	63	71
Daptacel vials	9	0	9	68	1	68	77
Fluzone unit-dose vials (2012)	20	0	20	62	0	62	82
Havrix Adult unit-dose vials	13	2	13	16	0	16	29
IPOL multi-dose vials	9	0	9	44	0	44	53
Menactra unit-dose vials	39	12	39	126	42	125	165
Pediatric DT unit-dose vials	3	1	3	1	0	1	4
Tenivac vials	0	0	0	0	0	0	0
Non-2D-barcoded Vaccines **	45	45	44	166	160	162	211

* These include only LOT # that contained 2D barcode

** Includes all non-2D vaccines including the non-2D listed above.

Table 20. IIS Data: Data Quality by Total and Barcode Type (2D/Non-2D) Vaccinations

All Sites		Pre-Implementation **			Post-Implementation			Pre-Implementation **			Post-Implementation		
			Complete §			Complete §			Accurate §			Accurate §	
Lot Number	*n =*	Pre-I n=	n	%	Post-I n=	n	%	Pre-I n=	n	%	Post-I n=	n	%
Total Vaccinations	1,579,327	448,655	350,903	78.2%	1,130,672	1,047,574	92.7%	448,655	337,394	75.2%	1,130,672	995,140	88.0%
2D Barcoded *	50,454	1,270	1,270	100.0%	49,184	49,184	100.0%	1,270	1,192	93.9%	49,184	48,160	97.9%
Non-2D Barcoded	1,528,873	447,385	349,633	78.2%	1,081,488	998,390	92.3%	447,385	336,202	75.1%	1,081,488	946,980	87.6%
Expiration Date	*n =*	Pre-I n= †	n	%	Post-I n=	n	%	Pre-I n= †	n	%	Post-I n= †	n	%
Total Vaccinations	1,348,251	360,010	285,984	79.4%	988,241	680,962	68.9%	335,530	256,482	76.4%	936,735	618,526	66.0%
2D Barcoded *	43,060	1,133	920	81.2%	41,927	28,149	67.1%	1,133	910	80.3%	41,927	27,737	66.2%
Non-2D Barcoded	1,305,191	358,877	285,064	79.4%	946,314	652,813	69.0%	334,397	255,572	76.4%	894,808	590,789	66.0%

* 2D-Barcoded Vaccines include Adacel, Daptacel, Fluzone, Havrix, IPOL, Menactra, Pediatric DT, and Tenivac that contain a 2D barcode.

** Includes 2D and Non-2D barcoded vaccines. None of the pre-implementation vaccinations use 2D scanners. Numbers are shown for relative comparison only.

† These totals differ between "complete" and "accurate" because fewer expiration dates were provided.

§ Complete was measured by the presence of data in either the lot number or expiration date fields; Accurate is measured separately for lot number or expiration date: first, the field must have been complete and second, it must have matched the reference table “source of truth.”

Table 21. IIS Data: Data Quality by Total and Delivery Site (Public/Private) Vaccinations

		Pre-Implementation **			Post-Implementation			Pre-Implementation **			Post-Implementation		
			Complete §			Complete §			Accurate §			Accurate §	
Lot Number	*n* =	Pre-I n=	n	%	Post-I n=	n	%	Pre-I n=	n	%	Post-I n=	n	%
Total Vaccinations	1,579,327	448,655	350,903	78.2%	1,130,672	1,047,574	92.7%	448,655	337,394	75.2%	1,130,672	995,140	88.0%
Public *	354,025	120,707	102,298	84.7%	233,318	229,667	98.4%	120,707	95,163	78.8%	233,318	224,706	96.3%
Private	1,225,302	327,948	248,605	75.8%	897,354	817,907	91.1%	257,095	212,513	82.7%	897,354	770,434	85.9%
Expiration Date	*n* =	Pre-I n=	n	%	Post-I n=	n	%	Pre-I n=	n	%	Post-I n=	n	%
Total Vaccinations	1,348,251	360,010	285,984	79.4%	988,241	680,962	68.9%	335,530	256,482	76.4%	936,735	618,526	66.0%
Public *	318,325	102,915	95,175	92.5%	215,410	204,861	95.1%	97,377	87,589	89.9%	205,537	192,193	93.5%
Private	1,029,926	257,095	190,809	74.2%	772,831	476,101	61.6%	238,153	168,893	70.9%	731,198	426,333	58.3%

* Public sites were Public Health Department clinics. Private included both private practices and 1 commercial pharmacy site.

** Includes 2D and Non-2D barcoded vaccines.

† These totals differ between "complete" and "accurate" because fewer expiration dates were provided.

§ Complete was measured by the presence of data in either the lot number or expiration date fields; Accurate is measured separately for lot number or expiration date: first, the field must have been complete and second, it must have matched the reference table “source of truth.”

Chapter 5 – Discussion

5.1. Introduction

This chapter summarizes this thesis project and provides an overall discussion of the secondary analysis of the 2D Vaccine Barcode Pilot Data. The conclusion section will provide a summary and highlights of the study; discuss notable aspects, outcomes, and implications of the analysis; recommend future research and analysis worth exploring on the topic; and, provide a concluding statement.

5.2. Summary of study

CDC contracted with Deloitte Consulting to conduct the *Implementation Pilot for Two-Dimensional (2D) Vaccine Barcode Utilization* that occurred in 2011 – 2012. This pilot provided 2D scanning technology to 217 public, private, and pharmacy immunizer practices as an intervention to evaluate the effect of 2D scanners on the data quality (i.e., completeness and accuracy) of the immunizations records captured in the practices' electronic medical records (EMR) and the corresponding state/city Immunization Information System (IIS). This thesis project performed a secondary data analysis using the pilot EMR and IIS datasets focusing on two hypotheses: 1) the level of accuracy and completeness of the vaccination records recorded using 2D technology will be greater than those vaccinations recorded without the technology; and, 2) the records from public delivery sites (i.e., public health departments or Federally Qualified Health Centers) will have a greater level of accuracy and completeness than private practice delivery sites.

The literature review covered the subjects of 2D barcoding, the need for more accurate and complete vaccine record keeping, and the history of 2D barcode use with vaccines. The

National Childhood Vaccine Injury Act of 1986 was passed as a result of great scrutiny and controversy over DTP vaccinations and the alleged, but not confirmed, causal relationship to brain damage among young children (Centers for Disease Control and Prevention, 1991). This law established a mechanism for compensation to families of children injured by vaccines and required health providers to record vaccinations to accurately identify the lot number, type, and presentation of administered vaccines. Research studies on immunization records and EMR documentation showed sub-optimal accuracy and a need for better more automated record-keeping. The literature indicated that the use of 2D barcode technology could be a solution for better record keeping and could aid in more accurate reporting to the Vaccine Adverse Event Reporting System (VAERS). From the history of 2D barcodes on vaccines, the literature showed how both the industry and technology matured to the point of FDA acceptance of the 2D barcodes today. All of the literature highlighted the progression of studies and information that has led to the utilization of 2D barcodes.

The methodology of this thesis project relied exclusively on data previously gathered during the 2D Vaccine Barcode Pilot. The two separate de-identified datasets – EMR and IIS – included 1,346,837 and 1,687,366 vaccination records respectively. The data were further cleaned, standardized with missing data, and analyzed to test the stated hypotheses. The limitations of the study project included a lack of ability to determine which vaccinations were definitively recorded using the 2D scanners versus being manually entered. There were key data attributes that were missing that would have strengthened the study such as an exact indicator of the use of the 2D barcode scanner during administration, complete data about publicly-funded vaccine types, and having full consistent reference data that matched the administration records.

The results of the analyses showed three main findings. First, EMR data showed a greater level of completeness -- a 4.2% (i.e., 93.3% versus 97.5%) average increase in lot number data; a 9.9% (i.e., 86.0% versus 95.9%) average increase in expiration dates -- and accuracy – a 5.2% (i.e., 91.0% versus 96.2%) average increase in lot numbers, and a 12.8% (i.e., 79.8% versus 92.5%) increase in expiration dates -- of the records using 2D technology; 2) the public practices had greater data quality (i.e., for completeness: an average of 3.2% (99.0% public versus 95.8% private) and 6.4% (98.4% public versus 92.0% private) greater results for lot number and expiration dates respectively; and for accuracy: a 4.7% (98.3% public versus 93.6% private) and 12.6% (97.3% public versus 84.8% private) increase in lot number and expiration results respectively) than private sites; and 3) the private practices experienced an overall greater level of improvement of data record completeness and accuracy from pre- to post-implementation than the public sites (i.e., a greater improvement in lot number completeness by 4.2% (0.6% increase for public versus 4.8% increase for private), expiration date completeness by 5.8% (4.5% increase for public versus 10.3% increase for private), lot number accuracy by 2.5% (2.4% increase for public versus 4.9% increase for private), and expiration date accuracy by 3.0% (7.4% increase for public versus 10.4% increase for private)).

5.3. Discussion and Implications

Inconsistencies with IIS versus EMR Data

As displayed in the results Section 4.5 above, the IIS data tables displayed data results in the IIS dataset that were inconsistent with the EMR dataset. The IIS expiration date data showed less complete (10.5% decrease in completeness (79.4% pre- versus 68.9% post-implementation)) and less accurate (10.4% decrease in accuracy (76.4% pre- versus 66.0% post-implementation)) results then the EMR data (9.9% increase in completeness (86.0% pre- versus 95.9% post-

implementation); 12.8% increase in accuracy (79.8% pre- versus 95.9% post-implementation)) after the barcode scanners were installed. There were differences in the two datasets that may explain the inconsistencies. First, the EMR data were received directly from the practices to the pilot study administrators as raw data dumps. The IIS data were provided by the ten IIS grantees after some amount of data cleansing and/or manipulation may have occurred (Deloitte Corporation, 2014). This manipulation may have skewed the data. Further study could be done to determine if the data entry method into the IIS (i.e., direct IIS only, EMR connected to IIS, manual upload to IIS, or double data entry) was a factor (Deloitte Corporation, 2014). A variable for these data were present within the records and could be analyzed.

Second, due to inconsistent procedures with some of the IIS grantees and differences in protocols and available data, it was unclear how each of the fields in the IIS data was reported by the practices. For example, it was unclear if missing fields occurred due to a data entry error or if the information was omitted from being transmitted to the IIS. Third, some of the IIS grantees did not collect nor did they submit expiration dates for any practices. Although these omissions did not negatively affect the overall quantities needed for the sample to be significant, the absence of that data may have skewed the results. For those reasons, the results from the EMR data likely are a closer representation of the broader population.

Expanding 2D Barcode Utilization

Based on the results of the EMR data, there were improvements in completeness and accuracy of both lot numbers and expiration dates in the data records. This pilot population experienced modest increases in records for some categories from pre- to post-implementation such as public practices' completion rate of lot numbers that increased only by 0.6% or the accuracy only increasing by 2.4%. Also, the pilot practices started at impressively high levels of

completeness (e.g., lot number at 93%) and accuracy (e.g., lot number at 91%) pre-implementation. These data are not consistent with the 2011 Immunization Information System Annual Report (IISAR), a survey of the 56 IIS grantees, which showed that only 60% of the vaccination records contained in the lot number field (Cardemil et al., 2013).

The data quality may have been artificially high due to the population in the pilot. There were several attributes of the population that likely resulted in some selection bias that skewed the results. The 10 participating grantees were chosen out of convenience as being more capable and cooperative. These grantees also recommended lists of providers to participate in the study. Participation in the pilot was voluntary and 99% of those surveyed from the pilot practices believed 2D scanning would have somewhat or a very positive impact on data accuracy (Deloitte Corporation, 2014). This may have biased the results to have such dedicated professionals willing to use the scanning technology. The actual rate of increased data quality may be much higher.

Private Practices Vaccination Recording Procedures

A major finding of this study showed that public practices had a much higher rate of data quality both pre- and post-implementation than private practices. These findings are significant for two reasons. First, there may be some best practices or lessons learned that can be gleaned from the public practices that could be adopted by the private practices to obtain similar positive results. Second, the rate of improvement was higher on average in the private practices. In part this was due to a lower pre-implementation starting point (e.g., the private expiration date completeness started at an average rate of 81.7% compared to 93.9% of public sites – See Table 12 in Section 4.5). The results seen in the private practices may be more representative of a broad adoption of 2D barcode scanning in the U.S.

Potential Impact

The impact of 2D barcoding on vaccination record could result in a substantial impact if adopted and implemented nationally. For example, according to the 2011 IIS annual report of the 56 IIS grantees, 19.2 million children aged less than six received vaccinations that were reported to an IIS. Using the metric found in this analysis for the increase in EMR data lot number completeness (4.2% increase (from 93.3% complete to 97.5% complete), there could be a potential increase of 806,400 records each year that could be more complete in this age group alone (Cardemil et al., 2013). Using the accuracy rate of expiration dates metric (12.8% increase (from 79.8% accurate to 92.5% accurate), there could be a potential increase of 2,457,600 more records with accurate expiration dates in this age group. If the use of barcode scanners were to expand out to cover the entire population of the U.S. the number of vaccination records with near-perfect completeness and accuracy would potentially measure in the millions each year.

Improved Patient Safety

As the results of this analysis have shown, adding 2D barcode scanning into an EMR or IIS can improve the accuracy and completeness of immunization records. This has patient safety improvement implications by being able to correctly document the quantities, dosages, and types of vaccines administered to a patient. In the event of a vaccine recall or the identification of an impotent lot (i.e., one that is less effective), more patients that received the recalled vaccines could be identified.

Barcoding as a stand-alone technology solution has its limitations to just reading and delivering information into a particular field. However, if barcoding were to be fully integrated into an EMR or IIS, the full system could provide additional safety features. The EMR or IIS software integrator could program decision support features that would enable health

professionals to catch potential errors in the administration of an outdated or expired vaccine, an incorrect vaccine than the one ordered, a vaccine that may produce an allergic reaction, or a duplicate vaccination. An 2D barcoded-enabled EMR system that is fully integrated with the vaccine inventory system could free up time diverted to documentation allowing more time for patient care (American Academy of Pediatrics, 2011).

It should be noted that clinical best practices state that documentation of vaccinations should occur after that vaccine has been administered (i.e., the shot should be given then the EMR or IIS record should be notated). Vaccinations should not be recorded ahead of time as the patient may refuse the shot and there could be a risk of improper or inaccurate documentation in the medical records (Orenstein, 2014). This recommended timing has implications for 2D barcoding with vaccination documentation. Some of the potential safety improvements of catching potential administration errors (i.e., expired vaccines or incorrect vaccines) would not necessarily prevent these errors from occurring unless the barcode scanner was utilized before and after the vaccine was administered. It is not recommended to follow a practice of using the 2D scanner to document the vaccination prior to actual administration. However, 2D barcoding can help to accurately record and catch any mistakes.

5.4. Recommendations

This analysis produced convincing results that data quality was increased after the 2D scanners were a factor in increasing data quality. Due to the limitations of both the original data collection from the 2D Vaccine Barcode Pilot as well as the methods for this thesis project data analysis, further research should be conducted.

Additional Statistical Methods

The Deloitte pilot team utilized statistical models and multilevel logistic regression analysis to account for potential confounding. They analyzed the following independent variables: a) Temporal pattern of heightened vaccination activity that may have negatively affected data quality; b) the Proportion of vaccines that were publicly funded could have skewed the results because of more attention being placed on those types of vaccines; c) Individual practice data quality could have affected the results if a practice during pre-implementation had significantly lower results making the improvement appear higher; and d) For practices that had missing manufacturer or vaccine names it was a higher predictor for also having incorrect lot number and expiration date; and, e) the use of a generic vaccine name in place of the actual vaccine (e.g., “flu”) was a possible predictor for data quality (Deloitte Corporation, 2014). This level of analysis is recommended to account for the numerous variables and potential confounding.

Similarly, the post-implementation results of lot number completeness were always 100% due to the need to identify a 2D-barcoded vaccine by lot number. To counter this effect the pilot team utilized probabilistic or “fuzzy” matching to determine which of the incorrect lot numbers should have been correct. Fuzzy matching, also known as probabilistic linkage, is the mathematical process of determining similarities between strings of data using logical algorithms (e.g., replacements of the character “8” with a “B” or a zero with the letter “O” in the same position with the lot number string) (Deloitte Corporation, 2014). For the lot number field the pilot team looked to see if any of the incorrect lot numbers were actually close to an actual 2D lot. These were flagged as 2D and marked as inaccurate. Additional statistical and mathematical modeling was done to estimate how many of the incomplete lot numbers were actually 2D to

lower the completeness rate. The pilot team's results lowered the average lot number completeness rate down from 100% to 98.1% (Deloitte Corporation, 2014). Although this is still a very high outcome, the 1.9% difference could potentially make a significant change in the results. Using the same example of 19.2 million annual vaccinations in children under six, this 1.9% decrease in lot number completeness could relate to 364,800 fewer complete records (i.e., 806,400 originally estimated versus 441,600 after accounting for fuzzy matching estimate in this population) (Cardemil et al., 2013). For future research it is recommended to use either this kind of fuzzy matching or to design a study that can have greater clarity into the data points.

Lack of 2D Barcoded Vaccines

The 2D Vaccine Barcode Pilot occurred when there were limited numbers of 2D barcoded vaccines in production. As described in the history section of Chapter 2, this was due to several factors related to FDA restricting the vaccine manufacturers from printing 2D barcodes on the vaccines and then delays in inventories of 2D barcoded vaccines becoming available. There were only eight vaccines available during any part of the pilot and over half of the instances of the 2D vaccines occurred in the last 129 days of the pilot. The pilot was even extended to include an extra month of data collection for the majority of the sites (Fierro et al., 2014). Further research should occur now that there are at least 26 different vaccine presentations across three manufacturers currently shipping 2D barcoded vaccines in the U.S. (Centers for Disease Control and Prevention, 2014). The ideal scenario would be to have nearly 100% of a practice's vaccines labeled with a 2D barcode. This way there could be one consistent protocol for recording vaccinations that would use the barcode scanner. During the pilot study, a common theme for potentially not using the barcode scanner was the infrequency of use that sometimes would lead to forgetting to use the scanner (Fierro et al., 2014). Having more 2D

barcoded vaccines available in a future study could reduce or eliminate this potential confounding factor.

EMR Full Integration of 2D Barcoding

During this pilot study there were two EMR systems that had native[19] ability programmed into the system to capture lot number, expiration date, and product codes from a 2D barcode scan: Office Practicum and Mitchell & McCormick. These two EMRs accounted for 10.7% of the EMR dataset records (Deloitte Corporation, 2014). Having full integration of 2D barcoding should be the ideal situation to have greater level of data quality because data is transferred electronically directly into the EMR with the risk of introducing human factor mistakes (e.g., scanning data into an incorrect field or location on the EMR). Some new EMR systems (e.g., AthenaHealth's EMR[20]) not seen in this pilot study have the ability to notate a flag in the record when a vaccine has been scanned instead of being manually entered. This ability can provide researchers the ability to make a more definitive comparison of records' data quality. It is recommended that future research be completed on this existing data and future studies to analyze fully integrated EMR compared to others. If this type of analysis were to show a significant improvement to data quality, recommendations could be made to the EMR integrators to develop the 2D scanning capability in new releases of their software. This could further promote the usage of the 2D technology and break down barriers to adoption.

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[19] For all other EMR systems without native 2D scanning integration, the barcode scanners were programmed to type lot number and/or expiration date information directly into appropriate fields. This was a work around solution to pilot functionality.

[20] Based on conversations with 2D Barcode Pilot Team in 2014.

5.3. Conclusion

Despite some inconsistencies between the EMR and IIS datasets and limitations in data, the use of 2D barcode scanning for vaccine immunization record keeping results in a modestly higher level of completeness and accuracy. The results of this study showed increases of record data quality from pre- to post-implementation of the 2D scanners as well as higher data quality of 2D-barcoded vaccines compared to the non-2D vaccines recorded during the pilot. These results indicate a benefit to the immunization community in adopting and using the technology into the mainstream. For example as demonstrated in Section 5.3 “Discussions” above, 2D barcode use could result in a potential increase of 2,457,600 more records with accurate expiration dates among children under six that receive vaccinations. More complete, accurate, and consistent records are beneficial to public health by providing a more accurate account of individual and population vaccination history in the event of a vaccine adverse event, or if a specific vaccine lot was shown to have lost its potency requiring the need to track down recipients and re-immunize them with a potent vaccine.

A secondary finding showed that public practice delivery sites had higher levels of data quality in their vaccination records than private sites. This was a consistent finding across the entire study both pre- and post-implementation of 2D barcode scanners. This is a significant finding for two reasons. First, private practices can potentially glean best practices from the public sites on how vaccination documentation and record-keeping can be improved. Workflow studies similar to those completed during the 2D Vaccine Barcode Pilot study could be performed on a sample of public sites to note the major differences in protocols. The second significance in this public versus private analysis showed that private practices had greater improvement of data quality after using 2D barcode scanners. This increase may be used to

create a national predictive model for the amount of adoption of the 2D technology and the corresponding growth in overall vaccination record data quality.

References

American Academy of Pediatrics. (2009). Meeting Minutes.

American Academy of Pediatrics. (2011). Guideline for Practitioners. Retrieved April 22, 2013, from http://www2.aap.org/immunization/pediatricians/BarcodingClinicianGuidance.doc

Bundy, D. G., Shore, A. D., Morlock, L. L., & Miller, M. R. (2009). Pediatric vaccination errors: Application of the "5 Rights" framework to a national error reporting database. *Vaccine, 27*(29), 3890-3896. doi: 10.1016/j.vaccine.2009.04.005

Cardemil, C., Pabst, L., & Gerlach, K. (2013). Progress in Immunization Information Systems — United States, 2011. *Morbidy and Mortality Weekly Report, 62*(3), 48-51.

Centers for Disease Control and Prevention. (1991). Diphtheria, Tetanus, and Pertussis: Recommendations for Vaccine Use and Other Preventive Measures Recommendations of the Immunization Practices Advisory Committee (ACIP). *MMWR, 40*(RR-10), 1-28.

Centers for Disease Control and Prevention. (2011). Some Common Misconceptions About Vaccination and How to Respond to Them. Retrieved October 18, 2014, from http://www.cdc.gov/VACCINes/vac-gen/6mishome.htm#hotlots

Centers for Disease Control and Prevention. (2013). *VAERS unpublished data*.

Centers for Disease Control and Prevention. (2014, October 31, 2014). Two-Dimensional (2D) Vaccine Barcodes. Retrieved November 7, 2014, from http://www.cdc.gov/vaccines/programs/iis/2d-vaccine-barcodes/index.html

Chen, R. T., Pool, V., Takahashi, H., Weniger, B. G., & Patel, B. (2001). Combination vaccines: Postlicensure safety evaluation. *Clinical Infectious Diseases, 33*, S327-S333. doi: 10.1086/322569

Deloitte Corporation. (2014). Implementation Pilot for Two-Dimensional (2D) Vaccine Barcode Utilization: Final Report.

Douglas, J., & Larrabee, S. (2003). Bring barcoding to the bedside. *Nurs Manage, 34*(5), 36-40.

Fierro, L., Gaddis, M., Kinney, M., Reed, J., Kirkwood, B., Greene, M., . . . Friedman, D. (2014). Implementation Pilot for Two-Dimensional (2D) Vaccine Barcode Utilization: Summary Report: Deloitte Consulting, LLP.

Freed, G. L., Katz, S. L., & Clark, S. J. (1996). Safety of vaccinations. Miss America, the media, and public health. *Jama, 276*(23), 1869-1872.

Gaddis, M. (2013). Two-Dimensional Vaccine Barcode Pilot Educational Forum: 2D Barcode Pilot Lessons Learned & Early Findings Deloitte Consulting.

Garrett, P. (2011). EMR vs EHR - What is the Difference? Retrieved November 8, 2014, from http://www.healthit.gov/buzz-blog/electronic-health-and-medical-records/emr-vs-ehr-difference/

Gerlach, K., & Robinson, P. (2014). Moving Forward with 2D Barcodes. Powerpoint Presentation to the Immunization Services Division Seminar: U.S. Centers for Disease Control and Prevention.

GS1 US. (2013). A Brief History of GS1. Retrieved September 24, 2014, from http://www.gs1us.org/DesktopModules/Bring2mind/DMX/Download.aspx?Command=Core_Download&EntryId=393&PortalId=0&TabId=785

GS1 US. (2014). Barcodes. Retrieved October 18, 2014, from http://www.gs1us.org/resources/standards/barcodes

Institute of Medicine. (2000). *To Err Is Human: Building a Safer Health System*. Washington, DC: The National Academies Press.

Iskander, J. K. M. D. M. P. H., Miller, E. R. R. N. M. P. H., & Chen, R. T. M. D. M. A. (2004). The Role of the Vaccine Adverse Event Reporting System (VAERS) in Monitoring Vaccine Safety. *Pediatric Annals, 33*(9), 599-606.

Kennedy, E. D. (2013). 2D Barcode Pilot. Retrieved September 20, 2014, from http://www.cdc.gov/vaccines/programs/iis/2d-vaccine-barcodes/downloads/ed-forum-presentation-kennedy.pdf

National Childhood Vaccine Injury Act, 42 U.S.C. 300aa-301 to 300aa-334, Pub. L. No. 99-660 (1986).

O'Connor, A. C., Haque, S. N., Layton, C. M., Loomis, R. J., Braun, F. M., Amoozegar, J. B., . . . Chamiec-Case, L. A. (2012). Report to CDC: Impact of a Two-Dimensional Barcode for Vaccin Production, Clinical Documentation, and Public Health Reporting and Tracking. Research Triangle Park, NC: RTI International.

O'Connor, A. C., Kennedy, E. D., Loomis, R. J., Haque, S. N., Layton, C. M., Williams, W. W., . . . Weinbaum, C. (2013). Prospective cost-benefit analysis of a two-dimensional barcode for vaccine production, clinical documentation, and public health reporting and tracking. *Vaccine, 31*(31), 3179-3186. doi: 10.1016/j.vaccine.2013.04.073

Orenstein, W. (2014). Discussion of Relevance of 2D Barcodes on Vaccinations. In J. Durbin (Ed.).

Ortega, A. N., Andrews, S. F., Katz, S. H., Dowshen, S. A., Curtice, W. S., Cannon, M. E., . . . Kaiser, K. (1997). Comparing a computer-based childhood vaccination registry with parental vaccination cards: A population-based study of Delaware children. *Clinical Pediatrics, 36*(4), 217-221. doi: 10.1177/000992289703600406

Pereira, J. A., Quach, S., Hamid, J. S., Heidebrecht, C. L., Quan, S. D., Nassif, J., . . . Public Hlth Agcy, C. (2012). Exploring the feasibility of integrating barcode scanning technology into vaccine inventory recording in seasonal influenza vaccination clinics. *Vaccine, 30*(4), 794-802. doi: 10.1016/j.vaccine.2011.11.043

Pereira, J. A., Quach, S., Hamid, J. S., Quan, S. D., Diniz, A. J., Van Exan, R., . . . Canada Canadian Inst Hlth Res, I. (2014). The integration of barcode scanning technology into Canadian public health immunization settings. *Vaccine, 32*(23), 2748-2755. doi: 10.1016/j.vaccine.2013.11.015

Pickering, L. K., Baker, C., D, K., & Long, S. (2012). *Red Book: Report of the Committee on Infectious Diseases* (28th ed.): American Academy of Pediatrics.

Severyn, K. M. (1995). Jacobson v. Massachusetts: Impact on Informed Consent and Vaccine Policy. *J. Pharmacy & L., 5*, 249.

Simpson, N. (2001). Advocacy White Paper: Bar Coding for Patient Safety. Chicago, IL: Healthcare Information and Management Systems Society.

Bar Code Label Requirement for Human Drug Products and Biological Products (2004).

Guidance for Industry on Bar Code Label Requirements-Questions and Answers, 71 FR 58739 C.F.R. (2006).

U.S. Food and Drug Administration. (2011). Guidance for Industry: Bar Code Label Requirements, Questions and Answers: U.S. Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research.

U.S. Food and Drug Administration. (2012). FDA Basics > Vaccines, Blood, and Biologics. Retrieved November 8, 2014, from http://www.fda.gov/AboutFDA/Transparency/Basics/ucm193816.htm

Wilton, R., & Pennisi, A. J. (1994). EVALUATING THE ACCURACY OF TRANSCRIBED COMPUTER-STORED IMMUNIZATION DATA. *Pediatrics, 94*(6), 902-906.

Zhou, W., Pool, V., Iskander, J. K., English-Bullard, R., Ball, R., Wise, R. P., . . . Chen, R. T. (2003). Surveillance for Safety After Immunization: Vaccine Adverse Event Reporting System (VAERS) --- United States, 1991--2001. *Morbidy and Mortality Weekly Report, 52*(2201), 1-24.

Appendix 1 – Full List of Vaccines in Pilot Data

The following tables list the original values for all unique vaccines in the EMR and IIS records. In order to standardize the naming convention in order to make analysis more streamlined, the following values were changed: 'MENACTRA' → 'Menactra'; 'FLUZONE'→ 'Fluzone'; 'FLU' → 'Flu'.

Before the names of the vaccines were not changed, there were 69 unique vaccines in the EMR data and 68 unique vaccines in the IIS data.

EMR Data - Unique Vaccine Names

		Frequency	Percent
Valid	<*blank*>	26,281	1.9
1	ACTHIB	19,503	1.4
2	ADACEL	30,437	2.2
3	AFLURIA	941	.1
4	BOOSTRIX	23,310	1.7
5	CERVARIX	57	.0
6	COMVAX	99	.0
7	DAPTACEL	20,512	1.5
8	DECAVAC	523	.0
9	DTAP	7,343	.5
10	ENGERIX-B	46,562	3.4
11	Flu	15,878	1.2
12	FLU	7	.0
13	FLUARIX	15,741	1.2
14	FLULAVAL	530	.0
15	FLUMIST	55,685	4.1
16	FLUVARIX	297	.0
17	FLUVIRIN	2,880	.2
18	Fluzone	205	.0
19	FLUZONE	324,115	23.8

IIS Data - Unique Vaccine Names

		Frequency	Percent
Valid	<*blank*>	398	.0
1	ACTHIB	27,761	1.6
2	ADACEL	35,079	2.1
3	AFLURIA	105	.0
4	BIOTHRAX	1	.0
5	BOOSTRIX	31,171	1.8
6	CERVARIX	171	.0
7	COMVAX	984	.1
8	DAPTACEL	30,903	1.8
9	DECAVAC	1,956	.1
10	DTAP	13,200	.8
11	ENGERIX-B	90,873	5.4
12	Flu	41,974	2.5
13	FLUARIX	61,227	3.6
14	FLUMIST	77,418	4.6
15	FLUVIRIN	4,264	.3
16	Fluzone	428	.0
17	FLUZONE	200,889	11.9
18	GARDASIL	85,780	5.1
19	HAVRIX	122,580	7.3

20	GARDASIL	59,651	4.4
21	HAVRIX	86,859	6.4
22	HEP A	2,179	.2
23	HEP B	7,326	.5
24	HIB	2,585	.2
25	HIBERIX	276	.0
26	HIBTITER	153	.0
27	HPV	971	.1
28	IMOVAX	38	.0
29	INFANRIX	12,473	.9
30	IPOL	17,645	1.3
31	IXIARO	74	.0
32	KINRIX	19,091	1.4
33	Menactra	342	.0
34	MENACTRA	50,501	3.7
35	MENING	566	.0
36	MENOMUNE	244	.0
37	MENVEO	2,957	.2
38	MMR	61,095	4.5
39	PEDIARIX	29,403	2.2
40	PEDIATRIC DT	52,315	3.8
41	PEDVAX	23,515	1.7
42	PENTACEL	50,118	3.7
43	PNEUMO	18,398	1.4
44	PNEUMOVAX	6,594	.5
45	PNU-IMMUNE	2	.0
46	PREVNAR	2,385	.2
47	PREVNAR 13	77,700	5.7
48	PROHIBIT	3	.0
49	PROQUAD	3,862	.3
50	RABAVERT	158	.0

20	HEP A	251	.0
21	HEP B	1,968	.1
22	HIB	11,276	.7
23	HIBERIX	341	.0
24	HIBTITER	2,255	.1
25	HPV	268	.0
26	IMOVAX	241	.0
27	INFANRIX	13,756	.8
28	IPOL	45,369	2.7
29	IXIARO	83	.0
30	JE-VAX	8	.0
31	KINRIX	20,776	1.2
32	Menactra	566	.0
33	MENACTRA	47,795	2.8
34	MENING	5,965	.4
35	MENOMUNE	310	.0
36	MENVEO	4,394	.3
37	MMR	114,395	6.8
38	N/A	2,642	.2
39	PEDIARIX	45,072	2.7
40	PEDIATRIC DT	1,682	.1
41	PEDVAX	22,299	1.3
42	PENTACEL	98,910	5.9
43	PNEUMO	3,772	.2
44	PNEUMOVAX	10,436	.6
45	PNU-IMMUNE	22	.0
46	PREVNAR	2,119	.1
47	PREVNAR 13	125,749	7.5
48	PROHIBIT	10	.0
49	PROQUAD	4,384	.3
50	RABAVERT	81	.0

51	RECOMBIVAX	10,384	.8
52	ROTA	5,284	.4
53	ROTARIX	2,389	.2
54	ROTATEQ	46,270	3.4
55	ROTAVIRUS	1,600	.1
56	TD	5,677	.4
57	TDAP	1,634	.1
58	TENIVAC	2,200	.2
59	TETANUS	21	.0
60	THERACYS	1	.0
61	TRIPEDIA	319	.0
62	TWINRIX	5,763	.4
63	TYPHIUM	4,279	.3
64	VAQTA	11,473	.8
65	VARICELLA	2,433	.2
66	VARIVAX	70,747	5.2
67	VIVOTIF	66	.0
68	YF-VAX	1,796	.1
69	ZOSTAVAX	6,915	.5
	Total	1,359,636	100.0

51	RECOMBIVAX	10,169	.6
52	ROTA	843	.0
53	ROTARIX	7,448	.4
54	ROTATEQ	72,769	4.3
55	TD	58,269	3.5
56	TDAP	2,307	.1
57	TENIVAC	1,744	.1
58	TETANUS	16	.0
59	THERACYS	1	.0
60	TRIHIBIT	9	.0
61	TRIPEDIA	304	.0
62	TWINRIX	5,188	.3
63	TYPHIUM	4,584	.3
64	VAQTA	865	.1
65	VARIVAX	92,862	5.5
66	VIVOTIF	11	.0
67	YF-VAX	2,180	.1
68	ZOSTAVAX	13,440	.8
	Total	1,687,366	100.0

Appendix 2 – Full List of Variables

The pilot team provided this full list of variables provided for the analysis. Note that most of these were not used during this secondary data analysis.

NAME	LENGTH	VARNUM	LABEL	FORMAT
compliance_flag_exp	8	34		
compliance_flag_lot	8	33		
Corded_Scanners	8	10	Number of scanners given to practice	BEST
CPT	5	6	CPT code as reported by practice	$
CVX	12	3	CVX code as reported by practice	$
EMR_Base_Flag	8	35	Indicator of record being from EMR Baseline period	
EMR_Learn_Flag	8	36		
EMR_Maturity_Flag	8	37		
EMR_Vendor	26	9	Text description of EMR vendor used by practice	$
Exp_Acc_Comp	8	31	Expiration accurate and complete	
Exp_accurate	8	28	Expiration date accurate	
Exp_complete	8	24	Expiration date complete	
Exp_InRef	8	26	Reference Data had an Expiration Date	
Exp_Provided	8	21	Expiration date provided by site	
Flag_2D_Lot	8	18		
Funding_Source	28	4		$
Grantee	103	8		$
Group	1	16		$
Install_Date	8	15		MMDDYY
Install_yyyymm	8	39		
Lot_Acc_Comp	8	30	Lot number accurate and complete	
Lot_Accurate	8	17	Lot number accurate	
Lot_complete	8	23	Lot number complete	
Lot_Provided	8	20	Lot number provided by site	
Manufacturer	32	2		$
N	8	40	Record number for transfer	
NDC	12	7		$
Number_of_Physicians	11	12		$
Pilot_2D	8	43		
Pilot_Status	11	14		$

Pilot_Vaccine	8	42		
Private	8	46		
Prod_Acc_Comp	8	32	Product code accurate and complete	
Prod_accurate	8	29	Product code accurate	
Prod_complete	8	25	Product code complete	
Prod_InRef	8	27	Reference Data had a Product Code	
Prod_Provided	8	22	Product code provided by site	
Provider_ID	8	1		BEST
Public	8	45		
Reporting_Type	13	11		$
Scanner_Install	8	41		
Specialty	21	13		$
Unknown	8	47		
Vaccination_Date	8	5		MMDDYY
Vaccine_Generic	8	44		
Vaccine_Name	50	19		
yyyymm	8	38		