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Impact of a Two-Dimensional Barcode for Vaccine Production, Clinical Documentation, and Public Health Reporting and Tracking

Final Report

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EXECUTIVE SUMMARY

According to the National Childhood Vaccine Injury Act (NCVIA) (1986), documentation for immunization must include manufacturer and lot number and the American Academy of Pediatrics (AAP) recommends recording the expiration date (AAP Committee on Infectious Diseases, 2012). Since 2004, the U.S. Food and Drug Administration (FDA) has required that vaccine product labels be printed with a linear barcode containing a product's National Drug Code (NDC), which identifies the manufacturer, product name, and packaging information (FDA, 2004). Linear barcodes that could contain these data would be too large to appear on a label affixed to a 0.5 mL single-dose vial. Thus, barcodes appearing on vials, ampoules, and syringes of vaccines do not contain the lot number or expiration date.

The intent of the FDA's linear barcode rule was to enhance patient safety using machine-readable codes (FDA, 2004), but AAP (2010) noted that these barcodes are ineffective for patient safety because they omit lot number and expiration date. AAP has since assembled vaccine manufacturers, providers, public health groups (including the Centers for Disease Control and Prevention [CDC]), and other immunization stakeholders in an initiative to transition barcodes on unit-of-use vaccine containers from linear to two dimensional (2D).

2D barcodes are capable of containing product, expiration date, and lot number on product labels (Figure ES-1). AAP cited changes since FDA's 2004 rule was enacted, including decreasing costs of using 2D barcodes, changing immunization schedules, new vaccine products, and the prospect of meeting FDA's safety goals in its initiative. The FDA (2011) agreed with AAP's assessment and issued industry guidance in 2011 that stated it would grant vaccine manufacturers waivers to replace linear barcodes with 2D ones. A waiver is not necessary if both linear and 2D barcodes appear on a label.

Figure ES-1. Example Linear and 2D Barcodes

Example of linear barcode
Current linear barcodes required by the FDA contain only the vaccine product identification information.

Example of 2D barcode
A 2D, or data matrix, barcode can include product identification information as well as expiration date and lot number.

ES.1 Project Scope, Objectives, and Methodology Overview

In October 2010, CDC's Immunization Services Division contracted with RTI International, an independent, nonprofit research institute, to study the impacts 2D barcodes may have on

vaccine production, clinical documentation, and public health reporting and tracking for stakeholders in the U.S. immunization system. The study included a prospective economic analysis and an information systems analysis.[1] Stakeholders included in the study were vaccine manufacturers, vaccine users (e.g., immunization providers, immunization program managers), and immunization data users (e.g., immunization information systems [IIS], data exchange groups, vaccine-related tracking systems).

The United States has more than 30,000 pediatric, family health, internal medicine, and obstetric-gynecology (ob-gyn) practices (American Medical Association [AMA], 2011); nearly 4,000 health departments (National Association of County and City Health Officials [NACCHO], 2010); and thousands of pharmacies, retail-based clinics (RBCs), and mobile immunization sites. Because of this breadth, the scope for all quantitative analyses was narrowed to primary care providers (pediatric, family medicine, internal medicine, ob-gyn practices) and health departments. Impacts for other immunizers were reviewed qualitatively.

This study had three overarching objectives, which were organized into tasks:

1. **Stakeholder engagement to document knowledge, attitudes, and beliefs** about the impacts and implications of 2D barcodes for automated identification of vaccine products. Methods included semistructured interviews with representatives of all stakeholder groups and an internet survey of immunization providers.

2. **Prospective economic impact analyses** to assess public economic benefits and costs and the distribution of these costs and benefits across stakeholders. Primary and secondary data were inputted into economic models to analyze costs and benefits over a 10-year period of barcode use by immunizers, analyzing three different rates of barcode usage uptake for providers. The models developed analyzed the period from 2011 through 2023, which is 10 years beyond a predicted 2D barcode availability date of late 2012 or early 2013.

3. **Data exchange analysis and information technology standards mapping** to assess technical feasibility and identify any gaps in the technology infrastructure supporting standards-based exchange of immunization data. We reviewed health information exchange and data standards relevant to 2D barcodes to assess how information can be transmitted across stakeholders. This issue is particularly important as the United States moves from a largely paper-based records system to an electronic one.

ES.2 Two-Dimensional Barcoding of Product, Expiration Date, and Lot Number on Unit-of-Use Vaccine Product Labels

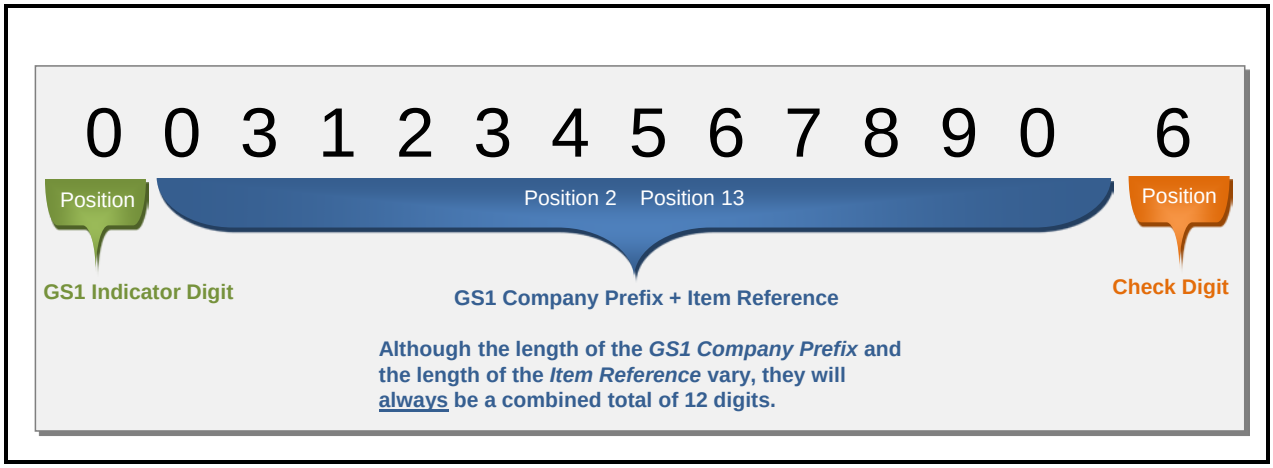
2D barcodes have the potential to improve the accuracy and efficiency of documentation for immunization. Information that is currently handwritten, typed into a computer, or both could be automatically captured by an inexpensive imaging device or scanner (currently

[1] Contract number GS10F0097L, awarded October 1, 2010, with a period of performance to September 30, 2011, and extended through March 31, 2012.

about $300). This information could automatically populate an electronic health record (EHR), practice management system, or IIS or be printed and placed in a paper file.

AAP, Canada's Automated Identification of Vaccine Products initiative, and other countries' groups are recommending the use of internationally-standard product identifiers, particularly the Global Trade Item Number (GTIN) (Public Health Agency of Canada and GS1 Canada, 2010). GS1, a global product identification standards organization, created the GTIN to identify products in the supply change. For prescription pharmaceutical products in the United States, the GTIN is a 14-digit numerical identifier with the NDC embedded in it (Figure ES-2). AAP has collaborated with GS1 to develop guidance for vaccine manufacturers on using GS1 standards for vaccine products. A principal advantage of using GTINs is that they must be registered with GS1 to ensure that a GTIN only refers to one specific product.

Figure ES-2. National Drug Code (NDC) Embedded in Global Trade Item Number (GTIN)



Source: GS1 Healthcare US

ES.3 Public Health Opportunity

2D barcoding of vaccines has the potential to prevent medication errors and ensure that the information about the vaccine received is entered accurately into the patient record (Simpson, 2001). Collecting product, expiration date, and lot information is critically important because of the possibility, however remote, that there may be specific vaccine safety concerns following administration. Public health agencies and providers must be able to locate persons that may have been administered a recalled product. Knowing the lot number can also identify safety concerns with a specific lot.

A review of the literature revealed that using 2D barcodes and scanners to document immunizations could improve patient safety and immunization surveillance:

- Wilton and Pennisi (1994) found that at least 10% of 2,098 children immunized at UCLA's Children's Health Center had transcription errors in their electronic immunization records.
- Bundy et al. (2009) found errors in recording product data (i.e., DTaP, Tdap, DT, or Td), errors in prescription (11%), errors in transcribing and documenting (10%), and dispensing errors (4.1%) in 607 patients' immunization records.
- More than 25% of records in the Vaccine Adverse Event Reporting System (VAERS) are missing lot number data (Kennedy, 2012).
- Between 2005 and 2010, 14 recalls out of 138 (10.1%) for biologics were for vaccines.
- As long as they enroll by 2012, eligible Medicare providers may earn up to $44,000 over 5 years; eligible Medicaid providers may earn up to $63,750 over 6 years. The Centers for Medicare & Medicaid Services' (CMS's) incentives are anticipated to have a dramatic impact on health care providers' adoption of EHRs and, by association, the potential adoption of barcoding for data collection.

ES.4 Impact on Vaccine Production

Of the 11 manufacturers that have FDA-approved vaccine products on the U.S. market, seven participated in our study. These seven manufacturers produce, market, or distribute over 90% of the total number of vaccine products licensed for sale in the United States. Five have plans to adopt 2D barcoding on the unit of use, one has no current plans to do so, and one is currently undecided.

Based on manufacturers' feasibility assessments, the technology is available to enable rapid 2D barcode printing, imaging, and image verification, and manufacturers will be able to optimize the printing process. Neither of the two manufacturers indicating they would not be implementing 2D barcoding objected to 2D barcoding because of technically infeasibility, suggesting that this is an engineering exercise and one-time expense rather than a cross-cutting change in production.

The 2D barcode will contain static NDC data and the variable expiration date and lot number, essentially precluding the option of having the symbol printed off site by a vendor. Having the 2D barcode printed off site, as is commonplace with linear barcodes today, would present significant coordination and inventory management challenges, as well as operational and regulatory risks. Therefore, manufacturers will have vendors produce the label but will print the 2D barcode at their production facilities.

The time required to implement barcoding was estimated to be at least 12 months but no more than 24 months and depended on such factors as number of packaging and labeling lines, capital budgeting and procurement procedures, and scheduled production downtime.

Post implementation, most manufacturers expect negligible incremental printing or other costs that would be above current expense levels.

We estimate one-time costs of $30.60 million for the 5 manufacturers indicating they intend to implement 2D barcoding, accruing between 2011 and 2013. The only incremental costs or benefits estimated pertain to eliminating peel-off labels from syringes and vials. These incremental benefits are expected to total $54.08 million (2010$) over this period, offsetting one-time costs to yield net benefits of $23.48 million through the end of the period of analysis of 2023.

The net present value (NPV) of expected manufacturer costs and benefits is $5.02 million when the Office of Management and Budget (OMB) specified 7% real social discount rate is applied (OMB, 1992).[2] At a rate set to 10%, which is closer to the biopharmaceutical industry real working average cost of capital (Harrington & Miller, 2010), the NPV is $0.17 million. A rate of 10.12% sets the NPV to zero, confirming our interview findings that manufacturers view the 2D barcoding initiative as a one-time cost.

ES.5 Impact on Clinical Documentation

Our approach to quantifying economic benefits was to analyze how scanning 2D barcodes could reduce the amount of time spent documenting immunizations relative to a business-as-usual case in which product, expiration date, and lot number are recorded by hand when reading product labels. The economic model combined survey data on expected barcode usage with time savings per dose associated with more efficient documentation.

ES.5.1 Survey Data Collection and Results

To ascertain the impacts on clinical documentation, RTI conducted telephone interviews with major professional associations and organizations, including AAP, American Academy of Family Physicians, American Congress of Obstetricians and Gynecologists, American College of Physicians, American Medical Association, American Pharmacy Association, American Hospital Association, Convenient Care Association, CDC, Association of Immunization Managers, American Immunization Registry Association, NACCHO, Visiting Nurses Association of America, Maxim Healthcare, and Walgreen's.

[2] Net present value is the sum of benefits and costs after discounting cash flows to a single year in order to determine whether an investment is acceptable, given some minimum rate of return (i.e., the discount rate).

We also fielded an internet survey to primary care providers and local health departments (LHDs) in late spring 2011.[3] The total number of completed surveys was 4,568, but after data cleaning and application of inclusion criteria, 3,669 were included in our analysis. Of these, 2,816 were private-practice providers and 853 were LHDs. If respondents did not provide their specialty or number of physicians, their responses were excluded from the analysis. We also applied an algorithm that reviewed respondents' contact information, zip codes, number of staff, and immunization volume to exclude duplicate records and outlier responses to the number of doses per physician.

Survey responses varied greatly by specialty; the greatest rate of response came from pediatrics and the lowest came from internal medicine. Out of an estimated population of 4,937 pediatric practices in the United States (AMA, 2011), 1,442 responses were received, equating to an estimated coverage rate of 29.2%. We received 968 responses from family practices (10.1% of 9,561 practices) and 853 from LHDs (24% of 3,669). Only 101 responses were from ob-gyn practices (1.8% of 5,725) and 57 from internal medicine practices (0.5% of 12,462).

Table ES-1 presents the anticipated likelihood of 2D barcode adoption by provider:

- 43.0% of pediatric practices would likely use 2D barcodes, and an additional 19.5% would if they had an EHR system. Only 4.0% said they would not use them, and only 16.5% said they did not know if they would use them.
- 53.5% of family medicine practices would likely use 2D barcodes, 16.3% would use them if they had an EHR system, 7.0% would not use them, and 23.2% said they did not know if they would use them.
- Less than half of ob-gyn (48.9%) and internal medicine (34.5%) practices said they would use 2D barcodes. About 20% of ob-gyn practices and 36.4% of internal medicine practices said they did not know whether they would use them. These results must be interpreted cautiously because of the low number of responses for these two specialties.
- 39.2% of LHDs would likely use 2D barcodes, 26.3% would if they had an EHR system, 3.6% would not use them, and 30.9% said they did not know if they would use them.

[3] The project's available resources precluded conducting a representative sample survey. Instead, we developed a marketing strategy "Take 10 to Enhance Vaccine Barcodes" and partnered with AAP, American Academy of Family Physicians (AAFP), American College of Obstetrician Gynecologists (ACOG), AMA, Association of Immunization Managers (AIM), and Vaccines for Children [VFC] Program coordinators to promote the survey. Partnering organizations received electronic files that included PDF and MS Word documents containing descriptions about and links to the World Wide Web-based survey. To encourage participation in the survey, respondents were entered into a raffle to receive one of 10 iPads. Participating VFC jurisdictions will receive survey results compiled for their jurisdiction.

Table ES-1. Likelihood that Practices and LHDs[a] Would Use 2D Barcodes

Specialty	Yes, My Practice Would Likely Use the Barcode	My Practice Would Likely Use the Barcode If We Had an Electronic Medical Record System	No, My Practice Would Not Likely Use the Barcode	I Do Not Know If My Practice Would Use the Barcode
Pediatrics (n=1,442)	60.0%	19.5%	4.0%	16.5%
Family practice (n=968)	53.5%	16.3%	7.0%	23.2%
Ob-gyn (n=101)	48.9%	18.1%	12.8%	20.2%
Internal medicine (n=57)	34.5%	23.6%	5.5%	36.4%
LHDs (n=853)	39.2%	26.3%	3.6%	30.9%

[a]LHD (Local health department)

- Overall, 113 primary care respondents (7.0% of 1,619 providing sufficient information) indicated that they did not report immunizations to IIS currently but would be more likely to do so if the 2D barcode were available.

Deciding whether to implement a new technology includes considering a variety of different factors. We asked respondents to review various factors and their relative importance in deciding whether to implement 2D barcode scanning. Primary care providers, in general, ranked the following decision factors as the five most important (Table ES-2):[4]

1. increased accuracy of records
2. decreased time spent recording vaccine information and/or documenting immunization
3. reliability of the barcodes
4. usability of the barcode scanners
5. more efficient and accurate management of inventory

ES.5.2 Economic Model Results

An analysis of a time–motion study conducted by the Verden Group in 33 practices in 2009 suggests that practices with EHRs will save approximately 39.4 seconds per dose scanned (95% CI: 34.8–43.9) and practices without EHRs will save about 36.5 seconds per dose (32.3–40.5).[5]

[4]Responses were ranked, with unimportant equal to 0, somewhat unimportant equal to 1, neutral equal to 2, important equal to 3, and very important equal to 4.

[5]The resulting dataset includes activity-specific time–motion estimates for the administration of 724 vaccines to 302 patients (cases) at 33 practices (30 pediatric practices, 3 family practices) in 17 states.

Table ES-2. Primary Care Providers' Perceptions of the Importance of 2D Barcode Usage Decision Factors (0 = unimportant, 4 = very important)

Rank	Factor	Mean Score
1	Increased accuracy of records	3.657
2	Decreased time spent recording vaccine information and/or documenting immunization	3.631
3	Reliability of the barcodes	3.567
4	Usability of the barcode scanners	3.553
5	More efficient and accurate management of inventory	3.528
6	Readability of the barcodes	3.522
7	Cost of scanner(s)	3.198
8	Potential decrease in the number of vaccines that do not get billed to a private payer	3.182
9	Training	3.068
10	Possible changes to workflow	2.972

Based on practices responding to our survey's workflow, volume of immunizations performed, and size and specialty characteristics, we forecasted expected adoption costs and cost savings from reducing the amount of time spent documenting immunizations for all primary care providers and health departments in the United States.

The model estimated that, if primary care practices and LHDs follow their stated preferences to use the 2D barcode, net benefits would be $333.6 million over the period from 2013 through 2023 for these stakeholders alone. If the rate of adoption were slowed by 50%, net benefits would decline to $326.8 million. If the rate of adoption were slowed by 67%, net benefits would decline to $311.3 million.

ES.6 Impact on Public Health Reporting and Tracking

A 2D barcode has yet to be used for vaccine product identification in the United States; therefore, it was of paramount importance to understand how different data exchange standards would accommodate its use.

We analyzed data exchange standards involved in immunization messaging: GS1, Health Level 7 (HL7), CDC 2.5.1 Implementation Guide for Immunization Messaging under HL7, X12, Healthcare Information Technology Standards Panel (HITSP), and National Council for Prescription Drug Program (NCPDP). We assessed how data elements to be contained in the 2D barcodes would interoperate with these standards. We also interviewed stakeholders from IIS, EHR vendors, HL7, and CDC and compiled additional resources provided by those stakeholders.

Table ES-3 provides a summary of how different 2D barcode elements are transmitted across immunization messaging standards. Because the NDC has three segments (labeler, product, and package codes), and some standards require vaccine product data to be in these discrete segments, the unsegmented GTIN does not map directly to individual fields. In other words, there is a one-to-many relationship between the GTIN and most data exchange standards' vaccine product fields. In contrast to the GTIN, the expiration date and lot number map directly to individual fields across standards and, therefore, do not present similar challenges.

Table ES-3. Summary Mapping Table[a, b]

GS1	FDA's National Drug Code	HL7—Barcoding Message Segment	2.5.1 Implementation Guide	X12—837P Transaction	HITSP Immunization Messages	NCPDP
Global Trade Item Number (GTIN)	Label code	Administered code	Substance manufacturer name	Labeler code	Substance manufacturer	Labeler code
	Product segment	Substance manufacturer name	Administered code	Product segment	Administered code	Product segment
	Package segment	Administered barcode identifier	Administered drug strength volume	Package segment		Package segment
			Administered drug strength volume units			
Expiration date (YYMMDD)		Substance expiration date	Substance expiration date			
Batch or lot number		Substance lot number	Substance lot number		Substance lot number	

[a]The yellow cells denote how the GTIN is mapped, green denotes the expiration date, and orange denotes the lot number. Please note that there are two columns for HL7.

[b]The NDC within the GTIN is the information source for the other standards.

A mapping table of GTIN, NDC segments, CDC's product identifier (CVX) and the manufacturer identifier (MVX), and related codes will be necessary. The table helps facilitate information exchange by outlining where the information in the barcode would fall in each standard, providing those who will implement the barcode the specifications necessary to accommodate receiving and interpreting the GTIN.

An undercurrent to reviewing the implications of the 2D barcode for standards-based data exchange is legacy issues associated with the NDC, CVX, and MVX. Traditionally, the NDC has not been used in immunization documentation, reporting, and tracking. Although some systems are able to accommodate the NDC, most use the CVX and MVX. IIS, for example, require the CVX, MVX, and lot number to document an immunization (CDC, 2011e). In the

future, the NDC will be the cornerstone of inventory control systems; thus, it is important that techniques be developed to use the NDC code.

ES.7 Summary Economic Analysis Results

Our economic analysis forecasts net economic benefits of at least $326.3 million to $348.5 million from 2011 through 2023 (Table ES-4). We calculated a series of performance measures on the time series of benefits and costs. These measures lead us to conclude that transitioning to 2D barcoding for vaccine product labels will have a benefit-to-cost ratio of 2.7 to 2.8 (using the OMB-specified 7% social discount rate); in other words, for every $1 expended, $2.70 to $2.80 in benefits are expected to accrue over the period from 2011 through 2023.

Table ES-4. Summary Public Measures of Economic Return (All Primary Care Specialties)

Costs for vaccine manufacturers, primary care providers (pediatrics, family medicine, ob-gyn, and internal medicine), health departments, and public-sector organizations compared with quantified economic benefits of making documentation more efficient.

	Rate of Adoption		
Measure, 2011–2023 Only	**Scenario 1, Set by Survey**	**Scenario 2, Slowed 50%**	**Scenario 3, Slowed 67%**
Total benefits (million $)	501.87	481.36	460.82
Total costs (million $)	153.33	139.66	134.53
Total net benefits (million $)	348.53	341.71	326.29
Net present value (3% discount rate) (million $)	271.49	263.37	249.41
Net present value (7% discount rate) (million $)	196.81	188.10	175.97
Benefit-cost ratio (3% discount rate)	3.0	3.1	3.1
Benefit-cost ratio (7% discount rate)	2.7	2.8	2.7
Internal rate of return	49%	46%	43%

Note: Ultimate penetration estimated to be 75.2% (pediatrics), 68.2% (family practice), 62.0% (ob-gyn), 53.3% (internal medicine), and 50.2% (health departments).

Economic impacts were quantified for vaccine manufacturers, primary care providers, LHDs, AAP, and CDC. Economic benefits associated with saving time during record keeping were used in the comparison with economic costs incurred by manufacturers, providers, and public-sector stakeholders. Other potential benefits not included in this model because of the inability to accurately quantify them were reductions in extraimmunization, more efficient inventory management, improved immunization data capture in IIS and other information systems, and enhanced product recall capabilities. Thus, the results are conservative.

We calculated costs for immunizers under three scenarios. The scenarios present a range of expected benefit because although we expect practices to follow their stated preferences to use 2D barcodes, it is possible that they may not be able to do so. Therefore, we allowed the accrual of economic benefits to slow by 50% and 67% under the possibility that providers may take two to three times as long to begin using the 2D barcodes.

The results presented in Table ES-4 must be interpreted cautiously because fewer than 100 valid survey responses were received for both ob-gyn and internal medicine practices. Table ES-5 presents the same measures as Table ES-4 but excludes ob-gyn and internal medicine practices. Note that although net benefits are reduced, costs fall by a larger percentage and the benefit-to-cost ratio increases to >3.1, depending on the rate of adoption. Pediatric and family medicine practices are higher volume immunizers than other primary care specialties and are expected to accrue higher net benefits, explaining the increase in measures of economic return when ob-gyn and internal medicine are excluded.

Table ES-5. Summary Public Measures of Economic Return (Excluding Ob-Gyn and Internal Medicine Practices)

Costs for vaccine manufacturers, primary care providers (pediatrics and family medicine only), health departments, and public-sector organizations compared with quantified economic benefits of making documentation more efficient. Excludes estimated costs and benefits for ob-gyn and internal medicine practices because of lower response rates for these specialties.

	Rate of Adoption		
Measure, 2011–2023 Only	**Scenario 1, Set by Survey**	**Scenario 2, Slowed 50%**	**Scenario 3, Slowed 67%**
Total benefits (million $)	447.02	429.00	410.96
Total costs (million $)	113.95	95.41	101.30
Total net benefits (million $)	333.08	333.59	309.67
Net present value (3% discount rate) (million $)	260.62	258.85	237.95
Net present value (7% discount rate) (million $)	190.34	186.87	169.24
Benefit-cost ratio (3% discount rate)	3.6	4.0	3.6
Benefit-cost ratio (7% discount rate)	3.2	3.5	3.1
Internal rate of return	53%	50%	45%

Note: Ultimate penetration estimated to be 75.2% (pediatrics), 68.2% (family practice), and 50.2% (health departments).

ES.8 Summary Conclusions, Limitations, and Recommendations

Our research leads us to conclude that 2D barcodes for vaccine primary packaging will have substantial net benefits for stakeholders in the U.S. immunization system (Table ES-6). Scanning 2D barcodes is expected to enhance patient safety, lower the cost of documenting immunizations, and increase the quality and coverage of data housed in myriad information systems.

Table ES-6. Benefits and Costs of Transitioning to 2D Barcodes for Primary Packaging[a]

Benefits	Costs
Automated identification of vaccine products using 2D barcodes offers the following advantages: ▪ enhanced patient safety by ensuring that the patient is being administered the correct product ▪ streamlined documentation and record-keeping procedures ▪ more accurate and complete immunization records ▪ better data quality for downstream uses of immunization data for surveillance and safety such as immunization information systems (IIS) and the Vaccine Adverse Event Reporting System (VAERS) ▪ improved vaccine recall and withdrawal processes and ▪ enhanced inventory management	2D barcodes also have cost implications for stakeholders that must be considered throughout the immunization system: ▪ upgrading the printing and imaging functionalities of manufacturers' vaccine product packaging and labeling lines ▪ purchasing scanners, adapting immunization workflows, and training of immunizers to use scanners to capture product data ▪ developing capabilities for information systems to ensure that product data captured from barcodes are interpretable and may be exchanged correctly ▪ providing education, training, and troubleshooting support to immunizers

[a]IIS (immunization information systems), VAERS (Vaccine Adverse Event Reporting System)

However, despite the positive results, a number of notable limitations to this analysis must be considered when reviewing and acting upon our results:

- Economic benefits are based on forecasts, and underlying these forecasts are market trends, stakeholder perceptions, costs, and other factors that are subject to change.
- Results only reflect 7 of 11 manufacturers with FDA-licensed products on the market in the United States in 2011, and 2 of those 7 did not have implementation plans.
- Survey data were collected using a survey that received large numbers of responses but did not rely on a representative sample of the national population of immunization providers or other potential 2D barcode users.
- Economic benefits and costs for complementary immunizers, including pharmacists, RBCs, and mobile immunizers, were not included.
- Not all economic benefits were quantified, particularly changes in extraimmunization rates, improvements in inventory management, and improved immunization surveillance.
- There may be unexpected and unintended benefits and costs that emerge during implementation or routine use of 2D barcodes.

A key focus in our analysis was on data exchange standards. Although data exchange standards can accommodate the 2D barcode, implementation of 2D barcoding for vaccine products will require a comprehensive mapping of GTINs to the delimited NDCs and CVX and MVX. These mapping tables should support all vaccine products on the market both on the public side as well as the private-purchase side. Including Current Procedural

Terminology (CPT) codes would facilitate billing; thus, it would be advantageous to include them in the mapping table. Programming efforts, education, and coordination with stakeholders are needed to use 2D barcodes across immunization encounters, inventory, billing, and other tracking systems used for immunization. Specific recommendations follow (see also Table ES-7).

Table ES-7. Summary of Recommendations[a]

Recommendation	Rationale
Maintain GTIN to NDC to CVX and MVX mapping table	Enable legacy systems to be populated with 2D-barcoded data; support data exchange and interoperability.
Collaborate with GS1	Ensure consistent messaging to stakeholders; obtain access to GTIN registry.
Collaborate with the FDA	Obtain NDC data for mapping purposes; ensure consistent messaging to stakeholders.
Collaborate with AAP	Collaborate with AAP and other associations in development and roll-out of training and outreach programs; maintain participation in AAP 2D barcoding working group meetings.
Education and outreach	
Technical guidance	Provide specifications so that systems can be developed and tested to accommodate 2D barcoded data.
Implementation	Provide educational materials and training for end users.
Change management	
Stakeholder engagement	Ensure that roles and responsibilities among stakeholders are clear. Keep stakeholders engaged to facilitate their members' involvement and ensure that changes are communicated.
Update 2.5.1 guide	The 2.5.1 guide is the HL7 source for immunization information exchange; incorporating barcoding guidance into the guide will ensure that stakeholders are aware of changes.
Pilot implementation	Pilot implementation will test 2D barcodes in use, especially with EHRs and IIS, so that troubleshooting can occur prior to large-scale implementation.

[a]GTIN (Global Trade Item Number), NDC (National Drug Code), CVX (product identifier), MVX ((manufacturer identifier), FDA (Food and Drug Administration), AAP (American Academy of Physicians), EHR (electronic health record)

We recommend ongoing collaboration among CDC, AAP, GS1, the FDA, and other stakeholders to ensure that all parties responsible for the GTIN, NDC, and CVX and MVX understand the data exchange implications of the 2D barcode for stakeholders in the immunization domain. Coordination and discussion are particularly important during implementation and ongoing maintenance.

One concern that has been universally mentioned is the importance of education and training of those who will print, maintain, and use the barcode. Each person will need to understand the content of the standards mapping to make necessary changes to their systems. Thus, CDC should ensure that the mapping is readily available and communicated

to all stakeholders, especially to information systems vendors and those in the health IT technical and policy community.

A commonly cited concern of interviewees was how changes will be accommodated in the future. Vaccines themselves could change, such as when new products come on the market, or manufacturers could change. Sometimes the standards themselves change. For example, the HL7 standards are updated periodically. The regulatory environment might also change, such as the new Health Insurance Portability and Accountability Act (HIPAA) transactions and the updates to the privacy and security rules. In addition, vendor products and functionalities could change as the meaningful use criteria continue to evolve. Regardless of the source of change, a consistent way of citing and accommodating future change in standards or barcode content is necessary. This issue points to the need for more consistent communication channels for stakeholders throughout the health care delivery system.

Although we have conducted interviews and document review, testing an implementation is the best way to fully understand how the 2D barcode will be operationalized in practice. We recommend conducting a staged pilot to test implementation, with an emphasis on information systems integration and usage at the practice level and data exchange between provider locations and IIS. The pilot should also be part of a technical assistance program that reviews functionality and capabilities for IIS and guides or supports implementation. The results of the pilot can be used to test information systems, work flows, and educational materials.

1. INTRODUCTION AND BACKGROUND

Vaccine product labels must be compliant with U.S. Food and Drug Administration (FDA) labeling requirements. Since 2004, one of those requirements has been the inclusion of a linear barcode containing a pharmaceutical product's National Drug Code (NDC). The intent of the rule was to avoid adverse events by using machine-readable codes when preparing medicines for patients (Bar Code Label Requirement for Human Drug Products and Biological Products, 2004).

The objective of FDA's linear barcode requirement was patient safety, yet according to the National Childhood Vaccine Injury Act (NCVIA) (1986), documentation for immunizations must include product, manufacturer, and lot number information. Recording of expiration date is recommended by the American Academy of Pediatrics (AAP) (AAP Committee on Infectious Diseases, 2012). Encoding all these data in a linear barcode would make that barcode too large for a 0.5 mL single-dose vial. In a question submitted to the FDA in 2006, a party asked whether it would be acceptable to include lot number and expiration date along with the NDC in a two-dimensional (2D) barcode. The FDA responded that printing and reading technologies were not yet cost-effective; therefore, the barcode must be linear, but also that it would consider future revisions (FDA, 2006).

Five years later, AAP launched its Vaccine Barcoding Initiative, bringing together physicians, vaccine manufacturers, and public health groups (including the Centers for Disease Control and Prevention [CDC]) to review the feasibility of transitioning to 2D barcodes. AAP's rationale was that costs had decreased sufficiently, that technologies had matured, and that accelerating rates of electronic health record (EHR) adoption made 2D barcodes cost effective and would constitute a significant gain in patient safety (AAP, 2010). In January 2010, AAP recommended to the FDA that the agency permit the use of alternative symbologies for vaccine product labeling.

In August 2010, the FDA issued draft guidance to permit the use of "alternative symbologies" on vaccine products, including 2D barcodes (FDA, 2010a). That draft guidance cited as justification increases in the number of recommended immunizations, record-keeping requirements of the NCVIA, and changes in technology availability and cost. This guidance was finalized in August 2011 (FDA, 2011).

During the intervening period between draft and final FDA guidance, in October 2010, CDC's Immunization Services Division contracted with RTI International, an independent not-for-profit research institute, to study the impacts a transition to 2D barcodes appearing on the label on the unit of use containing product, expiration date, and lot number may have on

vaccine production, clinical documentation, and public health reporting and tracking. The study included an economic analysis and an information systems analysis.[1]

Automated identification of vaccine products are expected to offer the following advantages:

- enhanced patient safety, by using automated identification to ensure that the patient is being administered the correct product, thereby avoiding the administration of invalid or unnecessary doses;
- streamlined documentation and record-keeping procedures, by using imaging technology to capture data from labels and populate EHRs, practice management systems, and other information systems rather than entering these data by hand;
- more accurate and complete immunization records, by avoiding transcription errors from manual data entry and ensuring that the expiration date and lot number are entered into the record;
- better data quality for downstream uses for surveillance and safety, such as immunization information systems (IIS), the Vaccine Adverse Event Reporting System (VAERS), and the Vaccine Safety DataLink (VSD);
- enhanced inventory management, by permitting practices to scan dosing units into inventory software; and
- more efficient records review in the event of a vaccine recall.

2D barcodes also have cost implications throughout the immunization value chain that must be considered:

- upgrading the printing and imaging functionalities of manufacturers' vaccine product packaging and labeling lines;
- purchasing scanners, adapting immunization workflows, and training immunizers to use scanners to capture product data;
- developing information system functionalities to ensure that product data captured from 2D barcodes are interpretable and can be exchanged correctly across all immunization reporting systems via data exchange standards; and
- providing educational, training, and troubleshooting support to more than 30,000 pediatric, family health, internal medicine, and obstetric-gynecology (ob-gyn) practices; nearly 4,000 health departments; and thousands of pharmacies, retail-based clinics (RBCs), and mobile immunization sites across the United States.

1.1 Project Scope and Objectives

This study analyzed the impact of adding 2D barcodes to vaccine product labels appearing on primary packaging (e.g., the unit of use, such as a single-dose vial or prefilled syringe).

[1]Contract number GS10F0097L, awarded October 1, 2010, with a period of performance to September 30, 2011, and extended through March 31, 2012.

Stakeholders included in the study were vaccine manufacturers, vaccine users (e.g., immunization providers, immunization program managers), and immunization data users (e.g., immunization information systems, data exchange groups, vaccine-related tracking systems). Because of the breadth of immunization providers in the United States, the scope for all quantitative analyses was narrowed to primary care providers (pediatric, family medicine, internal medicine, ob-gyn practices) and health departments. Impacts for other immunizers were reviewed qualitatively.

This study had three overarching objectives, which were organized into tasks:

1. **Stakeholder engagement to document knowledge, attitudes, and beliefs** about the impacts and implications of 2D barcodes for automated identification of vaccine products. Methods included semistructured interviews with representatives of all stakeholder groups and an internet survey of immunization providers.

2. **Prospective economic impact analyses** to assess economic benefits and costs and the distribution of these costs and benefits across stakeholders. We converted the results from the first task into economic models to analyze costs and benefits. The models developed analyzed the period from 2011 through 2023, which is 10 years beyond a predicted barcode availability date of late 2012 or early 2013.

3. **Data exchange analysis and information technology standards mapping** to assess technical feasibility and identify any gaps in the technology infrastructure supporting standards-based exchange of immunization data. We reviewed health information exchange and data standards relevant to 2D barcodes to assess how information can be transmitted across stakeholders. The product of this analysis was a feasibility assessment and a series of recommendations about how to incorporate the information captured from the barcode into both the relevant standards and the guidance. This way, not only will information be captured appropriately, but also users will understand what to do with it and how to incorporate it into their systems. This issue is particularly important as the United States moves from a largely paper-based records system to an electronic one.

1.2 2D Barcoding of Product, Expiration Date, and Lot Data Using GS1 Product Identification Standards

2D barcodes have the potential to improve the accuracy and efficiency of documentation for immunization. Information that is currently handwritten, typed into a computer, or both could be automatically captured by an imaging device or scanner. This information could then populate an EHR, practice management system, or IIS or a record could be printed and placed in a paper file.

As mentioned previously, immunization documentation includes product identification, expiration date, and lot number. Product identification entails both the antigen and the

manufacturer.[2] A 2D barcode allows for the inclusion of both static (i.e., manufacturer and product name) and variable information (i.e., lot number and expiration date). A 2D barcode allows for the inclusion of this information in a single symbol appearing in the limited space available affixed to a label on a single-dose vial containing about 0.5 mL of product.

Vaccines currently include a linear barcode with the NDC (Figure 1-1) on the immediate container label (or on intermediate packaging if curvature or space is not available). These barcodes do not include the lot number and expiration date. Thus, this information must be recorded by hand or keyed into a software system.

Figure 1-1. Example Linear and 2D Barcodes

Example of linear barcode
Current linear barcodes required by the FDA contain only the vaccine product identification information.

Example of 2D barcode
A 2D, or data matrix, barcode can include product identification information as well as expiration date and lot number.

AAP, Canada's Automated Identification of Vaccine Products Advisory Task Group (AIVP ATG), and other countries' groups are recommending the use of internationally-standard product identifiers, particularly the Global Trade Item Number (GTIN). GS1, a global product identification standards organization, created the GTIN to identify products as they move from the manufacturer to end-user use.

For prescription pharmaceutical products in the United States, the GTIN is a 14-digit numerical identifier with the NDC embedded in it. The expiration date is in the YYMMDD format, as per the GS1 Healthcare US guidelines (GS1, 2011a). The lot number is a variable number of digits assigned by the manufacturer. AAP collaborated with GS1 to develop guidance for vaccine manufacturers on using GS1 standards for vaccine products. A principal advantage of using GTINs is that they must be registered with GS1 to ensure that a GTIN only refers to one specific product. Chapter 6 explores GTINs and NDCs in greater detail.

1.3 Relationship of 2D Barcoding to Serialization Initiatives

2D barcoding of vaccine product, expiration date, and lot number on unit-of-use vaccine product labels is a primary packaging initiative that complements and does not conflict with

[2] Although funding source is commonly documented (Vaccines for Children [VFC] or non-VFC), that information will not be part of the barcode because the barcode will be applied at the point of manufacture, and it is not possible to know the funding source at that time.

other initiatives, such as serialization and track and trace, that will affect the secondary packaging (e.g., unit of sale) and higher packaging levels.

Serialization refers to the inclusion of a unique serial number on a saleable package that allows manufacturers, distributors, and regulatory bodies to assess the pedigree of that package. For sale and shipment, vials and syringes are packaged in cartons, boxes, and pallets, and it is these packaging levels that may be affected by serialization initiatives in the United States. The product label appearing on the vial should not be affected by serialization or track and trace because an individual vial or syringe without a box is not a saleable unit.

In FDA's guidance for industry, Standards for Securing the Drug Supply Chain—Standardized Numerical Identification for prescription Drug Packages, the FDA states,

> [e]vidence that a unit is intended for individual sale, and thus constitutes a separate "package" for purposes of this guidance, would include the package being accompanied by labeling intended to be sufficient to permit its individual distribution. For example, if a manufacturer's smallest unit of sale package is a container holding six drug-filled syringes, a single SNI [standardized numerical identifier] would be the package-level identifier for the container holding the six drug-filled syringes; there would be no SNIs for the individual syringes, not intended by the manufacturer for individual sale. (FDA, 2010b, p. 3).

Secondary, tertiary, and other packaging levels, which are expected to be affected by serialization, are outside of the scope of this study. Yet it is important that stakeholders recognize that 2D barcoding of the unit-of-use and serialization of higher packaging levels both affect manufacturers' packaging operations.

1.4 Automated Identification of Vaccine Products Initiatives

The 2D barcoding initiative is occurring as part of a global trend toward automated identification of pharmaceutical products in health care settings. In this section, we review past and current initiatives that are relevant, including the Vaccine Identification Standards Initiative (VISI), the FDA Barcoding Rule (Bar Code Label Requirement for Human Drug Products and Biological Products, 2004), AAP's Vaccine Barcoding Initiative, Canada's Automated Identification of Vaccine Products Advisory Task Group, and current and future product identification initiatives in the United States and abroad that have implications for the United States.

1.4.1 Vaccine Identification Standards Initiative (VISI)

VISI was launched in 1997 by CDC's Immunization Safety Office in concert with other immunization stakeholders to enhance the safety of vaccination through improving accuracy of vaccine information. Safety enhancements were expected to accrue via development and dissemination of uniform guidance for administrative functions of vaccines, including packaging, labeling, and record keeping.

VISI proposed guidelines in six areas: peel-off labels, barcoding, uniform vaccine administration record, NDC vaccine database, vaccine facts sidebar, and standard abbreviations for vaccine and antibody types, manufacturers, and distributors (Grabenstein, 2002).

Although the group made progress, including the adoption of peel-off labels by some manufacturers for portions of their product portfolios, FDA's *Barcode Label Requirement for Human Drug Products and Blood: Final Rule* (69 FR 9120) ultimately superseded the VISI initiative by specifying barcode labeling requirements. Implementing 2D barcoding builds on the initial goals of VISI to improve vaccine safety and streamline documentation.

1.4.2 Food and Drug Administration's Barcoding Rule (CFR 69 FR 9120)

On March 14, 2003, the FDA introduced a proposed rule (Bar Code Label Requirement For Human Drug Products and Blood, 2003) that required prescription human drug products, including vaccines, to be labeled with a linear barcode. The rule followed an Institute of Medicine (IOM) report entitled *To Err Is Human: Building a Safer Health System*, which estimated the number of American deaths as a result of medication errors in 1993 at 7,000 (Kohn, Corrigan, & Donaldson, 2000).[3] IOM noted that many of these deaths were likely easily preventable and suggested barcoding as a solution. A timeline of important barcoding events is displayed in Table 1-1.

In the *Federal Register* of February 26, 2004, the FDA published the barcoding final rule (Bar Code Label Requirement for Human Drug Products and Biological Products, 2004). The rule became effective April 26, 2004, and specifies that the barcode must

- be linear,
- include the drug's NDC,
- meet European Article Number/Uniform Code Council or Health Industry Business Communications Council standards,

[3]In 2005, the IOM released a follow-up report entitled *Five Years After 'To Err Is Human': What Have We Learned?*, which stated that, although small positive impacts had been observed and the groundwork for safety improvements had been laid, there was little national impact and progress was slow.

- be surrounded by enough blank space to allow it to be scanned correctly,
- outlast normal use, and
- be placed on both the drug's immediate container label and the outside packaging label, unless the immediate label is machine-readable through the outer packaging.

Table 1-1. Timeline of Important Vaccine Barcoding Legislation and Guidance

Year	Legislation and Guidance
1997	CDC launches the VISI
1999	IOM: *To Err Is Human: Building a Safer Health System*: Described safety problems in the administration of pharmaceutical products and established the concept of the 5 rights
2003	FDA: *Barcode Label Requirement for Human Drug Products and Blood: Proposed Rule (68 FR 12500)*: Proposed that all pharmaceutical products include a linear barcode on packaging labels
2004	FDA: *Barcode Label Requirement for Human Drug Products and Blood: Final Rule (69 FR 9120)*: Finalized linear barcode requirement
2005	IOM: *Five Years After 'To Err Is Human': What Have We Learned?*: Reaffirmed that safety challenges associated with medicine administration remain prevalent in the United States
2006	FDA: *Guidance for Industry: Barcode Label Requirements—Questions and Answers (71 FR 58739)*: Stated that alternative symbologies to the linear barcode are not cost-effective or permitted
2010	FDA*: Draft Guidance for Industry: Barcode Label Requirements—Questions and Answers (Question 12 Update); Availability (75 FR 54347)*: Stated that the FDA may consider issuance of waivers to permit 2D barcodes for vaccine products
2011	FDA: *Final Guidance for Industry: Barcode Label Requirements—Questions and Answers: Availability (76 FR 49772):* Stated that the FDA will accept requests to waive the linear barcode requirement in favor of including a 2D barcode for vaccine products only
2011	AAP and GS1: American Academy of Pediatrics & GS1 US Guideline for Suppliers: The Application of GS1 DataMatrix Barcodes to Vaccines for Point-of-Care: Established the AAP-approved specification of GTIN, expiration date, and lot number as data fields for 2D barcodes for vaccine product labels affixed to the unit of use in the United States

In the final rule (Bar Code Label Requirement for Human Drug Products and Biological Products, 2004), the FDA stated that they were unable to justify mandating inclusion of expiration date and lot number in the barcode based on current knowledge of the costs and benefits of including this information.

On October 5, 2006, the FDA released a document entitled *Guidance for Industry: Barcode Label Requirements—Questions and Answers*. Question 12 of the document asks whether a manufacturer may use an alternative symbology, such as a 2D barcode, instead of a linear barcode. The FDA reiterated that a linear barcode must be used but added that they will consider future revisions to the rule.

1.4.3 American Academy of Pediatrics Vaccine Barcoding Initiative

AAP supports the implementation of 2D barcodes and presented their perspective in a presentation to the FDA on February 2, 2010. AAP requested the inclusion of the GTIN, expiration date, and lot number in vaccine barcodes (AAP, 2010). AAP noted that the transition to 2D barcodes has become necessary since the 2004 FDA rule for a number of reasons, including the following:

- the number of recommended vaccines has increased since the original rule in 2004, and several combination products have been introduced;
- the number of private practices using EHRs has increased;
- 2D barcodes, even in areas such as retail, are moving toward becoming the standard; and
- the cost of printing and scanning 2D barcodes has decreased (AAP, 2010).

During 2010 and 2011, AAP led a working group of vaccine manufacturers, immunization providers, and public health agencies to further 2D barcoding, including establishing consensus standards, convening discussion panels, and developing guidance for manufacturers and guidance and training programs for providers. AAP coordinated with GS1 to provide written, AAP-approved guidance to manufacturers and clinicians (GS1, 2011a).[4]

1.4.4 Food and Drug Administration's Updated Question 12 Guidance

In August 2010, the FDA issued a revision to the 2006 document entitled *Draft Guidance for Industry: Barcode Label Requirements—Questions and Answers; Availability*, stating that 2D barcode technology had advanced to the point that the benefits of 2D technology may exceed costs. The FDA stated that since the finalization of the original rule it has become clear that 2D barcodes could play an important role in safe and efficient vaccination.

The document notes that sites administering childhood vaccines may particularly benefit from 2D barcodes, given that these locations are bound by the NCVIA and often have little administrative support. NCVIA requires that the date the vaccine was administered; the manufacturer; lot number of the vaccine; and the name, address, and title of the person administering the vaccine be recorded. Administrators must log all information not stored in a linear barcode manually, a process that is time consuming and prone to error. Errors can lead to safety issues and expensive duplicate vaccinations.

The FDA (2011) finalized the vaccine industry guidance in August 2011 called *Guidance for Industry: Bar Code Label Requirements—Questions and Answers; Availability*. The guidance

[4] AAP facilitated meetings between stakeholders to obtain feedback on draft guidance. At these meetings the guidance was reviewed, comments were solicited, and changes from earlier versions were outlined.

opened the door for manufacturers to submit requests to use alternative symbology, including the 2D barcode. It allows for the vaccine products to replace linear barcodes with 2D barcodes, if granted a waiver by the FDA. Childhood vaccines were cited as a reason for this guidance, but the guidance applies to all vaccines. It is important to note that the FDA stated specifically that its guidance does not apply outside of vaccine products and that it applies only to the unit-of-use. Linear and 2D barcodes may be placed on a label together.

1.4.5 Automated Identification of Vaccine Products (AIVP) Advisory Task Group (Canada)

Efforts related to vaccine barcoding have been ongoing in Canada since 1999, when the National Advisory Committee on Immunization passed a resolution recommending that 2D barcodes be included on vaccines. This resolution came about after the Public Health Agency of Canada (PHAC) released information showing that up to 10% of the population was being reimmunized because of faulty immunization records, resulting in unnecessary costs and health consequences (HDR, 2009).Canada established the AIVP ATG to develop solutions leveraging information systems technologies.[5] This group completed feasibility studies on vaccine barcoding alternatives, ran a pilot project to demonstrate the benefits of automated identification for inventory management, and met with manufacturers to develop a list of necessary standards. The Canadian initiative is notable because many products and manufacturers are common across the United States and Canada, and, like AAP, the AIVP ATG is also requesting that GTIN and lot number are in a 2D barcode (Public Health Agency of Canada and GS1 Canada, 2010).

In 2009, PHAC completed a commissioned study entitled "Cost-Benefit Analysis for Adoption and Implementation of the Automated Identification (Bar Coding) of Vaccine Products" (HDR, 2009). The study estimated the direct and indirect costs and benefits of implementing barcode standards and establishing a Vaccine Identification Database System (VIDS) for all vaccine products in Canada. It analyzed six different labeling scenarios (HDR, 2009). The most comprehensive scenario, recommended by the Canadian Immunization Registry Network, includes a 2D barcode on the primary package, a linear or 2D barcode on the secondary package, and two peel-off labels with barcodes and human-readable information on the primary package. The benefit-cost ratio for this scenario was estimated at 4.0, and the net present value (NPV) estimate was C$797 million. The most cost-effective scenario (requiring a static data barcode on primary and secondary packages) was projected to have a benefit-cost ratio of 8.2 and an NPV of C$919 million.

[5]Voting AIVP ATG Members include BIOTECanada, Canadian Immunization Registry Network, Canadian Nurses Coalition on Immunization, Canadian Pediatric Society, Canadian Information Technology Associations of Canada, Canadian Medical Association, GlaxoSmithKline, GS1 Canada, Health Canada, Institute for Safe Medication Practices Canada, Merck Canada Ltd., Novartis Pharmaceuticals Canada, Pfizer Canada, Public Health Agency of Canada, Sanofi Pasteur Ltd., and Solvay Pharma Inc.

Although the costs and benefits discussed in the Canadian study provide a good framework for implementing a 2D barcode in the United States, the Canadian study examines a far broader and more comprehensive initiative. For example, costs assessed in the Canadian study include development of a vaccine inventory management database to store data on vaccines, reconfiguration of the centralized database that combines records on vaccines from providers to incorporate barcodes, and ongoing collection of vaccine data. The study also included benefits from reduced wastage and extraimmunization, as well as streamlined public-sector vaccine inventory management.

Implementation of vaccine barcoding in Canada also differs from implementation in the United States, in large part because health care is regulated by the 10 provinces and 3 territories, so less coordination is needed than in the United States, where regulation occurs in all 50 states. In addition, the health care system in Canada is largely public, and most vaccines are paid for by provincial/territorial governments. There is a single purchasing group, the Vaccine Supply Working Group, and one distribution system in each province and territory.

1.5 Initiatives Outside of North America

The United States and Canada are not alone in pursuing pharmaceutical product identification initiatives. Although underlying rationales and operating models differ by country, a common factor is often a decision to leverage GS1 standards (Table 1-2). See Appendix A for a description of initiatives occurring outside of North America.

Table 1-2. Countries with Known Automated Prescription Pharmaceutical Product Identification Initiatives Outside of the North America, as of August 2011

Argentina	Germany	South Korea
Belgium	Greece	Sweden
Brazil	India	Turkey
China	Italy	United Kingdom
France		

Note: See also Appendix A.

1.6 Report Organization

This report is organized as follows:

- ***Chapter 2, Literature Review***, presents a synthesis of the literature organized thematically: barcoding in health care, immunization practice, and electronic data exchange. Because 2D barcodes for vaccines have yet to be introduced to the market, we reviewed relevant literature from the perspective of how eliminating human error from verifying that the correct product is being administered to the

correct patient and from recording product, lot, and expiration date could enhance safety and efficiency.

- ***Chapter 3, Impact on Vaccine Production***, analyzes the perspectives of manufacturers and presents a benefit-cost analysis for 2011 through 2023, with 2023 being the end point of a 10-year period of 2D barcode availability. The results indicate that five manufacturers plan to implement 2D barcoding at a cost of $30.6 million.

- ***Chapter 4, Knowledge, Attitudes, and Beliefs of Primary Care Providers and Local Health Departments*** (LHDs), describes the results from semistructured interviews and an internet survey. Nearly 3,700 valid survey responses were received. When presented with descriptions of potential benefits and costs, over 70% of pediatric and family medicine practices indicated they would use the barcode or that they would use it when they have an EHR system in place. In contrast, only 39.2% of LHDs said they would use it.

- ***Chapter 5, Economic Analysis of the Impact of 2D Barcodes on Clinical Documentation***, presents a benefit-cost analysis of adopting and using 2D barcodes to record product, expiration date, and lot number information in primary care and LHD settings. Only benefits from more efficient documentation were able to be quantified, yet we included comprehensive cost estimates. Results are, therefore, a lower bound. We estimate that 2D barcodes would decrease time spent on documentation by 58% to 63% per dose. Despite adoption costs, net benefits to primary care providers and LHDs are expected to be $311 million to $333 million between 2013 and 2023.

- ***Chapter 6, Impact on Exchange and Management of Immunization Information***, reviews issues surrounding standards-based data exchange and maps fields and identifiers for relevant standards to assess feasibility. Ultimately, we concluded that in order to maximize the promise of 2D barcodes, a mapping of GTIN to NDC to CDC's manufacturer identifier (MVX) and product identifier (CVX) is required.

- ***Chapter 7, Impacts and Implications for Other Stakeholders in the U.S. Immunization Ecosystem***, reviews how the transition to 2D barcoding of vaccine product labels could affect complementary immunizers, public health authorities, and other stakeholders in the immunization system. Pharmacists, RBCs, and other immunizers were consulted for this work, and it became apparent from our interviews that pharmacies and RBCs are likely 2D barcode users.

- ***Chapter 8, Summary Results and Conclusions***, presents summary remarks and recommendations. A lower-bound benefit-to-cost ratio of 2.7 to 2.8 was estimated, meaning that for every $1 invested in 2D barcoding at least $2.70 is expected to accrue between 2011 and 2023.

2. LITERATURE REVIEW

In an effort to clarify the potential impact(s) of adding a 2D barcode to vaccine product labels, we conducted a targeted literature review and scan of unpublished grey literature. Because 2D barcodes for vaccines had yet to be introduced to the market when this study launched in October 2010, we reviewed relevant literature from the perspective of how the following could enhance patient safety and efficiency: 1) eliminating human error from verifying that the correct product is being administered to the correct patient and 2) recording product, lot, and expiration date accurately and completely. We synthesized evidence from the literature into 3 categories: impacts of barcoding on health care, current immunization practice, and electronic data exchange (Table 2-1).

Table 2-1. Summary Literature Review Findings

Category	Relevance to Vaccine Barcoding	Literature Highlights
Barcoding in health care	The implementation of barcoding technologies in health care settings may provide lessons for its implementation within immunization practice.	Barcoding has the potential to ▪ reduce human errors in record keeping, ▪ facilitate response to product recalls, and ▪ conduct post-marketing safety surveillance.
Immunization practice	Barcoded vaccines may have a significant impact on immunization practice.	Barcoding has the potential to ▪ reduce vaccine wastage, ▪ reduce extraimmunization, and ▪ improve efficiency in record keeping.
Electronic data exchange	2D-barcoded vaccines have the potential to facilitate data collection and electronic data exchange in a variety of settings.	Barcoding has the potential to ▪ improve accuracy and completeness of record keeping, ▪ facilitate data entry into immunization information systems (IIS), and ▪ improve the quality of data shared with IIS. Indirectly, these improvements in the ease with which data can be shared and their improved quality may increase the amount of data included in IIS, as well as public health data exchange more generally.

2.1 Literature Review Methodology

Our review encompassed health informatics, public health, economics, and industry literature because of the crosscutting issues of interest. Peer-reviewed articles were identified via indexed databases such as PubMed and EconLit. We also searched unpublished grey literature through web-based searches and reviews of materials identified during interviews with key informants and stakeholder organizations, including the American Academy of Pediatrics (AAP), the American Academy of Family Physicians (AAFP), American

College of Obstetrician Gynecologists (ACOG), American Medical Association (AMA), Biotechnology Industry Organization (BIO), GS1 Healthcare US, Association of Immunization Managers (AIM), and the American Medical Informatics Association (AMIA).

Searches were performed using a combination of keywords, which included vaccine, immunization, barcode, health care, practice, pediatric, obstetric-gynecology (ob-gyn), internal medicine, family physician, public health clinic, time–motion, economic, safety, medical errors, record keeping, electronic health records, health information technology, immunization information system, and data. We excluded articles that were not in the English language and those that were specific to developing health care systems (e.g., we included references from Australia but not from sub-Saharan Africa). References for these sources were catalogued using EndNote X4 software.

2.2 Barcoding in Health Care

Barcoding vaccines has the potential to ensure that individuals receive the correct vaccine and that the information about the vaccine received is entered accurately into the patient record (i.e., preventing medication errors). Collecting this information is critically important because of the possibility, however remote, that there may be specific vaccine safety concerns following administration.

2.2.1 Barcoding and Patient Safety

Health care providers have striven "to do no harm" since Hippocrates. In recent years, medical errors, in particular, human errors, have been highlighted as a significant threat to patient safety (Kohn, Corrigan, & Donaldson, 2000). The extant literature addressing the intersection between barcodes and patient safety predominantly focuses on the adoption and implementation of barcode technology to improve the safety of medication administration. Barcoding has been advocated as one technological approach to improve patient safety by reducing human error. The Healthcare Information Management Systems Society (HIMSS) asserts that barcoding is a means to reduce medical errors, as well as improve health care quality more broadly (Simpson, 2001).The concept of barcoding reducing human error has implications for what may be described as medication errors, vaccine management, and the ability to respond to product recalls.

The literature includes many references to the concept of the "5 rights" when assessing the administration of medications (Figure 2-1). Although the 5 rights has its limitations, Bundy et al. (2009) used it as a framework to report pediatric vaccination errors. In their study of 607 outpatient, vaccination errors reported voluntarily to the largest adverse drug event

database in the United States, MEDMARX,[1] were evaluated to determine the characteristics of the errors and how they fit into the 5 rights.

Figure 2-1. The "5 Rights" to Reduce Medication Errors

- Right patient (the medication is being administered to the person for whom it is intended)
- Right medication (the correct medication is being administered)
- Right dosage (the medication prescribed is administered at the correct dosage)
- Right time (the medication is being administered at the correct interval)
- Right route (the medication is being administered via the correct route, e.g., intramuscular vs. subcutaneous injection)

1. Wrong-patient errors in which vaccines administered to the wrong child occurred rarely (4.4% of administration errors). Bundy et al. (2009) estimate more than 40% of wrong-patient errors are related to sibling confusion. Wrong-patient errors did not reflect vaccines administered to a child for whom the vaccine was contraindicated.

2. The wrong vaccine was the error most commonly identified by Bundy et al. (2009). They examined errors based on look-alike/sound-alike generic names. The tetanus group (DTaP, Tdap, DT, and Td) represented more than one-third of all errors cited. Errors also occurred with the pneumococcal and meningococcal groups. Sound-alike trade names were hypothesized to be a source of error as well, but the data did not permit analysis at this level.

3. The wrong dose includes "wrong drug" (25% of errors), "extra dose" (25%), "improper dose/quantity" (14%), and "wrong dosage form" (1%). Extra doses were reported as occurring more commonly with scheduled vaccines (as opposed to seasonal or electively administered vaccines). Because the data collection permitted reporting in more than one category, there may be overlaps in reporting (i.e., a given dose error could be reported as "wrong drug" as well as "extra dose" and "wrong dosage form"). This highlights the need to critically evaluate such reports.

4. The wrong time was reported among 8% of errors. This category included extraimmunization as well as underimmunization. As with extra doses, wrong time and "omission" occurred more commonly with scheduled vaccines (as opposed to seasonal or electively administered vaccines).

5. The wrong route occurred infrequently (<.5%).

Of further relevance to barcoding, errors occurred in prescribing (11%), transcribing and documenting (10%), and dispensing (4.1%) (Bundy et al., 2009). 2D barcoded vaccines' capacity to improve record keeping would likely reduce human errors in "transcribing and documenting"; barcoded vaccines' capacity to be integrated into EHRs and their clinical support tools would likely reduce errors in "prescribing" and "dispensing" by identifying instances in which a patient may otherwise receive the wrong vaccine (e.g., DTaP instead of Tdap) or inappropriate dispensing (e.g., using the wrong diluents).

[1] MEDMARX is an anonymous, deidentified, voluntary national internet-accessible database established in 1998. MEDMARX is used by hospitals and health care systems to collect, report, track, and share adverse drug events and medication errors in a standardized format. The database includes nearly 1.4 million medication error reports (MEDMARX, 2011).

The study by Bundy et al. (2009) is consistent with Wilton and Pennisi (1994) who found that at least 10% of 2,098 children immunized at UCLA's Children's Health Center had transcription errors in their electronic immunization records.

Feikema, Klevins, Washington, and Barker (2000) describe extraimmunization as "vaccine doses given in excess of the recommended [immunization] schedule." Implementing a system in which 2D-barcoded vaccines improve record keeping has the potential to reduce the incidence of extraimmunizations.

Currently, extraimmunizations commonly occur when immunization providers attempt to ensure adherence with the Advisory Committee on Immunization Practices (ACIP)-recommended immunization schedule and children lack accurate or adequate immunization documentation or require updating earlier mistimed doses (Feikema et al., 2000). Likewise, extraimmunization of specific antigens can occur in the course of administering a series of combination vaccines.

Estimates of the frequency of extraimmunization vary by vaccine. Feikema and colleagues (2000) examined extraimmunization of hepatitis B, DTP/DTaP, Hib, polio, and measles vaccines and found a range of weighted percentages by vaccine of 14.1% for polio to 2.5% for measles. Strine and colleagues (2002) recognized that the rate of extraimmunization is decreasing (from an estimated 1.8 million extra doses in 1997 to 775,000 in 2000) but assert the financial impact remains a concern.

Darden et al. (2001) used data from the National Immunization Survey to estimate rates of extraimmunization in children aged 19 to 35 months for the years 1999 through 2003. Overall, they found an average extraimmunization rate of 9.4%. Like Strine, they found the overall percentage of extraimmunization declined over time and varied by vaccine. Extraimmunzation generally results from a lack of adequately documented immunization history. We anticipate that the improved record keeping that barcoded vaccines can facilitate will result in reduced extraimmunization.

One benefit of implementing barcode medication administration systems can be summarized as reducing preventable errors associated with the "5 rights" and producing data that can be used for quality and patient safety improvement initiatives (Akiyama, Koshio, & Kaihotsu, 2010; Douglas & Larrabee, 2003; Hook et al., 2008; Johnson et al., 2004).

As described by Akiyama et al. (2010), "in addition to their contribution to the authentication of the 5 rights, data captured by barcode administration systems have the potential to provide sources of research to improve patient safety in terms of actual injections and medications data." Akiyama et al. studied a sophisticated system that used barcodes to capture data on each medical action that took place in the hospital, including details about when, where, what, why, for what, to whom, and how each action occurred.

These data yielded a rich understanding of the context of errors and enabled them to efficiently investigate potential solutions to avoid similar errors in the future.

Douglas et al. (2003) echoed these sentiments, saying that "this input of previously elusive medication error data gives [their] medication error team—as well as [their] pharmacy and therapeutics, patient safety, and quality improvement committees—a plethora of information from which to devise informative and useful root cause analyses, and implement effective quality improvement programs."

Johnson et al. (2004) took a step further by explaining how such data on errors and the solutions identified from them could ultimately even lead to financial benefits: "Understanding the type and circumstances of errors intercepted by BPOC (barcode-point-of-care technology) will provide insight into potential systems issues that cause the errors to occur. The resulting reduction in errors will produce a substantial financial benefit by reducing costs associated with medication errors."

To fully realize the potential benefits of barcodes for patient safety, however, the barcodes must actually be used by clinical staff. In other words, clinical workarounds developed as a result of technology flaws, failures, inconveniences, and a host of other reasons (e.g., task related, patient related, environmental, policy) can undermine or defeat the utility of barcode technology from a patient safety standpoint; the workarounds must be identified and addressed to ensure compliance (Koppel et al., 2008; McNulty et al., 2009).[2] Barriers and facilitators that were commonly cited in the literature are summarized in Table 2-2.

The literature suggests that maximizing the benefits of barcode technology also involves selecting a sophisticated system with the capacity to identify various types of potential errors; operating the system in conjunction with other sophisticated technologies, including electronic medication administration records and computerized physician order entry systems rather than in isolation; and incorporating its use into other processes (e.g., verification of accurate blood transfusions, identification of laboratory specimens, biologics inventory management) (Akiyama et al., 2010; Douglas & Larrabee, 2003; Johnson et al., 2004). Although many of these reports focus on inpatient settings that do not always reflect the outpatient setting in which most immunizations occur, these studies highlight the significance of integrating barcoded data collection and reporting within a broader system.

[2]To understand the causes of workarounds, McNulty et al. conducted interviews with frontline nurses and their managers, reviewed monthly technical support desk logs to find out what software and device issues had been encountered, created and reviewed monthly reports on barcode-scanning compliance by unit, and disseminated a staff accountability guide addressing repeated noncompliance. Armed with this heightened understanding of the reasons behind workarounds, they categorized the issues by type (education, technology, or process) and department (nursing, pharmacy, physician, and information technology), developed solutions to overcome the use of workarounds, and ultimately were able to achieve and sustain their goal of 95% compliance.

Table 2-2. Insights from Literature Regarding Barriers and Facilitators to Change That May Affect Adoption and Use of 2D Barcodes

Barriers	Facilitators
▪ Barcode technology may represent a "fundamental" or "radical" change to medication administration and documentation and can require social and cultural changes in the adopting organization (Douglas & Larrabee, 2003; Hook et al., 2008; McNulty et al., 2009) ▪ Initial resistance among some clinical staff (Douglas & Larrabee, 2003; Hook et al., 2008; McNulty et al., 2009) ▪ Concerns about the volume of alerts/warnings generated by the system and time spent responding to them (Douglas & Larrabee, 2003; Johnson et al., 2004) ▪ Time and cost associated with barcoding actual medications in cases of incompatibility with scanners, receipt without barcode (prior to mandate or despite mandate), or cases in which medications need to be repackaged (Douglas & Larrabee, 2003; Hook et al., 2008; Johnson et al., 2004) ▪ Development of clinical workarounds[3] (Koppel, Wetterneck, Telles, & Karsh, 2008; McNulty et al., 2009)	▪ Demonstrating leadership's commitment to patient safety, in general, and specifically to successful implementation (Johnson, Hummel, Kinninger, & Lewis, 2004; McNulty, Donnelly, & Iorio, 2009) ▪ Involving ultimate users (i.e., clinical staff) in product selection to foster buy-in (Johnson et al., 2004) ▪ Using a multidisciplinary team approach to developing understanding of how implementation will affect process flows (Douglas & Larrabee, 2003; McNulty et al., 2009) ▪ Using a pilot study or phased implementation (Douglas & Larrabee, 2003; Hook, Pearlstein, Samarth, & Cusack, 2008; Johnson et al., 2004; McNulty et al., 2009) ▪ Providing a strong training and support system (Douglas & Larrabee, 2003; Hook et al., 2008; McNulty et al., 2009) ▪ Cultivating champion(s) among clinical staff to encourage/intervene with reluctant users (Douglas & Larrabee, 2003; Hook et al., 2008; Johnson et al., 2004) ▪ Making benefits visible to staff (i.e., improved staff satisfaction and retention) and patients (i.e., improved patient satisfaction) (Johnson et al., 2004; McNulty et al., 2009)

In 2011, the American Society of Health System Pharmacists (ASHP) published the "ASHP Statement on Bar-Code Verification During Inventory, Preparation, and Dispensing of Medications." ASHP "encourages hospital and health-system pharmacies to incorporate bar-code scanning into inventory management, dose preparation and packaging, and dispensing of medications." Their rationale for such scanning technologies is that it will ensure that drugs administered are the correct products, are in date, and are not subject to a recall.

2.2.2 Barcoding and Vaccine Safety Issues

Separate from patient safety issues, evaluating specific vaccine concerns requires tracking who received a given vaccine and any adverse events that may have followed. In addition to research studies on the safety of vaccines, tracking who received what product and,

[3]A clinical workaround is a means to respond to a problem or challenge without eliminating the problem or challenge. An example of a problem or challenge that might result in a clinical workaround is when a clinician is immunizing a patient in a clinical setting that uses an EHR that requires data entry into a field for which the clinician lacks the relevant information. A clinical workaround for this example could be for the clinician to enter a dummy variable or erroneous data.

specifically, the lot number of that product, is important, especially when a safety concern arises about a specific vaccine lot. Scanning 2D barcodes would add lot data to records automatically, which could facilitate recalls and improve data completeness and accuracy in Vaccine Adverse Event Reporting System (VAERS) and the Vaccine Safety Datalink (VSD). As discussed in a later section, IIS can also be used to identify patients who were given a recalled vaccine or be used to obtain a lot number when reporting an adverse event.

The Food and Drug Administration's (FDA's) Center for Biologics Evaluation and Research (CBER) reports recalls of vaccines and biologics:

> Recalls are a firm's [manufacturer's] removal or correction of a marketed product that the FDA considers to be in violation of the laws it administers and against which the agency would initiate legal action, e.g., seizure. Recalls may be conducted on a firm's own initiative, by the FDA request, or by the FDA order under statutory authority. (FDA, 2011)

Between 2005 and 2010, we found a total of 14 recalls out of 138 (10.1%) for biologics that were for vaccines (Table 2-3). Although recalls are cause for concern, they do not necessarily mean that the vaccine recipient is in imminent danger of harm. Barcodes could facilitate recalls by making inventory reviews and identification of patients that may have received a recalled product more efficient. Table 2-4 summarizes the reasons for seven vaccine recalls in 2010.

In addition to recall notices, there are also systems for collecting and monitoring vaccine safety, notably VAERS and VSD. VAERS is a post-marketing safety surveillance system cosponsored by the Centers for Disease Control and Prevention (CDC) and the FDA.[4] It was created to receive reports about adverse events ranging in severity from mild (e.g., fever, local reactions, irritability) to severe (e.g., hospitalization, permanent disability, death) occurring after vaccinations (U.S. Department of Health and Human Services [HHS], 2011a). VAERS's intent is to identify specific vaccines or vaccine lots that may be associated with higher than expected rates of adverse events. However, one limitation of VAERS data is the absence of lot numbers in approximately 20% of reports (Kennedy, 2012).[5]

[4]The National Childhood Vaccine Injury Act (NCVIA) of 1986 requires health professionals and vaccine manufacturers to report to HHS specific adverse events that occur after the administration of routinely recommended vaccines. In response to NCVIA, CDC and the FDA established VAERS in 1990 (Chen et al., 1994).

[5]VAERS is a passive surveillance system (meaning that it relies on health care providers, vaccine recipients or their guardians, and other sources to identify and voluntarily report adverse events), limitations of the data include known underreporting, inconsistent reporting standards and biases in reporting, data quality issues (incomplete or inaccurate submissions), and the inability to determine causality using the data (HHS, 2011a, 2011b). These limitations mean that VAERS is often described as a tool for hypothesis generation rather than epidemiological assessment.

Table 2-3. Vaccine and Other Biologic Product Recalls, 2005–2010

Year	Total Number Vaccine and Other Biologic Recalls	Number of Vaccine Recalls Only	Vaccine Recalls as Percentage of All Biologic Recalls
2005	40	0	—
2006	19	2	11%
2007	18	1	6%
2008	29	0	—
2009	11	4	36%
2010	22	7[a]	32%
Total	**138**	**14**	**10%**

[a]Additional information for vaccine recalls in 2010 is included in Table 2-4.

Source: U.S. Food and Drug Administration. Recalls (biologics). Retrieved from http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/Recalls/default.htm

Table 2-4. Vaccine Recalls Reported by CBER in 2010

Date of Notification	Brand Name	Company (Location)	Product Description	Reason for Recall
12/17/2010	FLUVIRIN (influenza virus vaccine) 2010–2011	Novartis Vaccines and Diagnostics, Inc. (Cambridge, MA)	Formula multidose vials, Lot # 111812P1	Cracks in the vial necks carry the potential risk of compromising product sterility
8/16/2010	Influenza A (H1N1) 2009 monovalent vaccine NDC 49281-640-15	Sanofi Pasteur (Swiftwater, PA)	5 mL multidose vials	Shorter expiration period than indicated on the label
4/13/2010	RabAvert rabies vaccine (rabies vaccine for human use) kits	Novartis Vaccines and Diagnostics (Marburg, Germany)	RabAvert kit batch #458011A diluent vial batch #927011	The stopper and the metal crimp dislodge from the vial completely when removing the protective cap
3/25/2010	Influenza A (H1N1) 2009 monovalent vaccine, live, intranasal	MedImmune LLC (Philadelphia, PA)		Expiration date update
3/22/2010	Prevnar, pneumococcal 7-valent conjugate vaccine	Wyeth (Pearl River, NY)	0.5 mL single dose prefilled syringe (10 per package)	Syringes distributed with a rubber formulation in the syringe tip caps that was not approved for use with Prevnar
2/3/2010	Influenza A (H1N1) 2009 monovalent vaccine	Sanofi Pasteur (Swiftwater, PA)	Prefilled syringes UT023AA, UT023BA, UT023CA, UT023EA, UT023FA	Prefilled syringes after routine stability testing determined that those lots no longer met the potency specification
1/7/2010	Influenza A (H1N1) 2009 monovalent vaccine, live, intranasal	MedImmune (Philadelphia, PA)		Expiration date update: expiration period different than date indicated on the label

Source: U.S. Food and Drug Administration. Recalls (biologics). Retrieved from http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/Recalls/default.htm

The VSD system is a population-based, active surveillance system (i.e., does not rely on voluntary reports) that includes medical records data from millions of individuals enrolled in 10 U.S. health care systems (Yih et al., 2011).[6] These health care systems' EHRs enable VSD's large, linked database to be used in research studies to examine the safety of a specific vaccine by determining the incidence rate of a specific illness/condition following vaccination and comparing it with the rate in patients who did not receive that vaccination (National Network for Immunization Information, 2010). Despite the limited number of health plans that participate in the VSD, policy makers and immunization stakeholders rely on VSD's capacity to produce rapid-cycle analysis to investigate vaccine safety questions.

Although lot numbers are already included in VAERS and in VSD (National Network for Immunization Information, 2010), barcoded vaccines' capacity to reduce human error in record keeping suggests that data quality may be improved. Such improvements can enhance these systems' capacity to reliably answer vaccine safety questions.

2.3 Immunization Practice

Immunization practice requires considerable documentation as part of inventory management, vaccine administration, and billing (Figure 2-2). At each point where documentation occurs, there is an opportunity for inaccurate reporting (e.g., recording TDaP instead of Tdap; HBV instead of HPV, or inaccurate lot number or expiration date). Likewise, the need for the same information to be entered into multiple systems not only increases the likelihood of error but is also inefficient. In this section of our review, we examine literature related to time–motion studies, extraimmunization, vaccine wastage, inventory management, and the prevalence of immunization by provider type.

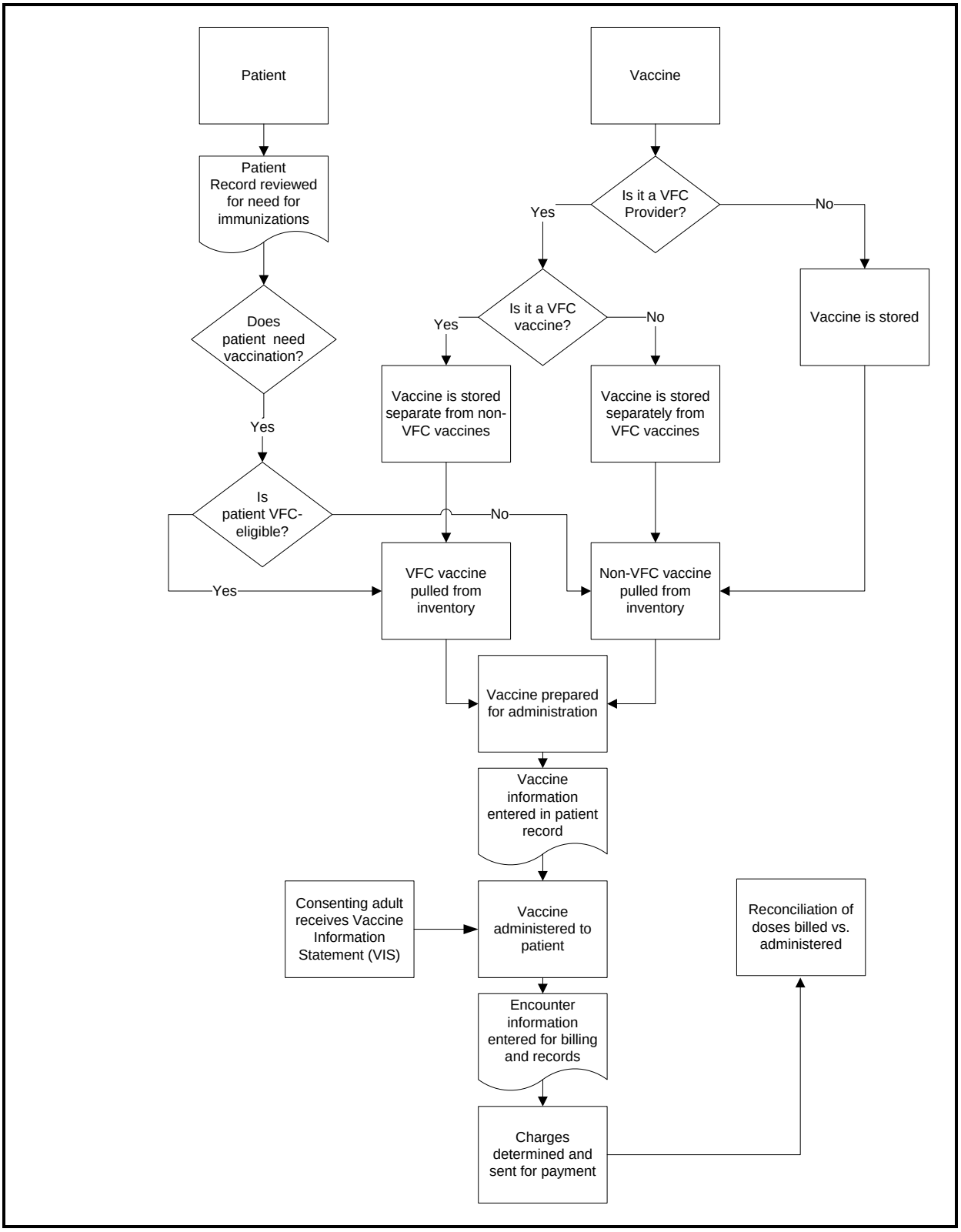
2.3.1 Time–Motion Studies

Time–motion studies have been performed since the 1920s to measure efficiency in the workplace. In the area of immunization practice, we found five articles reporting on time–motion studies in immunization practice (Quach et al., 2011; Glazner et al., 2004; Davis et al., 2002, 2004; Washington et al., 2005), although only Quach et al. (2011) considered outcomes that are relevant to addressing the impact of barcoded vaccines on provider time.

Quach et al. (2011) compared data collection systems in Canada during the 2009 H1N1 influenza pandemic, focusing on differences in the time to complete data collection tasks across three types of data collection systems: wholly electronic, hybrid (electronic plus

[6]The following health care systems participate in the VSD: Group Health Cooperative of Puget Sound, Seattle, Washington; Harvard Pilgrim Health Care, Boston, Massachusetts; HealthPartners Research Foundation, Minneapolis, Minnesota; Kaiser Permanente Northwest, Portland, Oregon; Kaiser Permanente Medical Care Program of Northern California, Oakland, California; Kaiser Permanente Colorado, Denver, Colorado; Kaiser Permanente of Georgia, Atlanta, GA; Kaiser Permanente of Hawaii, Honolulu, Hawaii; Marshfield Clinic Research Foundation, Marshfield, Wisconsin; Southern California Kaiser Permanente Health Care Program, Los Angeles, California.

Figure 2-2. Common Immunization Administration Process Flow



Source: RTI International based on observation of clinical practice.

paper) systems with paper client registration, and hybrid systems with electronic client registration. Within each data collection system, provider tasks were characterized as either paper based or electronic. Table 2-5 shows each of the defined tasks that Quach et al. (2011) tracked, how they differed across paper-based and electronic data collection systems, and RTI's estimate of the impact of vaccine barcoding on the task.

Table 2-5. Comparison of Data Collection Tasks in Paper-Based vs. Electronic Systems

Task	Description	Paper Example	Electronic Example	Anticipated Impact of Barcoded Vaccine
Client registration	Time to collect and record demographic information	Clerk fills out demographic information for client	Swipe card or prepopulated database to obtain demographic information	Not applicable (N/A)
Collecting medical history	Time to collect and record information regarding potential contraindications and previous administration of seasonal influenza vaccine	Clerk/nurse records medical information consent form	Clerk clicks series of boxes to record medical information	No direct impact
Immunization record keeping	Time to record information about vaccine (vaccine, dosage, dose number, lot number, vaccinators' name, site)	Nurse writes lot numbers on form or checks off details if prefilled	Nurse clicks screen with prepopulated vaccine lot information	One swipe with barcode reader would allow for data capture of vaccine lot numbers and expiration date
Preparing proof of vaccination documentation	Time to prepare immunization record for client	Nurse fills out card for client or provides preprinted vaccine proof or carbonless copy	Nurse prints vaccine proof	Information on lot number and expiration date could be easily included in vaccination documentation

Source: Adapted from Quach et al. (2011).

Quach et al. (2011) found that electronic methods for influenza vaccine record keeping took an average of 9.4 seconds per client vaccinated compared with paper-based methods, which took 30.1 seconds on average. The time to prepare proof of vaccination documentation was an average of 13.4 seconds per client using a paper-based data collection approach and 0 seconds per client using an electronic approach, because the documentation was automatically printed for clients. These findings suggest that vaccine barcoding, in

combination with EHRs, is likely to reduce the time spent on immunization data collection by approximately 34 seconds per client.

2.3.2 Vaccine Inventory Management

Surveys of family physicians and ob-gyns have identified vaccine inventory management (or components thereof) as barriers to their immunization practice (Campos-Outcalt, Jeffcott-Pera, Carter-Smith, Schoof, & Young, 2010; Power et al., 2009). Providers who participate in the Vaccines for Children (VFC) Program have their own specific requirements for inventory management in addition to whatever inventory management activities they are already performing (Immunization Services Division, 2007). Barcoded vaccines' capacity to facilitate efficient and accurate record keeping shows promise to facilitate vaccine inventory management. As a result, one may anticipate that barcoded vaccines could indirectly address one barrier to immunization practice. It is also possible that monitoring usage over time would provide the practice with greater insight into its utilization, which in turn may improve vaccine ordering procedures and the frequency with which orders are placed.

In addition, improved vaccine inventory management may reduce vaccine wastage. Vaccine wastage occurs when vaccine doses go unused before their expiration date. Setia et al.'s study examined wastage due to interruptions of the cold chain (heat or freezing), physical damage of package or label, loss in transit or inventory, or incomplete use of all doses in a multidose vial (Setia et al., 2002). Although Setia's data did not specifically examine wastage of single-dose vaccine products, one may further assert that wastage may include not using a single-dose vaccine before the expiration date. As with extraimmunization, 2D-barcoded vaccines offer the means to potentially improve record keeping—including vaccine management—which could reduce vaccine wastage.

The incidence of vaccine wastage is poorly documented. Setia et al.'s (2002) article continues to be the primary citation on the subject. Although it is presumed that less vaccine is wasted in developed nations with more robust immunization systems than in less developed nations (in large part due to a more reliable cold chain), the high cost of many vaccines recommended for routine administration in developed nations makes even relatively low rates of vaccine wastage costly. Setia et al.'s study included a close analysis of vaccine wastage in five states. They found wastage variation by vaccine type (hepatitis B—1.1%, measles—43.8%) and geographic region in which the five states were located (Northwest—1.4%, Southwest—5.4%). The greatest proportion of vaccines wasted was 2.6% because the vaccine was "spoiled/lost/other." The smallest proportion of vaccines wasted was 0.0002% because the vaccine's label was "missing."

Although Setia et al. do not specifically report what proportion of wasted vaccine doses were due to poor vaccine management, their findings combined with our understanding of the attributes associated with an optimally implemented electronic data collection system

suggest that using barcoded vaccines could reduce at least some vaccine wastage, particularly wastage caused by poor vaccine management. For example, barcoded vaccines facilitate more precise monitoring of vaccine inventory. By more precisely monitoring inventory, immunization providers can more easily ensure that vaccines are used in order of their expiration date. Such an approach may reduce vaccine wastage due to expiration prior to administration. Likewise, barcoded vaccines facilitate more reliable recording of doses administered, thus reducing the waste associated with extraimmunization.

2.3.3 Immunization by Provider

Vaccines are administered in a variety of locations by a variety of providers. The reasons why this distinction is relevant when considering the impact of 2D-barcoded vaccines include the following:

- Different locations have different infrastructures for data collection and reporting. A pediatric practice is likely to have a completely different administrative structure than a pharmacy. These differences have implications when considering cost estimates as well as when considering the practicalities associated with implementing barcode technologies.

- Providers may practice in a variety of locations. For example, a nurse may provide immunizations in a private practice, shopping mall, or pharmacy. This may be relevant when designing training programs. For example, one should not assume that training simply targeting pharmacy locations will necessarily reach pharmacists.

- Immunization locations may include a variety of providers. For example, a vaccine administered in a pharmacy may be provided by a nurse or a pharmacist. This variety has implications when interpreting literature that reports on the location where a vaccination was received.

- Different provider and location types may have different needs for training materials.

No comprehensive data source reports which health care providers administer what vaccines to particular clients. In this review, we present literature that reports on immunizations provided by pediatric and adult primary care physicians, including pediatricians, family physicians, internal medicine physicians, and ob-gyns. Unfortunately, information on the proportion of vaccines administered by health departments is not available.

Pediatric Practices

The National Immunization Survey (NIS) categorizes immunization providers into public and private. The NIS reports that more than half (60.4%) of childhood immunizations are provided by private providers, nearly a quarter are provided by a mixed public/private provider, and the remainder (14.2%) at public health departments (Lindley, Shen, Orenstein, Rodewald, & Birkhead, 2009).

A 1999 study reported that 74% of children in a nationally representative survey received all or some of their immunizations from a provider considered to be the child's medical home. For these children, 70% were immunized by pediatricians, 12% by family physicians, and 18% by a combination of provider types (Santoli, Rodewald, Maes, Battaglia, & Coronado, 1999).

Family Medicine Practices

The AAFP surveyed 2,000 of its nearly 25,000 members who had self-identified as spending at least 80% or more of their time providing direct patient care. From the 637 eligible (office-based) respondents, at least 80% or more reported providing most routinely provided child, adolescent, and adult vaccines within their practice (Campos-Outcalt et al., 2010). Many family physicians also referred patients elsewhere for immunization services either in addition to or in lieu of the immunizations provided within their practice setting. Referral was more common for adults (53.5%) than for children and adolescents (44.1%).

Internal Medicine Practices

A survey of 1,109 adult primary care providers (internal medicine and family physicians) in office-based, direct patient care revealed 37 whose practices did not stock any vaccines for adults (Freed et al., 2011). Of the remainder who did stock vaccines, a broad range of vaccines was stocked. The most commonly stocked vaccine was Td (92%); the least commonly stocked was zoster (45%). Two percent of respondents reported plans for their practice to cease stocking any vaccine in the coming year, whereas 12% reported plans for their practice to increase the variety of vaccines stocked. Reasons for not stocking specific vaccines include inadequate reimbursement, inconsistent insurance coverage of patients, and high inventory cost.

Obstetrics-Gynecology Practices

Ob-gyns are regarded by many women as their primary care provider and their role as an immunization provider is evolving. A study by Power et al. (2009) revealed that most ob-gyns disagreed (40.9%) or strongly disagreed (24.6%) with the statement "routine screening for vaccine-preventable diseases falls outside the routine practice of an ob/gyn." A majority (78.7%) of ob-gyns reported stocking at least one vaccine in their practice.

Pharmacy and Retail-Based Settings

Pharmacists are a growing provider of immunization services. As mentioned above, some data report the number of persons receiving vaccinations at pharmacies, but it is not clear whether the pharmacist provided the vaccination. This distinction is relevant when estimating the costs associated with different provider types as well as when considering approaches to implementing vaccine barcode technologies. A survey conducted by the American Pharmacists Association (APhA) (2011) found that licensed pharmacists may administer at least one type of vaccine in all 50 states and the District of Columbia. There is

considerable variation among states regarding which vaccines can be administered to people in various age groups.

For example, in the District of Columbia, pharmacists are licensed to administer influenza vaccine only to people 18 years of age or older. Other states permit administration of certain vaccines to people as young as 3 years of age. The paucity of data quantifying pharmacists' contribution to vaccine administration presents a challenge when assessing the impact of 2D-barcoded vaccines. Nevertheless, our review of available information suggests that pharmacists who provide immunization services in a pharmacy setting are unlike other immunization providers. In particular, because most pharmacists do not administer to patients younger than 24 months, pharmacists are less likely than most other immunization providers to immunize young children (APhA, 2011).

2.4 Electronic Data Exchange for Immunization

2.4.1 Electronic Health Records

A robust electronic data exchange infrastructure is necessary to take the fullest advantage of automated identification of vaccine products using 2D barcodes. Although an EHR system is not required to use 2D barcodes, analyses presented in later chapters indicate that those practices that do use EHRs are more likely to benefits from 2D barcodes. Although studies of EHR adoption and use suffer from inconsistencies in terminology and methods, adoption is known to be accelerating.

DesRoches et al. (2008) reported that, as of early 2008, 13% of physicians reported having a basic EHR system and 4% reported having a fully functional system. The 2010 National Ambulatory Medical Care Survey (NAMCS) revealed that nearly half (50.7%) of office-based physician practices have "any" EHR system and only 10.1% have a "fully functional" EHR system (Hsiao, Hing, Socey, & Cai, 2010).[7]

The Medical Group Management Association (MGMA) found, based on a survey from a convenience sample, that 52.3% of respondents reported using an EHR for "health records storage" in 2010 (MGMA, 2011).[8] This same survey found that the majority of respondents' practices had integrated EHR and practice management systems (PMS): 78.8% of pediatric practices, 78.4% of family practice practices, 74.8% of ob-gyn practices, 71.1% of primary care multispecialty practices, and 63.8% of internal medicine practices. In 2011, MGMA

[7]According to Hsiao et al. (2010) a fully functional EHR include all functionalities of basic systems plus the following: medical history and follow-up, orders for tests, prescription and test orders sent electronically, warnings of drug interactions or contraindications, highlighting of out-of-range test levels, electronic images returned, and reminders for guideline-based interventions.

[8]We interpret the use of an EHR for "health records storage" is a kin to "any" EHR. Thus, our interpretation is that the responses are comparable, despite the fact that the NAMCS's respondents were randomly selected and MGMA's survey used a convenience sample.

found more providers with what the NAMCS defines as a fully functional EHR; 16.3% of all respondents reported that their implementation of EHR was complete.[9]

The Health Information Technology for Economic and Clinical Health Act (HITECH) supports the adoption of EHRs. As part of HITECH, the Centers for Medicare & Medicaid Services (CMS) will provide cash incentives for Medicare and Medicaid providers who implement EHR systems that meet certain requirements for meaningful use (HITECH Act, 2009). HITECH's meaningful-use provision is intended to ensure the quality of data included in EHRs by establishing benchmarks against which providers' use of EHRs is evaluated (Hogan & Kissam, 2010). Among the benchmarks against which providers' meaningful use can be assessed is the ability to submit electronic data to immunization information systems (IIS). As long as they enroll by 2012, eligible Medicare providers may earn up to $44,000 over 5 years; eligible Medicaid providers may earn up to $63,750 over 6 years. CMS's incentives are anticipated to have a dramatic impact on health care providers' adoption of EHRs and, by association, the potential adoption of barcoding for data collection. Seventy-two percent of respondents from medical practices reported that they planned to participate in the HITECH incentive program (MGMA, 2011).

2.4.2 Immunization Information Systems

Among the data systems that could be affected by 2D-barcoded vaccines are IIS (formerly known as immunization registries). IIS are confidential, population-based, computerized information systems for the collection of vaccination data for all residents within a geographic area.[10]

IIS is recognized by the Guide to Community Preventive Services as a means to support immunization programs (Guide to Community Preventive Services, 2011). The most recent Immunization Information Systems Annual Report (IISAR) estimated that in 2008 approximately 75% of children less than 6 years of age (18.4 million) had at least some immunization data in an IIS (*Morbidity and Mortality Weekly*, 2010). Although that number was an increase from surveys conducted in prior years, there are still challenges to IIS reaping the full benefits that barcoded vaccines promise.

In 2008, complete lot number information for children under the age of six was part of the IIS in 38% of reporting immunization grantees. This compares with 40% for vaccine manufacturer data and 98% for vaccine type data. Omitting vaccine lot from the IIS makes it impossible to rely on the IIS in the case of vaccine recalls or investigations of vaccine safety concerns associated with a specific lot number.

[9]See http://www.cdc.gov/nchs/data/hestat/emr_ehr_09/emr_ehr_09.htm.

[10]The following data elements are required for IIS: patient name: first, middle, last; patient birth date; patient sex; patient race; patient ethnicity; patient birth order; patient birth state/country; mother's name: first, middle, last, maiden; vaccine type; vaccine manufacturer; vaccination date; and vaccine lot number.

2.5 Limitations

This availability of literature and related information limits the degree to which we can identify the impact of 2D barcoding on vaccines. The complexities of the U.S. immunization system mean that seemingly straightforward questions such as "How many doses of vaccine are administered by pediatricians?" cannot be answered by available information. Publically collected data, like BRFSS, have significant limitations. An additional, fundamental limitation is that because 2D-barcoded vaccines do not yet exist, assessing their impact using available literature requires inference. Although our inference is based on our understanding of the U.S. immunization system and technology assessment, it is not without limitations.

2.6 Conclusions

Our review of the literature focused on barcoding in health care, safety issues, immunization practice, inventory management, immunization information systems, and electronic data exchange. Based on this literature, we anticipate that 2D-barcoded vaccines have the potential to impact (directly or indirectly) a variety of aspects related to immunization practice. 2D-barcoded vaccines' capacity to capture vaccine information, most notably lot and expiration date, which is free of human error can result in improved record keeping and overall data quality. When this information is integrated into a robust EHR, the information can be used to support clinician decision making to ensure patients receive the right vaccine at the right time. The result of such supported decision making may be reduced rates of extraimmunization and vaccine wastage. This, in turn, may reduce costs associated with vaccine doses that are unnecessary or wasted. In addition, improving the accuracy and completeness of vaccine lot and expiry information in electronic data systems can facilitate the inclusion of this information in IIS and enhance the quality of the data included in IIS. Furthermore, improvements in collecting and sharing vaccine information can facilitate the means to identify and respond to vaccine safety concerns.

3. IMPACT ON VACCINE PRODUCTION

This chapter presents our analysis of the impact of the transition to 2D barcoding on vaccine production. It reviews manufacturers' knowledge, attitudes, and beliefs; their assessment of technical feasibility; and the economic costs of upgrading packaging and labeling lines to include online 2D barcode printing technology. At present, linear barcodes appearing on product labels are printed off site by third-party vendors and then delivered to production facilities. In contrast, to ensure that the correct expiration date and lot number are encoded on the label affixed to the primary packaging, 2D barcodes will be printed on the packaging and labeling line.

According to the five of seven manufacturers participating in this analysis, adding online 2D barcode printing is technically feasible and will not significantly alter routine production operations once implemented. It is a one-time capital expense. Indeed, analysis of data provided by manufacturers indicates that the average cost per line will amount to $1.22 million. Because five manufacturers plan to upgrade 25 lines located in the United States and other countries, the total implementation cost is estimated to be $30.60 million between 2011 and 2013. One additional firm is considering implementation, while another does not plan to upgrade because of the expense of doing so and not because of technical infeasibility.

3.1 Methodology for Assessing Impacts on Vaccine Production

Impacts on vaccine manufacturers were collected via semistructured interviews with manufacturers and tabulated via quantitative analyses of the capital, labor, and materials required to upgrade manufacturers' packaging and labeling lines. In addition to one-time implementation costs, ongoing incremental impacts on the costs of production were analyzed, which required us to estimate the annual number of doses produced for distribution in the United States.[1] The estimated production volume also served as a frontier against which the volume of immunizations by medical specialties included in the study and by local health departments (LHDs) could be compared to ensure that our model did not forecast numbers of immunizations that exceed production volumes.

3.1.1 Primary Data Collection

Of the 11 manufacturers that have the Food and Drug Administration (FDA)-approved vaccine products on the U.S. market (Table 3-1), 7 participated in our study. They produce, market, or distribute over 90% of the total number of vaccine products licensed for sale in

[1]In this analysis, we defined dose as a discrete unit of a vaccine product.

Table 3-1. Manufacturers that Produce, Market, and/or Distribute Licensed Vaccine Products in the United States

Berna Products Corp. (Crucell)	Intercell	Novartis
CSL Biotherapies	MassBiologics	Pfizer
Emergent Biosolutions	MedImmune	Sanofi Pasteur
GlaxoSmithKline	Merck	

Note: As of October 2011.

the United States.[2] Six manufacturers participated in three stages of primary data collection: preliminary interviews, site visits, and follow-up interviews.[3] One manufacturer only participated in a telephone call. Repeated attempts to contact the remaining four manufacturers were unsuccessful.

The purpose of the preliminary interview was to rapidly acquire information regarding the firms' knowledge, attitudes, and beliefs about 2D barcoding; their preliminary assessment of feasibility; and any implementation plans they might have.[4] The interview also permitted manufacturers to ask questions about the study, to review the discussion guide with RTI, and to assess the level of effort for participation. Telephone interviews lasted between 30 and 90 minutes, with the exception of one call that ran for no more than 5 minutes.[5] These interviews were held between November 2010 and March 2011.

For the site visits, RTI's personnel traveled to manufacturer locations for meetings lasting between 90 minutes and 4 hours each. Using the discussion guide as a *de facto* agenda (see Appendix B), manufacturers' representatives took the lead on coordinating the site visits and determining the meeting date, location, attendees, and duration in consultation with RTI. The site visits, which were held between January and April 2011, yielded details and quantitative data that complemented the information gained during telephone interviews.

[2]Note that we emphasize the total number of vaccine products licensed for sale in the United States and not the total volume of doses produced for the U.S. market. This distinction is important because a manufacturer may have only one or two licensed products but produce a large volume of doses.

[3]Because of adverse weather conditions in February 2011 a teleconference was conducted in lieu of one site visit. One additional manufacturer was not available for a site visit and preferred a teleconference. Lastly, one manufacturer declined to participate in a site visit.

[4]Our first preliminary interview was conducted on site by researchers with backgrounds in business and finance, as well as public health and immunization policies and programs. This interview was used as a pilot to ensure discussion guide questions were appropriately phrased and sequenced and to learn about historical American Academy of Pediatrics (AAP), FDA, and manufacturer conversations about 2D barcoding. Because of schedule and resource constraints, all other preliminary interviews were conducted by telephone.

[5]Some manufacturers included a large number of staff on the introductory telephone call. It was quickly determined that it would be most effective and efficient to conduct the bulk of the interview in person during the site visit.

Manufacturers included representatives from departments such as marketing, immunization policy, production management, packaging and labeling operations, logistics, and information technology (Table 3-2). Following the telephone interviews and site visits, RTI remained in contact with manufacturers to follow up on outstanding questions or request clarifications and to ask manufacturers to verify entries for their respective companies made by RTI in our benefit-cost model.

Table 3-2. Interviewed Manufacturer Representatives

Manufacturer	Representative Titles[a]	Modes of Data Collection
A	Director, Supply Chain Technology; Director, Packaging Technology; Senior Packaging Engineers; Senior Director, Packaging Operations	Telephone, site visit, conference call, e-mail
B	Senior Director, Marketing; Senior Director, Packaging Technology; Director, Packaging Technology	Telephone, site visit, conference call, e-mail
C	Senior Director, Marketing; Senior Director, Packaging Technology; Consultant; Representative from Regulatory Affairs	Telephone, conference calls, e-mail
D	Senior Packaging Engineer; Director, Packaging Technology	Telephone, conference calls, e-mail
E	Director, Operations	Telephone, e-mail
F	Senior Packaging Engineer; Director, Marketing	Telephone, site visit, conference call, e-mail
G	Director, Supply Chain Technology; Director, Packaging Technology	Telephone, site visit, conference call, e-mail

[a]Titles for manufacturer representatives were harmonized across interview respondents to avoid identifying individuals and responding companies.

Interviews were conducted under confidentiality agreements that specified that only aggregated responses would be available in any format outside of the RTI project team, including project documentation made available to the Centers for Disease Control and Prevention (CDC). Notes were taken during all meetings. Some meetings were also audio-recorded, when the manufacturer approved, to help resolve discrepancies should alternative interpretations of a manufacturer's response exist in an interviewer's notes when compared across the team. RTI's institutional review board (IRB) determined that manufacturer data collection protocols were exempt from IRB requirements. CDC was not engaged.

3.1.2 Estimation of One-Time Fixed and Ongoing Variable Costs

Manufacturers were asked to provide actual or forecasted data on their capital equipment, labor, and materials requirements, either in dollar terms or in physical units that RTI could later monetize through discussions with vendors and compare with other manufacturers' estimates for similar packaging and labeling lines. Cost estimates were also compared with

a benefit-cost study prepared by HDR, Inc. for the Canadian Automated Identification of Vaccine Products Advisory Task Group (HDR, 2009).

Any one-time costs were expected to fall into the following categories: capital equipment (e.g., printers, vision systems, and associated tooling); project management, implementation, and trials; changes in standard operating protocols; software and interface programming and testing; training and certification; label redesign; and regulatory reviews and submissions to the FDA. Manufacturers were given the option to discuss other categories if the costs were material to the entire project value.

Any recurring costs were expected to fall into the following categories: labor; label media; periodic interface programming and line testing; consumables, such as inks or other inputs; quality control and assurance; fees associated with membership in standards groups (such as GS1, if they were not already members); and annual software licensing costs.[6]

In addition to cost estimates, operational and production data were provided by manufacturers to allow RTI to aggregate responses across manufacturers to form industry-level impact estimates. Manufacturers provided data on their global packaging and labeling lines, product portfolio, production volume for the U.S. market, label media, and primary packaging.

3.1.3 Estimation of Doses Distributed in the United States, 2013 to 2023

The number of doses for the U.S. vaccine market for 2013 to 2023 was estimated by reviewing production data provided by manufacturers, CDC, the Advisory Committee on Immunization Practices (ACIP)-recommended schedule as of February 2011 (CDC, 2011b), and current immunization rates and scaling to U.S. population estimates by single year of age (U.S. Census, 2005, 2009), assuming immunization and series completion rates remain constant over time.[7] Market data on the number of doses for 2010 were provided by CDC (flu products only; Kennedy, 2011) and vaccine manufacturers (all products). The quantity demanded of flu products was assumed to be proportional to the projected U.S. population, and the ratio of nonflu doses to persons for 2013 to 2023 was assumed to be equal to that for 2010.

The quantity demanded for nonflu products was estimated in a two-step process. In the first step, immunization rates for vaccines on the ACIP-recommended immunization schedule as of January 2011 were multiplied by annual population estimates by single year of age for the 30-year period ending in 2030. The source for immunization rates was the 2009

[6]Manufacturers were given the option to discuss other categories if the costs were material to the entire project value. However, no additional cost categories were identified.

[7]Dose estimation was necessary to estimate the incremental impacts associated with changes in label media and to form a frontier in the analysis against which to check project immunization volume conducted by provider groups included in the quantitative analysis.

National Immunization Survey (CDC, 2010), which includes data on series completion, and the source for the population by single year of age data was the U.S. Census Bureau (2005, 2009). To account for wastage and extraimmunization, dose estimates were inflated by wastage and extraimmunization rates from the literature. Yet our literature review revealed that actual rates for wastage and extraimmunization are ill defined.[8] Therefore, the results of this first step became an index of the ratio of pediatric/adolescent and adult vaccines to total nonflu production volumes.

In the second step, the total production volume for each year beginning in 2013 was assumed to be proportional to the projected U.S. population, with actual data for 2010 serving as the reference year. Flu doses were subtracted from total doses, and then the index created as part of Step 1 was used to segment the balance into pediatric and adult doses. The results of these calculations were then rounded to the nearest 100,000 doses to account for measurement error. See Appendix C for additional detail on forecasting the number of doses for the U.S. market.

3.1.4 Assumptions

The model of manufacturers' costs and benefits makes the following assumptions:

- All dollar values are in 2010 dollars and the unit-level costs are held constant over time. In other words, real ("inflation-adjusted") costs do not change.
- No new vaccine products or new product container types are introduced, and there is no change in the relative proportion of individual products across prefilled syringes, single-dose vials, multidose vials, or other container types.
- No changes to label media, apart from peel-off to flat labels, are introduced.
- Vaccine manufacturers' market shares within each product segment remain constant.
- Immunization and series completion rates are constant. In other words, there is no change in immunization rates in the United States over the time period of analysis, only in the population overall and by the population by single year of age. There are also no changes in ACIP-recommended schedules.
- 2D barcodes appear on all vaccine product labels beginning January 1, 2013.

[8]Setia et al.'s 2002 study of wastage showed variation by vaccine type (hep B—1.1%; measles—43.8%) and geographic region in which the five states were located (Northwest 1.4%; Southwest 5.4%) (Setia et al., 2002). Feikema and colleagues (2000) examined extraimmunization of hepatitis B, DTP/DTaP, Hib, polio, and measles vaccines and found a range of weighted percentage by vaccine of 14.1% for polio to 2.5% for measles. Strine and colleagues (2002) recognized that the rate of extraimmunization is decreasing (from an estimated 1.8 million extra doses in 1997 to 775K in 2000) but assert the financial magnitude remains a concern.

3.2 Qualitative Manufacturer Interview Findings

Of the seven manufacturers interviewed, five reported that they had plans to implement 2D barcoding of Global Trade Item Number (GTIN), expiration date, and lot number data; one reported that they were undecided; and one reported that they do not plan to implement 2D barcoding at this time. The time required to implement barcoding was estimated to be at least 12 months but no more than 24 months and depended on such factors as number of packaging and labeling lines, capital budgeting and procurement procedures, and scheduled production downtime.

3.2.1 Perceptions of Benefits of 2D Barcodes

Five of seven manufacturers interviewed believe that a 2D barcode on vaccine product labels appearing on primary packaging will enhance vaccine safety while simultaneously offering efficiency benefits for providers' immunization businesses. During interviews, some manufacturers observed that, although they are part of pharmaceutical businesses, vaccine divisions within these businesses have a strong public health focus and see the 2D barcode as an advantageous public health opportunity.

One industry veteran cited the Vaccine Identification Standards Initiative (VISI), noting that technologies for providers (vaccine end users) were not sufficiently mature or available at low enough cost at the time, causing that effort to stall. In contrast, manufacturers pointed to a confluence of factors in the current environment:

- Leadership: AAP is leading the initiative, coordinating with GS1 to providing guidance to manufacturers on using GS1 data matrix standards.[9]
- Familiarity with Technology: There is greater familiarity with health care technologies, and there are broad shifts toward achieving greater efficiency through them.
- Federal Legislation Supporting Electronic Health Record (EHR) Adoption: Providers are adopting EHRs at a greater pace because of incentives and support to adopt EHRs funded through the American Recovery and Reinvestment Act (ARRA) and the HITECH Act.
- Market Demand: Vaccine purchasers, especially large ones like Cook Children's Health Care System, are requesting barcodes on vaccines that include product and expiration date and that will allow them to improve vaccine supply management.

2D barcoding may decrease the administrative burden associated with vaccination. It is anticipated that reducing time spent on documentation could increase the number of

[9]Manufacturers have complied with the FDA's linear barcode requirement since 2004 for new products and since 2006 for existing products. All vaccine product labels currently contain a linear code. The extent to which providers (vaccine end users) use these barcodes is unknown. Accordingly, our provider survey included questions to ascertain whether the transition to a data matrix may have unintended negative consequences for providers using the linear barcode.

providers administering immunizations. Although average rates for pediatric immunization coverage are good, there are "pockets of low rates … that must be reached," according to one interviewee. If logistical barriers to immunization are lowered, then vaccination rates could improve.

Automating vaccine inventory management and record keeping may lower the cost of immunization practice and encourage providers who are reluctant to immunize to continue or perhaps broaden their immunization practice. One manufacturer representative indicated that he believes vaccines may be the second or third greatest expense for pediatric practices after payroll.

Other possible advantages to providers and the immunization system cited by manufacturers include:

- more efficient vaccine administration with fewer record-keeping steps;
- automated record keeping that populates patients' EHRs, adjusts inventory and ordering systems, interfaces with billing and practice management systems, and sends data to IIS;
- lower vaccine wastage and improved inventory management; and
- lower reimmunization through improved record keeping in registries.

Although increased immunization rates would result in increased demand, better data capture and population coverage in registries could reduce the amount of reimmunization and offset any sales gains. Any discussion of effects on product sales is purely theoretical because the net effects are indeterminate.

3.2.2 Perceptions of AAP 2D Barcoding Initiative and Use of GS1 Standards

Manufacturers expressed support for AAP and believe that AAP is the appropriate "unifying organization" and advocate for the 2D barcoding initiative at the FDA.[10] They also viewed GS1 as the appropriate standards organization because GS1 product identification standards are used globally, and they are already familiar with the organization and its procedures. Implementation of 2D barcoding requires universal, or near universal, adoption by manufacturers to be effective. It is a standards issue, and manufacturers must align to a common format. Thus, a unifying organization is needed to facilitate standards adoption across organizations. Interviewees indicated that this feasibility and economics study is an important contribution to filling the data gaps and will ultimately produce an objective and

[10] In response to questions about BIO and its involvement in the barcoding initiative, one manufacturer noted that "BIO has enough on its plate." His view was that there are only 9 or 10 vaccine manufacturers (with unique interests) compared with hundreds of biologics firms, and that through the unifying forum of AAP/GS1, a consensus industry standard can be reached.

independent assessment of costs, benefits, and technical requirements. They would like this final report to be a publicly available document.

In December 2011, the 2D barcode standard and barcode data fields for vaccine product labels were determined: a GS1 data matrix containing the GTIN (which includes the National Drug Code [NDC]), expiration date in YYMMDD format, and lot number. If acceptable to the FDA, and if the FDA grants a waiver to a manufacturer(s), this 2D barcode will appear on primary packaging. The inclusion of different data elements in the 2D barcode was largely precluded by the availability of sufficient area ("real estate") on the label for an enlarged data matrix. Some manufacturers may include a 2D barcode on the secondary packaging to assist with inventory management.

3.2.3 Perceptions of Outstanding Questions for the FDA

During interviews, manufacturers indicated that additional guidance from the FDA on the following questions would be useful:

- What is the exact procedure for requesting the linear barcode waiver, and what documentation or validation data are required as part of the waiver request?
- Is it permissible to place a 2D barcode on the product label appearing on the primary packaging to replace the linear barcode, or must both the linear and 2D barcodes appear on that label?
- Do product labels need to be reapproved by the FDA if the linear barcode is removed and the data matrix placed on the product label in its place?
- Is the change in the labeling and packaging line an annual reportable change, or is it a CBE-30, under which manufacturers notify the FDA, wait 30 days, and then implement the change?

Multiple manufacturers have projects at some stage of implementation, while others have waited for more concrete guidance from the FDA. As long as ambiguities remain, for some manufacturers, capital budgeting, implementation plans, and, ultimately, equipment vendor selection and implementation schedules may not be finalized.

3.2.4 One-Time Implementation Costs

Manufacturers currently outsource production and printing of their product labels, with labels arriving at plants on spools fully printed except for the final human-readable expiration date and lot number information. These last two items are printed on the label in a production step that coincides with affixing the label to the product container ("online

printing"). If the label has a linear barcode, it is printed by a vendor offline because the NDC data encoded in linear barcodes are static and do not vary by expiration date or lot.[11]

In 2D barcoding, however, the symbology contains the static NDC data and the variable expiration date and lot number, essentially precluding the option of having the symbol printed off site by third-party vendors. Having the symbol printed off site would present significant coordination and inventory management challenges, as well as operational and regulatory risks. Therefore, under 2D barcoding, manufacturers will have vendors produce the label but print the data matrix and human-readable elements online at their location.

The dot matrix or inkjet printing technology manufacturers currently use for printing expiration dates and lot numbers prints at a quality that allows humans to read alphanumeric characters but is not capable of printing 2D barcodes of the quality required for machines to read data matrices, given the label's space constraints (ISO/IEC, 2004). Therefore, manufacturers that implement 2D barcoding will need to procure and integrate appropriate printing and vision systems into their lines.

Manufacturers' one-time implementation costs will vary because they depend on the

- number of packaging and labeling lines for vaccines;
- primary packaging types (e.g., prefilled syringes, single-dose vials, multidose vials);
- label materials (e.g., paper or plastic, coatings);
- overall state, age, and flexibility of tooling;
- facility footprints and regional manufacturing strategy and legacy operations;
- planned shutdowns and project scheduling; and
- their manufacturing flexibility, generally.[12]

Capital requirements will include such items as online printers, imaging and image verification technology (often referred to as a vision system), and accompanying tooling and information systems. Labor requirements will be, at a minimum, resources from regulatory affairs, marketing, information technology, packaging and labeling operations, and logistics. Implementation timelines are expected to be 12 to 24 months, and we expect that 2D barcodes will begin to appear on product labels in calendar years 2012 and 2013.

[11]Some vaccine products labels affixed to primary packaging do not include linear barcodes because the manufacturers received a waiver from the FDA in recognition of the containers' physical characteristics, such as curvature and size. In such cases, the linear barcode often appears on blister packs or other packaging.

[12]For example, if a manufacturer with 16 products has only four packaging and labeling lines at four facilities, their costs could be in the same range as another manufacturer with only four products but with each of those products produced at different facilities.

Selection of printing technology depends on the type of packaging (e.g., prefilled syringe, single-dose vial, multidose vial) and the label medium used. For flat labels on single dose and multidose vials, online printing will likely be accomplished using high-quality inkjet technology. Inkjet technology is currently used to print human-readable expiration date and lot number information on product labels. However, the quality levels are unacceptable for a machine-readable 2D barcode. The code would be too blurry; thus, new capital equipment will be required. For prefilled syringes, which often have plastic labels, online printing using laser technology will likely be used.

Other costs to be considered are label redesign and regulatory submission, inventory carrying costs, and international transactions costs. There may also be costs for redesigning the primary packaging labels to remove the linear barcode and include the data matrix barcode, to submit the changes to the FDA, and to manage the FDA regulatory submission. It is also possible that a manufacturer may be able to add the 2D barcode without removing a linear barcode, if sufficient label space is made available.

Line upgrades would be integrated into site-level plans to occur during planned facility shutdowns. Planned shutdowns occur at regular intervals for maintenance, inspections, and implementation of other projects. During these shutdowns, equipment will be installed, processes reengineered as necessary, and a series of line trials will be conducted to validate the online printing system. To meet demand, it is common for facilities to ramp up production prior to shutdowns, building to inventory, and then fulfilling orders from this inventory. Thus, inventory carrying costs spike before and during shutdowns before returning to normal levels. However, if implementation were to occur during planned shutdowns, as expected, building to inventory would take place anyway, and higher inventory carrying and shutdown costs are not directly traceable to the project. The only exception would be if the project extends the shutdown beyond what had been planned.

Lastly, some manufacturers have vaccine products administered in the United States that are produced, packaged, and labeled at facilities outside the United States. For example, Novartis Vaccines manufactures its products for the U.S. market in Germany, Scotland, Italy, and England; GSK in the United States and Belgium; and Sanofi Pasteur in the United States and Canada. The international dimension may add some additional complexity in terms of coordination, but the extent to which this is the case is unknown. Most facilities producing for multiple national markets do product runs by country because of the variation in labeling requirements, including language, barcode size and placement, and required human-readable elements. Because manufacturers produce vaccines for multiple markets, they are interested in general harmonization. There may be some opportunities to spread capital expenditures over larger production volumes than expected because of various automated identification regulations being implemented in Canada and other countries.

3.2.5 Effect of Implementation on Production Rates

Representatives from packaging and labeling operations are most concerned about the effect of online printing on production rates, barcode image quality, and the ability to conduct online imaging to ensure the barcode meets quality standards under Good Manufacturing Practices.

Many upstream and downstream processes are tied to the production rate. Major changes to this rate would be disruptive to any given firm's manufacturing strategy and would affect processes as diverse as order management and logistics (e.g., inventory management, shipping). In addition, it could affect supply chain operations for distributors and, ultimately, customers.

Packaging and labeling lines often operate at speeds of 400 to 1,000 units per minute, and manufacturers will need to optimize printing, imaging, and image verification so that online printing and verification do not change the overall rate of production. For some manufacturers this is likely going to entail including two printers on one line.[13] No manufacturer implementing 2D barcoding expects their production rate to change significantly.

3.2.6 Effect of Implementation on Variable Costs

From the manufacturers' perspective, most ongoing variable costs are not likely to be appreciably different between the current practice of including linear barcodes and the proposed future practice of including the data matrix barcodes. Two exceptions vary by manufacturer: choice of label media and reject rates.

Some vaccine product containers have peel-off labels, which are more costly than flat labels and are incompatible with online printing. Peel-off labels are produced by vendors using a process that involves separately printing and then assembling the two layers of the label. Manufacturers that currently offer peel-off labels will discontinue them under 2D barcoding because of the technical challenge of printing the 2D barcode on both parts of the label online. For some manufacturers, flat labels may be 1.5 to 2 cents to as much as 19 cents

[13]The average cost per line presented in this report reflects the fact that some lines will require more than one printer.

less expensive per dose relative to the peel-off label, depending on the label and the container. Others see no material difference.[14]

It also is possible that manufacturers could see some increase in their reject rate—the rate of rejected units to the total number of units produced—because of poor 2D barcode legibility. Although not anticipated by manufacturers, there is the possibility that some barcodes would not be printed to a sufficient quality standard. If a unit exits the labeler, has its barcode imaged and verified, and is found to have a barcode failing quality standards, the unit could be ejected from the line. Ejection is often performed by air puffs, and the glass containers are compromised once they land in the reject bin. The unit becomes nonsaleable. During one interview, a senior packaging director indicated that a pilot conducted on site did not reveal any changes in its reject rate. We expect that any changes in reject rates would be a function of ultimate line configuration, container type, and process design.

3.2.7 Small Lot Sizes

In contrast to vaccines that may be produced in multiple lots per year, vaccines that are produced in small quantities, for example at a rate of one lot per year, may be able to have their labels printed with a 2D barcode offline by a vendor. In such cases it may not be cost-effective to implement online printing. This may be applicable for a traveler's vaccine, for example.

3.3 Benefit-Cost Analysis of Implementation on Vaccine Production

3.3.1 One-Time Implementation Costs

One-time implementation costs for 25 vaccine packaging and labeling lines are estimated to be $30.6 million and average $1.22 million per line (see Table 3-3).[15] Estimated costs are

[14]One manufacturer hypothesized that manufacturers could see net cost savings through operation efficiencies related to product labels, but he was quick to add that the company has yet to perform the calculations to determine if they would indeed recoup capital investments. It is possible that if the incremental ongoing variable costs of printing the data matrix barcode (relative to printing the linear barcode) are less than the cost savings from using flat labels instead of peel-off labels and any increases in the reject rate, then—ignoring the application of a discount rate or hurdle rate—the manufacturer could recoup its capital investment over time. The discount or hurdle rate is equivalent to a minimum rate of return required for a project to be considered an appropriate use of scarce capital funds. This rate varies by firm and is set by a firm's finance department based on their overall cost of capital and their capital project portfolio standards. Conversely, a manufacturer would have a disincentive to invest in this project if it faced a capital outlay and incremental costs that exceed all other variable cost savings. Although a disincentive may exist, the manufacturer may still implement the project. This would likely be true if the manufacturer has insufficient market share and its competitors implement the project, if the project is mandated by regulation (and the alternative would be to exit the market), or if vaccine purchasers and end users expect the label to include a data matrix barcode. The latter is one avenue through which public purchasers like CDC or the Department of Defense (DoD), for example, could use their purchasing power to affect producer behavior.

Table 3-3. Parameter Estimates for Economic Model of Vaccine Production

Parameter	Value
Number of manufacturers included in the model	7 of 11 firms
Number of packaging and labeling lines to be converted	25 lines
Located in the United States	15 lines
Located outside the United States	10 lines
Average implementation cost per packaging and labeling line	$1.22 million
Capital budget component	25–40%
Labor budget component	60–75%
Total implementation costs	$30.6 million
Implementation time	12–24 months
Time frame of code appearance	2012–2013
Number of doses produced for the U.S. market (2010)	336.8 million
Number of flu doses	163.0 million
Number of nonflu doses	173.8 million
Number of containers for which peel-off labels will be eliminated (2010)	83.9 million
Weighted average savings per dose from elimination of peel-off labels[a]	$0.057 per dose

[a]Cost savings from eliminating peel-off labels were weighted by volume of syringes and single-dose vials.

almost exclusively capital expenditures (25 to 40%) and project labor (60 to 75%). Fifteen lines are located at U.S. production facilities, and 10 lines are located outside of the United States. In addition to these 25 lines, 2 lines have already been upgraded; however, the costs associated with that upgrade are considered sunk costs because they were incurred as part of another initiative. Thus, based on manufacturers' statements, we expect that as many as 27 lines will have 2D barcoding functionality by the end of 2014.[16]

Manufacturers expect that upgrades will take between 12 and 24 months. The variation is due to the number of lines to be converted, the printing technologies required, and the number of printers to be installed per line. Precise schedules vary by manufacturer, and each considers its timing to be confidential business information. However, collectively, manufacturers estimate that the 2D barcode will begin to appear on product labels in late 2012 to mid-2013. It is possible that some manufacturers may have 2D barcodes appearing on labels earlier. It is also possible that some manufacturers may upgrade later than modeled.

[15]All dollar values are in real terms (2010).

[16]If all manufacturers were implementing online printing, at least an additional six lines would be converted at a cost of $7 million, bringing the total cost to $37.6 million. However, some manufacturers with small-volume products *may* have the alternative of printing 2D barcodes offline.

Based on manufacturers' best available forecasts, the model distributes costs from 2011 through 2013, allocated at 25% (2011), 50% (2012), and 25% (2013). The majority of capital purchases and upgrades are expected to occur in late 2011 or 2012. For the purposes of this analysis, although some products may have 2D barcodes appearing earlier, we assume that 2D barcodes first appear in 2013 and are available on all vaccine products on a full-year basis in 2014.

3.3.2 Ongoing Variable Costs

Most manufacturers expect negligible incremental printing or other costs that would be over and above current expense levels. However, elimination of peel-off labels will have some ongoing cost savings for the industry. To quantify these benefits, for any given year, the ratio of the total number of containers from which peel-off labels will be eliminated to the total number of doses was multiplied by the expected savings per dose and the estimated number of doses.[17] The ratio of containers to doses and the expected cost savings in 2010 were assumed to be representative of future years. The ratio of containers to doses for 2010 was 0.2492 (83.9 million containers/336.8 million doses), and the expected cost savings from eliminating peel-offs from syringes and single-dose vials is expected to be $0.057 per dose. (See also notable assumptions list.)

Table 3-4 presents our dose forecast for all vaccine products except travelers' and defense products.[18] For 2015, for example, we forecast 353.40 million doses and estimate that in the absence of 2D barcoding, 88.05 million containers (353.40 million doses x 0.2492 containers/dose) would have peel-off labels. Elimination of these peel-off labels from all nontravelers and nondefense products saves $4.99 million (88.05 million x $0.057).[19] This benefit is added to the time series of manufacturer costs and benefits presented in Table 3-5.

[17]Some products have two containers: one for the antigen and one for the diluents.

[18] Immunization rates for travelers and the DoD are not included in the NIS; thus, we were unable to assemble an accurate independent forecast for these products within the schedule constraints of this analysis. These products include anthrax, Japanese encephalitis, rabies, smallpox, typhoid, and yellow fever.

[19]According to AAP minutes (AAP, 2009): While those who still use paper charts, especially in public health, may find peel-off labels useful, records are moving into the electronic domain. As that trend continues, peel-off labels will become less useful. If it prevents manufacturers from implementing barcoding, they are not needed.

Table 3-4. U.S. Vaccine Market Forecast, Excluding Travelers' and Defense Products (Doses)

		Dose Forecast			
Year	Projected U.S. Population (millions)	Influenza Products (million units)	Pediatric/ Adolescent Products (million units)	Adult Products (million units)	Total, Excluding Travelers' and Defense Products (million units)
2013	319.33	167.80	155.80	23.20	346.70
2014	322.42	169.40	157.00	23.60	350.00
2015	325.54	171.00	158.20	24.10	353.40
2016	328.68	172.70	159.50	24.60	356.80
2017	331.83	174.30	160.80	25.10	360.30
2018	335.01	176.00	162.00	25.70	363.70
2019	338.19	177.70	163.20	26.30	367.20
2020	341.39	179.40	164.40	26.90	370.60
2021	344.59	181.10	165.60	27.50	374.10
2022	347.80	182.70	166.80	28.10	377.60
2023	351.02	184.40	168.00	28.70	381.10

Sources: RTI estimates based on U.S. Census Population data (U.S. Census Bureau, 2005, 2009), the 2009 National Immunization Survey (CDC, 2010), the ACIP Recommended Immunization schedule as of March 2011 (CDC, 2011b), and information provided by vaccine manufacturers on production volumes. Excluded travelers and defense products were for anthrax, Japanese encephalitis, rabies, smallpox, typhoid, and yellow fever.

3.3.3 Summary Benefit-Cost Analysis Results

Table 3-5 presents the time series of costs and benefits estimated for manufacturers. One-time costs of $30.60 million accrue between 2011 and 2013. The only incremental costs or benefits estimated pertain to eliminating peel-off labels from syringes and vials. These cost savings are estimated to accrue beginning in 2013, assuming that manufacturers complete barcode inclusion by the close of that year, and accrue through the end of the period of analysis of 2023. These incremental benefits are expected to total $54.08 million over this period, offsetting one-time costs to yield net benefits of $23.48 million.

The net present value (NPV) of expected manufacturer costs and benefits is $5.02 million when the Office of Management and Budget (OMB)-specified 7% real social discount rate is applied (OMB, 1992).[20] At a real discount rate set to 10%, which is closer to the biopharmaceutical industry real working average cost of capital (Harrington & Miller, 2010), the NPV is $0.17 million. A rate of 10.12% sets the NPV to zero, confirming our interview findings that manufacturers view the 2D barcoding initiative as a one-time cost.

[20]The NPV is the present value of actual or expected future benefits and costs for an investment project, given a discount rate. The discount rate sets a minimum rate of return required by the investor.

Table 3-5. Time Series of Costs and Benefits for Vaccine Manufacturers

Year	Total Doses, Excluding Travelers' and Defense Products (millions)	Containers without Peel-Off Labels (millions)	Economic Benefits from Eliminating Peel-Off Labels ($ millions)	Estimated One-Time Implementation Costs ($ millions)	Net Benefits ($ millions)
2011				7.65	−7.65
2012				15.30	−15.30
2013	346.70	43.19	2.45	7.65	−5.20
2014	350.00	87.21	4.94		4.94
2015	353.40	88.05	4.99		4.99
2016	356.80	88.90	5.04		5.04
2017	360.30	89.77	5.09		5.09
2018	363.70	90.62	5.14		5.14
2019	367.20	91.49	5.19		5.19
2020	370.60	92.34	5.24		5.24
2021	374.10	93.21	5.29		5.29
2022	377.60	94.08	5.33		5.33
2023	381.10	94.96	5.38		5.38
		Total	**54.08**	**30.60**	**23.48**
		NPV @ 7%			**5.02**
		NPV @10%			**0.17**

NPV = Net present value. NPV using the10% real working average cost of capital rate for the biopharamaceutical industry is presented for informational purposes only in this table.

3.4 Conclusions

Based on participating manufacturers' collective feasibility assessments, the technology is available to enable rapid printing, imaging, and image verification of 2D barcodes, and manufacturers will be able to optimize the printing process. The fact that no manufacturer objected to 2D barcoding as technically infeasible suggests that this is an engineering exercise and one-time expense rather than a cross-cutting change in production. Our supposition is that internally manufacturers view the adoption of 2D barcoding first as a technology solution for enhancing vaccine product safety through automated identification, second as an investment in improving customer satisfaction by enabling providers to economize on immunization documentation, and third to enhance the market's perception of their firm as a leader in using technology solutions in the public health arena.

4. KNOWLEDGE, ATTITUDES, AND BELIEFS OF PRIMARY CARE PROVIDERS AND LOCAL HEALTH OFFICIALS

This chapter reviews responses of primary care providers and local health officials regarding knowledge, attitudes, and beliefs related to immunization practice and the potential impact of implementing 2D vaccine barcode technologies in primary care practices and local health departments (LHDs). These findings are based on interviews with relevant stakeholders and a national survey fielded in the spring of 2011.

There were three objectives for primary data collection. First, we needed to assess perceptions of benefits, costs, and technical assistance needs. For example, what do immunizers think about using barcodes? What support may they need? Given what we know about expected adoption costs, would providers purchase scanners and incorporate their usage into their immunization practice? Second, we needed to understand what IT infrastructure was in place in primary care practices and LHDs, how their infrastructures vary by type and by size of practice (measured by number of physicians), and how it is changing. Third, in order to develop national estimates of the economic costs and benefits for providers for using the 2D barcode, we needed data on the number of doses administered, job positions engaged in immunization, and other cost and benefit variables.

4.1 Interview Data Collection with Immunization Provider Associations and Primary Care Physicians

Interview guides were developed based on our previous research experience in immunization practice, our review of the literature, early discussions with professional associations, and consultation with the Centers for Disease Control and Prevention's (CDC's) technical monitors.[1]

4.1.1 Vaccine End-User Definitions

RTI worked with CDC to clarify the end users to be included in assessing end users' knowledge, attitudes, and beliefs. End users include traditional and complementary immunization providers. Within this report, the term "traditional" immunization providers refers to primary care physicians (pediatricians, family physicians, internal medicine physicians, and obstetric-gynecology [ob-gyn]); the term "complementary" immunization providers refers to all other immunization providers, such as pharmacists, retail-based clinics (RBCs), and visiting nurses.

[1]All interview guides and surveys were submitted to RTI's institutional review board (IRB). The IRB provided this project with an exemption under the determination that it was program evaluation.

4.1.2 Traditional Immunization Providers

To represent primary care physicians, we identified key informants representing pediatricians (AAP), internal medicine physicians (American College of Physicians [ACP]), ob-gyns (American College of Obstetrician Gynecologists [ACOG]), family physicians (American Academy of Family Physicians [AAFP]), and the American Medical Association (AMA). Key informants were identified based on RTI's prior work with these organizations. See Table 4-1 for high-level, summary remarks.

Table 4-1. Summary of Anticipated Barriers and Facilitators to Adopting 2D Barcoded Vaccines by Provider Group

Provider	Anticipated Barriers to Adopting 2D Vaccine Barcoding	Anticipated Facilitators to Adopting 2D Vaccine Barcoding	Comments
Primary care practices (AAP, AAFP, ACOG, ACP, AMA)	Not all practices use electronic health record (EHR) systems, particularly smaller practices. Not all EHR systems have fields for vaccine lot number and expiration date. Cost of purchasing barcode readers.	EHRs are not required to use 2D barcodes. 2D barcodes are consistent with recent trends in increasing technology use in care delivery. Barcoding vaccines is regarded as a tool for quality assurance. Pediatricians are among those who are anticipated to be affected by the Health Information Technology for Economic and Clinical Health (HITECH) Act and to adopt EHR systems. Pediatricians administer the majority of pediatric vaccines. AAP strongly supports vaccine barcoding.	Family physicians are, along with pediatricians, more likely than other primary care providers to participate in the VFC Program. Pediatricians are receptive to means to reduce the "hassles" associated with vaccination documentation. Some internal medicine physicians use peel-off labels to record expiration date and lot in patient records. Eliminating peel-off labels may require some internal medicine practices to change office procedures. Scanners are expected to be installed at nurses' stations and laboratories or immunization rooms
Pharmacists (in a community-based pharmacy) APhA	Considerable variability in scope of practice, ability to charge for administration, and limited (no) access to immunization information systems (IIS) in most states.	Some pharmacies are already using barcoding for pharmaceutical products. Most (~90%) pharmacies are "computerized" and already doing some form of electronic data exchange.	Aside from a primary care physician, a pharmacy is a significant source of health care for many people. Barcoding vaccines is regarded as a tool for quality assurance.

(continued)

Table 4-1. Summary of Anticipated Barriers and Facilitators to Adopting Barcoded Vaccines by Provider Group (continued)

Provider	Anticipated Barriers to Adopting Vaccine Barcoding	Anticipated Facilitators to Adopting Vaccine Barcoding	Comments
Immunization clinic providers, Maxim Health Care	>90% of vaccine doses drawn from multidose vials. Lack of fixed location presents challenge to using bulky technology/ equipment that is difficult to move. Limited integration into health care system.	Some clinic providers are using e-books or similar devices to facilitate data collection and reporting.	Immunization clinic providers include an array of organizations. Some may be for-profit companies that offer many different wellness services; some may be small not-for-profit organizations that focus on immunization only.
RBCs (CCA)	Not all RBCs have computerized data collection and reporting systems.	All CCA member RBCs are computerized and use EHRs. Quality assurance is a high priority for CCA members.	Barcoding vaccines is regarded as a tool for quality assurance.
LHDs	LHDs are public facilities with limited resources.	Potential cost savings associated with improved efficiency and decreased extraimmunization and vaccine wastage is a potential motivator. As public health agencies, LHDs are a natural partner to support IIS.	Although nearly all LHDs provide immunization services, the degree to which they do so varies considerably across the United States.

The RTI team also interviewed staff and observed immunization practices at Altamonte Pediatrics, a pediatric primary care practice in Altamont Springs, FL. The purpose of the visit was to observe clinical and administrative procedures and discuss questions to be included in stakeholder discussion guides and the internet survey. The observations consisted of shadowing staff who demonstrated processes and systems associated with vaccine management, immunization practice, and record keeping. Throughout the observations, the project team asked both clarifying and open-ended questions. In addition, we reviewed documentation in both paper-based and electronic systems. This review encompassed processes from ordering through billing. Although we visited a single pediatric practice, the office's medical director is co-chair of the American Academy of Pediatrics' Automated Identification of Vaccine Products Committee. Thus, he represents AAP, explaining how workflows and policies in his practice compare with those in other pediatric practices throughout the country.

4.1.3 Complementary Immunization Providers

Although most vaccines are believed to be administered in a primary care setting, a considerable volume of vaccine, especially the seasonal influenza vaccine, is administered

outside primary care settings. Walgreen's, for example, administered over 6 million flu shots during the 2010/11 influenza campaign (Walgreens, 2011). As immunization programs expand their efforts to immunize adolescents and adults (who are less likely to have regular contact with primary care providers), the role of complementary immunization providers is likely to increase.

For complementary immunization providers, we conducted initial key informant interviews with representatives from relevant professional and/or trade. In addition, we used a modified snowball sampling approach in which we interviewed additional organizations recommended to us by these groups until no new organizations were recommended. For example, to obtain a comprehensive understanding of immunization practice in LHDs, we spoke with representatives from the National Association of County and City Health Officials (NACCHO) and individual health officials. Community immunizers were represented by a key informant, Maxim Health Services, that served as a de facto spokesperson for community immunizers. In addition, we spoke with a representative from the American Hospital Association, who spoke on behalf of hospitals, and the American Pharmacy Association (APhA).

4.1.4 Public-Sector Immunization Organizations

In addition to interviews with organizations representing immunization providers, we conducted a group interview with immunization program managers of CDC's 317 Immunization Grant Program, with a focus on program managers' knowledge and feedback regarding 2D vaccine barcoding. Telephone interviews were conducted with Association of Immunization Managers (AIM), American Immunization Registry Association (AIRA), Public Health Agency of Canada, and 18 out of the 20 immunization information systems (IIS) that received interoperability grants from CDC.

4.2 Internet Survey of Primary Care Physicians and Local Health Officials

RTI fielded an internet survey of primary care providers and local health officials between April 19 and June 1, 2011. The instrument was developed based on information from the literature review, key informant interviews, and input from CDC. The survey is included as Appendix D.

The project's timeline and available resources precluded conducting a representative sample survey. Instead, we developed a marketing strategy "Take 10 to Enhance Vaccine Barcodes" and partnered with AAP, AAFP, ACOG, AMA, NACCHO, the Association of Immunization Managers, and Vaccines for Children (VFC) Program coordinators to promote the survey (see Figure 4-1). Partnering organizations received electronic files that included PDF and MS Word documents containing descriptions about and links to the web-based survey. To encourage participation in the survey, respondents were entered into a raffle to receive one

Figure 4-1. Take 10 to Enhance Vaccine Barcodes Survey Announcement

of 10 Apple iPads. Participating VFC jurisdictions received survey results compiled for their jurisdiction.

4.2.1 Survey Population

The targeted survey population was pediatric, family medicine, internal medicine, and ob-gyn practices, as well as LHDs. Although there are many other immunization providers, including pharmacists, RBCs, and community immunizers, CDC recommended a focus on primary care practices and LHDs. Anecdotal evidence and a review of the ACIP-recommended immunization schedule suggests that these providers administer the majority of immunizations.

Respondent profile data were used to extrapolate survey responses to the population of practices meeting the same specialty and size criteria. We used the count of practices by physician specialty from the Group Practice Database, part of the AMA Physician Masterfile Data Collection (AMA, 2011). We estimated the percentage of practices by specialty falling in our defined size categories using data from the 2008 Physician Practice Information Survey (AMA, 2008). For LHDs, we relied on the NACCHO Directory of Local Health Departments for an estimate of the total number of LHDs (NACCHO, 2010).

In essence, this approach assumed that respondents within the same specialty-size category were representative of all the practices in that category. Although a representative sample would have been ideal, the survey focused primarily on immunization-associated

workflow, staffing structure, and activity measures, which are expected to be more consistent among practices than attitudinal information would be.

4.2.2 Survey Question Development and Pretesting

Table 4-2 presents the survey topics. Survey topics and response selections were developed through a review of the literature; a review of the Canadian benefit-cost analysis (HDR, 2009); assessment of the needs of the economic model; and interviewees' perspectives of barriers, facilitators, and technical assistance needs. We strove to increase survey completion by minimizing the effort required to complete the survey. The survey was designed to be completed in 10 minutes, not including the time that may be required for a respondent to obtain data on the number of doses administered per year. Questions were limited to only those questions that were minimally sufficient to capture practices' perspectives and populate economic models.

Table 4-2. Survey Question Topics

Survey Section, Question Item	Selections or Entries
Respondent profile	
Zip code	5-digit zip code
Medical specialty	Pediatrics, family practice, ob-gyn, internal medicine, other (specify)
Primary setting	Physician office, solo practice; physician office, single-specialty group practice; multispecialty group practice or clinic; teaching hospital; nonteaching hospital; other (specify)
Size	Number of staff in practice, and number that prepare and administer vaccines, for the following positions: physicians, physician assistants, nurse practitioners, registered nurses, licensed practical nurses, and medical assistants
Immunization activity measures	
Administration of vaccine product categories	Yes or no to administering childhood vaccines, adolescent vaccines, adult vaccines, and travelers' vaccines
Number of doses administered per year	Childhood vaccines, adolescent vaccines, adult vaccines, and travelers' vaccines; influenza vaccines (2010–2011 season[a])
VFC provider	Yes or no to participation in the VFC Program
Percentage VFC doses	Percentage of pediatric and adolescent doses that are VFC doses
Work areas for vaccine preparation	Number of nurses' stations, dedicated rooms for immunization or laboratories, examination rooms, other (specify)

(continued)

Table 4-2. Survey Question Topics (continued)

Survey Section, Question Item	Selections or Entries
Existing IT infrastructure	
Current systems	Use of EHRs, practice management and billing; automated input devices (e.g., weight scales or blood pressure); barcode or barcode scanning of any type for medical supplies, encounter forms, or documentation; other (specify)
EHR adoption horizon	If no EHR system, expected adoption by end of 2011, 2012, 2013, 2014, 2015, after 2015, or not sure or have no plans to adopt
EHR capable of recording expiration date and lot number	Availability of expiration date and lot number fields in EHR
Inventory systems	Registry- or internet-enabled system, inventory software system, system that is part of practice management or billing system, spreadsheets, paper-based systems, none (simply order when stock looks low), other
IIS reporting	Yes or no to reporting to IIS
IIS reporting method	If report to IIS, yes or no to methods, and percentage of records uploaded, by automated upload, manual entry, facsimile, other (specify)
Perceptions of 2D barcode utility	
Use of 2D barcode, if available	Yes, my practice would use the barcode; My practice would likely use the barcode if we had an EHR system; No, my practice would not likely use the barcode; I don't know if my practice would use the barcode
More likely to report to IIS	If use barcode but do not report to IIS, yes, no, unsure or don't know
Use of barcoded VIS, if available	Yes or no
Technical assistance needs	Software support for integration with EHR, software support for integration with practice management system, software development for integration with IIS, guidance for integration of barcode with workflow for immunization, staff training, scanner selection and installation, other (specify) [Yes or no]
Adoption factors	Cost of scanners, changes to workflow, training, reliability of barcodes, readability of barcodes, usability of barcode scanners, increased accuracy of records, decreased time spent recording vaccines information or documenting immunization; more efficient and accurate management of inventory; potential decrease in the number of vaccines that do not get billed to a private payer [unimportant, somewhat unimportant, neutral, important, very important]
Comments	Comments entry
Survey awareness	E-mail, postcard, newsletter, word of mouth, other (specify)
Raffle entry	Name, address, e-mail, telephone number

[a]The survey asked respondents to answer regarding TIV or LAIV for seasonal influenza, not monovalent influenza vaccine for novel H1N1.

Survey respondents provided the number of doses administered per year by their practice. The survey was also designed to capture information on the number of staff that may need training and the number of scanners that the practice may require, given that scanners were expected by professional association representatives to be installed at nurses' stations or in laboratories. Respondents were also asked to provide information on the information systems (e.g., EHRs, IIS, practice management systems) they have installed in their practices and to answer questions about whether they would use the 2D barcode and what types of technical assistance they may need.

Draft survey instruments were reviewed by CDC, AAP, vaccine manufacturers, members of the Canadian Automated Identification of Vaccine Products Advisory Task Group, the Verden Group, and immunization policy and practice management experts at RTI. The penultimate draft survey instrument was pretested with 14 pediatric practices and 1 ob-gyn practice and was revised based on their feedback.[2]

4.2.3 Survey Hosting, Availability, and Distribution

The survey was available online at http://vaccinebarcodingsurvey.rti.org between April 19 and June 1, 2011. Promotional materials included e-mails, sample articles for inclusion in newsletters, blast fax material, and example images. Survey partners included AAP, AAFP, ACOG, AIM, NACCHO, and VFC coordinators for many VFC jurisdictions (see Table 4-3).

The frequency of communications was determined by the partner, although RTI did follow up with partners via phone and/or e-mail to encourage partners' promotion of the survey. Generally, e-mails were sent 2 to 3 times at regular intervals over the survey period, blast faxes were sent 1 to 2 times, and newsletter mentions occurred once (national distribution) or 2 to 3 times (local distribution).

Because the survey results for individual VFC jurisdictions would assist immunization program managers and VFC coordinators with understanding the needs and characteristics of their jurisdictions, RTI agreed to provide participating jurisdictions with summary results for their jurisdictions alone, following the completion of the national analysis.

4.3 Survey Response

The total number of surveys with at least one question answered was 4,568, but after data cleaning and application of our criteria for what constituted a valid response, this number was reduced by 19.7% to 3,669. Of these 3,669 responses, 2,816 were private-practice respondents and 853 were LHD respondents.

[2]Pretesters received a $25 gift certificate to amazon.com in appreciation for their participation.

Table 4-3. Survey Distribution Mechanisms

Survey Partner	Survey Distribution Mechanisms
AAP	E-mails to Section on Practice Management (section), Community Physicians (section), Young Pediatricians (section), Infectious Disease (listserv); Inclusion in *AAP On Call*, *Immunization Update*, *AAP Smart Brief*
American Association of Family Practitioners	Inclusion in *AAFP News Now*; direct link from AAFP web site to survey web site
ACOG	E-mail to all listserv subscribers; inclusion in *Immunization News*
NACCHO	Inclusion in *NACCHO Connect*; mentions in monthly updates to statewide organizations
VFC Program coordinators and immunization program managers	E-mail listservs, blast fax, and newsletters distributed to VFC providers in Arizona, Arkansas, California, Chicago, Colorado, Connecticut, Delaware, Florida, Georgia, Idaho, Indiana, Kansas, Kentucky, Louisiana, Massachusetts, Michigan, Missouri, Nebraska, Nevada, New Jersey, New York, New York City, North Carolina, North Dakota, Ohio, Oregon, Pennsylvania, Philadelphia, Puerto Rico, South Carolina, South Dakota, Texas, Utah, Virginia, West Virginia, and Wyoming. Information on technology adoption patterns was provided by Washington, Wisconsin, and Wyoming[a]

[a]Jurisdictions declining to participate because of resource constraints or competing surveys in the field were Alaska, Hawaii, Illinois, Iowa, Minnesota, Mississippi, Montana, New Hampshire, San Antonio, Tennessee, and Washington. The remaining jurisdictions were not responsive to e-mail and telephone requests for participation.

If respondents did not provide a valid response for their practice specialty or for the total number of physicians in their practice, their responses were excluded from the survey. We also excluded outlier responses to the number of doses per physician, and duplicate records based on the respondents contact information (last record entered will be considered the valid record).[3]

[3]Respondents occasionally entered nonnumeric data for questions that included numeric calculations. These responses were evaluated individually and were estimated or set as missing based on the following criteria. Range—If a respondent gave a range of values, for example, 3 to 5, the midpoint was used (4). Lower bound—If a respondent provided a lower bound, for example, 100+, the bounded value was used (100). Uncertain description—If a respondent gave an uncertain description, for example, "many" or "hundreds," the value was set as missing for the purposes of analysis. Invalid responses—Responses requiring a percentage must fall between 0 and 100. Values over 100 were assumed to have misinterpreted the question to provide the total number rather than the percentage. If a value was over 100, and we had an appropriate denominator, for example, total number of vaccines, then we estimated the percentage. Values without an appropriate denominator were set as missing for the purposes of analysis. Interpreting missing values as zeros—For questions with multiple numeric responses, missing responses were interpreted as zero if the respondent provided answers to part of the question, for example, provider total number of physicians and medical assistants but left blank number of nurse practitioners, we assumed 0 nurse practitioners. If no responses were provided to questions with multiple numeric responses, missing responses were interpreted as missing. For questions without multiple numeric responses, such as the number of flu doses administered, missing responses were interpreted as zero.

The number of responses varied greatly by specialty; the largest number of responses came from pediatrics and the lowest came from internal medicine physicians (see Table 4-4). Out of an estimated population of 4,937 pediatric practices (according to AMA), 1,442 valid responses were received, equating to an estimated coverage rate of 29.2%. We received 968 valid responses from family practices, equating to a 10.1% coverage rate. Only 101 valid responses were from ob-gyn practices (1.8%) and 57 from internal medicine practices (0.5%).

Table 4-4. Estimated Survey Coverage for Primary Care Practices and Health Departments

		Survey Responses		AMA Masterfile and PPI Data		Estimated Survey Coverage
Specialty	**Practice Size**	**Count**	**Percent**	**Count**	**Percent**	
Pediatrics	1–1.5 physicians	408	28.3%	1,392	28.2%	29.3%
	2–9 physicians	889	61.7%	2,582	52.3%	34.4%
	More than 10 physicians	145	10.1%	963	19.5%	15.1%
	Total	1,442	100%	4,937	100%	29.2%
Family practice	1–1.5 physicians	362	37.4%	3,146	32.9%	11.5%
	2–9 physicians	497	51.3%	5,173	54.1%	9.6%
	More than 10 physicians	109	11.3%	1,243	13.0%	8.8%
	Total	968	100%	9,561	100%	10.1%
Ob-gyn	1–1.5 physicians	17	16.8%	1,592	27.8%	1.1%
	2–9 physicians	61	60.4%	3,481	60.8%	1.8%
	More than 10 physicians	23	22.8%	653	11.4%	3.5%
	Total	101	100%	5,725	100%	1.8%
Internal medicine	1–1.5 physicians	28	49.1%	4,947	39.7%	0.6%
	2–9 physicians	25	43.9%	5,197	41.7%	0.5%
	More than 10 physicians	4	7.0%	2,318	18.6%	0.2%
	Total	57	100%	12,462	100%	0.5%
Total of identified specialties		2,568		32,685		7.9%
Other		248				
Total of private-practice responses		2,816				
Total of health departments		853				
Total responses		3,669				

Source: RTI International and AMA (2008, 2011).

In the survey, 2,775 respondents answered with a valid zip code. Using these zip codes, we linked respondents to their respective cities and counties. We received responses from providers in 54 out of the 64 VFC jurisdictions, including all cities and Washington, DC, and 47 out of 50 states. Puerto Rico was the only U.S. territory VFC jurisdiction with provider responses. For LHDs, we received responses from four cities, 36 states, and Puerto Rico (see Figures 4-2 and 4-3). Appendix E provides a count of the responses by jurisdiction.

Figure 4-2. Primary Care Provider Survey Response, by 4-Digit Zip Code

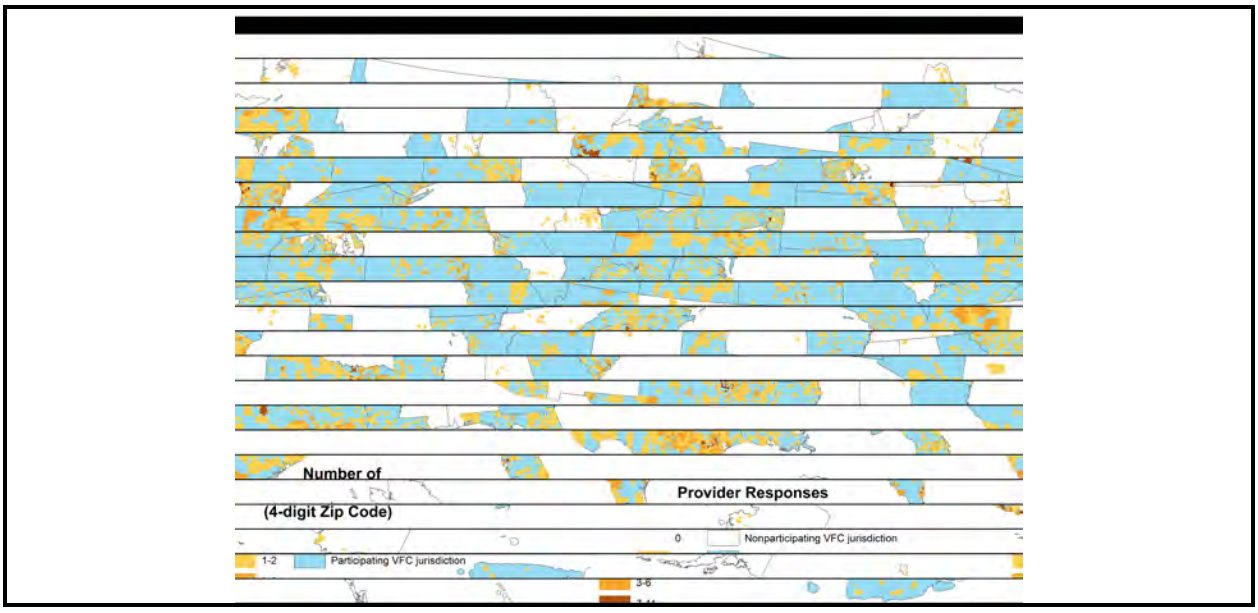
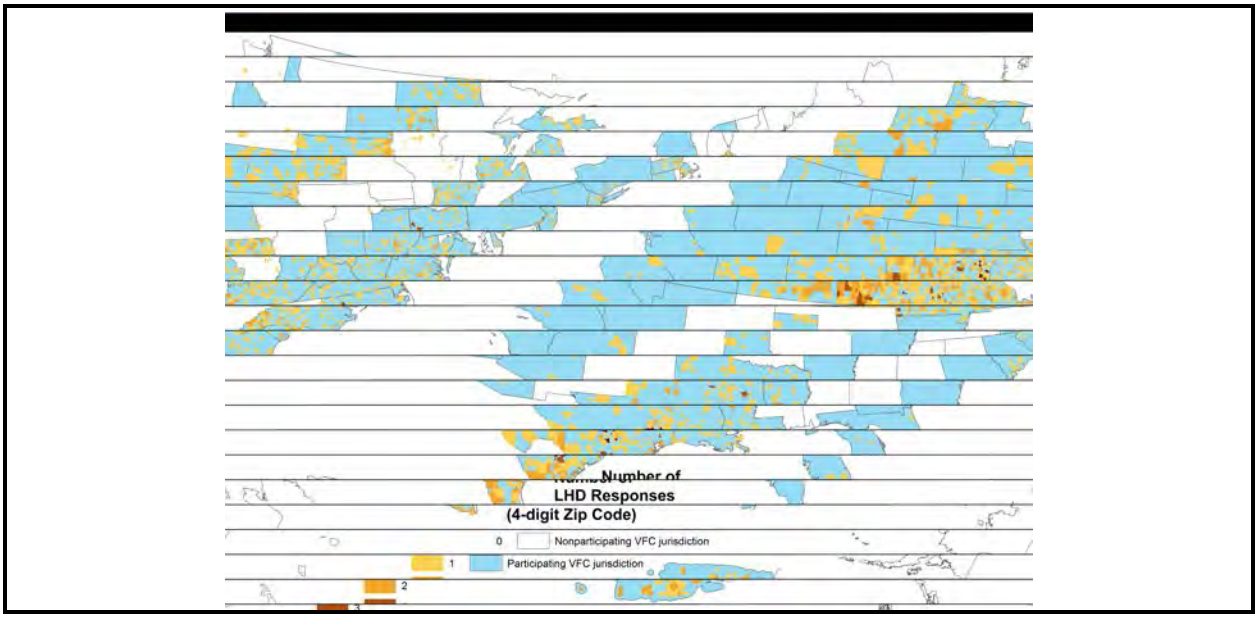


Figure 4-3. Health Department Survey Response, by 4-Digit Zip Code



4.4 Average Number of Staff per Practice

Table 4-5 presents our survey responses for the average number of primary care office staff per practice in total, as well as the number of staff who prepare vaccines for administration and the number of staff who administer vaccines. As anticipated, registered nurses, medical assistants, and licensed practical nurses are more likely than physicians, physician assistants, or nurse practitioners to prepare or administer vaccines. These findings have implications both for the economic benefits, given that wage rates vary by training and positions, and for the orientation and development of training materials.

For example, among responding practices, a pediatric practice in the 2 to 9 physicians size category has 12.6 FTEs in medical positions on average. Of these, on average, 7.3 prepare vaccines and 7.1 administer them. The average number of physicians was 4.0, but they are not likely to prepare or administer immunizations. That responsibility is more likely to be performed by registered nurses or medical assistants.

Table 4-6 summarizes the average number of staff in physician, nursing, and assistant positions in LHDs. Registered nurses are the most numerous and the most likely to prepare and administer vaccines in LHD settings.

4.5 Average Number of Vaccines Administered

The average number of doses administered per year by specialty and size is presented in Tables 4-7 and 4-8. Analyzing the potential to reduce the amount of time spent on documentation requires an understanding of the total volume of doses administered by practices on an annual basis. Assuming that there is no difference in the profile of staff administering vaccines among pediatric, adolescent, adult, or influenza vaccines, multiplying any time savings by the loaded hourly wage rate weighted by job position and by the number of doses administered per year should provide the economic benefit accruing to the practice from using scanners to image the 2D barcode and populate EHRs, practice management systems, and other record-keeping systems.

The typical pediatric practice administers more vaccines than other primary care practices. Compared with family medicine practices, pediatric respondents reported total annual vaccines administered to be 2,735 for pediatrics to 936 for family medicine (1 to 1.5 physicians), 8,891 to 2,632 (2 to 9 physicians), and 38,126 to 8,874 (10 or more physicians). Data for internal medicine practices may not be typical of the overall population because of the low number of responses and because the practices that did respond administered a large number of childhood vaccines.

Table 4-5. Mean Number of Staff in Physician, Nursing, and Assistant Positions in Primary Care Practices that Prepare and Administer Vaccines, by Specialty and Practice Size

Specialty	Staff Positions	How Many Total Staff Are in These Positions at Your Practice?			How Many of These Staff Prepare Vaccines?			How Many of These Staff Administer Vaccines?		
		1–1.5 Physicians	2–9 Physicians	More than 10 Physicians	1–1.5 Physicians	2–9 Physicians	More than 10 Physicians	1–1.5 Physicians	2–9 Physicians	More than 10 Physicians
Pediatrics (n=1,442)	Physicians	1.0	4.0	34.9	0.4	0.5	3.1	0.5	0.6	4.1
	Physician assistants	0.4	0.8	5.0	0.1	0.2	1.8	0.1	0.2	2.1
	Nurse practitioners	0.1	0.3	2.0	0.0	0.0	0.8	0.0	0.0	0.8
	Registered nurses	0.4	2.1	58.0	0.4	1.9	24.7	0.4	1.9	56.2
	Licensed practical nurses	0.4	1.7	10.7	0.4	1.6	9.5	0.4	1.6	9.5
	Medical assistants	1.6	3.6	20.8	1.4	3.1	10.8	1.3	2.8	10.7
	Total	**4.0**	**12.6**	**131.5**	**2.7**	**7.3**	**50.8**	**2.7**	**7.1**	**83.3**
Family practice (n=968)	Physicians	1.0	3.8	30.7	0.3	0.3	0.8	0.3	0.4	1.8
	Physician assistants	0.5	1.0	4.3	0.2	0.2	0.3	0.2	0.2	0.6
	Nurse practitioners	0.4	0.8	1.9	0.1	0.1	0.3	0.1	0.1	0.4
	Registered nurses	0.5	1.4	9.6	0.4	1.2	8.3	0.4	1.2	8.0
	Licensed practical nurses	0.5	1.7	8.6	0.5	1.6	8.5	0.5	1.6	8.3
	Medical assistants	1.6	4.6	22.5	1.4	3.9	14.3	1.4	3.8	13.7
	Total	**4.5**	**13.3**	**77.6**	**2.8**	**7.2**	**32.4**	**2.8**	**7.3**	**32.9**
Ob-gyn (n=101)	Physicians	1.0	4.4	20.7	0.5	0.2	1.2	0.5	0.2	1.8
	Physician assistants	1.5	1.1	1.6	0.5	0.2	0.3	0.6	0.4	0.4
	Nurse practitioners	0.1	0.2	0.7	0.1	0.0	0.2	0.1	0.0	0.2
	Registered nurses	0.5	2.2	17.8	0.5	1.8	14.7	0.5	1.9	14.7
	Licensed practical nurses	0.4	1.5	5.1	0.4	1.4	3.5	0.4	1.4	4.8
	Medical assistants	1.8	4.0	6.6	1.0	2.5	4.5	1.0	2.7	3.9
	Total	**5.4**	**13.4**	**52.5**	**3.1**	**6.2**	**24.5**	**3.1**	**6.7**	**25.8**
Internal medicine (n=57)	Physicians	1.0	4.1	22.5	0.7	0.6	3.8	0.6	0.8	3.8
	Physician assistants	0.2	1.4	2.5	0.1	0.4	0.5	0.1	0.5	0.5
	Nurse practitioners	0.2	0.4	2.3	0.1	0.0	0.5	0.1	0.0	0.5
	Registered nurses	0.2	1.6	13.8	0.2	1.4	13.8	0.2	1.4	13.8
	Licensed practical nurses	0.2	1.1	10.0	0.2	1.1	2.5	0.2	1.1	2.5
	Medical assistants	1.1	4.8	15.5	0.9	3.6	0.0	0.9	3.8	0.0
	Total	**2.9**	**13.4**	**66.5**	**2.1**	**7.1**	**21.0**	**2.1**	**7.7**	**21.0**

Note: Sums may not add to totals because of independent rounding.

Table 4-6. Average Number of Staff in Physician, Nursing, and Assistant Positions that Prepare and Administer Vaccines in Local Health Departments

Staff Positions (n=853)	How Many Total Staff Are in These Positions at Your Practice?	How Many of These Staff Prepare Vaccines?	How Many of These Staff Administer Vaccines?
Physicians	2.7	0.1	0.1
Physician assistants	0.8	0.3	0.3
Nurse practitioners	0.1	0.1	0.1
Registered nurses	8.7	5.7	5.7
Licensed practical nurses	0.8	0.6	0.6
Medical assistants	0.5	0.3	0.2
Total	**13.5**	**7.0**	**7.1**

Note: Sums may not add to totals because of independent rounding

The number of locations where immunizers prepare vaccines for administration has bearing on the number of scanners that would be necessary to implement 2D barcoding. Table 4-9 summarizes the number of locations in primary care settings or LHDs where vaccines are prepared for administration. Our conversations with professional associations revealed that providers are most likely to locate scanners at nurses' stations and labs because these are likely to be outfitted with refrigerators already, allowing the immunizer to scan the product as it is removed from storage. The typical family practice may need 4 to 7 scanners and the typical health department may need 7 to 13.

Table 4-7. Average Number of Doses Administered per Year by Primary Care Practices, by Specialty and Practice Size

Specialty	Vaccine Type	Average Annual Doses Administered by Practice Size		
		1–1.5 Physicians	2–9 Physicians	More than 10 Physicians
Pediatrics (n=1,369)	Childhood vaccines	1,842	5,885	27,409
	Adolescent vaccines	457	1,316	4,267
	Adult vaccines	15	60	745
	Travelers' vaccines	4	9	135
	Flu	417	1,621	5,570
	Total	**2,735**	**8,891**	**38,126**
Family practice (n=925)	Childhood vaccines	416	1,049	4,044
	Adolescent vaccines	151	367	1,096
	Adult vaccines	88	337	1,134
	Travelers' vaccines	6	11	58
	Flu	275	868	2,542
	Total	**936**	**2,632**	**8,874**
Ob-gyn (n=101)	Childhood vaccines	49	23	439
	Adolescent vaccines	72	89	199
	Adult vaccines	48	128	328
	Travelers' vaccines	—	1	—
	Flu	91	323	683
	Total	**260**	**564**	**1,649**
Internal medicine (n=51)	Childhood vaccines	70	982	200
	Adolescent vaccines	59	425	5
	Adult vaccines	159	602	2,783
	Travelers' vaccines	4	26	433
	Flu	265	992	1,350
	Total	**557**	**3,027**	**4,771**

Table 4-8. Average Number of Doses Administered per Year by Health Departments

Specialty	Vaccine Type	Average Annual Doses Administered
Health departments (n=853)	Childhood vaccines	2,363
	Adolescent vaccines	1,178
	Adult vaccines	847
	Travelers' vaccines	97
	Flu	1,585
	Total	**6,070**

Table 4-9. Average Number of Locations within Primary Care Practice and Health Departments Where Vaccines Are Prepared for Administration, by Specialty and Practice Size

Specialty	Nurses' Stations	Dedicated Rooms for Immunization or Laboratories	Examination Rooms	Others	Absolute Number of Scanners[a]
Pediatrics (n=1,304)	**1.4**	**1.7**	**4.4**	**0.1**	**4 to 5**
1–1.5 physicians	0.7	0.9	1.5	0.1	2
2–9 physicians	1.3	1.8	4.8	0.0	3 to 5
More than 10 physicians	4.8	4.3	13.2	0.1	9 to 13
Family practice (n=879)	**1.7**	**2.1**	**6.2**	**0.1**	**4 to 7**
1–1.5 physicians	0.7	1.7	1.6	0.0	2 to 3
2–9 physicians	1.4	1.7	4.7	0.1	4 to 5
More than 10 physicians	6.5	5.4	31.7	0.1	12 to 32
Ob-gyn (n=97)	**1.8**	**0.9**	**5.5**	**0.5**	**3 to 6**
1–1.5 physicians	0.8	0.9	2.4	0.0	2 to 3
2–9 physicians	1.7	0.6	4.6	0.1	2 to 5
More than 10 physicians	3.5	1.3	11.9	2.2	7 to 12
Internal medicine (n=55)	**1.8**	**1.1**	**4.5**	**0.0**	**3 to 5**
1–1.5 physicians	0.4	0.6	2.0	0.0	2
2–9 physicians	1.5	1.8	7.0	0.0	4 to 7
More than 10 physicians	3.0	0.3	10.3	0.0	4 to 11
Health departments (n=806)	**2.2**	**4.8**	**4.4**	**13**	**7 to 13**

[a]The number of scanners range represents the absolute value of the sum of nurses' states and dedicated rooms for immunization or laboratories compared with the absolute value of the greater of examination rooms or other.

4.6 IT Infrastructure

To understand the information systems that primary care practices and LHDs have in place, respondents were asked to indicate whether they had an EHR, practice management and billing system, automated data input devices (e.g., computer-connected weight scales or blood pressure devices), and barcoding or barcode scanning system. Family and ob-gyn practices were more likely to use EHRs (69.3% and 66.7%, respectively) than pediatric practices (58.9%) and internal medicine practices (52.6%). Slightly more than one-third of LHDs reported having some form of EHR (Table 4-10).

Most respondents reported having practice management and billing systems: greater than 80% of respondents for primary care practices and 67.5% for LHDs. Use of automated input

Table 4-10. Percentage of Primary Care Practices and Health Departments Currently Using Computerized Systems, by Specialty and Practice Size

Specialty (n= practices)	Electronic Health Record System	Practice Management and Billing System	Automated Data Input Devices, such as Weight Scales or Blood Pressure Devices	Barcoding and Barcode Scanning of any Type for Medical Supplies, Encounter Forms, Documentation, etc.	Other Computerized System
Pediatrics (n=1,293)	**58.9%**	**87.6%**	**27.6%**	**11.5%**	**24.1%**
1–1.5 physicians	44.0%	83.9%	30.3%	8.6%	23.6%
2–9 physicians	62.2%	88.8%	26.2%	10.9%	22.8%
More than 10 physicians	79.9%	90.8%	28.8%	22.6%	33.3%
Family practice (n=882)	**69.3%**	**86.9%**	**32.0%**	**12.6%**	**20.9%**
1–1.5 physicians	59.7%	82.7%	29.9%	9.9%	20.6%
2–9 physicians	71.9%	88.9%	32.2%	13.5%	21.6%
More than 10 physicians	89.9%	91.8%	38.4%	18.2%	19.0%
Ob-gyn (n=96)	**66.7%**	**88.3%**	**25.3%**	**20.0%**	**19.7%**
1–1.5 physicians	41.2%	93.8%	11.8%	11.8%	38.5%
2–9 physicians	70.2%	89.3%	21.2%	16.4%	19.5%
More than 10 physicians	77.3%	81.8%	45.5%	34.8%	N/A
Internal medicine (n=57)	**52.6%**	**83.6%**	**29.8%**	**12.3%**	**22.2%**
1–1.5 physicians	46.4%	73.1%	14.3%	7.1%	22.7%
2–9 physicians	56.0%	92.0%	44.0%	16.0%	18.2%
More than 10 physicians	75.0%	100.0%	50.0%	25.0%	33.3%
Health departments (n=804)	**35.7%**	**67.5%**	**27.5%**	**7.6%**	**45.1%**

devices was less than 33% in general, and the use of barcoding of any type was less than 20%. Thus, although practice management systems are commonplace, adoption of EHR systems and barcode technologies was low (52 to 69%) at the time of the survey. However, the rate of EHR adoption is increasing and low adoption of barcodes at the time of the survey may be more indicative of utility in relation to workflows rather than reluctance to adopt these technologies.

Accordingly, respondents who reported not using an EHR in the spring of 2011 were asked when they expected to begin using one, particularly because of American Recovery and Reinvestment Act (ARRA) HITECH incentive payments and future changes to Centers for Medicare & Medicaid Services (CMS) reimbursement structures. Table 4-11 summarizes responses. For pediatric practices, an additional 24% of respondents are expected to have adopted some form of EHR system by the end of 2013. Similar growth is expected for family medicine (19%), ob-gyn (24%), and internal medicine (30%). In contrast, few LHD respondents expected to adopt an EHR system by 2015, and 42% have no plans to adopt one.

Vaccine inventory management could be improved by 2D barcodes, particularly if software systems (either web based or on site) permit tracking stock on hand. To develop a general understanding of inventory management processes employed, practices were requested to provide the combination of systems they use to monitor their inventory, selecting from the following choices: internet- or registry-based systems, inventory software, inventory module that is part of a practice management system, spreadsheets, paper-based systems, no system, or other. Based on key informant interviews and survey pretesting, we included seven different options for systems used (including "other"). Results show a range and combination of methods. With the exception of internal medicine practices (38.5%), more than 50% of practices in other specialties reported using paper-based inventory systems most, when a system was used (Table 4-12). Notably, 37.7% of pediatric and 43.5% of family medicine practices indicated that they simply order when the stock looks low. LHDs were most likely to use an internet- or registry-based system.

4.7 Perceptions of Barcode Benefits, Costs, and Needs

In posing the important question of whether the practice would use the barcode, we described the cost and benefit implications in our survey question (Figure 4-4). In Table 4-13, we summarize the anticipated likelihood of 2D barcode adoption by provider. Possible benefits were presented, as were expected costs for scanners, training, and workflow redesign. The results, by specialty, are as follows:

Figure 4-4. Survey Question for Primary Care Practices' and Health Departments' Likelihood to Use 2D Barcodes

Consider the following: The American Academy of Pediatrics (AAP) is recommending that labels on vaccine vials and syringes have a two-dimensional barcode containing product name, expiration date, and lot number (see Figures 1 and 2).

Rather than have staff read and manually enter this information into records and forms, the information could be automatically scanned into your computer systems (patient records, practice management system, etc.) using an inexpensive handheld or tabletop reader. You could also use barcodes to track and manage vaccine inventory and insure vaccines administered are recorded in your practice management and billing system.

Using barcodes to record vaccine information in patient records may take less time, be more accurate, and insure the proper vaccine is being administered. Using barcodes to manage vaccine inventory could decrease staff time spent to manually track inventory and could also insure proper billing of all vaccines administered.

Changes to practices include purchasing scanners (which cost about $300 each), training staff to use the barcode scanners, and modifying your computer systems to accept input from the barcode reader.

Based on this description, do you think your practice would use the barcode? Please select one choice.

- Yes, my practice would likely use the barcode.
- My practice would likely use the barcode if we had an Electronic Health Record system.
- No, my practice would not likely use the barcode.
- I do not know if my practice would use the barcode.

Figure 1: Example of linear barcode
Current linear barcodes required by the FDA contain only the vaccine product identification information.

Figure 2: Example of two-dimensional barcode
A two-dimensional, or data matrix, barcode can include product identification information as well as lot number and expiration date.

- 43.0% of pediatric practices would likely use the barcode, and an additional 19.5% would use it if they had an EHR system. Only 4.0% said they would not use it, and only 16.5% said they did not know if they would use it.
- 53.5% of family medicine practices would likely use the barcode, 16.3% would use it if they had an EHR system, 7.0% would not use it, and 23.2% said they did not know if they would use it.
- Less than half of ob-gyn (48.9%) and internal medicine (34.5%) practices said they would use it. In addition, 20% of ob-gyn practices and 36.4% of internal medicine practices said they do not know whether they would use it. These results must be interpreted cautiously because of the low number of responses for these two specialties.
- 39.2% of LHDs would likely use the barcode, 26.3% would use it if they had an EHR system, 3.6% would not use it, and 30.9% said they did not know if they would use it.

Table 4-11. Percentage of Primary Care Practices and Health Departments without EHR Systems Currently, but Expecting to Adopt Them in the Future, by Specialty and Practice Size, 2011–2015

Specialty (n = practices)	By the End of 2011	By the End of 2012	By the End of 2013	By the End of 2014	By the End of 2015	After 2015	Not Sure or Have No Plans to Adopt
Pediatrics (n=1,290)	**70%**	**83%**	**87%**	**88%**	**89%**	**89%**	**11%**
1–1.5 physicians	59%	74%	78%	79%	79%	80%	20%
2–9 physicians	72%	85%	89%	91%	91%	92%	8%
More than 10 physicians	88%	96%	98%	98%	98%	98%	2%
Family practice (n=880)	**80%**	**89%**	**92%**	**93%**	**94%**	**94%**	**6%**
1–1.5 physicians	73%	83%	86%	87%	88%	88%	12%
2–9 physicians	81%	91%	96%	97%	97%	97%	2%
More than 10 physicians	96%	98%	98%	98%	98%	98%	1%
Ob-gyn (n=95)	**77%**	**90%**	**94%**	**94%**	**95%**	**95%**	**5%**
1–1.5 physicians	47%	66%	79%	79%	79%	79%	19%
2–9 physicians	82%	96%	98%	98%	98%	98%	2%
More than 10 physicians	86%	91%	95%	95%	100%	100%	0%
Internal medicine (n=57)	**70%**	**82%**	**84%**	**84%**	**84%**	**84%**	**16%**
1–1.5 physicians	61%	71%	71%	71%	71%	71%	29%
2–9 physicians	76%	92%	96%	96%	96%	96%	4%
More than 10 physicians	100%	100%	100%	100%	100%	100%	0%
Health departments (n=808)	**40%**	**49%**	**53%**	**55%**	**56%**	**58%**	**42%**

Table 4-12. Percentage of Primary Care Practices and Health Departments with Systems or Procedures in Place to Monitor the Number of Doses in Stock, by Specialty and Size

Specialty	Registry- or Internet-Based Inventory System	Inventory Software System Installed in your Practice	Computerized System that Is Part of your Practice Management and Billing System	MS Excel Spreadsheets or Similar Files Maintained by your Staff	Paper-Based Systems, such as a Ledger	None; We Simply Order When the Stock Looks Low	Other
Pediatrics (n=1,229)	**43.0%**	**14.1%**	**39.3%**	**31.3%**	**58.5%**	**37.7%**	**13.2%**
1–1.5 physicians	50%	15%	38%	28%	63%	36%	11%
2–9 physicians	39%	13%	40%	33%	58%	40%	13%
More than 10 physicians	49%	17%	40%	30%	52%	31%	20%
Family practice (n=827)	**50.5%**	**12.6%**	**36.9%**	**23.4%**	**53.4%**	**43.5%**	**9.2%**
1–1.5 physicians	46%	10%	34%	23%	55%	47%	7%
2–9 physicians	56%	14%	38%	23%	52%	43%	12%
More than 10 physicians	41%	14%	44%	24%	55%	31%	7%
Ob-gyn (n=91)	**24.4%**	**18.9%**	**38.5%**	**18.2%**	**50.6%**	**50.0%**	**6.3%**
1–1.5 physicians	40%	13%	27%	27%	63%	55%	0%
2–9 physicians	15%	17%	36%	12%	48%	56%	10%
More than 10 physicians	38%	29%	52%	29%	47%	32%	0%
Internal medicine (n=52)	**25.0%**	**13.5%**	**37.3%**	**28.0%**	**38.5%**	**82.2%**	**25.0%**
1–1.5 physicians	16%	4%	28%	30%	32%	88%	0%
2–9 physicians	30%	17%	48%	26%	48%	76%	33%
More than 10 physicians	50%	50%	33%	25%	25%	50%	100%
Health departments (n=792)	**69.3%**	**29.2%**	**44.5%**	**32.6%**	**52.3%**	**27.3%**	**9.9%**

Table 4-13. Likelihood of Primary Care Practices and Health Departments to Use 2D Barcode

Specialty	Practice Size	Yes, My Practice Would Likely Use the Barcode	My Practice Would Likely Use the Barcode If We Had an Electronic Health Record System	No, My Practice Would Not Likely Use the Barcode	I Do Not Know If My Practice Would Use the Barcode
Pediatrics (n=1,226)	1–1.5 physicians	48.5%	26.6%	6.2%	18.8%
	2–9 physicians	62.6%	18.0%	3.5%	15.9%
	More than 10 physicians	75.6%	9.2%	1.5%	13.7%
	Average	60.0%	19.5%	4.0%	16.5%
Family practice (n=861)	1–1.5 physicians	46.0%	26.6%	6.2%	18.8%
	2–9 physicians	54.7%	18.0%	3.5%	15.9%
	More than 10 physicians	74.0%	9.2%	1.5%	13.7%
	Average	53.5%	16.3%	7.0%	23.2%
Ob-gyn (n=94)	1–1.5 physicians	31.3%	26.6%	6.2%	18.8%
	2–9 physicians	54.7%	18.0%	3.5%	15.9%
	More than 10 physicians	74.0%	9.2%	1.5%	13.7%
	Average	48.9%	18.1%	12.8%	20.2%
Internal medicine (n=55)	1–1.5 physicians	31.3%	26.6%	6.2%	18.8%
	2–9 physicians	54.7%	18.0%	3.5%	15.9%
	More than 10 physicians	74.0%	9.2%	1.5%	13.7%
	Average	34.5%	23.6%	5.5%	36.4%
Health departments (n=796)		39.2%	26.3%	3.6%	30.9%

Among the barriers to taking full advantage of the benefits associated with an IIS is the lack of well-populated IIS. Respondents who indicated that they did not report immunizations to their IIS but also responded that they would likely use the barcode were asked whether they would be more likely to report to IIS if they used the 2D barcode. Table 4-14 reports the number and percentage of respondents who reported that they would be more likely to report immunization data to IIS if they could use a barcode that included vaccine product, expiration date, and lot number.

Table 4-14. Number and Percentage of Primary Care Practices Reporting They Are More Likely to Report Immunizations to IIS due to 2D-Barcoded Vaccines

			Likelihood of Nonreporters to Begin Reporting		
Specialty	**Yes (Percent)**	**No (Percent)**	**Yes, Likely to Begin Reporting (Percent)**	**No, Not Likely to Begin Reporting (Percent)**	**Don't Know (Percent)**
Pediatrics	1,073 (84.0%)	205 (16.0%)	54 (51.4%)	11 (10.5%)	40 (38.1%)
Family practice	746 (85.6%)	125 (14.4%)	32 (66.7%)	1 (2.1%)	15 (31.3%)
Ob-gyn	50 (53.8%)	43 (46.2%)	11 (68.8%)	0 (0.0%)	5 (31.3%)
Internal medicine	32 (58.2%)	23 (41.8%)	5 (50.0%)	5 (50.0%)	0 (0.0%)
Total	**1,901 (82.8%)**	**396 (17.2%)**	**113 (62.8%)**	**17 (9.4%)**	**50 (27.8%)**

Overall, 113 respondents indicated that they did not report immunizations to IIS currently but would be more likely to do so if the 2D barcode were available. Survey results indicate that 396 respondents (17.2% of respondents answering these questions) did not report immunizations to IIS at the time of the survey. When asked whether 2D barcoding may make them more likely to report to IIS, 113 respondents indicated they would be more likely to report immunizations to IIS. About 63% of likely 2D barcode users that do not report presently would be more likely to do so.

Implementing any change in immunization practice requires resources. This is particularly true when the change in immunization practice involves adopting a new technology. Respondents were asked whether they would need a certain type of assistance, and we then compared the percentage responding yes to understand which needs seemed to be most common. Table 4-15 shows the types of technical assistance that respondents anticipated being necessary to implement 2D barcode technology. In order, the most common technical assistance needs for respondents were:

- staff training,
- software support for integration into EHR systems, and
- scanner selection and installation.

Table 4-15. Providers' Perceptions of Types of Technical Assistance Needed to Implement 2D Barcode Scanning

Specialty	Software Support for Integration with Electronic Health Record System (Rank)	Software Support for Integration with Practice Management and Billing Systems (Rank)	Software Development for Integration with your State or Local Immunization Registry (Rank)	Guidance for Integration of the Barcode into your Practice's Workflow for Immunization (Rank)	Staff Training (Rank)	Scanner Selection and Installation (Rank)	Other
Pediatrics (n=1267)	79.9% (2)	62.5% (6)	68.0% (4)	65.2% (5)	80.9% (1)	79.8% (3)	7.7%
Family practice (n=862)	82.3% (2)	59.5% (5)	65.1% (6)	65.2% (4)	84.5% (1)	80.2% (3)	6.5%
Ob-gyn (n=93)	82.8% (1)	68.8% (4)	60.2% (5)	60.2% (6)	79.6% (2)	73.1% (3)	6.5%
Internal medicine (n=55)	74.5% (2)	63.6% (4)	50.9% (6)	52.7% (5)	67.3% (3)	80.0% (1)	5.5%
Health departments (n=789)	62.5% (5)	60.7% (6)	75.2% (4)	78.5% (3)	90.5% (1)	87.1% (2)	9.9%

Potential technical assistance needs for each specialty were ranked in ofer from 1 to 6.

Deciding whether to implement a new technology includes considering a variety of different factors. We asked respondents to review various factors and their relative importance in deciding whether to implement 2D barcode scanning. Responses were ranked, with unimportant equal to 0, somewhat unimportant equal to 1, neutral equal to 2, important equal to 3, and very important equal to 4.

Primary care providers, in general, ranked the following decision factors as the five most important (Table 4-16; 0 = unimportant, 4 = very important):

1. increased accuracy of records (mean score = 3.657)
2. decreased time spent recording vaccine information and/or documenting immunization (3.631)
3. reliability of the barcodes (3.567)
4. usability of the barcode scanners (3.553)
5. more efficient and accurate management of inventory (3.528)

LHDs, in general, concurred, although they emphasized readability of barcodes over time savings from using the barcodes (Table 4-17). Notably, neither primary care providers nor LHDs ranked costs, training, or changes to workflow as important. Indeed, changes to workflow ranked tenth for primary care and ninth for LHDs.

4.8 Limitations

The main limitation of this work is that results are from a very large convenience sample of 3,669 valid responses and not from a nationally representative sample. We expect that attitudinal data would be more subject to biases than economic data, because knowledge, attitudes, and beliefs are more likely to vary than cost structures within each specialty-size combination. The number of immunizations administered may be overrepresented because it is possible that immunizers were more likely to receive and agree to take the survey. A representative survey was not possible within the short period of performance and resource constraints afforded to survey data collection. The second main limitation is that very low survey coverage is estimated for ob-gyn and internal medicine practices, and each response is weighted heavily because only 100 ob-gyn and 58 internal medicine responses were used to analyze readiness and willingness to use 2D barcodes.

4.9 Conclusions

Primary care providers and LHDs are willing to purchase equipment, train employees, and redesign workflows as needed to reap the benefits of using 2D barcodes to improve the accuracy of records, decrease time spent on documenting immunizations, and improve inventory management. Providers cited increased records accuracy and efficiency gains from automating documentation as much more important considerations than cost of scanners, workflow changes, or training. Furthermore, transitioning to 2D barcoding would be in step with increased use of EHRs and other software systems.

Table 4-16. Stated Importance and Ranking of Factors in Primary Care Providers' Decision to Use 2D Barcodes

Factor (n=2,456)	Unimportant	Somewhat Unimportant	Neutral	Important	Very Important	Mean Score[a]	Rank
Cost of scanner(s)	2.2%	5.3%	10.1%	35.3%	47.1%	3.198	7
Possible changes to workflow	3.6%	5.7%	15.8%	39.7%	35.2%	2.972	10
Training	2.0%	4.9%	16.4%	37.7%	39.0%	3.068	9
Reliability of the barcodes	0.9%	0.9%	5.2%	26.2%	66.7%	3.567	3
Readability of the barcodes	0.9%	1.1%	6.2%	28.9%	63.0%	3.522	6
Usability of the barcode scanners	0.5%	0.8%	4.1%	32.5%	62.2%	3.553	4
Increased accuracy of records	0.3%	0.5%	3.8%	23.6%	71.7%	3.657	1
Decreased time spent recording vaccine information and/or documenting immunization	0.4%	0.5%	5.2%	23.4%	70.5%	3.631	2
More efficient and accurate management of inventory	0.9%	1.2%	6.8%	26.8%	64.4%	3.528	5
Potential decrease in the number of vaccines that do not get billed to a private payer	4.8%	2.6%	14.8%	25.2%	52.6%	3.182	8

[a]Mean score using a scale in which unimportant = 0 and very important = 4.

Table 4-17. Stated Importance and Ranking of Factors in Health Departments' Decision to Use 2D Barcodes

Factor (n=777)	Unimportant	Somewhat Unimportant	Neutral	Important	Very Important	Mean Score[a]	Rank
Cost of scanner(s)	1.3%	2.8%	6.8%	29.2%	59.8%	3.4357	7
Possible changes to workflow	3.7%	5.9%	18.2%	42.6%	29.5%	2.883	9
Training	0.6%	2.7%	9.8%	38.6%	48.2%	3.310	8
Reliability of the barcodes	0.4%	0.4%	4.4%	20.3%	74.5%	3.682	2
Readability of the barcodes	0.4%	0.5%	4.6%	24.0%	70.6%	3.684	4
Usability of the barcode scanners	0.4%	0.3%	2.8%	27.2%	69.3%	3.648	3
Increased accuracy of records	0.3%	0.0%	4.0%	21.3%	74.4%	3.696	1
Decreased time spent recording vaccine information and/or documenting immunization	0.5%	0.4%	5.0%	31.2%	62.9%	3.555	6
More efficient and accurate management of inventory	0.3%	0.3%	5.1%	26.9%	67.5%	3.611	5
Potential decrease in the number of vaccines that do not get billed to a private payer	12.1%	3.6%	23.2%	23.3%	37.7%	2.711	10

[a]Mean score using a scale in which unimportant = 0 and very important = 4.

5. ECONOMIC ANALYSIS OF THE IMPACT OF 2D BARCODES ON CLINICAL DOCUMENTATION

Our approach to quantifying economic benefits was to analyze how scanning 2D barcodes could reduce the amount of time spent documenting immunizations relative to a business-as-usual case in which product, expiration date, and lot number are recorded by hand while reading product labels. Other benefits apart from automating some documentation are likely; however, quantitative data to estimate them were unavailable. Such benefits include improved inventory management (including reductions in inventory-carrying costs and wastage), improved billing through correct product identification, and less extraimmunization due to more complete records in immunization information systems (IIS).

Our economic model combines survey data on expected barcode usage with time savings per dose associated with more efficient documentation. The survey data reviewed in Chapter 4 provided a wealth of information on readiness to use the barcode and on whether providers think they will use it. In this chapter, we discuss the economic model that combines survey data, a 33-practice time–motion study of immunization documentation, and estimated costs for scanner purchases and maintenance, workflow redesign, and training for different practice size–specialty combinations.

The model estimates that, if primary care practices and local health departments (LHDs) follow their stated preferences and use the 2D barcode, net benefits would be $333.6 million over the period from 2013 through 2023 for these stakeholders alone. For whatever reasons, providers may not follow their stated preference for 2D barcode use. If the rate of adoption were slowed by 50%, net benefits would decline to $326.8 million. If the rate of adoption were slowed by 67%, net benefits would decline to $311.3 million.

Because these estimates only account for a portion of benefits associated with saving time on documentation, yet include all expected adoption costs (e.g., cost of scanners, training, and workflow redesign), they are conservative.

5.1 Analysis of Time–Motion Study of Immunization Documentation and Record Keeping

In 2009, the Verden Group analyzed 36 private practices' immunization business. This assessment included a time–motion study of immunization workflow covering ordering, inventory management, administration, record keeping, and billing (Verden Group, 2009). The resulting dataset includes activity-specific time–motion estimates for the administration of 724 vaccines to 302 patients (cases) at 33 practices (30 pediatric practices, 3 family practices) across 17 states. These data were acquired by RTI to serve as the baseline from

which to study the potential time savings generated by using 2D barcodes because each step in immunization documentation was a discrete measurement for all cases.

The Verden Group recruited 36 practices to participate in the study, selecting participants to make the study as representative of the administration of pediatric and adolescent vaccines as possible. Selection criteria included size (number of physicians), state, rurality, specialty, electronic health record (EHR) use, and annual number of doses administered. Of 36 practices, 3 were used to pilot and refine protocols; the time–motion data used in this analysis were from the remaining 33 practices. Please see Appendix F for more information.

Across all practices, the amount of time required for vaccine administration averaged less than 4 minutes per dose (221 seconds), with a range of 1.5 minutes (92 seconds) to over 7 minutes (427 seconds).[1] The longest process step was the documentation taking place after the vaccine was administered at 62.9 seconds. Record keeping accounted for 28% of the labor time (Table 5-1).

Table 5-1. Average Time for Immunization Activities

Activity-specific time–motion estimates for the administration of 724 vaccines to 302 patients (cases) at 33 practices (30 pediatric practices, 3 family practices) across 17 states.

Step	Activity	Average Time in Seconds (95% CI)	Percentage of Total Time
1	Patient chart reviews for immunization	2.9 (2.0–3.9)	1
2	Provision of vaccine information statement	–	
3	Patient counseling and obtainment of consent	48.1 (42.8–53.3)	22
4	Ordering vaccine administration	8.0 (6.6–9.3)	4
5	Preparation of vaccine	59.9 (55.5–64.3)	27
6	Positioning of patient and vaccine administration	33.9 (30.1–37.6)	15
7	Waste disposal and clean-up	5.5 (4.6–6.3)	2
8	Documentation	62.9 (58.6–67.2)	28
	Total	221 (200.2-241.9)	100

Source: RTI based on data acquired from the Verden Group (2009).

In consultation with the Verden Group and consulting pediatricians, record keeping was disaggregated into documentation that is not expected to be eliminated by using 2D barcodes (chart notes, Vaccines for Children [VFC] usage sheets [which vary by VFC jurisdiction], superbill, other [including parental signatures]) and documentation that could

[1]Excludes time spent providing patient the vaccine information statement(process Step 2). Raw data were adjusted to account for multiple doses of a pediatric vaccine being administered to a patient during one visit.

be eliminated by 2D barcodes (logbooks, entry of vaccine details). Documentation that would not be affected amounted to 19.2 seconds (Table 5-2).

Table 5-2. Estimated Change in Documentation Time per Dose, with and without an EHR System

		Documentation Time Relative to Baseline	
	Baseline	**With EHR**	**Without EHR**
Unchanged documentation steps include items such as chart notes, VFC usage sheets, and superbills	19.2s	19.2s	19.2s
Affected documentation steps			
Private dose administration logbook	1.5s	−1.5s	−1.5s
Recording product, expiration date, and lot…			
…in patient records	26.7s	−26.7s	−26.7s
…in practice management system	8.5s	−8.5s	−8.5s
…in IIS	4.7s	−4.7s	−4.0s
…in EHR data fields	2.2s	−2.2s	–
Subtotal	43.7s	−43.7s	−40.8s
2D barcode scan time	–	+4.3s	+4.3s
Total estimated documentation time	62.9s	23.5s	26.4s
Change in documentation time		−39.4s	−36.5s
Percentage change in documentation time		−63%	−58%

S = seconds. Analysis of time–motion study data acquired from the Verden Group (2009), except for barcode scan time, which was Pereira et al. (2012).

The amount of time expended on documentation that could be eliminated by scanning a 2D barcode was 43.7 seconds per dose at practices with EHRs and 40.8 seconds per dose at practices without EHRs. Scanning a vial takes 4.3 seconds on average, according to the Canadian inventory pilot (Pereira et al., 2010).[2] Thus, we expect that practices with EHRs will save approximately 39.4 seconds per dose (95% CI: 34.8–43.9) and practices without EHRs will save about 36.5 seconds per dose (32.3–40.5).

5.2 Economic Model for Quantifying Economic Benefits and Costs

To estimate the number of practices and LHDs adopting barcodes, we estimated unique adoption rates for each provider specialty and size category and for LHDs. This rate was then multiplied by the total number of practices in each specialty and size category and the

[2]The 95% CI is 3.5 to 5.2 seconds per acceptable scan and includes 1.3 attempts per vial to obtain an acceptable read.

total number of LHDs to estimate the number of practices and LHDs adopting barcodes over time.

To properly allocate the costs and benefits, we developed separate adoption curves to estimate the following three parameters: the number of practices and LHDs adopting barcodes over time, the number of doses administered using a barcode with an EHR over time, and the number of doses administered using a barcode without an EHR over time.

The survey question that describes 2D barcodes and asks whether the respondent's practice or LHD would use the barcode is the primary input for our adoption curves. If the respondent answered "Yes, my practice would likely use the barcode," we assumed that barcodes would be adopted in the earliest period available or distributed over some period of time as discussed below. For respondents who answered, "My practice would likely use the barcode if we had an Electronic Health Record system," we assumed they will adopt the barcode when they expect to have an EHR system in use, as specified in another question. Respondents who answered they expect to have an EHR system in use "after 2015" were assumed to not adopt an EHR. Respondents who answered "No, my practice would not likely use the barcode," or "I do not know if my practice would use the barcode" were assumed not to use the barcode.

To estimate the number of doses administered using a barcode with and without an EHR system, we weighted responses by the respondent's reported number of vaccines administered for each provider specialty and size category and for LHDs. This rate was then multiplied by the estimated number of doses administered by each specialty and size category and LHDs to determine the number of doses administered using a barcode with and without an EHR system.

Respondents who answered "Yes, my practice would likely use the barcode" and whose practices currently use an EHR system were categorized as "using a barcode with an EHR." Respondents who answered "Yes, my practice would likely use the barcode" and do not currently have an EHR system in place were categorized as "using a barcode without an EHR." These respondents were reassigned to "using a barcode with an EHR" the year they expect to have an EHR system in use.

We estimated three categories of costs for the adoption and use of barcode scanners: adoption costs, scanner maintenance costs, and scanner replacement costs. Adoption costs were estimated using Equation 5.1:

$$AC_{ijt} = \Delta P_{ijt} \left(Scan_{ij} \times ScanCost + WFCost_{j} + \Sigma_{k} \left(VaxEmp_{ijk} \times Wage_{k} \times TrainT \right) \right) \qquad (5.1)$$

where

AC_{ijt}	the total adoption costs for the specialty and size category ij in time t
ΔP_{ijt}	the change in practices adopting barcodes in specialty and size category ij in time t
$Scan_{ij}$	the average number of scanners purchased by practices in specialty and size category ij
$ScanCost$	the cost of a barcode scanner
$WFCost_j$	the cost of adjusting workflow in practice size category j
$VaxEmp_{ijk}$	the average number of employees with occupation k, preparing or administering vaccines in specialty and size category ij
$Wage_k$	the fully loaded hourly wage rate for occupation k
$TrainT$	the time in hours required to train a staff member to use the barcode scanner and review changes in workflow

These parameters provide the total one-time costs for barcode scanning adoption for each practice specialty and size category and for LHDs. All dollar values are in real terms (2010). Scanner maintenance costs were estimated using Equation 5.2:

$$MC_{ijt} = P_{ijt}(SCan_{ij} \times Maint Cost) \quad (5.2)$$

where

MC_{ijt}	the total maintenance costs for the specialty and size category ij in time t
P_{ijt}	the number of practices using barcodes in specialty and size category ij in time t
$Maint Cost$	the annual cost of maintaining a barcode scanner

And finally, scanner replacement costs were estimated using Equation 5.3:

$$RC_{ijt} = \Delta Scan_{ij,t-5} \times ScanCost \quad (5.3)$$

where

RC_{ijt}	the total scanner replacement costs for the specialty and size category ij in time t
$\Delta Scan_{ij,t-5}$	the change in scanners purchased or replaced in specialty and size category ij in time t-

Total costs for each specialty and size category in a year are thus the sum of adoption costs, maintenance costs, and scanner replacement costs. By aggregating the costs across

all specialty and size categories, we can estimate the total cost of 2D barcode adoption for the four specialties of providers and LHDs.

Table 5-3 presents scanner costs, wage rates, and other parameters used to estimate economic benefits and costs. In January 2010, RTI's Information Technology Services group reviewed GS1's technical specifications for reading GTINs and then researched available scanners meeting those specifications and suitable for use in a medical setting.[3] The scanners identified cost between $300 and $350; the lower of these estimates was selected because we anticipate that the increase in demand and sales volumes associated with using barcodes will likely result in lower market prices. Scanners are expected to have a 5-year useful life and annual maintenance costs of 7% (HDR, 2009).

Table 5-3. Wage Rates and Other Estimated Parameters

Variable	Parameter Estimate	Notes
Scanners		Scanner specifications and costs were reviewed by RTI in January 2010, and the maintenance costs and expected useful life were provided by vendors (HDR, 2009). Scanners are expected to be installed at the point of documentation, such as nurses' stations.
Purchase cost, per scanner	$300	
Cost of annual scanner maintenance	$21 (7%)	
Expected life of scanner	5 years	
Scanner location	1 per station	
Labor positions ($/hour)		Labor rates were the mean national wage rates available from the BLS Occupational Employment Statistics (OES) for positions (BLS, 2011b). OES does not include a wage rate for NP, so the rate for PA was used as an approximation for NP. The cost of employment multiplier to account for benefits, payroll taxes, and other employment costs was specific to health care providers in a nonhospital setting (BLS, 2011a).
Licensed practical nurse (LPN)	19.66	
Medical assistant (MA)	14.16	
Nurse practitioner (NP)	40.78	
Physician assistant (PA)	40.78	
Physician (MD)	77.60	
Registered nurse (RN)	31.99	
Cost of employment multiplier	1.4372	
Cost of workflow redesign, practices with fewer than 10 physicians, at 8 hours of senior RN time	$367.81	Workflow redesign and staff training were estimated in consultation with VFC jurisdictions, consultants, IIS, and IT vendors that have rolled out scanner and signature pad usage. Labor hours were monetized using the 75th percentile wage rate for RNs and the cost of employment multiplier.
Cost of workflow redesign, practices with at least 10 physicians, at 24 hours of senior RN time	$1,103.42	
Training time, per employee	1 hour	

[3]See *Simplified Guide for U.S. Healthcare Bar Code Scanner Acquisition Criteria* at http://www.gs1us.org.

Discussions with provider associations, individual providers, and IT systems vendors indicate that the likely point of scanner installation will be at nurses' stations or dedicated laboratories for immunization. These are the principal places of documentation in common immunization practice for medical settings, as well as storage points for vaccine products. Products are expected to be scanned as they are removed from the refrigerator.

Workflow redesign costs and training costs were developed in consultation with IT systems vendors, IIS, and VFC jurisdictions that have implemented barcode scanning and/or signature pad systems analogous to those needed for 2D barcode scanning. Workflow redesign is expected to be appreciably different for large practices with more than 10 physicians because they have multiple locations. Whereas labor hours for training were compensated using mean wage rates for relevant positions, those for workflow redesign were compensated using the 75th percentile mean wage rate for registered nurses because head nurses earning higher wages were expected by interviewees to be charged with adjusting and implementing 2D barcode usage plans (Cho, Asay, Lorick, Tipton, Dube, Messonnier, 2011). Wage rate and cost of employment multiplier data were obtained from the Bureau of Labor Statistics (BLS, 2011a, 2011b).

The economic benefits quantified in this study are the staff member time savings associated with using barcodes in vaccine administration. We estimated these benefits for vaccines administered with a barcode and an EHR system using Equation 5.4.

$$B_{ijtvEMR} = Vax_{ijtvEMR}\left(\frac{ReT_{EMR}}{3600} \times \frac{\Sigma(VaxEmp_{ijk} \times Wage_k)}{\Sigma VaxEmp_{ijk}}\right) \quad (5.4)$$

where

$B_{ijt_{EMR}}$ monetized benefits of time savings associated with using barcodes in vaccine administration with an EHR in specialty and size category ij in time t

$Vax_{ijt_{EMR}}$ number of vaccines administered using a barcode with an EHR in specialty and size category ij in time t

ReT_{EMR} per-dose reduction in time associated with using a barcode in vaccine administration with an EHR

Similarly, benefits for vaccines administered using a barcode without an EHR were estimated with Equation 5.5.

$$B_{ijtvNOEMR} = Vax_{ijtvNOEMR}\left(\frac{ReT_{NOEMR}}{3600} \times \frac{\Sigma(VaxEmp_{ijk} \times Wage_k)}{\Sigma VaxEmp_{ijk}}\right) \quad (5.5)$$

where

$B_{ijtNOEMR}$ monetized benefits of time savings associated with using barcodes in vaccine administration without an EHR in specialty and size category ij in time t

$Vax_{ijtNOEMR}$ number of vaccines administered using a barcode without an EHR in specialty and size category ij in time t

$RedT_{NOEMR}$ per-dose reduction in time associated with using a barcode in vaccine administration without an EHR

Total benefits for each specialty and size category were calculated as the sum of benefits for vaccines administered using barcodes with and without an EHR system. Total benefits for using barcodes in vaccine administration for the four provider specialties and LHDs were estimated by summing across all specialty and size categories and years.

5.3 Benefit-Cost Analysis of Impact on Clinical Documentation for Primary Care Practices and Local Health Departments

This section begins by reviewing the expected adoption cost per practice and the expected documentation benefit per dose, and then reviews three adoption scenarios. The three scenarios selected are consistent with the 1-, 2-, and 3-year adoption scenarios ordered in the statement of work:

- rate of provider uptake set by survey results (Scenario 1);
- rate of provider uptake slowed by 50%, meaning that the level of adoption that would occur in 1 year would occur in 2 years (Scenario 2); and
- rate of provider uptake slowed by 67%, meaning that the level of adoption that would occur in 1 year would occur in 3 years (Scenario 3).

5.3.1 Expected Adoption Costs per Practice

Table 5-4 presents the expected adoption cost for practices, including the break out of the cost composition for workflow redesign, training, and scanner acquisition. Our cost estimates take into consideration differences among specialty and size combinations. These costs range from lows of $877 for internal medicine practices with 1 to 1.5 physicians and $1,016 for pediatric offices with 1 to 1.5 physicians to a high of $7,831 for pediatric practices with 10 or more physicians.

Table 5-4. Estimated Costs for Workflow Redesign, Training, and Scanner Purchases and Maintenance, per Practice and Health Department, by Specialty and Size

			Training Expense											
Specialty	Size	Workflow Redesign	Licensed Practical Nurses (FTE[a])	Medical Assistants (FTE)	Nurse Practitioners (FTE)	Physician Assistants (FTE)	Physicians (FTE)	Registered Nurses (FTE)	Total Staff (FTE)	Weighted Average Hourly Rate	Training Cost	Number of Scanners	Equipment Expense	Estimated Adoption Cost
Pediatrics	1–1.5 physicians	$437	0.38	1.37	0.03	0.15	0.50	0.38	2.80	$44.47	$124	1.52	$455	$1,016
	2–9 physicians	$437	1.64	3.11	0.02	0.18	0.61	1.90	7.46	$37.76	$282	3.08	$924	$1,643
	More than 10 physicians	$1,310	9.53	10.81	0.79	2.11	4.20	56.30	83.74	$45.19	$3,785	9.12	$2,736	$7,831
Family practice	1–1.5 physicians	$437	0.46	1.43	0.09	0.18	0.34	0.38	2.88	$39.96	$115	2.36	$708	$1,260
	2–9 physicians	$437	1.61	3.91	0.07	0.20	0.40	1.24	7.43	$33.22	$247	3.18	$955	$1,639
	More than 10 physicians	$1,310	8.47	14.31	0.40	0.63	1.99	8.29	34.10	$35.62	$1,215	11.97	$3,591	$6,116
Ob-gyn	1–1.5 physicians	$437	0.41	1.00	0.06	0.59	0.53	0.53	3.12	$50.26	$157	1.71	$512	$1,105
	2–9 physicians	$437	1.41	2.93	0.05	0.38	0.25	1.93	6.95	$35.24	$245	2.30	$689	$1,371
	More than 10 physicians	$1,310	5.14	4.82	0.22	0.39	1.83	14.73	27.12	$43.54	$1,181	4.83	$1,448	$3,939
Internal medicine	1–1.5 physicians	$437	0.18	0.93	0.07	0.07	0.68	0.18	2.11	$56.41	$119	1.07	$321	$877
	2–9 physicians	$437	1.12	3.92	0.04	0.52	0.76	1.40	7.76	$38.51	$299	3.25	$975	$1,711
	More than 10 physicians	$1,310	2.50	0.00	0.50	0.50	3.75	13.75	21.00	$57.35	$1,204	3.33	$1,000	$3,515
Health Departments		$478.83	0.58	0.31	0.06	0.33	0.11	5.79	7.18	$42.65	444	6.42	$1,927	$2,736

[a]FTE = Full-time equivalent

As an example, review the expected cost for family practices with 2 to 9 physicians. On average, for practices in this category, we estimate that the adoption cost will be $1,639. Of this amount,

- $437 will be for workflow redesign,
- $955 for scanners installed at an average of 3.18 locations, and
- $247 for training seven to eight staff members to use barcode scanners and review how they are to be incorporated into their immunization workflow.[4]

5.3.2 Estimated Economic Benefits per Dose

Table 5-5 presents the expected documentation benefit per dose. If our example family practice with 2 to 9 physicians had an EHR, we would expect that they would save $0.3506 per dose or $0.3244 per dose if they did not have an EHR. Although the savings are less than $1, when aggregated over the volume of doses administered over the course of 1 year, we expect benefits to be significant. For example, at 10,000 doses the savings would be $3,506 or $3,244 per year on more efficient documentation alone, respectively, with or without an EHR.

5.3.3 Forecast of Economic Benefits, Scenario 1: Rate of Adoption Set by Survey Results

In this scenario, the rate of adoption is set to 100% of survey respondents' expectations of whether and when they would begin to use the barcode (refer to Tables 4-7 to 4-11 in Chapter 4). Around 80% of respondents that expect to use the barcode either have EHRs in place currently or expect to have EHRs in place *before* the barcode is projected to appear on labels beginning in 2013. Those survey findings are consistent with the program in place under American Recovery and Reinvestment Act (ARRA) HITECH in which practices could receive incentives as high as $44,000 to adopt an EHR or face declining reimbursement rates from the Centers for Medicare & Medicaid Services (CMS) over time if they do not adopt EHRs. Eligible Medicaid providers may earn up to $63,750 over 6 years.

Table 5-6 shows the expected uptake among primary care practices and LHDs. By the close of 2015, if practices follow their preferences, we expect that the following numbers of practices would use the barcode:

[4]The training sessions for learning how to use the scanners and reviewing their incorporation into practice workflow is expected to be 1 hour per person. The weighted average cost of that hour, however, varies with the labor loading. The weighted average hourly wage rate for our example practice is $33.22, and because seven or eight people are expected to attend the training, the cost is $246.

Table 5-5. Estimated Documentation Benefit per Dose, by Practice and Health Departments, by Specialty and Size

		Percentage of Immunization by Occupation							Without EHR		With EHR	
Specialty	**Practice Size**	**Licensed Practical Nurse (%)**	**Medical Assistant (%)**	**Nurse Practi-tioner (%)**	**Physician Assistant (%)**	**Physician (%)**	**Registered Nurse (%)**	**Mean Hourly Cost, Wtd by Throughput, Position**	**Time Savings/ Dose (seconds)**	**Cost Savings per Dose ($)**	**Time Savings/ Dose (seconds)**	**Cost Savings per Dose ($)**
Pediatrics	1–1.5 physicians	11	56	1	4	17	12	$42.37	36.47	0.4293	39.42	0.4639
	2–9 physicians	23	43	0	2	6	26	$35.44	36.47	0.3591	39.42	0.3881
	More than 10 physicians	28	44	1	1	2	24	$31.92	36.47	0.3234	39.42	0.3495
Family practice	1–1.5 physicians	12	58	3	6	9	11	$36.66	36.47	0.3714	39.42	0.4014
	2–9 physicians	21	53	1	2	4	19	$32.02	36.47	0.3244	39.42	0.3506
	More than 10 physicians	33	42	2	3	1	19	$31.07	36.47	0.3148	39.42	0.3402
Ob-gyn	1–1.5 physicians	17	19	0	18	5	42	$44.75	36.47	0.4534	39.42	0.4900
	2–9 physicians	17	31	0	16	10	26	$44.35	36.47	0.4493	39.42	0.4855
	More than 10 physicians	27	11	0	2	4	55	$42.14	36.47	0.4269	39.42	0.4613
Internal medicine	1–1.5 physicians	16	44	5	7	20	8	$47.87	36.47	0.4850	39.42	0.5241
	2–9 physicians	9	78	1	2	5	5	$28.76	36.47	0.2914	39.42	0.3149
	More than 10 physicians	17	0	3	3	25	52	$61.26	36.47	0.6207	39.42	0.6707
Health Departments		9	5	0	3	1	81	**$45.20**	36.47	**0.4580**	39.42	**0.4950**

Table 5-6. Scenario 1: Forecast of Barcode Adoption, by Specialty and Size (Number of Practices and Health Departments)

Specialty	Practice Size	Number of Practices	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023
Pediatrics	1–1.5 physicians	1,392	914	918	918	918	918	918	918	918	918	918	918
	2–9 physicians	2,582	1,947	1,974	1,987	1,987	1,987	1,987	1,987	1,987	1,987	1,987	1,987
	More than 10 physicians	963	807	807	807	807	807	807	807	807	807	807	807
	Total	4,937	3,668	3,699	3,712	3,712	3,712	3,712	3,712	3,712	3,712	3,712	3,712
Family practice	1–1.5 physicians	3,146	1,905	1,924	1,943	1,943	1,943	1,943	1,943	1,943	1,943	1,943	1,943
	2–9 physicians	5,173	3,575	3,586	3,610	3,610	3,610	3,610	3,610	3,610	3,610	3,610	3,610
	More than 10 physicians	1,243	968	968	968	968	968	968	968	968	968	968	968
	Total	9,561	6,447	6,478	6,521	6,521	6,521	6,521	6,521	6,521	6,521	6,521	6,521
Ob-gyn	1–1.5 physicians	1,592	796	796	796	796	796	796	796	796	796	796	796
	2–9 physicians	3,481	2,278	2,278	2,278	2,278	2,278	2,278	2,278	2,278	2,278	2,278	2,278
	More than 10 physicians	653	475	475	475	475	475	475	475	475	475	475	475
	Total	5,725	3,549	3,549	3,549	3,549	3,549	3,549	3,549	3,549	3,549	3,549	3,549
Internal medicine	1–1.5 physicians	4,947	2,016	2,016	2,016	2,016	2,016	2,016	2,016	2,016	2,016	2,016	2,016
	2–9 physicians	5,197	3,464	3,464	3,464	3,464	3,464	3,464	3,464	3,464	3,464	3,464	3,464
	More than 10 physicians	2,318	1,159	1,159	1,159	1,159	1,159	1,159	1,159	1,159	1,159	1,159	1,159
	Total	12,462	6,639	6,639	6,639	6,639	6,639	6,639	6,639	6,639	6,639	6,639	6,639
Total of Identified Specialties		32,685	20,303	20,365	20,421	20,421	20,421	20,421	20,421	20,421	20,421	20,421	20,421
Health Departments		3,669	1,800	1,828	1,841	1,841	1,841	1,841	1,841	1,841	1,841	1,841	1,841

Note: Scenario 1 rate of adoption set by survey response with no adjustments. Ultimate penetration estimated to be 75.2% (pediatrics), 68.2% (family practice), 62.0% (ob-gyn), 53.3% (internal medicine), and 50.2% (health departments). Practice data are from AMA (2008, 2011) and NAACHO (2011).

- 3,712 pediatric practices (75.2% of 4,937 practices in the United States)
- 6,521 family medicine practices (68.2% of 9,561)
- 3,549 obstetric-gynecology (ob-gyn) practices (62.0% of 5,725)
- 6,639 internal medicine practices (53.3% of 12,462)
- 1,841 LHDs (50.2% of 3,669)

The remaining practices said they would not use the barcode or that they do not know whether they would use the barcode.

Total economic benefits from automating product identification and populating expiration dates and lot numbers in records are projected to be $447.8 million over 2013 to 2023 (Table 5-7). When the costs for all adopting primary care practices and LHDs are summed, the model estimates $114.2 million in costs. Thus, inclusive of adoption and scanner maintenance and replacement costs, net benefits are projected to be $333.6 million for these stakeholders.

Continuing with the earlier example of family medicine practices with 2 to 9 physicians, Tables 5-6 through 5-9 can be interpreted as follows:

- A total of 3,573 family medicine practices with 2 to 9 physicians are expected to purchase scanners and begin using these scanners by the end of 2013. See Table 5-6.
- Annual benefits for these practices amount to $3.9 million in 2014, the first full year of barcode use. Benefits from more efficient documentation procedures are low during 2013 (the first year of adoption) as practices come online and products enter the market with a 2D barcode appearing on the label. Total benefits through 2023 are $42.4 million. See Table 5-7.
- Adoption costs for these practices are estimated at $6.1 million in 2013 for workflow redesign, scanner purchases, and training. Costs are estimated to be lower in subsequent years because the practice is expected to only incur costs for miscellaneous scanner replacement costs. The presence of outlays in later years represents scanner replacement costs once these units have reached the end of their useful life. Total costs through 2023 are $15.4 million. See Table 5-8.
- For all practices in this specialty–size combination, net benefits of adoption costs are negative in 2013 at –$4.2 million, swinging positive in 2014 at $3.6 million, with payback achieved early in the third year (2015). Net benefits through 2023 are $26.9 million. See Table 5-9.

Table 5-7. Scenario 1: Forecast of Documentation Benefits by Practice and Health Department ($ thousands)

Specialty	Practice Size	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	Total
Pediatrics	1–1.5 physicians	629	1,271	1,282	1,292	1,302	1,311	1,320	1,329	1,338	1,347	1,356	13,776
	2–9 physicians	3,691	7,504	7,658	7,748	7,804	7,860	7,916	7,971	8,026	8,081	8,135	82,394
	More than 10 physicians	6,028	12,162	12,265	12,360	12,452	12,542	12,632	12,722	12,811	12,899	12,987	131,859
	Total	10,348	20,936	21,206	21,400	21,557	21,713	21,868	22,022	22,175	22,327	22,477	228,029
Family practice	1–1.5 physicians	392	796	810	819	826	834	841	848	856	863	870	8,755
	2–9 physicians	1,907	3,856	3,907	3,954	3,991	4,029	4,067	4,106	4,143	4,181	4,220	42,362
	More than 10 physicians	1,661	3,356	3,390	3,421	3,453	3,485	3,516	3,549	3,581	3,613	3,645	36,670
	Total	3,961	8,008	8,107	8,194	8,271	8,347	8,424	8,503	8,580	8,658	8,735	87,788
Ob-gyn	1–1.5 physicians	91	185	187	189	190	192	194	196	198	200	202	2,026
	2–9 physicians	293	593	600	607	613	620	627	635	642	649	656	6,535
	More than 10 physicians	191	387	393	398	403	407	411	415	419	424	428	4,275
	Total	576	1,164	1,179	1,194	1,206	1,219	1,233	1,246	1,260	1,273	1,286	12,836
Internal medicine	1–1.5 physicians	180	363	367	371	374	378	381	385	389	392	396	3,976
	2–9 physicians	1,002	2,025	2,046	2,066	2,085	2,105	2,125	2,146	2,166	2,186	2,206	22,158
	More than 10 physicians	711	1,438	1,455	1,472	1,489	1,506	1,524	1,542	1,560	1,578	1,596	15,871
	Total	1,892	3,826	3,869	3,908	3,949	3,989	4,030	4,073	4,114	4,156	4,198	42,005
Total of Identified Specialties			16,777	33,935	34,360	34,696	34,983	35,269	35,555	35,844	36,129	36,414	36,697
Health Departments		3,436	6,996	7,127	7,202	7,271	7,340	7,409	7,481	7,550	7,621	7,691	77,122
Total		**20,213**	**40,930**	**41,487**	**41,898**	**42,254**	**42,608**	**42,964**	**43,325**	**43,679**	**44,034**	**44,388**	**447,781**

Note: Sums may not add to totals because of independent rounding. Scenario 1 rate of adoption set by survey response with no adjustments. Ultimate penetration estimated to be 75.2% (pediatrics), 68.2% (family practice), 62.0% (ob-gyn), 53.3% (internal medicine), and 50.2% (health departments).

Table 5-8. Scenario 1: Forecast of Adoption and Usage Costs, by Practice and Health Department ($ thousands)

Specialty	Practice Size	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	Total
Pediatrics	1–1.5 physicians	958	33	29	29	29	445	31	29	29	29	445	2,087
	2–9 physicians	3,326	170	150	129	129	1,929	153	141	129	129	1,929	8,312
	More than 10 physicians	6,476	155	155	155	155	2,363	155	155	155	155	2,363	12,438
	Total	10,759	358	334	312	312	4,737	339	325	312	312	4,737	22,837
Family practice	1–1.5 physicians	2,494	119	120	96	96	1,445	110	110	96	96	1,445	6,227
	2–9 physicians	6,098	258	279	241	241	3,656	253	264	241	241	3,656	15,429
	More than 10 physicians	6,165	243	243	243	243	3,720	243	243	243	243	3,720	15,552
	Total	14,756	620	642	581	581	8,821	606	617	581	581	8,821	37,208
Ob-gyn	1–1.5 physicians	908	29	29	29	29	436	29	29	29	29	436	2,008
	2–9 physicians	3,234	110	110	110	110	1,681	110	110	110	110	1,681	7,475
	More than 10 physicians	1,918	48	48	48	48	735	48	48	48	48	735	3,773
	Total	6,060	187	187	187	187	2,852	187	187	187	187	2,852	13,256
Internal medicine	1–1.5 physicians	1,813	45	45	45	45	693	45	45	45	45	693	3,562
	2–9 physicians	6,163	236	236	236	236	3,614	236	236	236	236	3,614	15,283
	More than 10 physicians	4,155	81	81	81	81	1,240	81	81	81	81	1,240	7,284
	Total	12,131	363	363	363	363	5,548	363	363	363	363	5,548	26,129
Total of Identified Specialties			43,706	1,528	1,525	1,443	1,443	21,957	1,494	1,492	1,443	1,443	21,957
Health Departments		5,166	319	285	248	248	3,715	302	275	248	248	3,715	14,771
Total		**48,872**	**1,847**	**1,809**	**1,691**	**1,691**	**25,673**	**1,797**	**1,767**	**1,691**	**1,691**	**25,673**	**114,202**

Note: Sums may not add to totals because of independent rounding. Annual scanner operations and maintenance expenses are estimated to be 7% of the purchase price of $300 per unit. Scanners are assumed to be replaced at 5-year intervals. Scenario 1 rate of adoption set by survey response with no adjustments. Ultimate penetration estimated to be 75.2% (pediatrics), 68.2% (family practice), 62.0% (ob-gyn), 53.3% (internal medicine), and 50.2% (health departments).

Table 5-9. Scenario 1: Forecast of Net Benefits by Practice and Health Department ($ thousands)

Specialty	Practice Size	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	Total
Pediatrics	1–1.5 physicians	−328	1,237	1,253	1,263	1,272	866	1,289	1,300	1,309	1,318	911	11,689
	2–9 physicians	365	7,334	7,508	7,619	7,676	5,931	7,763	7,830	7,898	7,952	6,206	74,082
	More than 10 physicians	−447	12,007	12,111	12,205	12,297	10,179	12,477	12,567	12,656	12,745	10,624	119,421
	Total	−411	20,579	20,872	21,087	21,245	16,976	21,529	21,697	21,863	22,015	17,741	205,192
Family practice	1–1.5 physicians	−2,101	677	690	723	730	−611	731	738	759	767	−574	2,528
	2–9 physicians	−4,190	3,598	3,629	3,713	3,750	373	3,814	3,841	3,902	3,940	564	26,933
	More than 10 physicians	−4,504	3,112	3,146	3,178	3,210	−235	3,273	3,306	3,338	3,370	−75	21,118
	Total	−10,795	7,387	7,465	7,613	7,690	−474	7,818	7,886	7,999	8,076	−86	50,580
Ob-gyn	1–1.5 physicians	−817	156	158	160	162	−243	166	168	170	172	−233	18
	2–9 physicians	−2,941	483	490	497	503	−1,060	517	525	532	539	−1,025	−940
	More than 10 physicians	−1,727	339	345	350	354	−329	363	367	371	376	−307	502
	Total	−5,484	978	993	1,007	1,020	−1,632	1,046	1,060	1,073	1,086	−1,565	−420
Internal medicine	1–1.5 physicians	−1,633	318	322	325	329	−315	336	340	343	347	−297	414
	2–9 physicians	−5,161	1,788	1,810	1,829	1,849	−1,509	1,889	1,909	1,929	1,949	−1,408	6,875
	More than 10 physicians	−3,444	1,357	1,374	1,391	1,408	266	1,443	1,461	1,479	1,497	356	8,587
	Total	−10,238	3,463	3,506	3,545	3,586	−1,558	3,667	3,710	3,751	3,793	−1,350	15,876
Total of Identified Specialties			−26,929	32,407	32,835	33,253	33,540	13,311	34,060	34,353	34,686	34,971	14,740
Health Departments		−1,730	6,676	6,842	6,954	7,022	3,624	7,107	7,205	7,302	7,372	3,975	62,351
Total		**−28,659**	**39,084**	**39,678**	**40,207**	**40,563**	**16,936**	**41,167**	**41,558**	**41,988**	**42,343**	**18,715**	**333,579**

Note: Sums may not add to totals because of independent rounding. Scenario 1 rate of adoption set by survey response with no adjustments. Ultimate penetration estimated to be 75.2% (pediatrics), 68.2% (family practice), 62.0% (ob-gyn), 53.3% (internal medicine), and 50.2% (health departments).

5.3.4 Forecast of Economic Benefits, Scenario 2: Slowing Rate of Adoption by 50%

In Scenario 2, the rate of adoption was slowed by 50%, which is the equivalent of achieving the same level of adoption in 2 years instead of 1 year or, alternatively, allowing for the rate of adoption to take twice as long as indicated (Table 5-10). The rationale for this scenario is because some practices and health departments may not follow their stated preferences for using the barcode. Practices may wish to use it, but for whatever reason they do not acquire the scanners or invest in workflow redesign at the same rate as suggested by the survey response data. In essence, this scenario contributes to a range of expected benefits by incorporating a possibility that it takes longer for practices to begin using the barcodes. It has the effect of delaying the accrual of costs and benefits and a proportion of immunizations that would have been documented using automated data capture under Scenario 1 would instead be documented using manual methods. Although the ultimate market penetration is the same, net benefits by 2023 amount to $326.8 million instead of $333.6 million (Table 5-11).

5.3.5 Forecast of Economic Benefits, Scenario 3: Slowing Rate of Adoption by 67%

In Scenario 3, the rate of adoption was slowed by 67%, which is the equivalent of achieving the same level of adoption in 3 years instead of 1 year (Table 5-12). Slowing the rate of adoption by 67% is equivalent to allowing for the rate of adoption to take three times as long as indicated. Net benefits in this scenario amount of $311.3 million by 2023 instead of $333.6 million (Table 5-13).

5.4 Conclusions

Table 5-14 presents a comparison of the net benefits from each scenario. The principal difference in these estimates is the time frame of adoption. Model results suggest that a lower-bound range of economic benefit for primary care practices is $311.3 million to $333.6 million from implementing 2D barcode scanning because of a reduction in documentation time of 58% to 63%.

A number of limitations, apart from benefits that were not quantified, must be kept in mind when reviewing these results. First, time savings were based on a time–motion data set and not based on actual, routine 2D barcode usage, simply because 2D barcodes for vaccines have yet to be introduced. A counterpoint, however, is that the range of time savings benefit predicted—36 to 39 seconds per dose—is consistent with the possible 34 seconds per dose suggested as possible in Quach et al. (2011). Second, additional benefits that are not included in these data are improved inventory management (including reductions in inventory-carrying costs and wastage), improved billing through correct product identification, and less extraimmunization due to more complete records in IIS. Third,

Table 5-10. Scenario 2: Forecast of Barcode Adoption, by Specialty and Size (Number of Practices and Health Departments)

Specialty	Practice Size	Number of Practices	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023
Pediatrics	1–1.5 physicians	1,392	457	916	918	918	918	918	918	918	918	918	918
	2–9 physicians	2,582	974	1,961	1,981	1,987	1,987	1,987	1,987	1,987	1,987	1,987	1,987
	More than 10 physicians	963	404	807	807	807	807	807	807	807	807	807	807
	Total	4,937	1,834	3,684	3,706	3,712	3,712	3,712	3,712	3,712	3,712	3,712	3,712
Family practice	1–1.5 physicians	3,146	952	1,914	1,934	1,943	1,943	1,943	1,943	1,943	1,943	1,943	1,943
	2–9 physicians	5,173	1,787	3,581	3,598	3,610	3,610	3,610	3,610	3,610	3,610	3,610	3,610
	More than 10 physicians	1,243	484	968	968	968	968	968	968	968	968	968	968
	Total	9,561	3,224	6,463	6,500	6,521	6,521	6,521	6,521	6,521	6,521	6,521	6,521
Ob-gyn	1–1.5 physicians	1,592	398	796	796	796	796	796	796	796	796	796	796
	2–9 physicians	3,481	1,139	2,278	2,278	2,278	2,278	2,278	2,278	2,278	2,278	2,278	2,278
	More than 10 physicians	653	237	475	475	475	475	475	475	475	475	475	475
	Total	5,725	1,774	3,549	3,549	3,549	3,549	3,549	3,549	3,549	3,549	3,549	3,549
Internal medicine	1–1.5 physicians	4,947	1,008	2,016	2,016	2,016	2,016	2,016	2,016	2,016	2,016	2,016	2,016
	2–9 physicians	5,197	1,732	3,464	3,464	3,464	3,464	3,464	3,464	3,464	3,464	3,464	3,464
	More than 10 physicians	2,318	579	1,159	1,159	1,159	1,159	1,159	1,159	1,159	1,159	1,159	1,159
	Total	12,462	3,320	6,639	6,639	6,639	6,639	6,639	6,639	6,639	6,639	6,639	6,639
Total of Identified Specialties		32,685	10,152	20,334	20,393	20,421	20,421	20,421	20,421	20,421	20,421	20,421	20,421
Health Departments		3,669	900	1,814	1,835	1,841	1,841	1,841	1,841	1,841	1,841	1,841	1,841

Note: Sums may not add to totals because of independent rounding. Scenario 2 rate of adoption is the survey respondents' rate slowed by 50%. Ultimate penetration estimated to be 75.2% (pediatrics), 68.2% (family practice), 62.0% (ob-gyn), 53.3% (internal medicine), and 50.2% (health departments). Practice count data are from AMA (2008, 2011) and NACCHO (2010).

Table 5-11. Scenario 2: Forecast of Net Benefits by Practice and Health Department ($ thousands)

Specialty	Practice Size	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	Total
Pediatrics	1–1.5 physicians	−164	472	1,251	1,263	1,272	1,074	1,082	1,299	1,309	1,318	1,119	11,293
	2–9 physicians	182	3,928	7,453	7,577	7,676	6,831	6,875	7,824	7,892	7,952	7,106	71,297
	More than 10 physicians	−224	5,883	12,111	12,205	12,297	11,283	11,373	12,567	12,656	12,745	11,728	114,625
	Total	−205	10,284	20,814	21,046	21,245	19,188	19,330	21,690	21,857	22,015	19,953	197,215
Family practice	1–1.5 physicians	−1,051	−663	688	709	730	63	64	738	753	767	100	2,897
	2–9 physicians	−2,095	−167	3,633	3,685	3,750	2,080	2,112	3,847	3,891	3,940	2,271	26,947
	More than 10 physicians	−2,252	−565	3,146	3,178	3,210	1,503	1,535	3,306	3,338	3,370	1,663	21,431
	Total	−5,398	−1,395	7,467	7,571	7,690	3,646	3,711	7,891	7,981	8,076	4,034	51,274
Ob-gyn	1–1.5 physicians	−408	−316	158	160	162	−40	−38	168	170	172	−30	159
	2–9 physicians	−1,471	−1,172	490	497	503	−275	−268	525	532	539	−239	−340
	More than 10 physicians	−863	−669	344	349	354	15	19	367	371	376	36	699
	Total	−2,742	−2,157	992	1,005	1,020	−300	−287	1,060	1,073	1,086	−233	518
Internal medicine	1–1.5 physicians	−817	−634	322	325	329	8	12	340	343	347	27	602
	2–9 physicians	−2,580	−1,563	1,810	1,829	1,849	180	200	1,909	1,929	1,949	281	7,793
	More than 10 physicians	−1,722	−999	1,374	1,391	1,408	846	863	1,461	1,479	1,497	935	8,533
	Total	−5,119	−3,196	3,506	3,545	3,586	1,034	1,075	3,710	3,751	3,793	1,243	16,928
Total of Identified Specialties			−13,464	3,536	32,778	33,168	33,540	23,569	23,829	34,351	34,662	34,971	24,997
Health Departments		−865	2,612	6,796	6,929	7,022	5,358	5,400	7,192	7,289	7,372	5,709	60,814
Total		**−14,329**	**6,148**	**39,574**	**40,097**	**40,563**	**28,926**	**29,229**	**41,543**	**41,950**	**42,343**	**30,706**	**326,750**

Note: Sums may not add to totals because of independent rounding. Annual scanner operations and maintenance expenses are estimated to be 7% of the purchase price of $300 per unit. Scanners are assumed to be replaced at 5-year intervals (i.e., 2018 and 2023). Scenario 2 rate of adoption is the survey respondents' rate slowed by 50%. Ultimate penetration estimated to be 75.2% (pediatrics), 68.2% (family practice), 62.0% (ob-gyn), 53.3% (internal medicine), and 50.2% (health departments). Practice count data are from AMA (2008, 2011) and NACCHO (2010).

Table 5-12. Scenario 3: Forecast of Barcode Adoption, by Specialty and Size (Number of Practices and Health Departments)

Specialty	Practice Size	Starting # Practices	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023
Pediatrics	1–1.5 physicians	1,392	305	610	916	918	918	918	918	918	918	918	918
	2–9 physicians	2,582	649	1,307	1,970	1,983	1,987	1,987	1,987	1,987	1,987	1,987	1,987
	More than 10 physicians	963	269	538	807	807	807	807	807	807	807	807	807
	Total	4,937	1,223	2,456	3,693	3,708	3,712	3,712	3,712	3,712	3,712	3,712	3,712
Family practice	1–1.5 physicians	3,146	635	1,276	1,924	1,937	1,943	1,943	1,943	1,943	1,943	1,943	1,943
	2–9 physicians	5,173	1,192	2,387	3,590	3,602	3,610	3,610	3,610	3,610	3,610	3,610	3,610
	More than 10 physicians	1,243	323	645	968	968	968	968	968	968	968	968	968
	Total	9,561	2,149	4,309	6,482	6,507	6,521	6,521	6,521	6,521	6,521	6,521	6,521
Ob-gyn	1–1.5 physicians	1,592	265	531	796	796	796	796	796	796	796	796	796
	2–9 physicians	3,481	759	1,519	2,278	2,278	2,278	2,278	2,278	2,278	2,278	2,278	2,278
	More than 10 physicians	653	158	316	475	475	475	475	475	475	475	475	475
	Total	5,725	1,183	2,366	3,549	3,549	3,549	3,549	3,549	3,549	3,549	3,549	3,549
Internal medicine	1–1.5 physicians	4,947	672	1,344	2,016	2,016	2,016	2,016	2,016	2,016	2,016	2,016	2,016
	2–9 physicians	5,197	1,155	2,310	3,464	3,464	3,464	3,464	3,464	3,464	3,464	3,464	3,464
	More than 10 physicians	2,318	386	773	1,159	1,159	1,159	1,159	1,159	1,159	1,159	1,159	1,159
	Total	12,462	2,213	4,426	6,639	6,639	6,639	6,639	6,639	6,639	6,639	6,639	6,639
Total of Identified Specialties		32,685	6,768	13,556	20,363	20,403	20,421	20,421	20,421	20,421	20,421	20,421	20,421
Health Departments		3,669	600	1,209	1,823	1,837	1,841	1,841	1,841	1,841	1,841	1,841	1,841

Note: Sums may not add to totals because of independent rounding. Scenario 2 rate of adoption is the survey respondents' rate slowed by 67%. Ultimate penetration was estimated to be 75.2% (pediatrics), 68.2% (family practice), 62.0% (ob-gyn), 53.3% (internal medicine), and 50.2% (health departments). Practice count data are from AMA (2008, 2011) and NACCHO (2010).

Table 5-13. Scenario 3: Forecast of Net Benefits by specialty and size and Health Department ($ thousands)

Specialty	Practice Size	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	Total
Pediatrics	1–1.5 physicians	−94	361	769	1,261	1,272	1,143	1,151	1,161	1,308	1,318	1,188	10,837
	2–9 physicians	122	2,619	5,153	7,537	7,638	7,131	7,179	7,230	7,885	7,948	7,406	67,848
	More than 10 physicians	−149	3,922	8,011	12,205	12,297	11,651	11,741	11,831	12,656	12,745	12,096	109,007
	Total	−122	6,902	13,933	21,003	21,207	19,925	20,072	20,222	21,850	22,011	20,690	187,692
Family practice	1–1.5 physicians	−700	−442	−208	703	720	288	291	293	750	762	325	2,782
	2–9 physicians	−1,397	−111	1,118	3,681	3,728	2,649	2,683	2,715	3,891	3,933	2,840	25,729
	More than 10 physicians	−1,501	−377	689	3,178	3,210	2,082	2,114	2,147	3,338	3,370	2,243	20,492
	Total	−3,598	−930	1,599	7,563	7,658	5,019	5,088	5,155	7,979	8,064	5,407	49,003
Ob-gyn	1–1.5 physicians	−272	−210	−157	160	162	28	30	32	170	172	38	153
	2–9 physicians	−980	−782	−615	497	503	−13	−6	1	532	539	23	−301
	More than 10 physicians	−576	−446	−329	348	353	129	134	138	371	376	151	649
	Total	−1,828	−1,438	−1,100	1,005	1,018	144	158	171	1,073	1,086	211	500
Internal medicine	1–1.5 physicians	−544	−423	−314	325	329	116	120	124	343	347	135	559
	2–9 physicians	−1,720	−1,042	−428	1,829	1,849	743	763	783	1,929	1,949	844	7,499
	More than 10 physicians	−1,148	−666	−199	1,391	1,408	1,039	1,056	1,075	1,479	1,497	1,129	8,060
	Total	−3,413	−2,130	−941	3,545	3,586	1,898	1,939	1,982	3,751	3,793	2,107	16,118
Total of Identified Specialties			−8,961	2,403	13,490	33,116	33,468	26,988	27,256	27,530	34,653	34,954	28,416
Health Departments		−577	1,742	4,059	6,892	7,004	5,936	5,987	6,050	7,275	7,363	6,287	58,017
Total		**−9,538**	**4,145**	**17,549**	**40,008**	**40,472**	**32,923**	**33,244**	**33,580**	**41,928**	**42,318**	**34,703**	**311,330**

Note: Sums may not add to totals because of independent rounding. Annual scanner operations and maintenance expenses are estimated to be 7% of the purchase price of $300 per unit. Scanners are assumed to be replaced at 5-year intervals. Scenario 3 rate of adoption is the survey respondents' rate slowed by 67%. Ultimate penetration estimated to be 75.2% (pediatrics), 68.2% (family practice), 62.0% (ob-gyn), 53.3% (internal medicine), and 50.2% (health departments).

Table 5-14. Comparison of Net Benefit Forecasts Accruing to Primary Care Practices and Health Departments for Three Adoption Scenarios

	Net Benefits (Thousand $)		
Year	**Scenario 1, Rate of Adoption Set by Survey**	**Scenario 2, Rate of Adoption Slowed 50%**	**Scenario 3, Rate of Adoption Slowed 67%**
2013	–28,659	–14,329	–9,538
2014	39,084	6,148	4,145
2015	39,678	39,574	17,549
2016	40,207	40,097	40,008
2017	40,563	40,563	40,472
2018	16,936	28,926	32,923
2019	41,167	29,229	33,244
2020	41,558	41,543	33,580
2021	41,988	41,950	41,928
2022	42,343	42,343	42,318
2023	18,715	30,706	34,703
Total	**333,579**	**326,750**	**311,330**

Note: Sums may not add to totals because of independent rounding. Annual scanner operations and maintenance expenses are estimated to be 7% of the purchase price of $300 per unit. Scanners are assumed to be replaced at 5-year intervals.

adoption curves drive results, particularly for ob-gyn and internal medicine practices. Yet recall that we received fewer than 100 responses for each of these two specialties, which translates to each response having very large weight. Better survey coverage for pediatric and family medicine practices lowered each individual practice's weight, but there may still be issues of regional or population bias that may influence the results, given that not all VFC jurisdictions participated in the survey.

6. IMPACT ON EXCHANGE AND MANAGEMENT OF IMMUNIZATION INFORMATION

Because a 2D barcode with Global Trade Item Number (GTIN), lot number, and expiration date has yet to be used for vaccine product identification in the United States, it is of paramount importance to understand how it will affect exchange and management of immunization information. This chapter describes how data from a 2D barcode can populate electronic health records (EHRs), immunization information systems (IIS), and inventory management, billing, and other immunization tracking systems.

The information systems used by immunization stakeholders are governed by a set of standards that help ensure that data are stored in a consistent manner. This consistency, as provided by standards, helps enable efficient and accurate data exchange between systems. For example, immunization data entered into a provider's EHR can be transferred to the provider's billing system and to the state IIS. Through interviews and a review of the standards, we analyzed how the GTIN, expiration date, and lot number from the 2D barcode could be exchanged with other data systems, any associated challenges, and potential solutions to overcome those challenges.

6.1 Methodology for Mapping 2D Barcode Contents Across Data Exchange Standards

We reviewed information technology standards that immunization stakeholders commonly use, including Health Level 7 (HL7), X12, Healthcare Information Technology Standards Panel (HITSP), and National Council for Prescription Drug Program (NCPDP). Standards outline data definitions, formats, and representations in information systems to facilitate consistent and efficient data exchange and sharing. Because vaccine product information will be shared across stakeholders (e.g., manufacturers, providers, public health authorities) using different standards for specific transactions, it is necessary to understand how information would be translated across each standard. The process for developing this understanding is referred to as standards mapping.

Standards mapping is critical to provide input to software engineers and information architects about potential adjustments to affected information systems. We also sought to identify any critical gaps in the standards that would preclude adequate exchange of 2D barcoded data. The standards mapping was augmented by interviews to more fully understand contextual factors and validate the draft mapping. The balance of this section describes methods for standards selection, review, mapping, and validation.

6.1.1 Selection of Standards for Review

Several health care and product standards may be applicable for immunization, including barcoding standards (GS1, 2011a), EHR use and messaging (HL7), the Centers for Disease

Control and Prevention (CDC) Implementation Guide (CDC, 2011c), Healthcare Information Technology Standards Panel (HITSP) (2006), and billing (X12 and NCPDP). Standards for review were identified in consultation with technical representatives from GS1 Healthcare US, CDC and its contractors, provider organizations, EHR and IIS vendors, and HL7. Table 6-1 outlines the standards, where they apply, and the relevant systems that use them.

Table 6-1. Standards Reviewed and Their Application

Standard	How Used	Major Stakeholders	Relevant Systems
GS1	Manufacturers to register GTINs and print the 2D barcodes. Downstream systems to read the barcode	All	All
HL7 EHR Functional Model	Information exchange for health information technology	Vendors, providers, registries, CDC	EHR systems, IIS systems, practice management systems
CDC 2.5.1 implementation guide	Translation of HL7 standards for provider community	Vendors, providers, registries, CDC	EHR systems, IIS systems, practice management systems
X12–837P transaction (4010 and 5010)	Providers to submit claims	Providers, health plans	EHR systems, practice management systems, payer billing systems
NCPDP (Pharmacy EDI)	Pharmacies	Pharmacy immunizers	Pharmacy systems
HITSP immunization messaging	Providers, vendors, and payers to understand immunization messages	Providers, vendors, payers	EHR systems, IIS systems, practice management systems, payer billing systems

GS1 (2011a) provided vaccine-specific guidance about expected content and format of the 2D barcode. This guidance was endorsed by the American Academy of Pediatrics (AAP). As discussed in Chapter 1, the GS1 guidance for vaccines includes the GTIN, expiration date, and lot number. The GTIN has the National Drug Code (NDC), a universal identifier for human drugs, embedded in it. Thus, the placement and formatting of these data elements were reviewed across standards.

The HL7 standard is used in a variety of health care contexts, including messaging, EHR functions, information exchange, and reporting to an IIS. We reviewed HL7's EHR Functional Model, which details functionality, storage, and messaging for EHRs. However, it is not immunization specific. The CDC 2.5.1 implementation guide constrains the HL7 messaging specifications for immunization. Thus, we reviewed the standard itself (HL7, 2007) and CDC's guide to translating the messaging aspect of the standard (CDC, 2011d).

Claims submission and other health care transactions are governed by a set of electronic data interchange (EDI) standards, as per the Health Insurance Portability and Accountability Act (HIPAA) (Health Insurance Portability and Accountability Act of 1996, 1996). There are different structures for various transactions. For example, claims submission has one structure, and verifying eligibility has another.[1] As per the HIPAA transaction set, the specific billing transaction used by providers is called the 837. The 837 claims transaction has two components: professional and institutional. Because the majority of vaccines are administered by providers, not institutions, the 837 Provider (837P) transaction was reviewed. We reviewed both the current 4010 version (ASC X12, 2003) and the upcoming 5010 version (ASC X12, 2006), which will be operational in January 2012.

Although many vaccines are administered at physicians' offices, some are administered in settings such as pharmacies. Pharmacies conduct transactions using the pharmacy-specific NCPDP standard. However, when an authorized immunizer at a retail pharmacy administers a vaccine, the individual is not acting as a pharmacy but as an immunization provider. Thus, the 837P transaction is used for billing. This is true for pharmacists as well as for nurses and others who immunize in the pharmacy setting. Because retail-based pharmacies largely conduct pharmacy operations, their systems are set up according to the pharmacy standard. Pharmacies translate from the NCPDP standard to the X12 standard prior to claims submission. Accordingly, we included the NCPDP standard in the mapping (NCPDP, 2010a, 2010b).

We also reviewed the HITSP, which was developed to harmonize and integrate standards. Although the panel is not active currently, we reviewed the HITSP Immunization Messaging documentation because their work is used as an educational guide for implementations (HITSP, 2006).

Thus, the standards reviewed were GS1, HL7, the CDC 2.5.1 implementation guide (which is based on HL7), the 837P transaction in both the current and future incarnations, the pharmacy EDI standard, and the HITSP immunization messaging guidance.

6.1.2 Standards Review, Mapping, and Mapping Validation

We conducted source-based mapping, which analyzes items from a source document to find corresponding items in target documents. Each standard was reviewed to understand how the items in the 2D barcode, or the source, would flow across the standards, or the targets. This review was done to identify similarities and gaps in data elements across standards and to determine the complexity of interoperability. Mapping allows the relationships between fields across different standards to be identified.

[1]Initially, we had planned to review the Eligibility EDI transaction: the X12 guidance for determining eligibility of benefits. However, eligibility is not obtained at the vaccine level using the HIPAA transactions, so there is no need to map the specific information on the vaccine barcode.

Our review consisted of taking the GS1 guidance and applying it to the other standards to identify placements for the three data elements. First, we reviewed these elements and documented their length, format, and definition. Then, we reviewed each standard and identified where the elements would be located. The length, format, data type, definition, and other identifying information were documented for each field. Throughout mapping, notes and examples were documented for further information and reference. In addition to the standards themselves, document review included the Food and Drug Administration (FDA) guidance (FDA, 2010a) and background material provided by interviewees about their organizations.

Once we mapped the standards, we validated the results with the author of the CDC 2.5.1 implementation guide, who is also a member of HL7, and incorporated his feedback into our final results. Validation included determining the appropriate segment of the standard for the barcoded information. We also validated the mapping with a pharmacy provider, which did not result in any changes. We also attempted validation with X12 provider working groups, the Centers for Medicare & Medicaid Services (CMS), EHR vendors, and IIS vendors but were unable to secure meaningful feedback.

6.1.3 Interviews with Stakeholder Representatives

We supplemented the standards review with semistructured interviews with stakeholders. We interviewed representatives from stakeholder associations Association of Immunization Managers (AIM), American Immunization Registry Association (AIRA), American Academy of Family Physicians (AAFP), and AAP; 18 out of the 20 IIS that received interoperability grants from CDC; IIS software vendors and implementers; physician providers; other immunization providers; and EHR vendors. The purpose of the interviews was to understand stakeholder perspectives and concerns about modern barcoding of vaccine products. These were recorded and transcribed for analysis.

Interviews generally lasted 45 minutes. Many interviewees were unfamiliar with the scope of AAP's 2D barcoding initiative; thus, interviews often began with an educational component. Lessons were also gleaned from those with experience in similar areas, such as other types of barcoding or different automated input devices (e.g., scanners, weight-measurement devices, signature pads).

6.2 Standards Mapping Results

Figure 6-1 illustrates a broad overview of the immunization process, stakeholders affected, and systems. If a provider uses the barcode when the vaccine is ordered and administered at the point of care, some or all manual documentation processes will be replaced by automated ones. Rather than writing down or hand-keying into computer systems the product number, manufacturer ID, expiration date, lot number, and administration date, these data will be noted by scanning a 2D barcode and tying it to other information. For

example, the administration date is not included in the label but can be construed from the scan date. Similarly, the GTIN does not automatically populate the product and manufacturer information, but that information can be extracted from it. Downstream, this information will populate a variety of systems such as EHRs, IIS, billing, Vaccine Adverse Event Reporting System (VAERS), and other reporting systems. In addition, it will be used to pull up reports such as vaccination records for schools.[2]

The importance of interoperability is emphasized by the number of systems and processes, as indicated in Figure 6-1. A variety of different standards and systems are involved at different stages in the data flow for immunization. The boxes are color coded by stakeholder, and the relevant standards are listed in the figure in a red dotted box.

The balance of this section reviews

- the one-to-many relationship between the GTIN and vaccine product fields in different standards,
- the difficulty of parsing the NDC components from NDCs embedded in GTINs, and
- emerging issues associated with using the NDC and legacy codes in information systems.

6.2.1 One-to-Many Relationship of GTIN to Vaccine Product Fields

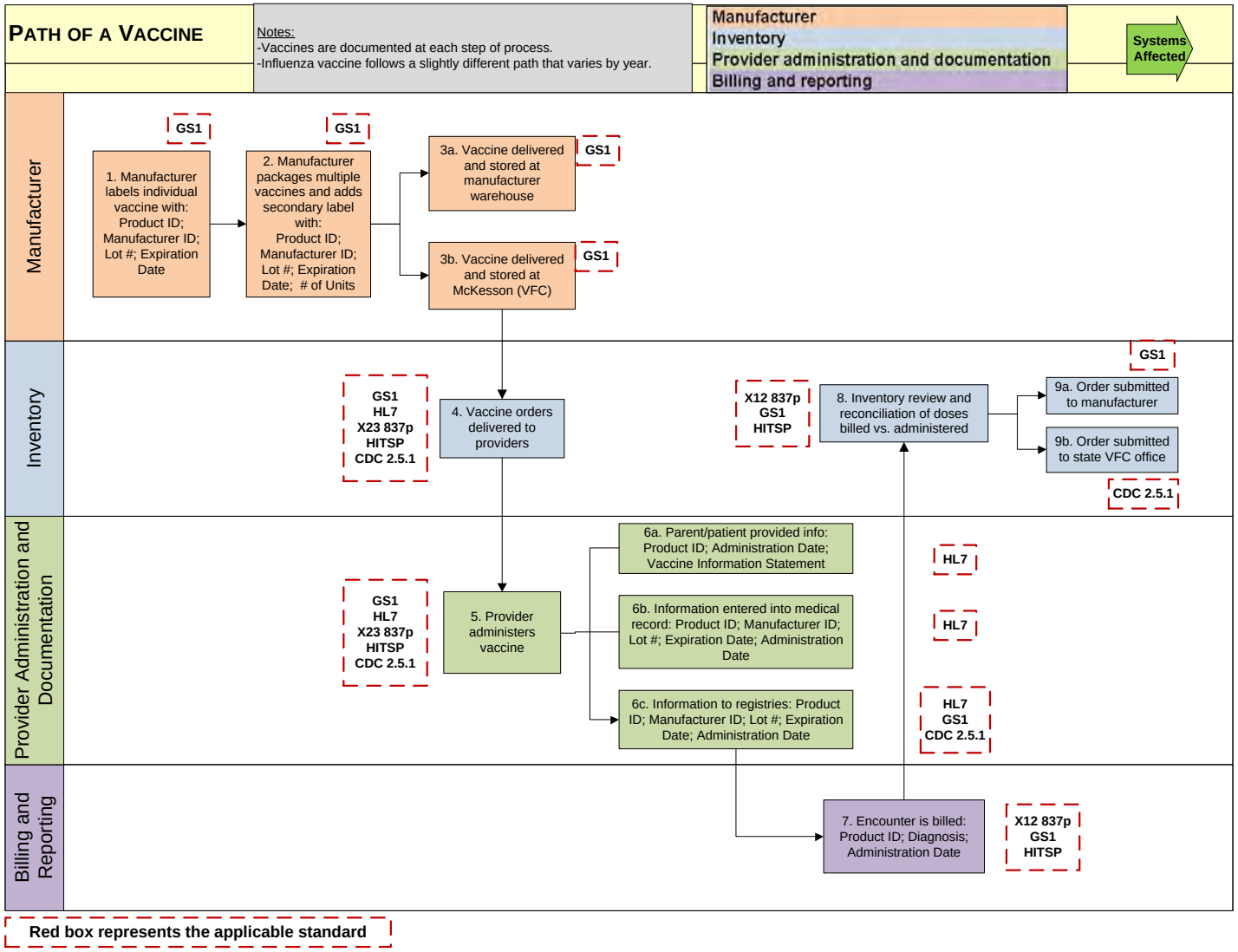
Table 6-2 provides a summary of how different 2D barcode elements will be transmitted across standards. The GTIN contains the NDC as a continuous character string. Yet because the NDC has three components, and some standards require vaccine product data to be in these three discrete segments, the GTIN does not map directly to individual fields across standards (FDA, 2011). In other words, there is a one-to-many relationship between the GTIN and most data exchange standards' vaccine product fields.

Unless the NDC can be parsed from the GTIN, a look-up table between the GTIN and a segmented NDC code will be required to facilitate electronic data exchange. A look-up table will facilitate meeting meaningful use criteria, which specifically cite the CDC implementation guide, and IIS reporting requirements.

In contrast to the GTIN, the expiration date and lot number map directly to individual fields across standards and, therefore, do not present similar challenges. There is no expiration date or lot number information in the X12, HITSP, or pharmacy EDI standards, which is to be expected because the expiration date and lot number of a given vaccine are not necessary for billing purposes.

[2]Although the general process is the same for flu, ordering differs because the flu vaccine is often ordered seasonally rather than on a just-in-time basis. Thus, flu inventory management does not occur relative to inventory review and reconciliation in the same way as it does for vaccines that are ordered throughout the year.

Figure 6-1. Immunization Processes, Systems, and Standards



(continued)

Figure 6-1. Immunization Processes, Systems, and Standards (continued)

Vaccination Step		Systems Affected at Each Vaccination Step							
		A. Labeling (Mfg)	B. Inventory (Mfg)	C. Inventory (CDC)	D. Immunizing Pharmacies	E. Immunization Information Systems (IIS)	F. Electronic Health Records (Providers)	G. Practice Management Systems (Providers)	H. Claims (Providers, Health Plans)
1	Mfg Labels Vaccine	x							
2	Mfg Packages Vaccine		x						
3a	Vaccine Delivered to Mfg Warehouse		x						
3b	Vaccine delivered to McKesson		x	x					
4	Vaccine Ordered, Delivered to Provider		x			x			
5	Provider Administers Vaccine				x		x	x	x
6a	Parent/Patient-Provided Info				x		x		
6b	Information Input into Medical Record				x		x		
6c	Information Supplied to IIS				x	x	x	x	
7	Administered Vaccine is Billed				x				x
8	Inventory is Reconciled: Billed vs. Administered		x			x			x
9a	Order Submitted to Mfg		x	x		x			
9b	Order Submitted VFC Office		x	x		x			

Manufacturer
Inventory
Provider administration and documentation
Billing and reporting

Table 6-2. Summary Mapping Table[a, b]

GS1	FDA's National Drug Code	HL7—Barcoding Message Segment	2.5.1 Implementation Guide	X12—837P Transaction	HITSP Immunization Messages	NCPDP
Global Trade Item Number (GTIN)	Label code	Administered code	Substance manufacturer name	Labeler code	Substance manufacturer	Labeler code
	Product segment	Substance manufacturer name	Administered code	Product segment	Administered code	Product segment
	Package segment	Administered barcode identifier	Administered drug strength volume	Package segment		Package segment
			Administered drug strength volume units			
Expiration date (YYMMDD)		Substance expiration date	Substance expiration date			
Batch or lot number		Substance lot number	Substance lot number		Substance lot number	

[a]The yellow cells denote how the GTIN is mapped, green denotes the expiration date, and orange denotes the lot number. Please note that there are two columns for HL7.

[b]The NDC within the GTIN is the information source for the other standards.

More detail about the fields listed in Table 6-2, including segment length and location in the standard, can be found in Appendix F's tables.

6.2.2 Review of NDC Construction

At the root of the challenge of mapping GTINs to fields across different standards is the construction of the NDC itself. If the NDC segments followed a fixed character length, then a decision rule could be written to extract segments of the NDC based on characters' positions. However, the labeler, product, and package segments do not have consistent field lengths, precluding the option of writing a decision rule.

The FDA does not issue complete NDC numbers. Rather, the NDC is a combination of three segments: labeler code, product code, and package code. Only the labeler code is assigned by the FDA. Because each manufacturer is permitted to create product and package codes, and the FDA does not require a specific field length for them, it is not possible to write automated logic to parse an NDC without delimiters into these three components. The FDA (2011) is aware of this issue and includes the following statement on its web site:

> Each listed drug product is assigned a unique 10-digit, 3-segment number. This number, known as the NDC, identifies the labeler, product, and trade package size. The first segment, the labeler code, is assigned by the FDA. A labeler is any firm that manufactures (including repackers or relabelers), or distributes (under its own

name) the drug. The second segment, the product code, identifies a specific strength, dosage form, and formulation of a drug for a particular firm. Different formulations or different strengths of the same formulation should be assigned different product codes. This means even if the same formulations of a drug product ultimately deliver different strengths of the active ingredient to the recipient, they should be assigned different product codes. Also, drug products that share the same formulation but have different product characteristics that clearly distinguish one drug product version from another cannot share the same product code under the same labeler code. The third segment, the package code, identifies package sizes and types. Different package codes only differentiate between different quantitative and qualitative attributes of the product packaging. Both the product and package codes are assigned by the firm. The NDC will be in one of the following configurations: 4-4-2, 5-3-2, or 5-4-1.

Based on the above rules, the following character string 1234567809 could refer to three hypothetical products, depending on the configuration chosen:

- 12345-678-09
- 1234-5678-09
- 12345-6780-9

All of these could be 1234567809 in the NDC segment of the GTIN with no delimiters between NDC segments.

A further complication is that the HIPAA standard is for an 11-digit NDC, not the 10-digit NDC used by the FDA. Because of this conflict, many information systems pad the labeler code, product code, or package code segments of the NDC with a leading zero instead of an asterisk. Thus, a product with a 5-digit labeler code may have a 4-digit product code and a 2-digit packaging code for some systems.

To resolve this conflict, for its internal use, the FDA uses an asterisk in either a product code or a package code. The asterisk simply acts as a placeholder and indicates the configuration of the NDC. The FDA does not use zeros as a delimiter because a zero can be a valid digit in the NDC. By storing the segments as character data and using the asterisk as a placeholder, the FDA eliminates the confusion. In the example, the FDA could store the segments as 12345-*678-09 for a 5-3-2 configuration or 12345-0678-*9 for a 5-4-1 configuration. Because the asterisk is for FDA internal use and the GTIN cannot accommodate special characters, there must be another way to identify the three NDC segments.

6.2.3 Review of NDC Position in the GTIN

GS1 does not pad NDCs with zeros, use delimiters, or make any other adjustments. Rather, the GS1 standard is to use the 10-digit NDC code free of delimiters. This means that a given

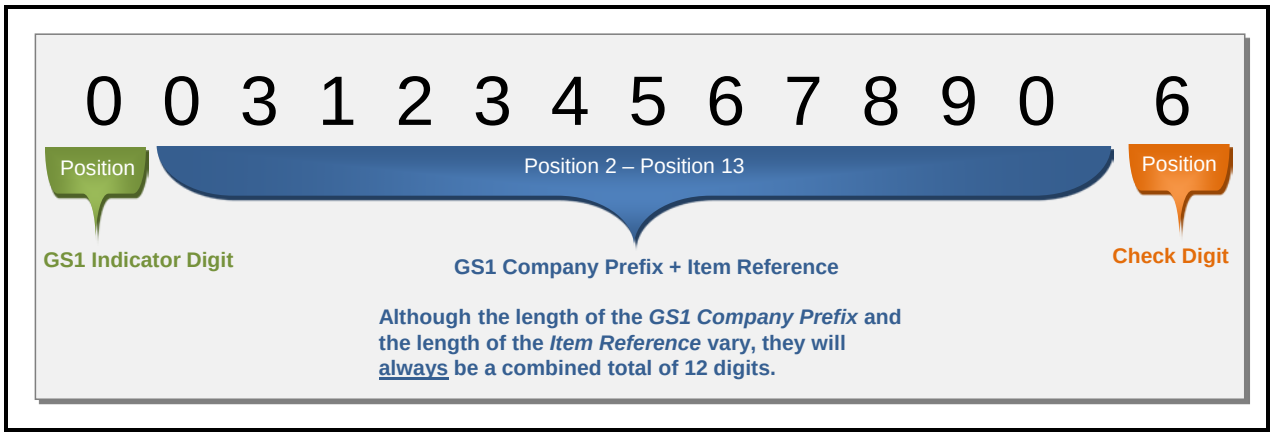
10-character NDC code within the GTIN may not be directly linkable to a single vaccine product. GS1 does not support or recommend parsing the GTIN or NDC (when it is presented without delimiters); it recommends that these codes be read as a whole and not be parsed to reduce the chance of confusion due to variable-length fields and to avoid the risk of incorrect parsing.

GS1 maintains a registry of unique GTINs that refer to only one specific product, and it does so by using indicators and the NDC to construct the GTIN. All firms must submit their requested GTINs to GS1 to verify that there are no duplicates and to ensure that the GTIN is not duplicated in the future.

Figure 6-2 was taken directly from the GS1 (2011a), *Draft US Guideline for Application of GS1 DataMatrix Barcodes for Vaccines at Point of Care*, to illustrate how the NDC is encoded within the GTIN. It shows the specific positions of each character:

- Position 1: A one-digit indicator (value from 0 to 8).
- Position 2: Always zero.
- Position 3: Always 3 to indicate that what follows is the NDC number.
- Positions 4 through 13: Always the 10-digit NDC code. The NDC labeler code (with the 3 prefix) must be registered with GS1 US to be valid as a GTIN.
- Position 14: Check Digit (a Modulo 10 data check character calculated from the first 13 digits of the GTIN).

Figure 6-2. National Drug Code (NDC) Embedded in Global Trade Item Number (GTIN)



Source: GS1 Healthcare US

The following example demonstrates how the lack of delimiters would work. The NDC code for Fluzone is 49281-0388-15. Table 6-3 shows how it would look if it were scanned by a reader.

Table 6-3. Fluzone NDC Embedded in GTIN

Field	Indicator	Always 0	Always 3 to Denote NDC is Next	10-digit NDC Code										Check Digit
Position Number	1	2	3	4	5	6	7	8	9	10	11	12	13	14
GTIN	0	0	3	4	9	2	8	1	3	8	8	1	5	x

As indicated by the table, the 5-4-2 formatting of the NDC code is lost in scanning and the NDC would come across as 10-digit ASCII text between positions 4 and 13. Systems that rely on the delimited NDC such as the CDC Vaccine Tracking Systems (VTrckS), EHRs, and IIS and reporting would require an additional service.

The FDA has procedures in place to ensure that there are no duplicate NDCs (Perkins, 2012). We also reviewed the NDC structure for all vaccine products in the FDA database as of June 15, 2011, to learn how manufacturers constructed their NDC codes. The FDA database includes 339 NDCs for vaccine products. Table 6-4 outlines the typical NDC structure for major vaccine manufacturers. The asterisk in the column denotes that the manufacturer includes an asterisk before the digit for that particular component of the NDC.

6.2.4 Use of NDC, CVX, and MVX in Information Systems

An undercurrent to reviewing the implications of the 2D barcode for standards-based data exchange is legacy issues associated with the NDC, CVX, and MVX. Traditionally, the NDC has not been used in immunization documentation, reporting, and tracking. Although some systems are able to accommodate the NDC, most use CDC's product identifier (CVX) and manufacturer identifier (MVX).

IIS, for example, require the CVX, MVX, and lot number to document an immunization (CDC, 2011g). In the future, the NDC will be the cornerstone of inventory control systems (CDC, 2011a); thus, it is important that techniques be developed to use the NDC code.

Currently, CDC maintains mapping tables between the components of the NDC and the CVX and MVX codes (CDC, 2011e), allowing systems to read the NDC and then assign the appropriate CVX and MVX codes via a look-up table. The current CDC mapping tables are not appropriate for extracting the NDC or its components from the GTIN because they do not account for varying field lengths for the three NDC segments. Because GS1 is an

international standards organization and the CVX and MVX are codes specific to CDC and the United States, they will not be supported by GS1. A mapping table of GTIN to NDC will be necessary to support GTIN to CVX and MVX. These mapping tables should support all vaccine products on the market both on the public side as well as the private-purchase side.

Table 6-4. NDC Structure for Vaccine Products by Licensee in the FDA Database

Manufacturer or Repackager	Labeler Digits[a]	Product Digits[a]	Package Digits[a]
Berna Biotech Ltd.	5	4	*1
Cardinal Health	5	4	*1
CSL Biotherapies, Inc.	5	*3	2
Dispensing Solutions, Inc.	5	4	*1
Emergent Biodefense	5	*3	2
GSK	5	*3	2
ID Biomedical Corporation	5	*3	2
Intercell Biomedical, Ltd.	5	*3	2
Medeva Pharma, Ltd.	5	*3	2
MedImmune Vaccines, Inc.	5	*3	2
Merck	5	4	2
Novartis	5	*3	2
PD Rx Pharmaceuticals, Inc.	5	*3	2
Physicians Total Care, Inc.	5	4	*1
Rebel Distributors Corp.	5	*3	2
Research Foundation	5	*3	2
Sanofi Pasteur	5	*3	2
Wyeth	5	4	2

[a]The asterisk denotes that the manufacturer includes an asterisk before the digit for that particular component of the NDC.

6.2.5 Other Considerations

Current vaccine barcoding efforts are occurring simultaneously with efforts to promote adoption of EHRs by primary care providers. The benefits of barcoding are predicated on providers' ability to integrate technology use in their practices. The Office of the National Coordinator (ONC) recently reported that 80% of hospitals (AHA, 2009) and 41% of office-based physicians (Hsiao et al., 2010) intended to take advantage of incentive programs to adopt and demonstrate meaningful use for certified EHRs (ONC, 2011). This effort is partially due to federal incentive programs that are funded by the Health Information Technology for Economic and Clinical Health (HITECH) Act (HITECH Act, 2009), which was enacted as part of American Recovery and Reinvestment Act (ARRA) (Douglas & Larrabee,

2003). This program provides support and incentive payments to be given to eligible professionals who demonstrate meaningful use of certified EHRs (ONC, 2011). Immunizations are considered part of the meaningful use criteria. Thus, these funding streams and incentives are an impetus for increased submission of immunization information to IIS.[3]

Barcoding shows great promise for patient safety and quality. However, barcode standards cannot automate all vaccine documentation or solve existing problems. For example, many participants in the interviews asked about including Vaccines for Children (VFC) Program status in the barcode. Because vaccine products are not identified by funding source at the point of manufacture, it is not possible to include that information on the barcode. VFC participants were interested in including VFC identifiers in the 2D barcode to facilitate requirements for separately managing publicly and privately purchased vaccines.

Currently, VTrckS has provisions for manual checking of inventory. For Direct VTrckS users, updates would need to be made to the system so users can scan the barcode to aid in inventory tracking.

Interview participants cited existing concerns about products with multiple lot numbers, such as lyophilized vaccine products and combination vaccines. One example is Pentacel. The DTap-IPV is one component and the Hib is the other, each with its own identifier. In the antigen-diluent products, a lot number is associated with the antigen and one is associated with the diluent, which means there are multiple identifiers and there will be multiple 2D barcodes, packages, and numbers. Systems can accommodate one set of information, but not both. Currently, the practice is to document the antigen's information and not the diluent. It should be decided whether this practice should continue. If it is to continue, the practice of documenting only one of the items, and if so which one, should be codified and documented in educational materials. Also, methods should be put in place in case the incorrect item is scanned so that the incorrect information can be replaced with the appropriate information. If this practice is not to continue, then guidance is required indicating such.

Another reason for multiple product identifiers and lot numbers is repackaging, which occurs for a small number of vaccines. In this case, the repackager applies its own lot number and NDC, as it does for drugs. In this scenario, we expect the manufacturer label to be superseded by the repackager label, which is the practice today. This means that the repackager would require its own GTIN to generate the barcode. Repackagers are required

[3]To help providers with their technology adoption and to meet meaningful use criteria, a system of Regional Extension Centers (RECs) was established. Their charge is to support primary care clinicians. These RECs are a source of training, guidance, and technical assistance to these providers to help them with their implementation efforts from planning through evaluation and attestation of meaningful use.

to maintain a database of their product identifiers and lot numbers for recall purposes, and they will continue to do so. We do not expect that current procedures would change.

6.3 Limitations

Document review, interviews, and limited observations have yielded much information and contributed to understanding how the 2D barcode will be implemented. As in all feasibility studies, unexpected situations may arise in actual implementation based on unanticipated or infrequent data exchange or operational requirements. In addition, note that we attempted mapping validation with a variety of stakeholders but not all governmental agencies or private firms were able to devote resources to provide this level of detailed review. However, we did present the results at a health care informatics conference where a variety of stakeholders were present. We also were unable to discuss the project with representatives from the FDA or CMS directly. It is possible that representatives from those agencies might have insight that could contribute to implementation. To resolve these concerns, we worked with representatives from a variety of associations that span the immunization process. We also attended the National Immunization Conference (NIC) and discussed the effort with participants there to seek multiple perspectives.

6.4 Conclusions

Standards-based data exchange of the GTIN, expiration date, and lot number as captured through the 2D barcode has the potential to improve data quality and efficiency when documenting vaccine data. Improvement is predicated on a mapping table or other service so the GTIN can be mapped to the delimited NDC, CVX, and MVX. Mapping the expected GS1 2D barcode standard for vaccine products across the data exchange standards used by different stakeholders is a critical first step in implementation. It will help facilitate information exchange by outlining where the information in the barcode would fall in each standard, providing those who will implement the barcode the specifications necessary to accommodate receiving and interpreting the GTIN.

Over the near term, for implementation to be successful, the following will be necessary: education and outreach, dissemination of technical specifications and business requirements for data exchange, and collaboration with a variety of stakeholders. Accordingly, stakeholders such as the CDC, FDA, AAP, GS1, AIM, AIRA, and other provider organizations must work in concert. This is of particular importance given the advent of new technologies such as updated syringes and radio-frequency identification (RFID). In addition, regulatory changes such as serialization and updated meaningful use criteria may bring further changes. Thus, setting the foundation for collaboration and information sharing now will help with a smooth implementation and update efforts for the 2D barcode.

7. IMPACTS AND IMPLICATIONS FOR OTHER STAKEHOLDERS IN THE U.S. IMMUNIZATION ECOSYSTEM

Implementing 2D barcoding will likely result in a variety of direct and indirect impacts on immunization programs, public health data systems, pharmacies, retail-based clinics (RBCs), and their associated stakeholders. Here, we review anticipated impacts and implications for these parties identified through our literature review and through key informant interviews.

7.1 CDC 317 Immunization Program Grantees

The 64 grantees of the Centers for Disease Control and Prevention's (CDC's) 317 Immunization Grant Program (317 Program) are responsible for implementing immunization programs in 50 states, six cities, and eight current or past territories.[1] Their responsibilities include public vaccine provision, oversight of provider quality, and IIS support (CDC, 2007). Barcoded vaccines can potentially affect aspects of each of these responsibilities:

- Vaccine provision: Immunization grantees provide vaccines for administration through the Vaccines for Children (VFC) Program, as well as state and local purchasing mechanisms. Thus, immunization grantees are responsible for vaccine management in one way or another. Moreover, immunization program managers who participated in key informant interviews asserted that whenever there is a concern related to vaccines or their provision, the immunization program manager is asked to respond. 2D-barcoded vaccines' capacity to facilitate vaccine management through use of automated product identification promises to benefit immunization programs through greater efficiency and accuracy of data.

- Oversight of provider quality: Immunization grantees' oversight of provider quality includes strategies such as AFIX. AFIX (Assessment Feedback Incentives and eXchange) is a quality improvement strategy to improve standards of practice at the provider level. 2D-barcoded vaccines' potential to improve record keeping and data exchange offers promising means to improve AFIX. Such improvements could permit immunization programs to reallocate resources necessary for AFIX to other immunization activities.

- IIS support: IIS have been recognized as a data resource that can facilitate achieving immunization surveillance goals (Guide to Community Preventive Services, 2011). Like other data systems, IIS rely on data population and accuracy for success. 2D-barcoded vaccines' capacity to automate or otherwise improve the efficiency and accuracy of data capture will strengthen IIS capacity.

The impact of 2D-barcoded vaccines on IIS is of particular importance given the role IIS may play in demonstrating meaningful use. One of the criteria for meaningful use payments

[1]The six cities are Chicago, the District of Columbia, Houston, New York City, Philadelphia, and San Antonio; the eight current or past territories are American Samoa, Federated States of Micronesia, Guam, Marshall Islands, Northern Mariana Islands, Palau, Puerto Rico, and the U.S. Virgin Islands.

under the American Recovery and Reinvestment Act (ARRA) involves immunization messaging. Thus, providers who are implementing electronic health records (EHRs) and are anticipating meaningful use are incentivized to submit HL7 messages relaying immunization status.

In an effort to better understand the costs and benefits of 2D-barcoded vaccines on IIS, we elicited feedback from members of the Association of Immunization Manager's (AIM's) immunization registry working group and the American Immunization Registry Association (AIRA). AIM represents the 64 managers of CDC's 317 Immunization Grant Program. Its immunization registry working group is composed of immunization program managers with particular interest and/or experience related to IIS. AIM convened a discussion with the immunization registry working group to discuss costs and benefits of 2D barcodes and the implications for registries and immunization programs. Ten program managers also responded to a short e-mail request from AIM in May 2011 soliciting input on the following questions:

- What are some of the estimated costs associated with integrating barcodes with your IIS?
- What do you foresee are the costs associated with implementing barcodes in provider offices?
- What do you foresee are the costs associated with sustaining barcodes in provider offices?
- Do you have any other comments regarding the benefits, challenges, costs, or feasibility of barcodes?

7.1.1 Estimated Costs Associated with Integrating 2D Barcodes with IIS

Only two immunization programs offered judgments as to whether they expected the costs to outweigh benefits. Most reviewed the issues from their vantage point as program and IIS managers. Responding programs anticipate costs to fall within five principal categories:

- IIS modification and enhancement to accommodate acceptance of 2D barcode scanner functionalities,
- training of IIS staff,
- ongoing technical assistance from IIS staff to providers,
- ongoing system maintenance, and
- ensuring all IIS use information and business rules are aligned with barcode scanning.

Implementation costs would vary depending on preexisting IIS capabilities, but their estimates varied significantly because 2D barcode reading had not been costed out yet. Some jurisdictions have preexisting capabilities that were developed to support driver's license scanning. The comprehensive cost for one such program was $135,000 with a 10% annual maintenance cost, according to a representative. In this particular case, extending the features to accommodate reading scanner output and placing the data in the proper sequence to fill fields in the IIS may not be significant.

Some IIS vendors—Scientific Technologies Corporation (STC) and the Wisconsin Immunization Registry (WIR) consortium—have more than 20 jurisdictions as customers (WIR, 2010; Scientific Technologies Corporation, 2011). Vendors with many customers may be able to distribute programming-related costs over multiple jurisdictions, though costs related to reviewing and adjusting business rules would likely not be affected by such economies of scale. Despite shared platforms, there may still be customization costs for making adjustments jurisdiction specific.

Thus, in essence, the cost for IIS will vary by jurisdiction depending on existing capabilities and IIS business and contract models. Although programs were able to provide some guidance on expected costs, more detailed investigation into existing functionalities and provision of detailed technical specifications for IIS is required to ascertain costs.

Other costs are possible as well, depending on how barcode usage is rolled out. Some IIS staff may need to be trained on how to use scanners and software and may need to review EHR/IIS interfaces to support individual practices. IIS may also have to develop a training module for delivery to practice staff, which could be about $1,000 if it is an online program, according to two IIS. The largest possible cost could be for purchasing scanners, especially for highly centralized programs.

7.1.2 Expected Costs Associated with Implementing and Sustaining Barcodes in Provider Offices

Programs anticipate that the following costs could be associated with implementing and sustaining barcode use in provider offices:

- purchase of scanners and periodic replacements,
- modification or enhancement of EHRs to accommodate barcode scanning,
- staff training,
- miscellaneous scanner maintenance costs, and
- maintenance of connections to state IIS or any barcoding-specific software.

In addition, they anticipated that there could be costs for software; however, RTI has preliminarily determined that most vendors are likely to include 2D barcode reading support under their annual licensing agreements. Our model assumes that the scanner purchase costs are borne by practices.

7.1.3 Other Comments Regarding Benefits, Costs, and Feasibility

Program representatives offered perspectives on implementation, costs, benefits, and other considerations. They expect there to be challenges getting practices prepared and starting to use the barcodes. Concerns include competing priorities for practices, initial costs for scanner purchases, training, and installations. Some practices may require substantial support and coaching. These representatives also indicated that it is unlikely that public programs will be able to provide barcode scanners to practices at no cost.

Once practices have implemented barcode scanning, there may be issues supporting ongoing training due to staff turnover and maintenance of devices. Benefits, however, could include fewer mistakes in the data from improved record keeping and better vaccine inventory management. 2D barcode scanning could be of great use during mass immunization clinics. Overall, implicit in their remarks was the importance to review the change management process carefully for IIS; ensure that technical specifications are set, understood, and communicated; and prepare a training program carefully.

7.2 American Academy of Pediatrics (AAP), CDC, and National Organizations

Whereas the impacts and implications for regional immunization programs are emerging as the reality of 2D-barcoded vaccines draws near, activities have occurred at the national level to lead, assess, and coordinate the transition from linear to 2D barcodes. The activities, and the costs associated with them, represent an allocation of resources that must be considered as part of the social cost. Historical and projected cost data were provided by AAP and CDC. Although other organizations in the public sector (e.g., GS1, the FDA, and various HHS agencies) have been involved in the barcoding initiative, known costs as of December 2011 have been largely incurred by AAP and CDC.

AAP has led and coordinated the vaccine barcoding initiative since 2009, convening stakeholders, setting the strategic direction, developing guidance for manufacturers and clinicians, and advocating for the initiative at the FDA. AAP has also worked closely with GS1 Healthcare US to issue AAP-endorsed technical guidance. AAP also expects to design and roll out education programs to support implementation and use of 2D barcodes. Resources provided by AAP have averaged about 0.3 to.5 full-time equivalent (FTE) per year since 2009, distributed among pediatricians and AAP immunization initiatives managers' time. This level of effort is expected to continue through 2014.

CDC has complemented AAP by supporting feasibility studies, technical assessments, and analyses of the impacts and implications of using 2D barcodes on standards-based data exchange. Costs have included the assignment of personnel to serve as technical monitors on this technical feasibility and economics study and personnel to lead and implement a pilot and technical assistance program. CDC staffing has been approximately 0.3 FTE for 2010 and 1.5 FTE for 2011 through 2013.

AAP and CDC costs for leading the implementation of 2D barcoding for 2009 through 2014 are estimated to be at least $8.6 million, of which 12% is labor effort expended directly by AAP and CDC and 88% is for technical feasibility studies, economic analysis, and implementation and technical assistance (Table 7-1).[2] Although costs may have been incurred by other organizations, these cost data were not available, and it is assumed that the majority of costs incurred by national parties have been incurred by AAP and CDC.[3] Public-sector costs were not known for 2015 and later years.

Table 7-1. Known AAP and CDC Costs for the Barcoding Initiative

	FTE[a]	Labor Value ($ thousands)	Services ($ thousands)	Total ($ thousands)
2011	1.80	277	1,560	1,837
2012	1.80	277	3,584	3,860
2013	1.95	299	2,389	2,688
2014	0.25	33	—	33
Total		**1,006**	**7,624**	**8,631**

[a]FTE (full-time equivalent)

7.3 Information Systems Vendors

EHR vendors will also have to make changes to accommodate the barcode. Changes include support for the scanners themselves and for integrating scanned data into patients' records. In order for data to be placed in the EHR, an input device, such as a keyboard, is necessary. A scanner is another type of input device. In order for the system to recognize it as such, some work is necessary to update systems. One vendor noted that the level of effort is approximately 40 to 80 hours per product family (products in the same family often share component software code).

[2]Except for services contract values, CDC and AAP expenditures were provided in FTEs, which we then monetized using burdened Bureau of Labor Statistics (BLS) Occupational Employment Statistics wage rate data for pediatricians, social scientists and related workers (project managers) in social service organizations, and epidemiologists employed by the federal government (BLS, 2011b).

[3]Costs incurred prior to 2011 were treated as sunk costs. All dollar values are in real terms (2010).

In addition to the scanner itself, EHRs must accommodate how the data will be used. This means that the information that is scanned must be housed in the system and integrated with its software. For example, if an EHR has clinical decision support functionality, then it can use the scanned data to check against the doctor's order and to check against best practices for immunizations. In addition, the information can be used for reporting such as school reports, billing, and inventory. EHRs must be able to recognize the scanned data and integrate it with existing functions and software. Because this represents a change in how systems will be used, associated training must be provided to end users as well.

IT vendor costs to modify their products are not included in our economic model because it is not yet known how many EHR vendor product families would be modified to support barcode reading. Although not insignificant, the overall proportion of costs borne by EHR vendors would be small compared with other stakeholders' costs and benefits. At 15 product families, and using the 80-hour upper bound of the programming time requirement, the cost would be approximately $120,000, assuming a loaded hourly wage rate of $100. Further investigation was performed with EHR vendors to inquire about the revenue models that may be used to recoup these costs, or if these costs are low enough that they will be absorbed under provisions for software updates pushed to licensees. The EHR vendors with which we spoke expect that these changes would be included as part of the annual licensing agreement and not be a supplemental cost.

7.3.1 Public Health Agencies

Public health agencies (such as local health departments [LHDs] and immunization programs) are responsible for collecting and reporting sizeable amounts of immunization data for a variety of systems. Thus, the potential for improved efficiency and accuracy in data collection associated with 2D barcoding is very appealing. Nevertheless, numerous indirect impacts are anticipated when implementing 2D barcoding. The two issues that appear most relevant to this discussion are data integration and limited resources/technology.

The challenge of integrating data collection and reporting systems was identified repeatedly in the course of key informant interviews, group discussions, and informal communication. Public health agencies commonly report data to IIS. In our stakeholder interviews, many referred to public health agencies as having poor information technology systems and capabilities. As a result, what may be challenging in any setting may be particularly daunting in settings where technology has not been well integrated. However, the minority of public health agencies that are technologically advanced may face more challenges because they may have to spend more resources integrating their existing systems with 2D barcodes.

Related to integrating data systems is the implication of resources. Among the first responses from immunization program managers when discussing vaccine barcoding was

"Who's going to pay for it? Who's going to deal with providers?" In many areas, public health agencies not only provide immunizations, but they are also ultimately responsible for managing the overall immunization system. As a result, public health agencies anticipate that they may need to provide technical assistance for their use. This is anticipated to be especially true for VFC and other providers who rely on public financing.

7.4 Impacts and Implications for Complementary Immunization Providers

We define complementary immunization providers as locations, organizations, and individuals that provide immunization services that otherwise may be referred to as "nontraditional providers." Examples of such providers include locations such as schools and retail stores, organizations such as visiting nurse groups, and professionals such as pharmacists. Most of these providers offer immunization services in addition to other wellness or clinical services. The Department of Defense's immunization activities are also regarded as complementary providers but are outside the scope of this report.

As mentioned in the literature review in Chapter 2 of this report, there is a paucity of data reporting the number or proportion of immunizations administered by a given provider and/or in a given location. Based on information from the literature review and the key informant interviews, we anticipate that 2D-barcoded vaccines will affect and have implications for the vast majority of immunization providers. Based on our understanding of the literature included in Chapter 2 of this report and interpretation of key informant interviews, providers who are already using electronic data collection are the most likely to adopt 2D barcode technologies. Providers who do not use electronic data collection systems or who are mobile may be less likely to adopt barcode technologies.

It has been widely observed that increasing numbers of individuals are receiving immunizations in nontraditional locations (e.g., retail stores from nontraditional providers such as pharmacists [CDC, 2011f]). In Table 7-2, we summarize the characteristics of these complementary provider groups and aspects of their practice for which 2D-barcoded vaccines may have implications. The characteristics we include are those we anticipate may affect the use of 2D barcodes. The rationale is summarized in Table 7-3.

7.4.1 Pharmacies

We expect that pharmacies, especially large chains, will use the 2D barcode. Like their counterparts at RBCs, most pharmacies have systems in place for managing inventories and for processing documentation electronically (see Chapter 6).

Although a small sample size, our interviews with two independent pharmacies and one large chain suggest that uptake among pharmacy immunizers will be high.

Table 7-2. Characteristics of Complementary Provider Groups

Complementary Immunization Provider and Definition	Characteristics						
	Fixed Location	VFC Provider	Use of Electronic Health Records	Use of Electronic Billing	Current Use of Barcodes	Use of Multidose Vial	Health Care Personnel Vaccinating
Hospitals Inpatient or outpatient medical institution	Yes	Sometimes	Often	Usually	Often	Variable	Physicians Nurses Pharmacists
Pharmacies Independent or chain pharmacy. Does not include RBCs that may be located within confines of the pharmacy	Yes	Sometimes	No	Often	Often	Variable	Pharmacist
Retail-Based Clinics Clinics that offer prescribed limited services. May be located within larger retail store	Yes	No	Often	Usually	Often	Variable	Nurse or mid-level practitioner
Visiting Nurses Members of visiting nurses association. Primarily provide on-site immunization clinics. Often located in settings such as retail stores, shopping malls, senior centers, or other convenient locations	No	Sometimes	No	Often	Variable	Variable	Nurse
Immunization Clinic Providers Provide on-site immunization clinics. Often located in settings such as retail stores, workplaces shopping malls, senior centers, or other convenient locations	No	Sometimes	No	Sometimes	Variable	High	Nurse

(continued)

Table 7-2. Characteristics of Complementary Provider Groups (continued)

Complementary Immunization Provider and Definition	Characteristics						
	Fixed Location	**VFC Provider**	**Use of Electronic Health Records**	**Use of Electronic Billing**	**Current Use of Barcodes**	**Use of Multidose Vial**	**Health Care Personnel Vaccinating**
Health Departments/Public Clinics Considerable variation nationally. In some areas, health departments provide no direct clinical services; in some places, LHDs have established immunization clinics	Often	Often	Occasionally	Occasionally	Variable	Variable	Nurse
Travelers' Clinics (e.g., Passport Health) Provides consultation for international travelers and vaccines necessary for travel abroad (including those recommended for nontraveling adults). May provide on-site immunization clinics.	Usually	No	No	Sometimes	Sometimes	Variable	Nurse or mid-level practitioner

Table 7-3. Considerations for Complementary Immunizers

Characteristic	Relevance to Barcoded Vaccines
Fixed location	Interviewees explained that immunization clinics that were located in a fixed geographic location (i.e., a public health clinic) were more likely able to have the physical capacity to adopt a new technology such as 2D scanners than an immunization clinic in a temporary location, such as a public library or shopping mall.
VFC provider	VFC providers have established data collection requirements. Given the nature of these requirements, many interviewees inferred that any means to facilitate the data collection and reporting process such as 2D barcodes, would be appealing.
Use of EHRs	An EHR is required to fully leverage all the benefits that may result from 2D-barcoded vaccines.
Use of electronic billing	Data from vaccine barcodes can be uploaded to electronic billing systems.
Health care personnel vaccinating	In addition to the labor cost-related implications, there are also implications related to the type of training that would be required for different personnel to implement barcode technology.

As an example, for the flu campaign through March 2011, the retail pharmacy chain Walgreens administered 6.4 million flu shots (Walgreens, 2011). Assuming a documentation benefit of 30 seconds per dose and a fully loaded wage rate of $75.15 for a pharmacist (BLS, 2011b), time savings could have amounted to more than $4 million for this one organization alone, excluding any one-time adoption costs.

7.4.2 Retail-Based Clinics

RBCs are free-standing or located in pharmacies or large retail stores. RBCs are most often staffed by nurse practitioners or physician assistants who provide preventative services (like immunizations) and diagnosis and treatment of limited acute conditions. The Convenient Care Association (CCA) estimates that there are 1,200 RBCs located within 34 states. CCA represents 90% of RBCs, such as Target's Target Clinics, CVS Minute Clinics, and Walgreens' Take Care Clinics. A 2008 study reported that 19.7% of the 1.35 million RBC visits were for immunization services (Mehrotra, Wang, Lave, Adams, & McGlynn, 2008), and it appears that the role of RBCs as a source of health care will grow (Marketwire, 2011). RBCs' business model focuses on providing health care services that are high quality and low cost. Because RBCs are businesses, they are located where there is sufficient population to yield economic self-sufficiency; 88% of RBCs are located within a major metropolitan area (Pollack & Armstrong, 2009). CCA's membership guidelines include the use of EHRs and similar mechanisms whose efficiency promotes the business model of high quality and low cost. Given this, we anticipate that RBCs will likely adopt 2D barcodes. We anticipate that RBCs will face challenges when integrating barcoding into existing data systems, but that overall the anticipated long-term benefits from improved efficiency will outweigh the

short-term challenges of integrating the technology into existing systems. CCA believes that RBCs will adopt use of 2D barcodes.

7.4.3 Other Complementary Immunizers

Complementary immunizers such as visiting nurse groups may operate in a variety of locations, including senior centers, libraries, shopping centers, places of worship, and businesses. This variety and mobility means that there are logistical considerations that immunization providers in fixed locations do not face. For example, community immunizers must spend a considerable amount of time and resources simply moving supplies—including large insulated coolers that are required to maintain the cold chain. These logistical challenges mean that community immunizers are reluctant to bring with them any object that is more than they think is essential to providing immunizations (Personal interview with Steve Pellito, Maxim Health, January 7, 2011). Although most will directly bill Medicare, many operate primarily on a cash basis. In keeping with efforts to reduce paperwork and any activities beyond providing vaccination, stakeholders interviewed reported that many such immunizers may not report immunizations to IIS or other data systems. Thus, the potential benefits associated with implementing barcode technologies are less appealing to some community immunizers. Community immunizers with whom we spoke reported that they were unlikely to adopt 2D barcode technology.

7.5 Limitations

0ur assessment of the impact of 2D-barcoded vaccines on immunization stakeholders is limited because of the complexities of the U.S. immunization system. These complexities result in the limitations of the quantity and specificity of the information on which our assessment is based. In collaboration with CDC, we limited our focus to primary care physicians, who provide the majority of immunizations (pediatricians, family physicians, internal medicine physicians, and obstetricians-gynecologists [ob-gyns]) and complementary immunization providers (including public health agencies, community immunizers, RBCs, and pharmacists). Physicians and LHDs were surveyed; key informant interviews were conducted with those representing complementary immunization providers (visiting nurses associations, on-site immunization clinic providers, a large chain pharmacy, and RBCs). Despite focusing our assessment on these groups, the paucity of specific data reporting how many vaccinations are administered by which stakeholder group means that in many cases we can only suggest the relative impact of a given stakeholder group.

7.6 Summary

The impact of 2D-barcoded vaccines on immunization stakeholders varies according to the immunization provider and the location in which immunization services are provided. The success of implementing vaccine barcode technology depends on immunization providers integrating 2D-barcode scanning technology into current immunization practice. Providers

who are already using electronic systems for data collection and reporting are also anticipated to embrace 2D-barcoded vaccine technologies. For pharmacies and RBCs who already use electronic systems for tracking products (like pharmacies) or EHRs (like RBCs), the efficiency of using an electronic scanner to upload data is recognized as a means to reduce their costs. Providers who do not rely on electronic data collection and reporting systems are less likely to take advantage of 2D-barcoded vaccines.

LHDs have limited resources for acquiring or implementing new technologies. Although LHDs are generally eager to collect and report public health data, like other public agencies, LHDs are facing daunting economic challenges. As much as local health officials may recognize and aspire to achieve the potential benefits associated with 2D-barcoded vaccines, implementation of such technologies will likely be a considerable challenge. Although IIS will face costs associated with integrating data uploaded from barcoded vaccines, costs are outweighed by the anticipated benefits associated with IIS, which are populated with better-quality data.

Complementary immunization providers that are focused solely on administering vaccines, such as community immunizers who provide mobile vaccination clinics, appear to be less interested in implementing 2D barcode technologies. For these immunizers, the costs of implementation are seen as too great to make it worthwhile to change existing immunization and administrative practices.

In addition to considering the costs associated with different stakeholders' implementation of 2D barcode technologies, one must also recognize the differences in practice settings. In other words, one must consider not just the provider, but the practice as well. These differences influence aspects such as approaches to training, number of scanners required, and the costs associated with integrating barcode scanners into existing data collection systems. When considering the integration of 2D barcodes into immunization practice, consideration should be made regarding how hardware and software integrate with existing systems. Although stakeholders who already have EHRs and electronic data systems seem poised to readily adopt barcoded vaccines, integrating these new technologies into existing systems may, in fact, be as challenging (or even more so) for these stakeholders than for those without existing systems, and they may have to start from scratch.

8. SUMMARY RESULTS AND CONCLUSIONS

This summary chapter presents lower-bound economic impact results and several recommendations in light of the pending implementation of 2D barcodes for vials, syringes, and other primary packaging in the United States. We forecast between $326.3 and $348.5 million in net economic benefits between 2011 and 2023, including all known costs for manufacturers, provider adoption costs, and benefits from more efficient documentation.

We were unable to monetize all expected economic benefits. Rather than make a series of assumptions about reductions in extraimmunization, more efficient inventory management, and improved immunization surveillance and product recall, economic benefits associated with saving time during record keeping alone were used in the comparison with economic costs incurred by manufacturers, providers, and public-sector stakeholders. In contrast to benefits, economic costs were well defined. That the benefit-to-cost ratio (BCR) ranged between 2.7 to 2.8 under three adoption-rate scenarios indicates that even though this analysis took a conservative approach, implementation of 2D barcodes on primary packaging labels is socially optimal.

Economic benefits for reduced extraimmunization and improved immunization surveillance and product recall are, in part, predicated on the ability of immunization data to be populated within immunization information system (IIS), electronic health records (EHRs), practice management systems, and other software systems. Early in this study, we established as a focus reviews of data exchange standards to analyze how the data embedded within 2D barcodes would be translated across different standards and exchanged across different systems. It became apparent that there is a one-to-many relationship between a Global Trade Item Number (GTIN) in which the National Drug Code (NDC) is embedded and various standards' data fields for labeler, product, and packaging codes. In essence, whereas the GTIN contains items in one continuous string, other standards are structured to receive the delimited components of that string.

A recommendation we have for the Centers for Disease Control and Prevention (CDC), which is responsible for the immunization data exchange aspects under Health Level 7 (HL7), is to support and maintain a mapping of GTIN, NDC, MVX+CVX, and Current Procedural Terminology (CPT) to ensure that all stakeholders in the information systems ecosystem have access to accurate mapping tables that will be maintained consistently over time.

Our rationale for CDC maintaining the mapping is because CDC currently is responsible for HL7 implementation for immunization data exchange, and our recommendation extends current responsibilities rather than establishing new ones. We also believe that public-sector provision of the mapping, which would be an infratechnology, would be more cost-effective

than individual private companies developing and maintaining their own mapping. It also avoids risks associated with out-of-date mappings or organizations ceasing to support mappings, among others.

8.1 Summary Economic Impacts

Economic impacts were quantified prospectively for vaccine manufacturers, primary care providers, local health departments (LHDs), and public-sector stakeholders American Academy of Pediatrics (AAP) and CDC. We combined the economic benefits quantified under this analysis into the time series presented in Table 8-1.

Table 8-1. Comparison of Forecast of Quantified Net Benefits for Vaccine Manufacturers, Primary Care Providers, Health Departments, and Public-Sector Organizations

	Net Benefits (Million $)		
Year	**Scenario 1, Rate of Adoption Set by Survey**	**Scenario 2, Rate of Adoption Slowed 50%**	**Scenario 3, Rate of Adoption Slowed 67%**
2011	−9.60	−9.60	−9.60
2012	−19.16	−19.16	−19.16
2013	−36.55	−22.22	−17.43
2014	44.00	11.06	9.06
2015	44.67	44.57	22.54
2016	45.25	45.14	45.05
2017	45.65	45.65	45.56
2018	22.07	34.06	38.06
2019	46.36	34.42	38.43
2020	46.79	46.78	38.82
2021	47.27	47.24	47.21
2022	47.68	47.68	47.65
2023	24.10	36.09	40.09
Total	**348.53**	**341.71**	**326.29**

Note: Dips in benefits in 2018 and 2023 are associated with scanner replacement at the end of their estimated 5-year useful life. Annual scanner operations and maintenance expenses are estimated to be 7% of the purchase price of $300 per unit. Scanners are assumed to be replaced at 5-year intervals. Sums may not add to totals because of independent rounding.

We quantified costs for manufacturers, primary care and LHD providers, CDC, and AAP, but we present the benefits net of adoption costs from more efficient record keeping for immunizers under three scenarios. Because we included all known costs in the analysis, but only included quantified economic benefits for documenting immunization, the results are a lower-bound estimate. Benefits from improved inventory management and reductions in

extraimmunization are expected but were unable to be quantified at this time. The scenarios present a range of expected benefits because, although we expect practices to follow their stated preferences to use 2D barcodes, it is possible that they may not be able to follow their preference for when to do so. Therefore, we allowed the accrual of economic benefits to slow by 50% and by 67%, under the possibility that providers may take 2 to 3 times as long to begin using the barcodes.

When modeled at survey respondents' expected rate of adoption, total economic benefits are $348.5 million through 2023.[1] Despite slowing respondents' expected adoption by 50% and again by 67% in two alternative scenarios, net benefits remain positive.

8.1.1 Distribution of Quantified Economic Benefits and Costs among Stakeholders

Tables 8-2 through 8-4 present summary economic impacts by major stakeholder groups. At present, manufacturer, provider, and public-sector costs are fairly well defined. What this series of tables permits is a depiction of how different adoption rates for providers affect the accrual of economic benefits.

Table 8-2. Scenario 1: Forecast of Economic Benefits and Costs by Stakeholder, Rate of Adoption Set by Survey Results ($ Million)

	Providers			Manufacturers			Public-Sector Costs	Net Benefits
Year	Costs	Benefits	Net Benefits	Costs	Benefits	Net Benefits		
2011				7.65		−7.65	1.95	−9.60
2012				15.30		−15.30	3.86	−19.16
2013	48.87	20.21	−28.66	7.65	2.45	−5.20	2.69	−36.55
2014	1.85	40.93	39.08		4.94	4.94	0.03	44.00
2015	1.81	41.49	39.68		4.99	4.99		44.67
2016	1.69	41.90	40.21		5.04	5.04		45.25
2017	1.69	42.25	40.56		5.09	5.09		45.65
2018	25.67	42.61	16.94		5.14	5.14		22.07
2019	1.80	42.96	41.17		5.19	5.19		46.36
2020	1.77	43.32	41.56		5.24	5.24		46.79
2021	1.69	43.68	41.99		5.29	5.29		47.27
2022	1.69	44.03	42.34		5.33	5.33		47.68
2023	25.67	44.39	18.72		5.38	5.38		24.10
Total	**114.20**	**447.78**	**333.58**	**30.60**	**54.08**	**23.48**	**8.53**	**348.53**

Note: Occasional decreases in net benefits for providers are associated with scanner replacement at the end of their estimated 5-year useful life. Sums may not add to totals because of independent rounding.

[1]Note all dollar values are presented in real terms (2010).

Table 8-3. Scenario 2: Forecast of Economic Benefits and Costs by Stakeholder, Rate of Adoption Slowed by 50% ($ Million)

	Providers			Manufacturers			Public-Sector	
Year	Costs	Benefits	Net Benefits	Costs	Benefits	Net Benefits	Costs	Net Benefits
2011	—	—	—	7.65	—	−7.65	1.95	−9.60
2012	—	—	—	15.30	—	−15.30	3.86	−19.16
2013	24.44	10.11	−14.33	7.65	2.45	−5.20	2.69	−22.22
2014	24.52	30.67	6.15		4.94	4.94	0.03	11.06
2015	1.83	41.40	39.57		4.99	4.99		44.57
2016	1.75	41.85	40.10		5.04	5.04		45.14
2017	1.69	42.25	40.56		5.09	5.09		45.65
2018	13.68	42.61	28.93		5.14	5.14		34.06
2019	13.73	42.96	29.23		5.19	5.19		34.42
2020	1.78	43.32	41.54		5.24	5.24		46.78
2021	1.73	43.68	41.95		5.29	5.29		47.24
2022	1.69	44.03	42.34		5.33	5.33		47.68
2023	13.68	44.39	30.71		5.38	5.38		36.09
Total	**100.53**	**427.28**	**326.75**	**30.60**	**54.08**	**23.48**	**8.53**	**341.71**

Note: Occasional decreases in net benefits for providers are associated with scanner replacement at the end of their estimated 5-year useful life. Sums may not add to totals because of independent rounding.

Table 8-4. Scenario 3: Forecast of Economic Benefits and Costs by Stakeholder, Rate of Adoption Slowed by 67% ($ Million)

	Providers			Manufacturers			Public-Sector	
Year	Costs	Benefits	Net Benefits	Costs	Benefits	Net Benefits	Costs	Net Benefits
2011	—	—	—	7.65	—	−7.65	1.95	−9.60
2012	—	—	—	15.30	—	−15.30	3.86	−19.16
2013	16.29	6.75	−9.54	7.65	2.45	−5.20	2.69	−17.43
2014	16.35	20.49	4.14		4.94	4.94	0.03	9.06
2015	16.95	34.50	17.55		4.99	4.99		22.54
2016	1.78	41.79	40.01		5.04	5.04		45.05
2017	1.73	42.20	40.47		5.09	5.09		45.56
2018	9.69	42.61	32.92		5.14	5.14		38.06
2019	9.72	42.96	33.24		5.19	5.19		38.43
2020	9.75	43.32	33.58		5.24	5.24		38.82
2021	1.75	43.68	41.93		5.29	5.29		47.21
2022	1.72	44.03	42.32		5.33	5.33		47.65
2023	9.69	44.39	34.70		5.38	5.38		40.09
Total	**95.40**	**406.73**	**311.33**	**30.60**	**54.08**	**23.48**	**8.53**	**326.29**

Note: Occasional decreases in net benefits for providers are associated with scanner replacement at the end of their estimated 5-year useful life. Sums may not add to totals because of independent rounding.

8.1.2 Measures of Economic Return

We calculated a series of performance measures on the time series of benefits and costs. These measures led us to conclude that transitioning to 2D barcoding for vaccine product labels will have a benefit-to-cost ratio of 2.7 to 2.8 (Table 8-5); in other words, for every $1 expended, $2.70 to $2.80 in benefits are expected to accrue over the period from 2011 through 2023.

Table 8-5. Summary Measures of Economic Return, based on Forecast of Quantified Net Benefits for Vaccine Manufacturers, Primary Care Providers, Health Departments, and Public-Sector Organizations

Measure, 2011–2023 Only	Scenario 1, Rate of Adoption Set by Survey	Scenario 2, Rate of Adoption Slowed 50%	Scenario 3, Rate of Adoption Slowed 67%
Total benefits (million $)	501.87	481.36	460.82
Total costs (million $)	153.33	139.66	134.53
Total net benefits (million $)	348.53	341.71	326.29
Net present value (3% discount rate) (million $)	271.49	263.37	249.41
Net present value (7% discount rate) (million $)	196.81	188.10	175.97
Benefit-cost ratio (undiscounted)	3.3	3.4	3.4
Benefit-cost ratio (3% discount rate)	3.0	3.1	3.1
Benefit-cost ratio (7% discount rate)	2.7	2.8	2.7
Internal rate of return	49%	46%	43%

Note: Ultimate penetration estimated to be 75.2% (pediatrics), 68.2% (family practice), 62.0% (ob-gyn), 53.3% (internal medicine), and 50.2% (health departments).

8.1.3 Sensitivity Analysis

In essence, our inclusion of two additional adoption scenarios represents a sensitivity analysis. However, because this economic analysis is a prospective one, three additional model runs were performed:

- lower-bound time savings from use of barcodes, in which the *lower bound* of the 95% confidence interval (CI) for time savings was used to quantify economic benefits rather than the mean;
- upper-bound time savings from use of barcodes, in which the *upper bound* of the 95% CI for time savings was used to quantify economic benefits; and
- eliminating internal medicine and obstetric-gynecology (ob-gyn) practices as 2D barcode users because our model projections are relying on only 58 internal medicine respondents and 100 ob-gyn responses to represent their specialties.

Table 8-6 presents the results of sensitivity analyses using upper- and lower-bound time–motion study results. Time–motion savings are estimated to be 36.5s/dose (95% CI: 32.3–40.5) to 39.4s/dose (95% CI: 34.8–43.9), depending on EHR usage. The benefit-cost ratio (BCR) (7% social discount rate) when the lower-bound time–motion savings result is used is 2.4 to 2.5, and 3.0 when the upper-bound estimate is used. This compares with our analysis results of 2.7 to 2.8. Results raise or lower by 7 to 16%.

Time–motion estimates are not the greatest source of uncertainty, however. The greatest source is related to low response rates from internal medicine and ob-gyn practices. Therefore, we analyzed measures of economic return under the assumption that these practices do not use the barcode. The results of using the mean and upper-bound time motion savings without medicine and ob-gyn practices are depicted in Table 8-7. Because the ratio of benefits and costs is low for these two specialties (as they are low volume immunizers), their removal actually has the effect of increasing the BCR. Sensitivity analysis results for mean time–motion savings estimate excluding internal medicine and ob-gyn practices are recommended for use in peer-reviewed publications because of the low number of survey responses from internal medicine and ob-gyn practices.

We also ran a pessimistic scenario in which we excluded all ob-gyn and internal medicine practices, reduced adoption by pediatric and family medicine practices and health departments by 25%, and doubled workflow redesign and training costs.

8.2 Recommendations for Implementation

A key focus in our analysis was on data exchange standards. Although data exchange standards can accommodate the 2D barcode, implementation of 2D barcoding for vaccine products will require a comprehensive mapping of the GTIN to the delimited NDC to the CVX and MVX. Including CPT codes would facilitate billing; thus, it would be advantageous to include them in the mapping table. Programming efforts, education, and coordination with stakeholders are needed to use 2D barcodes across immunization encounter, inventory, billing, and other tracking systems used for immunization. Specific recommendations follow (see also Table 8-8).

8.2.1 Mapping Tables of GTIN to NDC to CVX and MVX

Because GS1 does not support parsing the GTIN and elements of the NDC embedded in it are required for vaccine identification, an additional service is needed to use the 2D barcode. One possibility is a look-up table for GTIN to NDC to the CVX and MVX and to CPT for both public and private purchasers. This is similar to CDC's current mapping of NDC to the CVX and MVX. CDC provides tables mapping the NDC to the CVX and MVX based on the FDA's NDC Directory (CDC, 2011e). These mapping tables could be augmented or additional ones created to allow for complete GTINs to be mapped to the CVX and MVX. The tables

Table 8-6. Sensitivity Analyses Using Upper- and Lower-Bound Time–Motion Savings Results

Measure, 2011–2023 Only	Mean Results			Lower-Bound Time–Motion Savings			Upper-Bound Time–Motion Savings		
	Rate of Adoption Set by Survey Results	Rate of Adoption Slowed by 50%	Rate of Adoption Slowed by 67%	Rate of Adoption Set by Survey Results (% Change from Mean)	Rate of Adoption Slowed by 50%(% Change from Mean)	Rate of Adoption Slowed by 67%(% Change from Mean)	Rate of Adoption Set by Survey Results(% Change from Mean)	Rate of Adoption Slowed by 50%(% Change from Mean)	Rate of Adoption Slowed by 67%(% Change from Mean)
Total benefits (million $)	501.87	481.36	460.82	449.86 (−10.4%)	431.74 (−10.3%)	413.58 (−10.4%)	552.73 (+10.1%)	529.90 (+10.1%	507.02 (+10.0%
Total costs (million $)	153.33	139.66	134.53	153.33 (n/c)	139.66 (n/c)	134.53 (n/c)	153.33 (n/c)	139.66 (n/c)	134.53 (n/c)
Total net benefits (million $)	348.53	341.71	326.29	296.53 (−14.9%)	292.08 (−14.5%)	279.05 (−14.5%)	399.40 (+14.6%)	390.24 (+14.2%)	372.49 (+14.2%)
Net present value (3% discount rate) (million $)	271.49	263.37	249.41	229.44 (−15.5%)	223.52 (−15.1%)	211.74 (−15.2%)	312.63 (+15.2%)	302.34 (+14.8%)	286.26 (+14.8%)
Net present value (7% discount rate) (million $)	196.81	188.10	175.97	164.44 (−16.4%)	157.74 (−16.1%)	147.53 (−16.2%)	228.47 (+16.1%)	217.79 (+15.8%)	203.78 (+15.8%)
Benefit-cost ratio (undiscounted)	3.3	3.4	3.4	2.9 (−12.1%)	3.1 (−8.8%)	3.1 (−8.8%)	3.6 (+9.1%)	3.8 (+11.8%)	3.8 (+11.8%)
Benefit-cost ratio (3% discount rate)	3.0	3.1	3.1	2.7 (−10.0%)	2.8 (−9.7%)	2.8 (−9.7%)	3.3 (+10.0%)	3.5 (+12.1%)	3.4 (+9.7%)
Benefit-cost ratio (7% discount rate)	2.7	2.8	2.7	2.4 (−11.1%)	2.5 (−10.7%)	2.4 (−11.1%)	3.0 (+11.1%)	3.0 (+7.1%)	3.0 (+11.1%)
Internal rate of return	49%	46%	43%	43% (−12.2%)	41% (−10.9%)	38% (−11.6%)	55% (+12.2%)	50% (+8.7%)	47% (+9.3%)

Table 8-7. Sensitivity Analyses Using Upper- and Lower-Bound Time–Motion Savings Results and Including Pediatric, Family Medicine, and Health Department Practices Only

Measure, 2011–2023 Only	Main Results			Mean Time–Motion Savings Estimate Excluding Internal Medicine and Ob-gyn Practices			Pessimistic Scenario: Lower-Bound Time–Motion Savings Estimate, Excluding Internal Medicine and Ob-gyn Practices, Reducing Endpoint Adoption by 25%, and Doubling Workflow Redesign and Training Costs			Upper-Bound Time–Motion Savings, Excluding Internal Medicine and Ob-gyn Practices		
	Rate of Adoption Set by Survey Results	Rate of Adoption Slowed by 50%	Rate of Adoption Slowed by 67%	Rate of Adoption Set by Survey Results (% Change)	Rate of Adoption Slowed by 50% (% Change)	Rate of Adoption Slowed by 67% (% Change)	Rate of Adoption Set by Survey Results (% Change)	Rate of Adoption Slowed by 50% (% Change)	Rate of Adoption Slowed by 67% (% Change)	Rate of Adoption Set by Survey Results (% Change)	Rate of Adoption Slowed by 50% (%Change)	Rate of Adoption Slowed by 67% (%Change)
Total benefits (million $)	501.87	481.36	460.82	447.02 (−12.3%)	429.00 (−12.2%)	410.96 (−12.1%)	401.39 (−25.0%)	385.46 (−24.9%)	369.52 (−24.7%)	491.66 (−2.1%)	471.59 (−2.1%)	451.50 (−2.1%)
Total costs (million $)	153.33	139.66	134.53	113.95 (−34.6%)	95.41 (−46.4%)	101.30 (−32.8%)	105.39 (−45.5%)	98.49 (−48.1%)	95.90 (−40.3%)	113.95 (−34.6%)	104.74 (−33.3%)	101.30 (−32.8%)
Total net benefits (million $)	348.53	341.71	326.29	333.08 (−4.6%)	333.59 (−2.4%)	309.67 (−5.4%)	296.00 (−17.7%)	286.97 (−19.1%)	273.62 (−19.2%)	377.71 (7.7%)	366.85 (6.9%)	350.21 (6.8%)
Net present value (3% discount rate) (million $)	271.49	263.37	249.41	260.62 (−4.2%)	258.85 (−1.7%)	237.95 (−4.8%)	229.88 (−18.1%)	220.72 (−19.3%)	208.71 (−19.5%)	296.71 (8.5%)	285.40 (7.7%)	270.28 (7.7%)
Net present value (7% discount rate) (million $)	196.81	188.10	175.97	190.34 (−3.4%)	186.87 (−0.7%)	169.24 (−4.0%)	165.91 (−18.6%)	157.06 (−19.8%)	146.67 (−20.0%)	218.13 (9.8%)	206.91 (9.1%)	193.64 (9.1%)
Benefit-cost ratio (undiscounted)	3.3	3.4	3.4	3.9 (15.4%)	4.5 (24.4%)	4.1 (17.1%)	3.8 (13.2%)	3.9 (12.8%)	3.9 (12.8%)	4.3 (23.3%)	4.5 (24.4%)	4.5 (24.4%)
Benefit-cost ratio (3% discount rate)	3.0	3.1	3.1	3.6 (16.7%)	4.0 (22.5%)	3.6 (13.9%)	3.4 (11.8%)	3.5 (11.4%)	3.4 (8.8%)	3.9 (23.1%)	4.0 (22.5%)	4.0 (22.5%)
Benefit-cost ratio (7% discount rate)	2.7	2.8	2.7	3.2 (15.6%)	3.5 (20.0)	3.1 (12.9)	3.0 (10.0%)	3.0 (6.7%)	2.9 (6.9%)	3.5 (22.9%)	3.5 (20.0%)	3.4 (20.6%)
Internal rate of return	49%	46%	43%	53% (7.5%)	50% (8.0%)	45% (4.4%)	47% (−4.3%	43% (−7.0%)	40% (−7.5%)	59% (16.9%)	53% (13.2%)	49% (12.2%)

Note: Sensitivity analysis results for mean time–motion savings estimate excluding internal medicine and ob-gyn practices are recommended for use in peer-reviewed publications because of the low number of survey responses from internal medicine and ob-gyn practices.

Table 8-8. Summary of Recommendations

Recommendation	Rationale
Maintain GTIN to NDC to CVX and MVX mapping table	Enable legacy systems to be populated with 2D-barcoded data; support data exchange and interoperability.
Collaborate with GS1	Ensure consistent messaging to stakeholders; obtain access to GTIN registry.
Collaborate with the Food and Drug Administration (FDA)	Ensure up-to-date list of NDCs and consistent messaging to stakeholders
Collaborate with AAP and other associations	Collaborate with AAP and other associations in development and roll-out of training and outreach programs; maintain participation in AAP 2D barcoding working group meetings.
Education and outreach	
Mapping table	Provide GTIN to NDC to CVX and MVX mapping so that systems can be developed and tested to accommodate 2D barcoded data.
Implementation	Provide educational materials and training for end users.
Change management	
Stakeholder engagement	Ensure that roles and responsibilities among stakeholders are clear. Keep stakeholders engaged to facilitate their members' involvement and ensure that changes are communicated.
Update 2.5.1 guide	The 2.5.1 guide is the HL7 source for immunization information exchange: incorporating barcoding guidance into the guide will ensure that stakeholders are aware of changes.
Pilot implementation	Pilot implementation will test 2D barcodes in use, especially with EHRs and IIS, so that troubleshooting can occur prior to large-scale implementation.

must be HL7 tables to support interoperability, and they should support all vaccine products on the market both on the public side as well as the private-purchase side.

This proposed solution leverages GS1's existing services for issuing and maintaining GTINs and CDC's current maintenance of mapping tables. The CDC 2.5.1 implementation guide can be updated to reflect these relationships and provide links to the necessary mapping tables as appropriate.

The CVX and MVX mappings are HL7 tables and, thus, are part of the overall standard. It is extremely important that look-up tables be kept up to date. Some legacy systems have CVX and MVX hard-coded in them, and having a centralized mapping table avoids the risk of having individual vendors maintain them. Stakeholders with whom we spoke asserted the importance of transparency and continuity in developing implementation guides and mapping tables. In addition, CDC's 2.5.1 implementation guide is referenced in the meaningful use criteria. Given that the tables and the guide need to be together, it is important that the guide be updated with the location of the mapping table.

CDC currently maintains mapping between the CVX and Current Procedural Terminology (CPT) codes and the NDC mapped to CVX and MVX codes. These mappings are to support users throughout the immunization life cycle. The NDC is used for a variety of purposes throughout the immunization life cycle. CPT codes are primarily used to describe procedures to facilitate payment. Thus, the GTIN mapping going forward should include both the NDC and CPT.

GS1 is responsible for issuing GTINs and maintaining them in a registry, which ensures that there are no duplicate GTINs. If a manufacturer submits a request for a duplicate GTIN, GS1 works with the manufacturer to identify alternatives. We determined that there are no duplicates in the FDA database, but using the GS1 registry will ensure that duplicates do not occur in the future.

8.2.2 Collaboration and Coordination with Stakeholders

We recommend ongoing collaboration among CDC, AAP, GS1, FDA, Association of Immunization Managers (AIM), American Immunization Registry Association (AIRA), and other stakeholders to ensure that all parties responsible for the GTIN, NDC, and CVX and MVX understand the data exchange implications of the 2D barcode for stakeholders in the immunization domain. Coordination and discussion are particularly important during implementation and ongoing maintenance.

Coordination with GS1 will be important because business processes will need to be established by which new GTINs are added to the proposed GTIN to NDC to CVX and MVX mapping table. During implementation, GTINs for vaccine products will need to be mapped to CVX MVX, etc. Sufficient time must be allowed for testing of system updates and processes. In addition, as new products come to market and the GTINs are updated, a consistent process for communicating changes is needed so that tables can be updated.

GS1 has indicated that it will assist providers once the guidance and content are finalized. Assistance includes continuing to maintain the GS1 specifications, issuing guidance to manufacturers, and providing general specifications as needed. GS1 also will provide guidance about how to purchase and use a scanner. As part of its regular processes, GS1 provides training to software consultants and certifications. But because GS1's role is to develop the standards and provide general support, they do not provide customized guidance. Thus, stakeholders will likely turn to other resources for support.

The FDA assigns labeler codes and maintains the database of segmented NDC numbers. The FDA is also a member of GS1 and, thus, has access to the GS1 registry of GTINs (GS1 Healthcare US, 2011b). Coordination with the FDA will support maintenance of accurate and timely mapping tables. Coordination will also allow both agencies to stay abreast of automated identification activities for biologics, such as 2D barcoding and serialization.

Because of the FDA's position, its communication with stakeholders is extremely important in the success of this effort. Collaborating with the FDA will facilitate consistent messaging to stakeholders.

Lastly, AAP has led the 2D barcoding initiative and offers a neutral forum where technical aspects of implementation and data exchange specific to immunization can be discussed. AAP, AIM, AIRA, and other professional associations can coordinate communications that will ultimately reach large numbers of providers beyond pediatricians.

8.2.3 Education and Outreach

One concern that has been universally mentioned is the importance of education and training of those who will print, maintain, and use the 2D barcode. In fact, our interviews often turned into educational sessions. As referenced in the process map, a variety of stakeholders are involved. Each of them will need to understand the content of the standards mapping to make necessary changes to their systems. Thus, CDC must ensure that mapping is readily available and communicated to all stakeholders, especially to information systems vendors and those in the health IT technical and policy community.

In addition to ensuring that business and technical requirements are available, educational materials also need to be developed and delivered. Although the barcode scanner is relatively easy to use, it still requires some training. The scanning itself is a piece of an overall education effort that can include workflow implications and downstream impacts. This training should include using the scanner, verifying scanned information, and developing procedures for recalling incorrect information and making changes. Troubleshooting should also be part of the training, which might include procedures for error management, such as accidentally scanning the wrong item or attributing a vaccine to the wrong person. Because of the large number of trainees who are geographically distributed, asynchronous methods are suggested. These methods include webinars, video, and instruction manuals. These can be supplemented with online synchronous methods as needed or appropriate for questions and answers. Then, materials can be updated accordingly.

8.2.4 Change Management

A commonly cited concern of interviewees was how changes will be accommodated in the future. There could be changes in vaccines themselves, such as in new products coming on the market, or changes in manufacturers. Sometimes the standards themselves change. For example, the HL7 standards are updated periodically. The regulatory environment might also change, such as the new Health Insurance Portability and Accountability Act (HIPAA) transactions and the updates to the privacy and security rules. In addition, vendor products and functionalities could change as the meaningful use criteria continue to evolve. Regardless of the source of change, a consistent way of citing and accommodating future

change in standards or barcode content is necessary. This issue points to the need for more consistent communication channels for stakeholders throughout the health care delivery system.

For change management procedures to be successful, roles and responsibilities of stakeholder groups should be clear. Although the AAP has been leading this effort, in the years following implementation, 2D barcode use may ultimately become accepted practice. Thus, representatives from stakeholder groups need to be kept apprised of status and engaged in the effort.

We suggest incorporating barcoding technical guidance in the CDC 2.5.1 implementation guide. The guide is a well-recognized source of information for immunization messaging. In addition, this guide is referenced in the meaningful use criteria. One of the public health requirements involves vaccine messages. If providers meet meaningful use criteria, then they qualify for payments. Thus, incorporating 2D barcoding in the guide provides an incentive for a variety of stakeholders to stay current with changes to the code.

8.2.5 Pilot Implementation

Although we have conducted interviews and document review, testing an implementation is the best way to fully understand how the 2D barcode will be operationalized in practice. We recommend conducting a staged pilot to test implementation, with an emphasis on information systems integration and usage at the practice level and data exchange between provider locations and IIS. The pilot should also be part of a technical assistance program that reviews functionality and capabilities for IIS and guides or supports implementation. The results of the pilot can be used to test information systems, work flows, and educational materials.

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APPENDIX A: INITIATIVES OUTSIDE NORTH AMERICA

The United States and Canada are not alone in pursuing vaccine product identification initiatives. Although there are differing underlying rationales and operating models for different countries' approaches, a common factor is a decision to leverage GS1 standards.

Brazil

In 2009, the Brazilian legislature passed a law (Act 11.903) to combat fraud and counterfeiting (*Brazil 11.903 Track and Trace Mandate*, 2010). The legislation aimed to build and implement a full serialization system for all prescription medications. The core of the proposed system was a randomized serial number located on a GS1-compliant 2D data matrix (called the Medicine Single Identifier) that would be found on every medical pack sold in the country (Taylor, 2010e).

The serial number would link to a database that contained each medical pack's ANVISA—the Brazilian regulatory agency charged with protecting the pharmaceutical market—registration number, lot number, manufacturing date, expiration date, the taxpayer numbers of the companies remitting and receiving the product, and the transaction date. The ANVISA system would have full track and trace capabilities; as proposed, the system would be able to trace all product movement, from manufacturer to end user (Taylor, 2010e). Manufacturers would be responsible for making sure that all of their products contain the necessary labels, and ANVISA would supply product dispensers with scanners to verify the authenticity of products they sell.[1]

However, after pharmaceutical resistance and the resignation of ANVISA's Chief Executive in January 2011, this plan reversed course (Allen, 2010). A task force was assigned to review and make recommendations for Act 11.903 and, ultimately, ANVISA decided to cease plans for a traceability system for medicines based on serialized security seals. Generally, drug makers seem to be lobbying for direct printing of codes onto the pack rather than a security label. Act 11.903 was ultimately repealed (Taylor, 2011a).

France

In 2007, the French Health Products Safety Agency (AFSSAPS) announced new CIP 13 coding requirements for pharmaceutical products (*France CIP 13 Coding Update*, 2009). The requirements stipulated that all pharmaceutical products distributed in France after January 1, 2011, must possess an ECC200 2D data matrix barcode that contains a 13-digit CIP 13 code, the lot number, and the expiration date. All products must also possess a vignette sticker, which pharmacists can use for reimbursement; the sticker includes the data matrix,

[1] The proposed system also sought to place a security hologram (printed by the national mint) and a 2D data matrix on a self-adhesive, tamper-evident label (Allen, 2010). Pharmaceutical companies have lobbied aggressively against this aspect of the system. In their view, placing a government-supplied security label on all products would be difficult to accomplish, and a serialization system is itself enough to protect against counterfeiting and reimbursement fraud (Taylor, 2010a).

the CIP 13 code, the reimbursement rate, and the price (*France CIP 13 Coding Update*, 2009).

France's CIP 13 scheme is used primarily for reimbursement, patient safety, and batch number traceability (AFSSAPS originally envisioned using a 7-digit CIP code but added digits to strengthen traceability). The CIP 13 code is not a serialization system. However, the hardware required for CIP 13 is the same as the hardware required for serialization, and the application of CIP 13 codes provides a foundation for serialization and future initiatives aimed at improved packaging and anticounterfeiting (*France CIP 13 Coding Update*, 2009). The CIP 13 scheme will also be compatible with the planned European coding system (the European Article Number [EAN] structure) (CIP, 2011).

South Korea

In 2008, South Korea laid out a timeline to implement a track and trace system using the Korean Drug Code (KDC) in a GS1-compliant barcode. Beginning in January 2008, South Korea mandated that all pharmaceutical products larger than 15 mL be labeled with the KDC (*Bosch Packaging Technology*, 2010). By January 2010, all pharmaceutical products, regardless of size, were to be labeled with the KDC. By January 2012, specified drugs must possess labels with a GS1 data matrix or a GS1-128 barcode. Finally, by January 2013, all prescription drugs must have labels with a GS1 data matrix or GS1-128 barcode (Rodgers, 2011).

In addition to introducing the KDC and requiring that labels include more advanced barcodes, South Korea is requiring that pharmaceutical drugs be equipped with radio-frequency identification (RFID) tags (Mansell, 2010; Ton-hyung, 2010). South Korea is requiring that at least 50% of all Korean pharmaceuticals sold by 2015 have RFID tags (Ton-hyung, 2010). RFID tagging may allow South Korea to improve their low recovery rate for substandard drugs (around 20%) (Ton-hyung, 2010). Additionally, the tags will aid in distribution efficiency, inventory control, reduction of prescription errors, prevention of theft, and identification of counterfeit drugs. Government officials estimate that RFID tagging would generate 910 billion won in drug production costs through 2015 and would save pharmaceutical companies 1.8 trillion won per year in distribution and inventory costs (Ton-hyung, 2010).

Turkey

In 2008, the Turkish Ministry of Health announced the creation of the Ilac Takip Sistemi (ITS). ITS is a serialization scheme that will give Turkey the ability to track and trace pharmaceutical products (down to the unit pack level) from importation through dispensing. Manufacturers would be required to equip all health care products—prescriptions, over-the-counter medications, dietary supplements—with a GS1-compliant 2D data matrix containing

a unique serialized identifier (Taylor, 2008). At each point in the supply chain, product handlers will scan the product into the system to allow the Ministry of Health to track all products in a centralized database (Taylor & Duman, 2009).

The impetus for creating ITS came from widespread reimbursement fraud that costs Turkey an estimated $150 million/year (Taylor & Duman, 2009). The system would also help decrease counterfeiting and the prevalence of illegal pharmaceutical drugs on the Turkish market (Taylor & Duman, 2009). When a pharmacist scans a product, the system would relay a message indicating whether the product should be dispensed.

The ITS system received pushback from Turkish pharmacists. Some pharmacists were concerned that upgrading their infrastructure was not in their financial best interests (Taylor & Duman, 2009). Turkish pharmacists had some difficulty with barcode scanners. Some scanners sold to pharmacies as 2D-readable are unable to read the new 2D data matrix. The algorithms used in the readers may not be sufficiently robust to give reliable results. Pharmacists have also been concerned that if the Ministry of Health does not provide reimbursement for products without a 2D barcode and if pharmaceutical manufacturers are unwilling to accept the return of unused products, they would be left to bear the cost of unused products (Taylor & Duman, 2009). These concerns have delayed repeatedly Turkey's aggressive timeline for implementation.

United Kingdom

There are no initiatives sponsored by the UK government; however, SecureTrace, a consortium of UK companies, began a pilot project in 2009 to track and authenticate drugs along the supply chain. SecureTrace's main project goal was to show how serialization and authentication could be done simultaneously and successfully (Taylor, 2010g). The SecureTrace consortium consists of several solution providers (Authentix, Camdata, Image Solutions, And Automation, Domino Printing Sciences, Ingenia Technology, Pera Innovation, and GIS), a university (Loughborough University), and a pharmaceutical drug company (Reckitt Benckiser) (*Case Study*, 2010).

The SecureTrace pilot uses serialization and tracking through RFID and on-pack data matrix tracking codes at the carton level. Authentication is accomplished through forensic signature inks and laser surface authentication (*Case Study*, 2009) and all information is stored in a master database. Based on this process, it is possible to authenticate and verify pharmaceuticals with handheld field readers at any point in the supply chain (*Case Study*, 2009). This pilot originated from the idea, held by SecureTrace, that serialization will not adequately prevent pharmaceutical counterfeiting and diversion without authentication (Taylor, 2010g). Thus, the SecureTrace pilot demonstrated the feasibility of simultaneous

serialization and authentication through its success in using different technologies simultaneously (Taylor, 2010g).[2]

Sweden

The European Federation of Pharmaceutical Industry Associations (EFPIA) chose Sweden to pilot its project to verify the identity of pharmaceuticals at the point of dispense. Through this project a 2D data matrix code is placed onto each medicine pack. This code contains the product code, expiration date, batch number, and a unique serial number. This code is readable with an optical scanner directly at the pharmacy (EFPIA, 2009). The motivation behind this project comes from the lack of conformity within mass serialization for medicines. Currently in Europe there are at minimum 10 different codes being used for serialization purposes (Taylor, 2010d). Without international standardization, significant investment will be wasted supporting various standards that will inevitably become obsolete (Barron et al., 2010).

Overall the pilot was extremely successful, boasting a 94% successful read rate of the code in 0.5 seconds and a 99.9% successful read rate in 2 seconds. Of the 230 pharmacists participating in the study, 123 provided feedback, and 94% of those providing feedback felt the system was easy or very easy to use; 96% reported that the extra effort needed to operate the system was acceptable or better (Barron et al., 2010). Projected benefits from the system include more efficient recalls, power to combat reimbursement fraud, assurance that patients receive the desired product before expiration, and counterfeit product detection (Taylor, 2009). Although achieving these benefits is important, the purpose of the pilot is not to improve existing systems, but rather to demonstrate the feasibility of implementing a system that would standardize international serialization (Barron et al., 2010).

Issues that arose in the pilot include confusion between the linear and 2D data matrix barcode, resulting in an error and a prompt to rescan. Another issue arose when customers decided not to purchase a product after it had been scanned. Because the product had been scanned it was marked as already dispensed, so when the next customer tried to purchase the product, it presented as already dispensed, causing an error. Based on these pilot results, the EFPIA's next steps are to fix kinks in the system and begin pushing for a harmonized product coding system in Europe that uses 2D datamatrix coding (Taylor, 2010d).

[2] It is important to note that SecureTrace's system is compatible with the BRIDGE traceability project and the European Federation of Pharmaceutical Industries and Associations (EFPIA). While aligning its pilot with EFPIA's objectives to support EFPIA's position and to contribute to some form of standardization in the industry, SecureTrace simultaneously branched out to investigate two other important areas: practical integration of technology in the supply chain and at the production line, and supplementary authentication technologies that do not affect packaging design (*Authentix-led Consortium Launches Pilot Program for Pharmaceutical Safety*, 2010).

India

In September 2010, India's Ministry of Commerce agreed to a proposal by Pharmexil, a trade group that represents drug exporters, to employ a track-and-trace system using barcode technology and GS1 coding standards for all exported pharmaceutical products. On January 10, 2011, India's government officially approved a resolution (Public Public Notice No. 21 [RE-2011]/2009–2014) that set implementation for the serialized coding scheme for July 1, 2011. In early June, this deadline was postponed. The current rollout is predicted to mandate codes on tertiary packaging by October 1, 2011, and codes on primary and secondary medicine packaging by January 1, 2012 (Taylor, 2011b). Postponement is due in part to aggressive lobbying from pharmaceutical companies who feel that the time frame is too short to test, employ, and validate the mandated changes (Taylor, 2011b).[3]

China

On April 9, 2008, China's State Food and Drug Administration (SFDA) launched a track-and-trace initiative declaring that all individual pharmaceutical products sold in the Chinese marketplace—not just those made in China—needed to be serialized by December 2011. The aims of this program include increasing patient safety; reducing drug counterfeiting; offering online, phone, and short message service (SMS) authentication of drugs; developing a national warning system to detect unusual drug movements; and tracking drug movement along the supply chain (*China SFDA Mandatory Serialization Update*, 2009).

SFDA plans to run a centralized national database of serial numbers through which they will issue and manage serial numbers for registered drugs. This database will include an online portal, through which pharmaceuticals can register products and obtain serial numbers. These services would be fee based, and the serial number would be 20 numerical digits that would include the serial number, manufacture code, and check digits. This check code maps one-to-one with China's NDC, 9-digit serial number and 4-digit encryption number. A final deadline for the serialization and track and trace of all drugs has not yet been set (*China SFDA Mandatory Serialization Update*, 2009).

Argentina

In 2011 Argentina adopted a datamatrix serialization system and beginning June 15, 2011, began requiring that laboratories operating in Argentina implement this government tracking system. This new system is compatible with GS1 international standards, and under this system drug authentication can be completed online or by telephone. This is a very important advancement for Argentina because counterfeited drugs are one of the most

[3] In response to the new traceability requirements, an Indian company, Goose, started a home-grown serialization system to assist pharmaceutical companies. The new platform is called "Procon Tracker" and enables serialization, e-pedigree, and drug validation for any pharmaceutical company. This system is GS1-compliant, and codes can be printed in a readable format to be validated over the phone, using a website, or through SMS (*Procon Tracker*, 2011).

serious issues facing their public health system. It is estimated that roughly 10% of medicines found in the country are counterfeited (Bitoren, 2011).

Germany

Aegate is a UK-based company whose authentication system scans a datamatrix code on pharmaceutical products when disbursed to verify their validity and check their expiration date. In early 2010 Aegate began collaborating with the Federal Union of German Associations of Pharmacists (ABDA) and announced plans to run a 7-month pilot of this system in Germany (*German Association of Pharmacists [ABDA]*, 2010). The idea of the pilot was not only to test this system, but also to test the viability of parallel importers participating in a mass serialized system. Therefore, the pilot involved removing and invalidating the old code, and replacing it with the new one (Taylor, 2010c).

In early 2010 the European Association of Euro-Pharmaceutical Companies (EAEPC) agreed to participate in the pilot, but later that year, the project began experiencing problems and the pilot was put on hold. One reason for this was that manufacturers and wholesalers were signing up for the pilot less quickly than expected. Another issue was that implementing barcodes, readers, and necessary IT infrastructure was estimated to cost at least €200,000 (Taylor, 2010c). Given that a legal mandate for a coding system in Europe is not guaranteed, this is a significant investment.

Another project just recently started in the place of the postponed Aegate-ABDA pilot. The SecurPharm project, a collaboration between Bundesverband der Arzneimittel-Hersteller e.v. (BAH), Blenheim Pharmacal, Inc., BPI Technologies Corporation, VFA Solutions, Pro Generika, PHAGRO, and ABDA was announced August 31, 2011 (Schmidt, 2011). It is predicted that SecurPharm will become the standard in Germany, and possibly Europe, based on the participation of the German Association of Pharmaceutical Manufacturers, the German Society of Hospital Pharmacists, and the German Wholesaler Association. The purpose of the project is to employ safety features mandated in the EU Directive 2001/83 (Pharma Directive). The initiative's motto is "end-to-end," indicating that validation and verification will take place in the pharmacy, not in each supply phase. This project will use 2D matrix codes (like in the EFPIA pilots in Sweden) and two separated data management systems (not a central database, as seen in other models). The pilot is set to begin in 2013 (Schmidt, 2011).

Italy, Greece, and Belgium: Aegate Users

Despite the current postponement of the German Aegate-ABDA pilot, Italy, Greece, and Belgium do use Aegate's system (*German Association of Pharmacists [ABDA]*, 2010). Aegate began working in Greece and Belgium in 2007 with the support of the Panhellenic Pharmacists Association and the Association of Pharmacists of Belgium (APB), respectively.

Over two-thirds of Belgium pharmacies can now access the Aegate system through their software providers, as can 80% of Belgium pharmacies (*History of Drug Identification Pilots*, 2009). With collaboration from software providers CSF, Newline, PharmaService, and Farma3, Aegate was launched in Italy in 2008. The service was fully integrated into existing pharmaceutical software and used the standard Bollini 1D barcoding technology. As previously described, the Aegate system uses 2D data-matrix serialization technology to authenticate pharmaceuticals when dispensed from a pharmacy.

The Centers for Disease Control and Prevention (CDC) has contracted with RTI International, a not-for-profit research institute, to conduct a study of the impacts a two-dimensional barcode would have on vaccine production, clinical documentation, and public health reporting for stakeholders in the U.S. immunization system.[1] Stakeholders include vaccine manufacturers, vaccine users (e.g., immunization providers, immunization program managers), and immunization data users (e.g., immunization information systems, data exchange groups, vaccine-related tracking systems). Please see also our accompanying Project Abstract.

The focus of our conversation is on the operational and regulatory issues, cost and benefit categories, and other considerations for including a two-dimensional barcode (including Global Trade Identification Number [GTIN], lot number, expiration date, and potentially other information) on all US-licensed vaccine products.

A comprehensive understanding of the issues, costs, benefits, and considerations is imperative for the success of this study. Our conversation is confidential. We will be speaking to all vaccine manufacturers, and in that respect it will be known that we engaged your organization. However, all comments, anecdotes, data, and other information provided by your firm will be aggregated with those of other firms in all deliverables and communications with third parties, including CDC.

To supplement our note-taking and fill any gaps or clarify any comments, with your permission, we would like to audio record our conversation. The recording will only be used to ensure we accurately documented your insights. A copy will be provided to you. We will permanently delete the recording after this project has ended.

Our questions are purposefully open-ended; while we have specific question topics we would like to discuss, we aspire to have a conversation as opposed to a strict Q&A session. Question topics cover:

- fill and finish operations and process engineering and how these may be affected by inclusion of a two-dimensional barcode on product labels;
- associated vaccine label requirements, considerations, and regulatory issues;
- pertinent cost and benefit categories [including, one-time vs. recurring; fixed vs. variable; capital, labor, services, and materials];
- information technology, barcode, and data exchange standards;
- indirect regulatory and cost considerations, including revalidation of production lines and changes to standard operating procedures (SOPs);
- non-manufacturing operations potentially affected, including information technology, marketing, and tracking and compliance groups; and

[1] Specifically, a two-dimensional barcode printed on the label affixed to the immediate container (i.e., vial, prefilled syringe) of a finished vaccine product licensed for sale in the US.

- perspectives on the relevance of such barcodes for vaccine-tracking systems, registries, and electronic health records both in general and specific to your company.

General Fill and Finish and Labeling Operations

1. Please review the accompanying table presenting our understanding of the products licensed for the US market. Is this information correct? If not, please offer corrections.

2. Characterize and describe your labeling operations beginning with how and where labels are printed, how those labels are affixed to finished products' immediate container (i.e., vial, prefilled syringe), and how completed products move to inventory and then through to shipment.

3. How many production lines do you have in the US? Is there a 1:1 ratio between labeling systems and production lines?

4. Describe any change-over processes from production of different vaccine products for the US market and those for non-US markets. What are the critical considerations?

5. Describe the interface and method by which systems are programmed to print and label products. What specific labeling technologies and systems are currently used and how do such systems vary according to different product containers, if at all? How flexible are these systems? Are these systems capable of printing two-dimensional barcodes?

6. What are important operational and quality considerations for the labeling process, and do these considerations vary by presentation or label type (i.e., printed label, peel-off label)?

7. What are common challenges (if any), current or past, with labeling operations, fill and finish lines, or other operations associated with changing labels, label media, or increasing the amount of information printed on a given label, including the addition of barcoded information?

8. After the label is affixed to the immediate container, how are products tracked as they move through the remainder of the facility, to warehousing, and for shipment? At what stages would barcoded information on an immediate container be advantageous to a manufacturer and why?

9. Apart from barcodes, are there any automated identification technologies or strategies used or are any such technologies emerging? If so, please explain the pros and cons of such technologies, as you understand them.

Product Labels

10. Explain the overarching considerations and implications associated with including a two-dimensional barcode on a product label.

11. Vaccine product labels are regulated by FDA, and changes to labels require FDA review and approval under 21 CFR 601.12(f). Labels include those on immediate outer packaging and wrapping, product labels on immediate containers, and product inserts.

    What FDA requirements, industry consensus standards, and any other standards are relevant for

what information is presented on labels and how that information is presented? What barcoding standards are followed by your firm?

12. What label media are used for your products? How does vaccine presentation impact the relative ease or difficulty of including two-dimensional barcodes on labels?

    - Multi-dose vials
    - Single-dose vials
    - Injectable pre-filled syringes
    - Intranasal pre-filled syringes
    - Lyophilized vaccines (require reconstitution)
    - Any thoughts about new technologies, e.g., transdermal?

13. How do different label media and different label sizes factor into the feasibility of including a two-dimensional barcode?

14. Do you currently manufacture in the US any products for any US or international markets that include two-dimensional barcodes on their labels? Does your company import vaccine products from non-US manufacturing plants that print two-dimensional product labels on products for any national markets? Please explain.

15. What experience(s) does your company have with two dimensional barcoding any of its products (whether vaccine or not)? What lessons have you learned from this experience?

16. Who are the major vendors for printing technologies, tooling, label media, and other consumables? Have technology or product offerings evolved in light of FDA's barcoding requirements, and if so, how?

One-time Costs, Time Requirements, and Similar Considerations

We need your assistance in characterizing and understanding what the one-time cost variables are for us to include in our economic analysis. While dollar-denominated estimates are helpful, it is most important for us to understand tooling, labor effort, and systems requirements denominated in technical units, such as number of labor hours, first.

17. What are the cost variables that would potentially be affected, such as:

    - Capital requirements and any changes in tooling (printers, automation systems)
    - Production line recertification
    - Changes in SOPs
    - Interface programming and line testing
    - Software technology
    - Training and certification for line managers and line workers
    - FDA approvals or inspections
    - Implementation planning and on-time management expenses
    - Others?

18. What would be the total implementation time to make such a change? How much lead time would be required? How much production-line down time would be required to implement two-dimensional barcoding?

19. How would this affect inventory and warehousing procedures? Would production cease temporarily, or would you alternate implementation by lines? Please explain.

20. Would this change trigger revalidation of the production line by FDA? Please explain.

21. Have any cost or feasibility studies been conducted by your company? Please explain.

22. How would one-time costs be recouped? Are there any benefits that may offset these costs and if so, what are they?

23. Are there any upcoming changes in your labeling operations that might facilitate implementation?

24. What considerations or facilitators in the broader immunization environment may influence or affect adoption decisions?

25. What factors would affect the timing of any adoption decisions? Characterize any differences under scenarios that vary by a 1-year, 2-year, or 3-year implementation time.

Recurring Costs and Considerations

26. How may including lot number and/or expiration date information affect the cost of implementing two-dimensional barcoding relative to linear barcodes? If there is an increase in cost, what would account for it? What could be done to offset any increase in cost?

27. Would inclusion of a two-dimensional bar code on a product label change the label media used? If so, please explain and offer a comparative assessment.

28. What are the recurring cost variables that would potentially be affected (and how many current activities be incrementally less or more resource intensive), such as:

    - Labor effort
    - Periodic interface programming and line testing
    - Selection of label media
    - Consumables, such as inks or other inputs
    - Quality control and assurance
    - Annual software licensing agreements or other costs
    - Fees associated with membership in standards groups
    - Others?

29. Would two-dimensional barcodes have special considerations for the following (and if so how):

    - Products with multiple lot numbers
    - Any products being alternately labeled as a pharmaceutical or a medical device
    - Products produced by one firm but marketed under agreement by another
    - Combination vaccines
    - Others?

30. How would operations such as those for information technology, marketing, and tracking and compliance groups be affected?

31. What economic benefits may offset these costs? Please describe key variables for us.

Other

32. Did your company respond to the FDA's request for comments on the proposed waiver for barcoding that may permit two-dimensional barcoding of vaccine product labels? What are your company's views, generally?

33. What non-US regulatory trends affecting labeling and automated vaccine product tracking are important for us to understand? What trends in general harmonization should we be aware of?

34. Does your company have an interface to and use vaccine-tracking systems maintained by the public health community, immunization information systems, and electronic health record systems? Does your company use the systems or accept data feeds from them? Please describe any advantages or disadvantages associated with these systems for your company.

35. What are your views on immunization registries?

36. Does your company track or monitor general compliance with immunization schedules? Please explain.

37. What industry trends about labeling, vaccine product presentations, or the introduction of new products influence willingness to adopt two-dimensional barcoding technologies?

38. Imagine 5 years from now. Do all of your company's vaccines have two-dimensional bar codes? If yes, what information does the barcode include? If no, why?

39. Are there any other benefits to two-dimensional barcodes that we have not yet addressed? Are there any other barriers/concerns about two-dimensional barcodes that we have not yet addressed?

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We are interested in gauging the impact of two-dimensional, or data matrix, barcodes containing product identifiers, lot number, and expiration date for vaccines on pediatricians, OB/GYNs, family physicians, and general internists (see Figures 1 and 2). Thus far, pediatricians, as represented by the American Academy of Pediatrics (AAP), have advocated for including two-dimensional bar codes on vaccine products. This is reflected in AAP's support for the Food and Drug Administration's (FDA's) Updated Draft Guidance for Industry (August 2010).

Two-dimensional barcodes would make it possible for immunization providers to use a scanner to read the barcode and automatically enter product, lot, and expiration data into electronic information systems, such as practice management software, electronic health records (EHRs), immunization information systems (IIS) or registries, and billing systems. The price of a barcode reader is between $50 and $100, generally.

The focus of our conversation is on prevalence of immunization administered by your members, vaccine inventory management, documentation (including the individual patient medical record), data exchange, and the use and uptake of information technology. Our conversation is confidential, and with your permission, may be recorded. All comments, anecdotes, data, and other information provided by your organization will be aggregated with those of others in all deliverables and communications with third parties, including CDC.

Questions are purposefully open-ended and are illustrative; while we have specific question topics we would like to discuss, we aspire to have a meaningful dialog as opposed to a strict Q&A session. We have used bold-font topic headers for easy scanning of the topics of interest. Some of our questions may be best answered by a practice manager or nurse supervisor.

	
Figure 1: Example of linear barcode *Current linear barcodes required by the FDA contain only the vaccine product identification information.*	**Figure 2: Example of two-dimensional barcode** *A two-dimensional, or data matrix, barcode can include product identification information as well as lot number and expiration date.*

[1] Specifically, a two-dimensional barcode printed on the label affixed to the immediate container (i.e., vial, prefilled syringe) of a finished vaccine product licensed for sale in the US. This code would also appear on secondary packaging.

1. What is the prevalence of vaccine administration by your members and what environmental factors or business drivers influence this prevalence?

2. How is immunization by members anticipated to change over time, to the best of your current knowledge?

3. What proportion of your members use electronic health records (EHRs)? How do you imagine your response will have changed 5 years from now? What is the prevalence of information technology use and electronic data exchange for your members generally?

4. Thinking generally, what concerns or potential benefits do you anticipate your members would have regarding the placement of a two-dimensional barcode with product identifiers (GTIN, which includes the NDC), lot number, and expiration date on a vaccine product label on the products immediate packaging, such as a vial or prefilled syringe, and on the product's secondary packaging, such as a 10-vial box?

5. Does your organization currently have a committee or individual looking into the barcoding issues? Is organization doing anything in support of barcoding or to learn more about the issue?

6. What does your organization need to move ahead in the barcoding arena, such as technical assistance or educational materials?

7. What investments would members need to make in workflow changes, training, hardware, etc. What do they have now and what will they need?

8. As part of this project, we will be doing an economic analysis of the costs associated with implementing vaccine barcoding. We anticipate that the costs may differ among different specialty groups based on the volume immunizations provided and the type of vaccines administered. What information do you have about the costs of your members' providing vaccines, if any?

9. What information resources are there for understanding and segmenting the population of your members in the U.S., such as number of providers, stratification by office type, size, and EHR usage, and location?

10. What issues haven't we discussed which you think we should consider?

Thank you.

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The focus of our conversation is on provision of immunizations, vaccine inventory management, documentation (including the individual patient medical record), data exchange, and the use and uptake of information technology. Our conversation is confidential, and with your permission, may be recorded. All comments, anecdotes, data, and other information provided by your organization will be aggregated with those of others in all deliverables and communications with third parties, including CDC.

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About Your Practice

1. Characterize your practice, including total staff headcount and number of locations. Is your practice part of a larger network, health system, or corporation?
2. If known and releasable, approximately how many patients are in your practice?
3. What classes of vaccine does your practice provide, such as pediatric vaccines, adolescent vaccines, adult vaccines, and/or seasonal influenza?
4. Approximately how many doses does your practice administer on a monthly or annual basis?
5. Are you a VFC provider?
    a. What proportion of the doses administered is privately purchased and what proportion is government supplied?
    b. What impact do you imagine barcoded vaccines would have in terms of whether or not providers participate in the VFC program?
6. How do you maintain medical records in your practice (paper, electronic, some combination)?
7. How do you maintain billing records in your practice (paper, electronic, some combination)?
8. What experience(s) (if any) have you had using barcoded products or barcode readers? Please describe any experience your office might have with using barcodes or other automated identification technology, for example with medical or office supplies.
9. What benefits/costs do you anticipate for your practice with respect to using two-dimensional barcodes, if any?
    a. What kinds of changes do you anticipate for your practice, such as for software, workflow, and hardware?
    b. What help do you anticipate you would need in order to integrate barcoding vaccines into your practice?
    c. How do you anticipate your workflow would change due to barcoded vaccines? How would you train your staff?
    d. What barriers and facilitators do you see in implementing barcoded vaccines in your practice?

Workflow for Vaccine Administration

10. How is it determined when a patient needs an immunization? What are the procedures and what information resources are accessed? Who among your staff are involved? How do these differ if a patient is new your practice?
11. Can you please briefly describe the process of administering vaccines in your practice? At what points during these steps is immunization data recorded, into what forms or systems, and for what purposes? Is the information later transcribed or transferred to other media?
12. Consider now that the vaccine product label on the dose container includes a barcode containing information (product, lot, expiration date) that typically is recorded by hand.
    a. How would this affect your procedures and workflow?
    b. How would you like to see barcoded vaccines interface with medical records, practice management systems, IIS, and clinical decision support systems?

13. What procedures does your practice have in place to ensure that your immunization providers administer the correct vaccines to the right patients?

Vaccine Inventory Management

14. Discuss the procedures and processes for managing your vaccine inventory, from ordering through waste disposal. If procedures vary for VFC and non-VFC vaccine, please discuss them individually. How do you, for example,
    a. manage your inventory, including ordering, unpacking, placing into inventory (both physically and recording), etc?
    b. document deliveries?
    c. reconcile and audit deliveries with packing slips and invoices?
15. What proportion of the vaccine delivered is contained in multi-dose vials? How do administration and recordkeeping practices vary when a dose is from a multi-dose container and not from a unit-dose container?
16. How would you anticipate that two-dimensional barcoding affect current inventory management processes? How would it affect future processes, such as if new information systems were installed in your practice?

Recordkeeping, Billing, and Claims

17. How does the information about a vaccine administered get into an individual's medical record? How does it enter the billing system? How do you anticipate this would change if vaccines included a barcode?
18. What is done to reconcile/verify that encounter (billing data) matches the medical record and inventory? What is done to assure that all vaccines which are administered are recorded and billed appropriately?
19. Do you record immunizations in IIS? How does the information about a vaccine administered get into an IIS (immunization information system or registry) or health plan registry?
20. How is the information about vaccine administration transferred to a billing system?
21. Have you automated any information exchange between your practice management systems, registries, or any other system?

Special Requests: HEDIS Audits, Pay for Performance Programs, School Forms, Camp Forms

22. How frequent are and what is the level of effort associated with producing school forms, camp forms, sports pre-participation forms, and others?
    a. Approximately how many of these forms are completed by your practice each year?
    b. Do you use registries or other electronic information systems to assist in the development of these forms?
    c. How would you streamline this process if you could?
    d. Do you think barcoded vaccines would help with this process?
23. With how many health plans does your practice contract (private contracts and Medicaid contracts)? On the average, how many audits (number of patient records) does each conduct in your practice each year for HEDIS and pay for performance programs? Do you think barcoded vaccines would help with this process?

The Centers for Disease Control and Prevention (CDC) has contracted with RTI International, a not-for-profit research institute, to conduct a study of the impacts a two-dimensional barcode would have on vaccine production, clinical documentation, and public health reporting for stakeholders in the U.S. immunization system.[1] Stakeholders include vaccine manufacturers, vaccine users (e.g., immunization providers, immunization program managers), and immunization data users (e.g., immunization information systems, data exchange groups, vaccine-related tracking systems). Please see also our accompanying Project Abstract.

The focus of this conversation is the impact on standards, data exchange, and related considerations for including a two-dimensional barcode (including Global Trade Identification Number [GTIN], lot number, expiration date, and potentially other information) on all US-licensed vaccine products. We will be reviewing the standards, but would like to gain an understanding of other considerations not included in the guidance.

A comprehensive understanding of the impacts of this change is imperative for the success of this study. Our conversation is confidential. We will be speaking to the major standards organizations, and in that respect it will be known that we engaged your organization. However, all comments, anecdotes, data, and other information provided by your firm will be aggregated and de-identified in all deliverables and communications with third parties, including CDC.

To supplement our note-taking and fill any gaps or clarify any comments, with your permission, we would like to audio record our conversation. The recording will only be used to ensure we accurately documented your insights. A copy will be provided to you. We will permanently delete the recording after this project has ended.

Our questions are purposefully open-ended; while we have specific question topics we would like to discuss, we aspire to have a conversation as opposed to a strict Q&A session. These questions are intended to spur the conversation.

[1] Specifically, a two-dimensional barcode printed on the label affixed to the immediate container (i.e., vial, prefilled syringe) of a finished vaccine product licensed for sale in the US.

Information technology, barcode and data exchange standards

1. Please explain the overarching considerations and implications associated with including a two-dimensional barcode on a product label.

2. What lessons can we learn from experiences with barcoding in other areas of healthcare, such as pharmacies and hospitals?

3. In your opinion, are there areas where the standards are unclear or where there is room for different interpretations? Please explain.

4. What non-US regulatory trends affecting labeling and automated vaccine product tracking are important for us to understand? What trends in harmonization should we be aware of?

5. Would two-dimensional barcodes have special considerations for the following (and if so how):

    - Products with multiple lot numbers
    - Any products being alternately labeled as a pharmaceutical or a medical device
    - Products produced by one firm but marketed under agreement by another
    - Combination vaccines

6. Apart from barcodes, are there any automated identification technologies or strategies used or are any such technologies emerging? If so, please explain the pros and cons of such technologies, as you understand them.

7. What timeframe would you anticipate being needed to put standards in place to support two-dimensional barcoding?

8. Can you provide an overview of the process that would be involved in introducing, formalizing, reviewing and publishing standards for two-dimensional barcodes? What other standards bodies or groups would refer to or collaborate with? What sorts of resources or tools do you use to propose, introduce, review, publish and promote standards (e.g. registries, stakeholder collaboration resources)?

9. When thinking about the barcode itself, what data elements would you and your members like to see in the code? Have your members expressed preferences or concerns about them?

10. Vaccine product labels are regulated by FDA, and changes to labels require FDA review and approval under 21 CFR 601.12(f). Labels include those on immediate outer packaging and wrapping, product labels on immediate containers, and product inserts.

    What FDA requirements, member considerations, and any other standards are relevant for what information is presented on labels and how that information is presented? What other standards do your members tend to follow?

11. Are there any backwards compatibility issues or requirements related to switching from one-dimensional to two-dimensional barcodes (e.g. legacy software/systems)

Downstream impacts

We need your assistance in characterizing and understanding downstream impacts of this change.

12. When considering barcoding, what downstream impacts do you see for providers, registries, payers etc?

13. What would the impact be on different areas that would potentially be affected, such as:

    - Internal and external interface planning
    - Interface programming and line testing
    - Software technology (medical records, registries etc)
    - FDA approvals or inspections
    - Others?

14. In your opinion, what do providers and registries need to do to accommodate two-dimensional barcoding? What concerns do they need to overcome?

15. What considerations do you have regarding interoperability of systems?

16. Would the barcodes be able to be used with patient-centered technologies such as web-based interfaces?

17. How do you anticipate meaningful use criteria being met through the use of two-dimensional barcodes?

Other

18. Imagine 5 years from now. Do all vaccines have two-dimensional bar codes? If yes, what information does the barcode include? If no, why? What else do you see for labeling?

19. Are there benefits to two-dimensional barcodes that are not commonly addressed? Are there any other barriers/concerns about two-dimensional barcodes that we have not yet addressed?

20. In your opinion, what emerging trends in labeling technology or standards should we review?

21. In your opinion, what other groups (standards or otherwise) should we talk to?

22. Is there anything else we did not ask that we should know as we move forward with this effort?

Thank you very much for your time. We appreciate your help with this important initiative.

APPENDIX C: DOSAGE ESTIMATION METHODOLOGY

The number of doses expected to be administered in the United States from 2013 to 2033 was estimated by analyzing data on U.S. population projections (U.S. Census Bureau, 2005; 2009), vaccination rates among different age groups (CDC, 2010c; CDC, 2009, 2010b), and wastage and extraimmunization rates (Setia, 2002; WHO, 2011). Estimates were developed in four separate vaccine groups—pediatric, adolescent, adult, and influenza—based on the ACIP-recommended immunization schedule as of February 2011 (CDC, 2011). Other vaccines such as traveler's vaccines (i.e., typhoid, yellow fever, anthrax) were not estimated. Immunization and series completion rates were assumed to remain stable over time.

The process of estimating the number of doses consisted of three key steps:

1. Acquiring and reviewing the vaccination rate (including series completion rates) for each vaccine in each age group.

2. Calculating total number of doses expected to be administered by multiplying vaccination rates by the appropriate population estimate.

3. Multiplying by wastage and extraimmunization to arrive at the total number of expected doses.

C.1 Pediatric Vaccines

Pediatric vaccination rates are the most complex. Data were gathered from the 2009 National Immunization Survey, which targets the vaccination history of children aged 19 to 35 months.[1] The survey covers diphtheria and tetanus toxoids and acellular pertussis vaccine (DTaP); poliovirus vaccine (polio); measles-containing vaccine (MCV); Haemophilus influenzae type b vaccine (Hib); hepatitis B vaccine (Hep B); varicella zoster vaccine, pneumococcal conjugate vaccine (PCV), hepatitis A vaccine (Hep A), and influenza vaccine (FLU).

Because most pediatric vaccines consist of multiple doses and not all persons receive the complete dose, an expected number of doses was developed for each vaccine using the following formula:

$$DOSE_{\in} = 4 * d_4 + 3 * Max((d_3 - d_4),0) + 2 * Max(Min((d_2 - d_3),(d_2 - d_4)),0) +$$

$$Max(Min((d_1 - d_2),(d_1 - d_3),(d_1 - d_4)),0)$$

where

[1] Source data tables include Estimated Vaccination Coverage for Hepatitis B Vaccine for Children from Birth to 3 Days of Age and Estimated Vaccination Coverage with Individual Vaccines by 3 Months, 5 Months, 7 Months, 13 Months, 19 Months, and 24 Months and Among 19-35 Months of Age. Available at http://www.cdc.gov/vaccines/stats-surv/nis/nis-2009-released.htm.

$DOSE_{\in}$ = Expected doses for each vaccine

d_n = Percentage of target population receiving *n* doses

C.2 Adolescent Vaccines

The data for estimating adolescent vaccines come from the National Immunization Survey-Teen, which gathers data on the percent of teens between the ages of 13 to 19.[2] The survey asked whether, since the age of 10, these teens had received the meningococcal (MenACWY), human papillomavirus (HPV), and combined tetanus, diphtheria and pertussis or tetanus and diphtheria (Tdap/Td) vaccines. All vaccines were assumed to be received at age 11. HPV rates were only for females so the expected dosage rate was divided in half to account for males' inclusion in the population estimates.[3] The estimated HPV vaccination rate was calculated using the same methodology as was used in estimating the multi-dose pediatrics vaccines. MenACWY and Tdap are single-dose vaccines (not including boosters).

C.3 Adult Vaccines

The data on adult vaccinations come from the 2009 National Health Interview Survey (CDC 2010b).[4] Vaccination rates for estimated for Td/Tdap 10-year boosters and the herpes zoster (shingles) vaccines. In the survey, adults over age 60 were asked if they had ever received the zoster vaccine. For simplicity, it was assumed that all adults received this vaccine at age 60. Adult survey respondents were also asked if they had received a Td/Tdap booster in the past 10 years. The percentage of adults reporting to have received this booster was then divided by 10 to yield an annual vaccination rate.

C.4 Influenza Vaccines

Annual influenza vaccinations are administered beginning at six months of age. Data from the Behavioral Risk Factor Surveillance System were used to estimate flu vaccination rates for all age groups (CDC, 2010a).[5] Data was grouped into the following categories: children aged 6 months to 17 years, aged 18 to 49 years at high risk, persons aged 18 to 49 years not at high risk, persons aged 50 to 64 years, and all persons aged 65 years or older. CDC defines high risk as including those suffering from "asthma, other lung problems, diabetes,

[2] Source data table was Estimated Vaccination Coverage With Selected Vaccines Among Adolescents Aged 13-17 Years. Available at http://www.cdc.gov/vaccines/stats-surv/nis/nis-2009-released.htm.

[3] The ACIP recommended schedule as of February 2011 did not recommend the HPV vaccine for males.

[4] Source data table was Table 2. Estimated proportion of adults aged >19 years who received selected vaccinations, by age group, high-risk status, National Health Interview Survey (NHIS), United States, 2009. Available at http://www.cdc.gov/nchs/nhis/nhis_2009_data_release.htm.

[5] Source data table was Table 1: Estimated seasonal influenza vaccination coverage among children and adults, by U.S. Department of Health and Human Services (HHS) region, state, and selected age and risk subgroups—United States, Behavioral Risk Factor Surveillance System (BRFSS) and National 2009 H1N1 Flu Survey (NHFS), end of January 2010. Available at http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5916a1.htm.

heart disease, kidney problems, anemia, or weakened immune system caused by a chronic illness or by medicines taken for a chronic illness." The not at high risk category was used for 18- to 49-year-olds because the difference in immunization rates between high and low risk was less than 10% at the national level. For the purposes of this study, it was determined that the cost of estimating the number of high risk individuals did not outweigh the benefit of doing so because it would not materially affect the benefit-to-cost ratio.

C.5 Total Projections

Population estimates were gathered from the U.S. Census Bureau. Because state-level projections were only available until 2030, state-level data for 2030 to 2033 were extrapolated. Total estimated vaccines for each year were calculated by simply multiplying the vaccination rates for each age by the estimated population of that age in each year.

Finally, the number of estimated vaccines was adjusted for wastage and extraimmunization. Wastage is defined as "doses discarded from opened vials after the immunization session, in accordance with multi-dose opened vial policy (MDVP) or otherwise; Doses damaged in unopened vials for any other reasons: e.g. problems with the cold chain (VVM at discard point, frozen DTP, TT, or Hep B), expired vaccine batches, broken vials during transport and handling; Doses diverted from the target population, i.e. booster doses or doses administered to populations outside the targeted group, etc." (WHO, 2011). Table C-1 shows the wastage rates by vaccine employed in this analysis.

Table C-1. Vaccine Wastage Rates

Vaccine	Waste Rate (%)
DTP	1.7
Hep A	1.6
Hep B	1.1
Hib	2.6
IPV	1.5
MMR	1.3
Td	2.1
VAR	1.7
Total	**2.6**

Source: Setia, 2002.

Extraimmunization is defined as having more than the recommended number of doses of any vaccine. Specific extraimmunization rates were gathered for polio, DTaP, MMR, Hib, and hepatitis B and are displayed in Table C-2. The extraimmunization rate for all other vaccines was estimated using the average of the other five.

Table C-2. Extraimmunization Rates among Difference Vaccines[a]

DTaP/DTP	3%
Polio	4%
MMR	2%
Hib	1%
Hep B	1%
Other[b]	2%

[a] Among children at 35 months of age.

[b] Estimated as mean of other values.

Source: CDC, 2007.

C.6 Sources

The Centers for Disease Control and Prevention (CDC). (2007). Assessing extraimmunization among children using immunization information systems. Retrieved from http://cdc.confex.com/cdc/nic2007/techprogram/P12366.HTM

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APPENDIX D: SURVEY MATERIALS

Take 10 to Enhance Vaccine Barcodes!

Vaccine Barcoding Survey

(You could win an iPad!)

VFC providers: Take 10 minutes to respond to a CDC survey about vaccine barcodes and you could win 1 of 10 iPads!

Two-dimensional barcodes could make it easier to collect and document information in patients' records. These barcodes could contain the manufacturer, product, expiration date, and lot number information needed for immunization records. Although manufacturers aren't placing them on vaccines yet, these barcodes could improve patient safety and record keeping.

Through a contract with the Centers for Disease Control and Prevention, RTI International is conducting a 10-minute Vaccine Barcoding Survey to learn more about the impact that including these barcodes on vaccines would have on providers like you.

Please help us explore the benefits and costs of using two-dimensional barcodes by telling us how you think it could affect your immunization practice.

Go now to https://vaccinebarcodingsurvey.rti.org. You can enter a raffle to win 1 of 10 iPads as a thank you for sharing your perspective!*

*You will need to know how many doses of childhood, adolescent, adult, travelers', and influenza vaccines you give per year before starting the survey. This information will improve our ability to understand responses we receive, but if this information is not available, please complete the rest of the survey. A sample survey is available for download from the website. All responses are confidential and will only be used to inform CDC's vaccine barcoding study. For questions and comments, contact barcodingsurvey@rti.org.

CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION

Vaccine Barcoding Survey (Private Medical Practices)

Thanks for taking the time to respond to the Vaccine Barcoding Survey! This is a version of the survey that you can print and use to prepare your response. You must respond to the survey over the Internet. The URL is https://vaccinebarcodingsurvey.rti.org.

To thank you for participating in the survey, you will be entered into a raffle to win 1 of 10 iPads. We anticipate notifying winners in early June.

If you have questions, please contact Fern Braun at 415-848-1370 (US Pacific Time) or send an email to barcodingsurvey@rti.org.

1. Are you a health department or a physician-provider's medical practice?

Respondent Profile

2. What is the 5-digit zip code of your primary or largest practice location?
   - Zip code:

Proceed to 3

3. What is your medical specialty? Please select one choice that best represents your primary practice.
   - Pediatrics
   - Family practice
   - OB/GYN
   - Internal medicine
   - Other (Specify)

Proceed to 4

4. What is the primary setting in which you provide most of your clinical care? Please select one choice.
   - Physician office, solo practice
   - Physician office, single specialty group practice
   - Multi-specialty group practice or clinic
   - Teaching hospital
   - Non-Teaching hospital
   - Other (Specify)

Proceed to 5

5. How many of the following staff are in your practice? If your practice performs immunizations, consider the staff involved in the workflow for immunization at your practice. How many of the following staff at your practice **prepare** vaccines and how many **administer** vaccines?

Staff positions	How many **total** staff are in these positions at your practice?	How many of these staff **prepare** vaccines?	How many of these staff **administer** vaccines?
Physicians			
Physicians assistants			
Nurse practitioners			
Registered nurses			
Licensed practical nurses			
Medical assistants			

Proceed to 6

Immunization Activity Measures

6. Which of the following categories of vaccines does your practice administer? For those vaccine types your practice administers, please provide the approximate number of doses administered in a typical year.

Please note that seasonal influenza is covered in a subsequent question.

Administer Yes or No?	**Vaccine Category**	**Approximate number of doses administered per year?**
	Childhood vaccines *(e.g., Hep B, Hep A, RV, Dtap, Hib, PCV, IPV, MMR, Varicella)*	
	Adolescent vaccines *(e.g., Tdap [for adolescents], MCV, HPV)*	
	Adult vaccines *(e.g., Tdap [for adults], PPSV, Zoster)*	
	Travelers' vaccines *(e.g., Japanese Encephalitis, Typhoid, Yellow Fever, Rabies, etc.)*	

Proceed to 7

7. By the end of the 2010-2011 influenza season, approximately how many doses of seasonal flu do you expect your practice will have administered?

- Doses:

Proceed to 8

8. Does your practice participate in the Vaccines for Children (VFC) program? Q8_VFC

- Yes, I participate in the VFC program.
- No, I do not participate in the VFC program.

If yes, proceed to 9; if no, proceed to 10

9. In a typical year, what percentage of childhood and adolescent vaccine doses administered by your practice do you estimate would be VFC doses?

- Percentage of doses:

Proceed to 10

10. In how many of the following work areas in your practice does your staff draw-up or otherwise **prepare** vaccines for administration?

If the number of staff and the number of doses have been for more than one office location, be sure to account for that here. For example, if you have two offices, each with two nurses' stations, you would enter four nurses' stations.

	Number of locations
Nurses' station(s)	
Dedicated room(s) for immunization or laboratory(-es)	
Examination room(s)	
Other(s) (specify)	

Proceed to 11

Existing IT Infrastructure

11. Does your practice *currently* use any of the following computer systems or functionalities?

System	**Do you have this system? (please indicate yes or no**
Electronic medical record system	
Practice management and billing system	
Automated data input devices, such weight scales or blood pressure devices	
Barcoding and barcode scanning of any type for medical supplies, encounter forms, documentation, etc.	
Other computerized system (specify)	
Other computerized system (specify)	

If no to EMR, go to 12; If yes to EMR go to 13

12. Although you do not have an electronic medical record system at present, when do you expect that you may have a system in use:

- By the end of 2011
- By the end of 2012
- By the end of 2013
- By the end of 2014
- By the end of 2015
- After 2015
- Not sure or have no plans to adopt

Proceed to 14

13. Is your electronic medical record system capable of capturing vaccine information such as lot number and expiration date?

- Yes
- No

Proceed to 14

14. In general, what systems or procedures do you have in place to monitor the number of doses that you have in stock at your practice? Please select the systems that are used at least monthly.

System or procedure?	Please select (Tick mark if yes)	Comment (if any)
Registry- or Internet-based inventory system		
Inventory software system installed in your practice		
Computerized system that is part of your practice management and billing system		
MS Excel spreadsheets or similar files maintained by your staff		
Paper-based systems, such as a ledger		
None; we simply order when the stock looks low		
Other (specify)		

Proceed to 15

15. Do you report immunizations to your state or local immunization registry? Q15_IIS_REP

- Yes
- No

Proceed to 16

16. How do you report immunizations provided by your practice to your state or local immunization registry?

Method	Do you use this method? Yes or No	Approximate percentage of immunizations entered this way (on an annual basis)
Automated upload from computer system into registry		
Manual entry of immunization records into registry		
Faxes of records to registry		
Other (specify)		

Proceed to 17

Perceptions of Two-Dimensional Barcode Utility

	
Figure 1: Example of linear barcode *Current linear barcodes required by the FDA contain only the vaccine product identification information.*	**Figure 2: Example of two-dimensional barcode** *A two-dimensional, or data matrix, barcode can include product identification information as well as lot number and expiration date.*

17. Consider the following: The American Academy of Pediatrics (AAP) is recommending that labels on vaccine vials and syringes have a two-dimensional barcode containing product name, expiration date, and lot number (see Figures 1 and 2).

Rather than have staff read and manually enter this information into records and forms, the information could be automatically scanned into your computer systems (patient records, practice management system, etc.) using an inexpensive handheld or tabletop reader. You could also use barcodes to track and manage vaccine inventory and insure vaccines administered are recorded in your practice management and billing system.

Using barcodes to record vaccine information in patient records may take less time, be more accurate, and insure the proper vaccine is being administered. Using barcodes to manage vaccine inventory could decrease staff time spent to manually track inventory and could also insure proper billing of all vaccines administered. Changes to practices include purchasing scanners, training staff to use the barcode scanners which cost about $300), and modifying your computer systems to accept input from the barcode reader.

Based on this description, do you think your practice would use the barcode? Please select one choice.

- Yes, my practice would likely use the barcode.
- My practice would likely use the barcode if we had an electronic medical record system.
- No, my practice would not likely use the barcode.
- I do not know if my practice would use the barcode.

If no to 15 and yes to 17, then go to 18; otherwise go to 19

18. You indicated that you do not report immunizations to your state or local immunization registry. Do you think that vaccines barcoded with product, expiration date, and lot information would make you more likely to report immunizations?

- Yes
- No
- Unsure or don’t know

Proceed to 19

19. If a vaccine information statement (VIS) included a barcode containing the vaccine type and VIS edition date and could be rapidly scanned into a computer system using a handheld or table-top barcode reader, do you think your practice would use the VIS barcode?

- Yes
- No

Proceed to 20

20 What kinds of assistance do you think your practice would need to start to use the two-dimensional barcode that will be on vaccine labels? Please select all that apply.

- Software support for integration with electronic medical record system
- Software support for integration with practice management and billing systems
- Software development for integration with your state or local immunization registry
- Guidance for integration of the barcode into your practice's workflow for immunization
- Staff training
- Scanner selection and installation
- Other (Specify)

Proceed to 21

21. How important is each of the following factors likely to be in your decision about whether to implement barcode scanning to capture vaccine product, expiration date, and lot number information?

	Unimportant	Somewhat unimportant	Neutral	Important	Very important
Cost of scanner(s)					
Possible changes to workflow					
Training					
Reliability of the barcodes					
Readability of the barcodes					
Usability of the barcode scanners					
Increased accuracy of records					
Decreased time spent recording vaccine information and/or documenting immunization					
More efficient and accurate management of inventory					
Potential decrease in the number of vaccines that do not get billed to a private payer					

Proceed to 22

22. Do you have specific comments or concerns about the acceptability or potential for using two-dimensional barcode scanning in your practice?

Proceed to 23

23. How did you hear about this survey?

- Email
- Postcard
- Newsletter
- Word of mouth
- Other (Specify)

Proceed to 24

24. Thank you for completing our survey. If you would like to be entered into the raffle for the chance to receive 1 of 10 iPads, please provide your contact information.

- Name:
- Address:
- Email:
- Telephone number:

Vaccine Barcoding Survey (Local Health Departments)

Thanks for taking the time to respond to the Vaccine Barcoding Survey! This is a version of the survey that you can print and use to prepare your response. You must respond to the survey over the Internet. The URL is https://vaccinebarcodingsurvey.rti.org.

To thank you for participating in the survey, you will be entered into a raffle to win 1 of 10 iPads. We anticipate notifying winners in early June.

If you have questions, please contact Fern Braun at 415-848-1370 (US Pacific Time) or send an email to barcodingsurvey@rti.org.

1. Are you a health department or a physician-provider's medical practice?

Respondent Profile

2. What is the 5-digit ZIP code of your health department's location? If your health department has more than one location, please use the ZIP code for your main location.
   - Zip Code:

Proceed to 3

3. How would you characterize your health department's organization?
   - State health department
   - County health department
   - City health department
   - Territorial or tribal health department
   - Other (Specify)

Proceed to 4

4. How many of the following staff are in your health department? If your practice performs immunizations, consider the staff involved in the workflow for immunization at your practice. How many of the following staff **prepare** vaccines and how many **administer** vaccines?

Staff positions	How many **total** staff are in these positions at your health department?	How many of these staff **prepare** vaccines?	How many of these staff **administer** vaccines?
Physicians			
Physicians assistants			
Nurse practitioners			
Registered nurses			
Licensed practical nurses			
Medical assistants			

Proceed to 5

Immunization Activity Measures

5. Which of the following categories of vaccines are administered in your immunization clinics? For those vaccine categories administered, please provide the approximate number of doses administered in a typical year.

Please note that seasonal influenza is covered in a subsequent question.

Vaccine Category	Administer this category of vaccine?	Approximate number of doses administered per year?
Childhood vaccines *(e.g., Hep B, Hep A, RV, Dtap, Hib, PCV, IPV, MMR, Varicella)*		
Adolescent vaccines *(e.g., Tdap (for adolescents), MCV, HPV)*		
Adult vaccines *(e.g., Tdap (for adults), PPSV, Zoster)*		
Travelers' vaccines *(e.g., Japanese Encephalitis, Typhoid, Yellow Fever, Rabies, etc.)*		

Proceed to 6

6. By the close of the 2010-2011 influenza season approximately how many doses of seasonal flu do you expect will have been administered in your clinics?

- Doses:

Proceed to 7

7. In how many of the following locations are vaccines drawn-up or otherwise prepared for administration?

If the number of staff and the number of doses have been for more than one office location, be sure to account for that here. For example, if you have two different offices, each with two nurses' stations, you would enter for nurses' stations.

Location	Number of locations (Please indicate below)
Nurses' station(s)	
Dedicated room(s) for immunization or laboratory(-es)	
Examination room(s)	
Other(s) (specify)	

Proceed to 8

Existing IT Infrastructure

8. Does your health department *currently* use any of the following computer systems or functionalities?

System	Do you have this system?
Electronic medical record system	
Health department management and billing system	
Automated data input devices, such as weight scales or blood pressure devices	
Barcoding and barcode scanning of any type for medical supplies, encounter forms, documentation, etc.	
Other computerized system (specify)	
Other computerized system (specify)	

If no to EMR, go to 9; If yes to EMR go to 10

9. Although you do not have an electronic medical record system at present, when do you expect that you may have a system in use:

- By the end of 2011
- By the end of 2012
- By the end of 2013
- By the end of 2014
- By the end of 2015
- After 2015
- Not sure or have no plans to adopt

Proceed to 11

10. Is your electronic medical record system capable of capturing vaccine information such as lot number and expiration date?

- Yes
- No

Proceed to 11

11. In general, what systems or procedures do you have in place to monitor the number of doses that you have in stock for your immunization clinic(s)? Please select the systems that are used at least monthly.

Systems or Procedures?	**Do you use this system or procedure?**	**Comment (if any)**
Registry- or Internet-based inventory system		
Inventory software system installed in your health department		
Computerized system that is part of your health department management and billing system		
MS Excel spreadsheets or similar files maintained by your staff		
Paper-based systems, such as a ledger		
None; we simply order when the stock looks low		
Other (Specify)		

Proceed to 12

12. Do you report immunizations provided in your health department's immunization clinic(s) to a state immunization registry?

- Yes
- No

If yes, proceed to 13; if no, proceed to 14

13. How do you report immunizations provided by your health department's immunization clinic(s) to your state immunization registry?

Method	**Do you use this method? Yes or No**	**Approximate percentage of immunizations entered this way (on an annual basis)**
Automated upload from computer system into registry		
Manual entry of immunization records into registry		
Faxes of records to registry		
Other (specify)		

Proceed to 14

Perceptions of Two-Dimensional Barcode Utility

	
Figure 1: Example of linear barcode *Current linear barcodes required by the FDA contain only the vaccine product identification information.*	**Figure 2: Example of two-dimensional barcode** *A two-dimensional, or data matrix, barcode can include product identification information as well as lot number and expiration date.*

14. Consider the following: The American Academy of Pediatrics (AAP) is recommending that labels on vaccine vials and syringes have a two-dimensional barcode containing product name, expiration date, and lot number (see Figures 1 and 2).

Rather than have staff read and manually enter this information into records and forms, the information could be automatically scanned into your computer systems (patient records, practice management system, etc.) using an inexpensive handheld or tabletop reader. You could also use barcodes to track and manage vaccine inventory and insure vaccines administered are recorded in your practice management and billing system.

Using barcodes to record vaccine information in patient records may take less time, be more accurate, and insure the proper vaccine is being administered. Using barcodes to manage vaccine inventory could decrease staff time spent to manually track inventory and could also insure proper billing of all vaccines administered. Changes to practices include purchasing scanners, training staff to use the barcode scanners which cost about $300), and modifying your computer systems to accept input from the barcode reader.

Based on this description, do you think your health department's immunization clinic(s) would use the barcode?

- Yes, my health department's immunization clinic(s) would likely use the barcode.
- My health department's immunization clinic(s) would likely use the barcode if we had an electronic medical record system.
- No, my health department's immunization clinic(s) would not likely use the barcode.
- I do not know if my health department's immunization clinic(s) would use the barcode.

If no to 12 and yes to 14, then go to 15; otherwise go to 16

15. You indicated that you do not report immunizations to an immunization registry. Do you think that vaccines barcoded with product, expiration date, and lot information would make you more likely to report immunizations to the registry?

- Yes
- No
- Unsure or don't know

Proceed to 16

16. If a vaccine information statement (VIS) included a barcode containing the vaccine type and VIS edition date and this information could be rapidly scanned into a computer system using a handheld or table-top barcode reader, do you think your health department may use the barcode? L16_VIS

- Yes
- No

Proceed to 17

17 What kinds of assistance do you think your health department would need to start to use the two-dimensional barcode that will be on vaccine labels?

- Software support for integration with electronic medical record system
- Software support for integration with health department management and billing systems
- Software support for integration with immunization registry
- Guidance for integration of the barcode into your health department's workflow for immunization
- Staff training
- Scanner selection and installation
- Other (Specify)

Proceed to 18

18. How important is each of the following factors likely to be in your decision about whether to implement barcode scanning to capture vaccine product, expiration date, and lot number information?

Factors	Unimportant	Somewhat unimportant	Neutral	Important	Very important
Cost of scanner(s)					
Possible changes to workflow					
Training					
Reliability of the barcodes					
Readability of the barcodes					
Usability of the barcode scanners					
Increased accuracy of records					
Decreased time spent recording vaccine information and/or documenting immunization					
More efficient and accurate management of inventory					
Potential decrease in the number of vaccines that do not get billed to a private payer					

Proceed to 19

19. Do you have specific comments or concerns about the acceptability or potential for using two-dimensional barcode scanning in your health department's immunization clinic(s)?

Proceed to 20

20. How did you hear about this survey?

- Email
- Postcard
- Newsletter
- Word of mouth
- Other: (Specify)

Proceed to 21

21. Thank you for completing our survey. If you would like to be entered into the raffle for the chance to receive 1 of 10 iPads, please provide your contact information. We will notify winners by telephone and email in June.

- Name:
- Address:
- Email:
- Telephone number:

APPENDIX E: RESPONSE COUNT BY VFC JURISDICTION

Using the USDA Rural-urban Continuum Code (RUCC) (USDA, 2004), we assigned respondent counties as either a county in a metro area or a nonmetro county. Based on these RUCC classifications, 82% of provider respondents were located in metro areas, while 55% of LHD respondents were located in metro areas (Table E-1). To map respondents, we aggregated responses based on the first four digits of the supplied zip code.

Table E-1. Number of Responses by VFC Jurisdiction

		Providers			LHDs		
Area	**Participated**	**Number of Responses**	**Metro (RUCC codes)**	**Nonmetro (RUCC codes)**	**Number of Responses (LHDs)**	**Metro (RUCC codes)**	**Nonmetro (RUCC codes)**
Alabama	No response	5	5	0	1	1	0
Alaska	Declined	3	2	1	0	0	0
American Samoa	No response	0	NA	NA	0	NA	NA
Arizona	Yes	48	41	7	5	4	1
Arkansas	Yes	24	15	9	0	0	0
California	Yes	124	119	5	12	9	3
Chicago	Yes	35	35	0	5	5	0
Colorado	Yes	74	55	19	23	10	13
Connecticut	Yes	65	62	3	10	10	0
Delaware	Yes	10	6	4	4	3	1
District of Columbia	Yes	4	4	0	0	0	0
Florida	Yes	199	190	9	7	6	1
Georgia	Yes	19	19	0	0	0	0
Guam	No response	0	NA	NA	0	NA	NA
Hawaii	Declined	3	3	0	0	0	0
Houston	Declined	40	40	0	3	3	0
Idaho	Yes	11	7	4	2	0	2
Illinois	Declined	27	23	4	2	0	2
Indiana	Yes	15	14	1	13	10	3
Iowa	Declined	4	3	1	1	1	0
Kansas	Yes	50	33	17	88	21	67
Kentucky	Yes	41	20	21	42	19	23
Louisiana	Yes	31	21	10	15	10	5
Maine	No response	7	4	3	0	0	0
Maryland	No response	9	8	1	0	0	0
Massachusetts	Yes	170	170	0	55	54	1
Michigan	Yes	206	162	44	37	23	14
Minnesota	No response	6	6	0	1	0	1
Mississippi	Declined	0	0	0	0	0	0
Missouri	Yes	6	5	1	80	25	55
Montana	Declined	0	0	0	1	1	0
Nebraska	Yes	57	34	23	8	2	6
Nevada	Yes	4	4	0	0	0	0
New Hampshire	Declined	2	1	1	0	0	0

(continued)

Table E-1. Number of Responses by VFC Jurisdiction (continued)

Area	Participated	Providers			LHDs		
		Number of Responses	Metro (RUCC codes)	Nonmetro (RUCC codes)	Number of Responses (LHDs)	Metro (RUCC codes)	Nonmetro (RUCC codes)
New Jersey	Yes	72	72	0	26	26	0
New Mexico	No response	5	3	2	0	0	0
New York City	Yes	81	81	0	2	2	0
New York State	Yes	35	32	3	3	3	0
North Carolina	Yes	83	63	20	39	23	16
North Dakota	Yes	14	6	8	15	0	15
Northern Mariana Islands	No response	0	NA	NA	0	NA	NA
Ohio	Yes	81	69	12	38	24	14
Oklahoma	No response	3	2	1	0	0	0
Oregon	Yes	111	70	41	24	9	15
Pennsylvania	Yes	87	72	15	5	2	3
Philadelphia	Yes	57	57	0	10	10	0
Puerto Rico	Yes	4	NA	NA	12	NA	NA
Rhode Island	No response	0	0	0	0	0	0
San Antonio	Declined	7	7	0	0	0	0
South Carolina	Yes	93	65	28	15	10	5
South Dakota	Yes	54	29	25	27	5	22
Tennessee	No response	9	8	1	0	0	0
Texas	Yes	435	350	85	119	81	38
Utah	Yes	58	53	5	13	10	3
Vermont	No response	4	1	3	0	0	0
Virgin Islands	No response	0	NA	NA	0	NA	NA
Virginia	Yes	76	64	12	42	28	14
Washington	Declined	10	9	1	2	2	0
West Virginia	Yes	81	41	40	32	14	18
Wisconsin	No response	6	5	1	2	2	0
Wyoming	Yes	10	4	6	10	1	9
Total		**2,775**	**2,274**	**497**	**851**	**469**	**370**

Source: RTI International.

References

U.S. Department of Agriculture, Economic Research Service. (2004). 2003 rural-urban continuum codes. Retrieved from http://www.ers.usda.gov/data-products/rural-urban-continuum-codes.aspx

APPENDIX F: TIME–MOTION STUDY

This appendix reviews a time–motion study conducted by the Verden Group (Nyack, NY) the data for which were analyzed by RTI International to determine the potential time savings associated by eliminating some documentation steps.

In 2009, the Verden Group performed a study of private practices' immunization business, including a time–motion study of immunization workflow covering ordering, inventory management, administration, record keeping, and billing. It recruited 36 practices to participate in the study, selecting practices to make the study as representative of the administration of pediatric and adolescent doses as possible. Selection criteria included size (number of physicians), urban/suburban/rural, specialty, EHR use, and annual number of doses administered. Of 36 practices, 3 were used to pilot and refine protocols; the time–motion data used in this analysis were from the remaining 33 practices (see Table 7-1).

The resulting study data included activity-specific estimates for the administration of 724 vaccines to 302 patients (cases) at 33 practices (30 pediatric practices, 3 family practices) across 17 states. RTI International purchased the time–motion data for multiple practices in lieu of conducting a study in just one practice. See also Table F-1.

Immunization workflow can be grouped into eight separate steps necessary for vaccine administration (Table F-2). For the purposes of our analysis, based on interviews, we expect the vaccine barcode will be read during the "Draw Vaccine" component of Step 5, and the time savings will result from reduced time spent documenting the vaccination (Step 8).

To provide the most accurate estimate of time per dose, RTI weighted each sample case by the number of doses received and the annual number of doses administered by the practice (Equation F.1).[1]

$$Weight_{ij} = \frac{CaseVax_{ij}}{\sum_{nj=1}^{Nj} CaseVax_{nj}} \times AnnualVax_{j} \qquad \text{(F.1)}$$

where

$Weight_{ij}$	Weight for sample case *i* in practice *j*.
$CaseVax_{ij}$	Number of vaccinations given to sample case *i*.
$\sum_{ni=1}^{Nj} CaseVax_{nj}$	Total number of vaccinations administered to sample cases in practice *j*.
$AnnualVax_{j}$	Total number of vaccines administered annually in practice *j*.

[1] Missing data were handled in a variety of ways. For many cases, Verden Group estimated the time for unobserved activities using the per-dose time of observed cases at the same practice. For missing data not estimated by the Verden Group, RTI used the weighted per-dose mean for the activity within the practice. If a practice was missing data for an entire activity, RTI used the weighted per-dose mean across all practices to replace the missing values. Unique weighted per-dose means were estimated separately for practice size and EHR to replace missing values when analyzing times for process steps by practice size and EHR.

Table F-1. Attributes of Practices Included in Time-Motion Study

Practice	State	Area	Practice Size[a]	Practice Type	EHR?	Total Annual Vaccinations
003	IL	Suburban	Small	Pediatrician	Yes	4,073
004	NJ	Suburban	Large	Pediatrician	No	14,463
005	NY	Suburban	Large	Pediatrician	No	7,850
006	MA	Suburban	Solo	Pediatrician	Yes	2,080
007	RI	Urban	Large	Pediatrician	Yes	13,336
008	RI	Suburban	Small	Pediatrician	Yes	9,215
009	CT	Suburban	Small	Pediatrician	Yes	10,208
010	FL	Suburban	Large	Pediatrician	No	19,480
011	TX	Urban	Solo	Pediatrician	Yes	3,446
012	NY	Suburban	Large	Pediatrician	No	10,950
013	CT	Suburban	Large	Pediatrician	Yes	111,524
014	NJ	Suburban	Small	Pediatrician	No	9,878
015	PA	Suburban	Large	Pediatrician	No	34,557
016	PA	Suburban	Small	Pediatrician	No	8,410
017	VA	Suburban	Large	Pediatrician	Yes	23,500
018	VA	Suburban	Small	Pediatrician	Yes	19,115
019	NV	Suburban	Small	Family Practice	Yes	1,262
020	NV	Suburban	Solo	Pediatrician	Yes	2,616
021	CA	Suburban	Solo	Pediatrician	Yes	7,774
022	NV	Urban	Solo	Pediatrician	Yes	8,178
023	OH	Suburban	Solo	Pediatrician	No	2,223
024	OH	Suburban	Solo	Pediatrician	Yes	7,937
025	NY	Urban	Large	Family Practice	Yes	3,240
026	OK	Suburban	Small	Family Practice	Yes	1,868
027	OK	Urban	Small	Pediatrician	No	13,567
028	FL	Suburban	Large	Pediatrician	No	6,549
029	NC	Suburban	Large	Pediatrician	No	4,708
030	TN	Rural	Small	Pediatrician	Yes	10,152
031	NY	Suburban	Large	Pediatrician	Yes	12,509
032	NC	Suburban	Large	Pediatrician	Yes	23,451
033	MO	Urban	Large	Pediatrician	Yes	24,527
034	CA	Suburban	Large	Pediatrician	No	13,815
035	PA	Suburban	Large	Pediatrician	Yes	12,157

[a] Solo (S) practices have 1–1.5 full-time physicians, small practices (S) have 2–7 full-time physicians, and large practices (L) have 8 or more full-time physicians. Source: The Verden Group for RTI International.

EHR (electronic health record)

Table F-2. Vaccine Administration Process

Step in Timeline	Resource Used	Process Involved	Data Collection Tool/Section/Field	How Time Was Calculated
1 (or just prior to 4) At the beginning of process or process prior to patient visit or just prior to being "roomed"/ set up or just prior to provider seeing patient in room	Nurse (MA, LPN, RN) or Provider (Physician/ NP/PA)	Nurse or provider reviews patient chart to see if vaccines are up to date or if any are missing. Involves reading chart and looking up vaccine history.	Observed vaccine administration form/Documentation and time > Record review	Timed start and end of review process, including reading chart information and communication between nurse and provider about when patient should be brought current
2 (or just prior to 5) This sometimes occurred when patient was being set up for the visit in the exam room, other times occurred just prior to nurse (or provider) giving the vaccine to patient	Nurse (MA, LPN, RN)	Nurse provides patient with a Vaccine Information Sheet (VIS) prior to patient receiving vaccine. VIS explains risks and benefits. Patients must be provided with this information to obtain consent.	Observed vaccine administration form/None/None (recorded free hand on form)	Timed nurses pulling VIS forms from file drawers, printing VIS sheet, or locating copy of VIS from other places
3	Provider (Physician/ NP/PA)	Provider counsels patient and obtains consent (occurs in room, provider explains vaccine risks and benefits)	Observed vaccine administration form/In room: Time and supplies > Counseling	Timed in-room discussion with patient about vaccine only
4	Provider (Physician/ NP/PA)	Provider gives order (either through verbal, written, or EHR methods)	Observed vaccine administration form/Orders given > Time > By	Timed start and end of writing, inputting, or verbalizing order to nurse
5	Nurse (MA, LPN, RN)	Nurse draws up/prepares vaccines. This may include drawing vaccine into syringes, reconstitution of vaccine, adding needle tip to prefilled syringes, etc.	Observed vaccine administration form > In lab: Time and supplies > Time to set up tray and total draw time	Two sets of timing For tray: timed gathering of supplies (bandaids, cotton, etc.) For drawing: timed from "hand on fridge handle" through all vaccines being ready on tray for dispensing. Each vaccine product draw time was timed separately
6	Nurse (MA, LPN, RN) or Provider (Physician/ NP/PA)	Nurse or provider positions patient and administers the vaccine(s)	Observed vaccine administration form > In room: Time and supplies > Giving vaccine	Timed from nurse/provider re-entering the exam room through all vaccines being administered physically

(continued)

Table F-2. Vaccine Administration Process (continued)

Step in Timeline	Resource Used	Process Involved	Data Collection Tool/Section/Field	How Time Was Calculated
7	Nurse (MA, LPN, RN) or Provider (Physician/ NP/PA)	Nurse or provider removes/disposes of needles and syringe and/or product packaging (vials, tubes, etc.) in appropriate receptacle	Observed vaccine administration form > Clean up time	Timed from nurse/provider concluding the administration (if sharps containers were in room) through exiting the room and disposing of sharps and product containers in lab
8	Nurse (MA, LPN, RN) and/or Provider (Physician/ NP/PA)	Nurse and/or provider documents administration (if provider wrote orders, likely does not have to chart anything further unless patient had specific concerns). Nurse must record vaccine site that vaccine was administered (e.g., right thigh), lot number, vaccine product and type, and date of administration. Documentation may also occur in several other places depending on process and protocol.	Observed vaccine administration form > Documentation and time > chart note and patient card (optional) and PM system (if inventory is tracked that way) and in log book (if inventory tracked that way) and in vaccine registry (if electronic submission is not available and it is mandatory)	Timed from nurse/provider entering data into a chart or repository through completion (no further handling required)
	Nurse (MA, LPN, RN) or Office Manager or Provider (Physician/ NP/PA)	Reporting administered vaccines to city and/or state registries. Involves either manually entering data into registry databases or submitting data electronically via an interface between PM system and registry.	**Estimated:** Record keeping Survey interview > Reporting > Registry and/or **Observed:** Observed vaccine administration form/documentation and Time > Free form notes	Some practices had observed time, others provided estimates. For observed time, if resources logged data to registry at same time as administration, they were timed from log on to registry through completion of fields in database and log off/file save

Source: The Verden Group for RTI International.

MA (medical assistant), LPN (licensed practical nurse), RN (registered nurse), NP (nurse practitioner), PA (physician's assistant), VIS (Vaccine Information Sheet), EHR (electronic health record), PM (practice management)

Vaccine administration[2] required less than 4 minutes (221 seconds) on average (Table F-3). Average times at each practice ranged between 1.5 minutes (92 seconds) and over 7 minutes (427 seconds).

Table F-3. Average Time per Process Step by Practice

Practice	Annual Vaccines	Size	EHR	Process Step 1	3	4	5	6	7	8	Total
003	4,073	S	Y	0.0	67.1	17.6	42.5	31.3	7.2	44.1	209.7
004	14,463	L	N	0.0	15.1	5.8	37.6	21.8	0.0	56.9	137.2
005	7,850	L	N	0.0	33.9	6.5	51.0	26.1	4.1	51.1	172.6
006	2,080	SO	Y	0.0	41.7	3.8	81.3	32.1	0.0	20.3	179.2
007	13,336	L	Y	0.0	46.1	1.5	45.0	22.2	0.0	18.5	133.3
008	9,215	S	Y	0.0	137.9	4.3	119.3	41.0	0.0	124.0	426.5
009	10,208	S	Y	0.0	36.8	5.0	141.0	41.5	0.0	38.3	262.6
010	19,480	L	N	0.0	33.9	0.0	118.6	33.6	0.0	22.2	208.2
011	3,446	SO	Y	0.0	13.2	1.3	55.6	10.3	0.0	12.0	92.4
012	10,950	L	N	0.0	45.0	3.4	55.6	38.5	0.0	69.4	211.9
013	111,524	L	Y	0.0	69.7	4.4	48.4	41.2	8.4	71.5	243.5
014	9,878	S	N	0.0	75.9	4.2	51.1	25.1	5.0	56.6	217.9
015	34,557	L	N	0.0	31.6	24.7	47.2	34.0	3.9	64.7	206.1
016	8,410	S	N	0.0	54.4	7.5	68.9	28.0	6.1	111.8	276.7
017	23,500	L	Y	0.0	26.3	13.9	73.8	25.4	13.1	57.1	209.6
018	19,115	S	Y	19.5	35.5	0.0	44.9	44.3	4.1	21.0	169.3
019	1,262	S	Y	0.0	78.0	9.8	68.4	57.8	6.4	201.4	421.8
020	2,616	SO	Y	24.1	41.5	0.0	75.6	49.7	7.4	74.6	272.9
021	7,774	SO	Y	0.0	47.3	4.6	47.3	16.1	8.1	57.0	180.3
022	8,178	SO	Y	24.9	57.2	12.3	35.7	20.1	7.0	61.3	218.4
023	2,223	SO	N	0.0	29.1	3.4	82.1	77.9	13.1	66.3	271.9
024	7,937	SO	Y	50.5	71.3	17.4	39.2	40.3	6.3	71.9	296.8
025	3,240	L	Y	18.1	77.1	9.5	100.9	44.7	10.2	65.8	326.3
026	1,868	S	Y	24.9	29.5	23.1	67.4	58.1	7.7	151.9	362.6
027	13,567	S	N	0.0	43.6	3.3	55.0	34.7	4.6	77.2	218.4
028	6,549	L	N	0.3	49.6	15.6	97.0	31.1	4.7	59.0	257.3
029	4,708	L	N	8.1	35.4	6.2	55.4	29.6	9.7	138.3	282.7
030	10,152	S	Y	4.4	17.8	15.0	66.6	35.6	5.5	64.5	209.5
031	12,509	L	Y	0.0	37.2	13.3	94.1	56.9	4.3	35.7	241.5
032	23,451	L	Y	0.0	13.5	0.0	43.2	23.5	4.5	103.3	188.0
033	24,527	L	Y	2.8	30.9	15.0	71.1	24.6	5.5	46.1	196.0
034	13,815	L	N	2.3	36.0	7.6	37.0	20.8	5.5	53.9	163.0
035	12,157	L	Y	1.7	89.9	15.0	47.4	28.2	3.5	68.3	254.0
Average				**2.9**	**48.1**	**8.0**	**59.9**	**33.9**	**5.5**	**62.9**	**221.0**

[a] Solo (S) practices have 1–1.5 full-time physicians, small practices (S) have 2–7 full-time physicians, and large practices (L) have 8 or more full-time physicians. EHR (electronic health record) Source: The Verden Group for RTI International.

[2] Excludes time spent providing patient the Vaccine Information Sheet (process Step 2).

The longest process step was the documentation taking place after the vaccine was administered at 62.9 seconds, accounting for 28% of the labor time. Record keeping was disaggregated into documentation that is not expected to be eliminated by using 2D barcodes (chart notes, VFC usage sheets [which vary by VFC jurisdiction], superbill, other [including parental signatures]) and documentation that could be eliminated by 2D barcodes (logbooks, entry of vaccine details). Documentation that would not be affected amounted to 19.2 seconds.

The amount of time expended on documentation that could be eliminated was 43.7 seconds per dose at practices with EHRs and 40.8 seconds per dose at practices without EHRs (Table F-4). Scanning a vial takes 4.3 seconds on average, according to the Canadian inventory pilot (Pererira & Bishai, 2010).[3] Thus, we expect that practices with EHRs will save approximately 39.4 seconds per dose and practices without EHRs will save about 36.5 seconds per dose.

[3] The 95% CI is 3.5 to 5.2 seconds per acceptable scan; includes 1.3 attempts per vial to get a good read.

Table F-4. Estimated Change in Documentation Time per Dose, with and without an EHR System

		Change in Documentation Time Relative to Baseline	
	Baseline	**With EHR**	**No EHR**
Unchanged documentation steps			
Chart notes for immunization	8.0	-	-
VFC usage sheets	0.3	-	-
Superbill	1.4	-	-
Other	9.6	-	-
Subtotal	19.2	19.2	19.2
Affected documentation steps			
Private dose administration logbook	1.5	−1.5	−1.5
Recording product, expiration date, and lot…			
…in patient records	26.7	−26.7	−26.7
…in practice management system	8.5	−8.5	−8.5
…in IIS	4.7	−4.7	−4.0
…in EHR data fields	2.2	−2.2	0.0
Subtotal	43.7	−43.7	−40.8
2D barcode scan time		+4.3	+4.3
Total estimated documentation time	62.9	23.5	26.4
Change in documentation time		−39.4	−36.5
Percentage change in documentation time		−63%	−58%

Source: RTI analysis of time–motion study data acquired from the Verden Group, except for barcode scan time, which was Pereira et al. (2010).

EHR (electronic health record), VFC (Vaccines for Children), IIS (immunization information system)

APPENDIX G: DATA MAPPING

The purpose of these tables is to provide mapping across standards for 2D barcoding. Table G-1 outlines the purpose of each table.

Table G-1. Introduction

Table Name	Purpose
Data Mapping	Includes the most comprehensive mapping across standards. For each standard, it includes the data content with each identifier, data type, data format, data field length, and position of each element in the standard
Data Mapping—Specific Data	Is a subset of the data in the data mapping table. Whereas the data mapping table includes information such as headers and footers, this table contains only the GTIN, lot number, and expiration date and how those pieces of information would be mapped across standards
Researcher Notes	Includes a summary of the NDC-GTIN mapping issue, notes for HL7, and a pictorial view of how elements from the GTIN are mapped to the NDC
Mapping—GTIN-NDC-CVX_MVX	Outlines the relationship between the GTIN, NDC, CVX, and MVX to demonstrate how mapping tables might work
Health Care—GS1-128	Summarizes the application identifiers used in the GS1 standard
X12 Formatting Example	Provides an example of how the barcode would work using an X12 message for drug billing
Abbreviations	Lists commonly used abbreviations
Summary Table	Is a summary table based on data mapping—specific data

Table G-2. Data Mapping for Vaccine Barcodes

This table has the most comprehensive mapping across standards. For each standard, it includes the data content with each identifier, data type, data format, data field length, and position of each element in the standard.

Legend: GTIN = Similar data content
Lot number = Similar data content
Expiration date = Similar data content

GS1			HL7 Vaccine Administration Data					HL7 — RXA Message Segment (Pharmacy/Treatment Administration)				CDC 2.5.1 Implementation Guide			X12 — 837 P Transaction					HITSP Immunization Message Component				Pharmacy EDI[b]			
Application Identifiers	Format	Data Content	SEQ	LEN	DT	ITEM #	Data Content	SEQ	LEN	DT	Data Content	LEN	DT	Data Content	SEQ	LEN	DT	Data Content	Notes	LEN	DT	Data Content	Notes	LEN	DT	Data Content	Notes
Header		Organization name, corporate logo, and GLN number of the producer	1	4	NM	00342	Give sub-ID counter	1		NM	Give sub-ID counter	4	NM	Give sub-ID counter	1	5	NM	Labeler code	The first five digits identify the manufacturer of the drug and are assigned by the Food and Drug Administration	-	NM	Substance lot number	-	4–5	NM	Labeler code	Follows NDC format
Header		Product description (e.g., brand / quality / age ref/ size / number in case / % ABV)	2	4	NM	00344	Administration sub-ID counter	2		DTM	Administration sub-ID counter	4	NM	Administration sub-ID counter	2	4	NM	Product segment	It identifies the strength, dosage form, and formulation			Substance manufacturer	Follows HL7	3–4	NM	Product segment	Follows NDC format
0	n2 + n18	SSCC (serial shipping container code)	3	26	TS	00345	Date/time start of administration	3		DTM	Date/time start of administration	26	TS	Date/time start of administration	3	2	NM	Package segment	It identifies package size			Administered code	Follows HL7. This field identifies the medical substance administered. If the substance administered is a vaccine, CVX codes should be used in the first triplet to code this field (see HL7 Table 0292—Codes for vaccines administered).	1–2	NM	Package segment	Follows NDC format
1	n2 + n14	Global Trade Item Number (GTIN)	4	26	TS	00346	Date/time end of administration	4		DTM	Date/time end of administration	26	TS	Date/time end of administration								Administration notes	Free text notes from the provider administering the medication.				
2	n2 + n14	GTIN of contained trade items	5	100	CE	00347	Administered code[a]	5		CWE	Administered code	100	CE	Administered code													
10	n2 + X..20	Batch or lot number	6	20	NM	00348	Administered amount	6		NM	Administered amount	20	NM	Administered amount													
11 (**)	n2 + n6	Production date (YYMMDD)	7	60	CE	00349	Administered units	7		CWE	Administered units	60	CE	Administered units													

Legend: GTIN = Similar data content
Lot number = Similar data content
Expiration date = Similar data content

GS1			HL7 Vaccine Administration Data					HL7 — RXA Message Segment (Pharmacy/Treatment Administration)				CDC 2.5.1 Implementation Guide			X12 — 837 P Transaction					HITSP Immunization Message Component				Pharmacy EDI[g]			
12 (**)	n2 + n6	Due date (YYMMDD)	8	60	CE	00350	Administered dosage form	8		CWE	Administered dosage form	60	CE	Administered dosage form														
13 (**)	n2 + n6	Packaging date (YYMMDD)	9	200	CE	00351	Administration notes	9		CWE	Administration notes	200	CE	Administration notes														
15 (**)	n2 + n6	Best before date (YYMMDD)	10	200	XCN	00352	Administering provider	10		XCN	Administering provider	200	XCN	Administering provider														
17 (**)	n2 + n6	Expiration date (YYMMDD)	11	200	CM	00353	Administered-at location	11		LA2	Administered-at location	200	CM	Administered-at location														
20	n2 + n2	Variant number	12	20	ST	00354	Administered per (time unit)	12		ST	Administered per (time unit)	20	ST	Administered per (time unit)														
21	n2 + X..20	Serial number	13	20	NM	01134	Administered strength	13		NM	Administered strength	20	NM	Administered strength														
22	n2 + X..29	Secondary data fields	14	60	CE	01135	Administered strength units	14		CWE	Administered strength units	60	CE	Administered strength units														
240	n3 + X..30	Additional Item Identification	15	20	ST[b]	01129	Substance lot number	15		ST	Substance lot number	20	ST	Substance lot number														
241	n3 + X..30	Customer part number	16	26	TS[c]	01130	Substance expiration date	16		DTM	Substance expiration date	26	TS	Substance expiration date														
242	n2 + n…6	Made-to-order variation number	17	60	CE[d]	01131	Substance manufacturer name	17		CWE	Substance manufacturer name	60	CE	Substance Manufacturer Name														
250	n3 + X..30	Secondary serial number	18	200	CE	01136	Substance refusal reason	18		CWE	Substance/treatment refusal reason	200	CE	Substance refusal reason														
251	n3 + X..30	Reference to source entity	19	200	CE	01123	Indication	19		CWE	Indication	200	CE	Indication														
253	n3 + n13 + n..17	Global Document Type Identifier (GDTI)	20	2	ID	01223	Completion status	20		ID	Completion status	2	ID	Completion status														
254	n3 + X..20	GLN extension component	21	2	ID	01224	Action code	21		ID	Action code—RXA	2	ID	Action code														
30	n2 + n..8	Count of items (variable measure trade item)	22	26	TS	01225	System entry date/time	22		DTM	System entry date/time	26	TS	System entry date/time														
			23	5	NM	01696	Administered drug strength volume	23		NM	Administered drug strength volume	5	NM	Administered drug strength volume														
			24	250	CWE	01697	Administered drug strength volume units	24		CWE	Administered drug strength volume units	250	CWE	Administered drug strength volume units														
			25	60	CWE	01698	Administered barcode identifier *****	25		CDW	Administered barcode identifier *	60	CWE	Administered barcode identifier														
			26	1	ID	01699	Pharmacy order type	26		ID	Pharmacy order type	1	ID	Pharmacy order type														

Legend: GTIN = Similar data content
Lot number = Similar data content
Expiration date = Similar data content

GS1			HL7 Vaccine Administration Data					HL7 — RXA Message Segment (Pharmacy/Treatment Administration)				CDC 2.5.1 Implementation Guide			X12 — 837 P Transaction					HITSP Immunization Message Component				Pharmacy EDI[g]			
			27	180	PL	02264	Administer-at	27		PL	Administer-at																
			28	106	XAD	02265	Administered-at address	28		XAD	Administered-at address																
			[a] See researcher notes [b] Any printable ASCII characters are allowed. [c] Time stamp data type [d] Coded element data type. [e] Definition: This field contains the pharmacy system's assigned barcode number for the give occurrence. For IV orders, many pharmacy systems generate a barcode number to identify a specific bag/bottle of the order. This number can be an instance identifier—unique for the patient, drug combination, and schedule instance, or it may be just a drug identifier. The composition and use of the barcode number depend on application negotiation. An example of this field follows: The barcode number is in the following format: 9XXXXXXX000. The number 9 is a constant, XXXXXXX is seven (7) ****characters for a unique identifier assigned or derived from the patient account and order ID, and 000 is the zero-filled three (3) character IV bottle number. The maximum length of the first component of this field is 40 characters to allow for the maximum existing barcode length in use today. The second component contains the description of the item being coded and the third component may define the barcode type. Example: 12345678901^IV bottle^3X9											[f] Data retrieved from health care claim professional 4010 and 5010 versions. For further information about this standard see researcher notes.					Data retrieved from HITSP Immunization Message Component document				[g] The pharmacy standard follows the National Drug Code (NDC) for the product administered			

Table G-3. Data Mapping—Specific Data

This table is a subset of the data in the data mapping table. Whereas the data mapping table includes information such as headers and footers, this table contains only the GTIN, expiration date, and lot number, and how those pieces of information would be mapped across standards.

Data Mapping for Vax Barcodes

Legend: GTIN = Similar data content
Lot Number = Similar data content
Expiration date = Similar data content

GS1			HL7 VACCINE ADMINISTRATION DATA					HL7 RXA message segment (Pharmacy/Treatment Administration)				CDC 2.5.1 Implementation Guide			X12 837 P Transaction**					HITSP Immunization Message Component				Pharmacy EDI *			
Application Identifiers	Format	Data Content	SEQ	LEN	DT	ITEM #	Data Content	SEQ	LEN	DT	Data Content	DT	LEN	Data Content	SEQ	LEN	DT	Data Content	Notes	LEN	DT	Data Content	Notes	LEN	DT	Data Content	Notes
1	n2 + n14	Global Trade Item Number (GTIN)	17	60	CE***	01131	Substance manufacturer name	5		CWE	Administered code	CE	60	Substance manufacturer name	1	5	NM	Labeler code	The first five digits identify the manufacturer of the drug and are assigned by the Food and Drug Administration			Substance manufacturer	Follows HL7	4–5	NM	Labeler code	Follows NDC format
			5	100	CE	00347	Administered code	17		CWE	Substance manufacturer name	CE	100	Administered code	2	4	NM	Product segment	It identifies the strength, dosage form and formulation			Administered code	Follows HL7-This field identifies the medical substance administered. If the substance administered is a vaccine, CVX codes should be used in the first triplet to code this field (see HL7 Table 0292 - Codes for vaccines administered).	3–4	NM	Product segment	Follows NDC format
			23	5	NM	01696	Administered drug strength volume	25		CDW	Administered barcode identifier *	NM	5	Administered drug strength volume	3	2	NM	Package segment	It identifies package size					1–2	NM	Package segment	Follows NDC format
			24	250	CWE	01697	Administered drug strength volume units	15		ST	Substance lot number	CWE	250	Administered drug strength volume units													
10	n2 + X..20	Batch or lot number	15	20	ST*	01129	Substance lot number	16		DTM	Substance expiration date	ST	20	Substance lot number						-	NM	Substance lot number	-				
17 (**)	n2 + n6	Expiration date (YYMMDD)	16	26	TS**	01130	Substance expiration date					TS	26	Substance expiration date													

Please note that the GTIN has the NDC embedded within it and the information in the NDC is what provides the information in the yellow-coded fields across standards

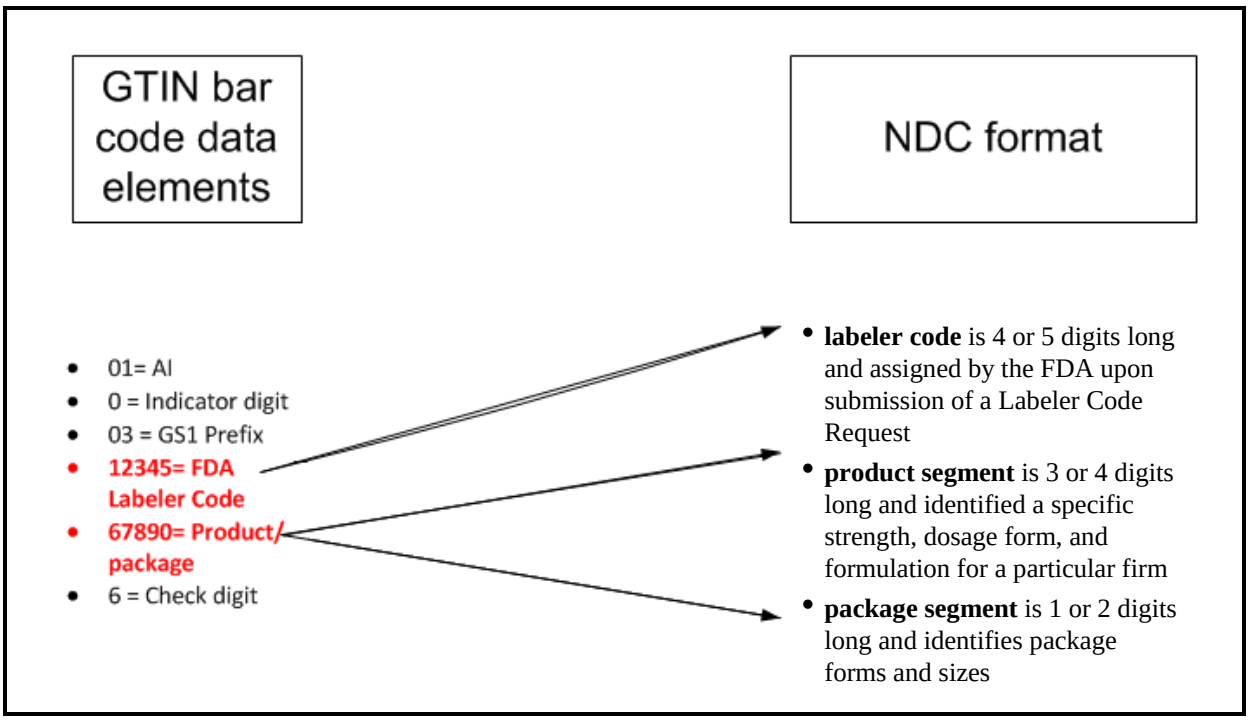
Researcher Notes

Figure G-1 includes a summary of the NDC-GTIN mapping issue, notes for HL7, and a pictorial view of how elements from the GTIN are mapped to the NDC.

NDC-GTIN Transaction Contention Area

The NDC is embedded in the GTIN. The NDC-coded product package begins with a 3 (UPC-A) or 03 (EAN-13). The remainder of the digits are the 10 NDC digits, plus the check digit. This is the most minimal form of the NDC code with 10 digits only. Because the NDC code has been linked with product barcodes in this way, the NDC code could contain ambiguities in this form. For example, 1234-5678-90, 12345-678-90, and 12345-6789-0 could all be entirely different products with the same barcode 1234567890.

Figure G-1. Data Mapping Elements for GTIN and NDC



Notes for HL7

Data Content:

1. **Administered Code** (CWE) 00347

Components: <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^ <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate Coding System

(ID)> ^ <Coding System Version ID (ST)> ^ <Alternate Coding System Version ID (ST)> ^ <Original Text (ST)>

Definition: This field contains the identifier of the medical substance/treatment administered. It is equivalent to the OBR-4-universal service ID in function. If the substance administered is a vaccine, CVX codes may be used to code this field.

2. **Administered Drug Strength Volume** (NM) 01696

Description: This numeric field defines the volume measurement in which the drug strength concentration is contained. For example, Acetaminophen 120 MG/5ML Elixir means that 120 MG of the drug is in a solution with a volume of 5 ML, which would be encoded in RXA-13, RXA-14, RXA-23, and RXA-24 as:
RXA||||||||||||120|mg^^ISO|||||||||5|ml^^ISO ...<cr>
4.14.7.24 RXA-24

3. **Administered Drug Strength Volume Units** (CWE) 01697

Components: <Identifier (ST)> ^ <Text (ST)> ^ <Name of Coding System (ID)> ^ <Alternate Identifier (ST)> ^ <Alternate Text (ST)> ^ <Name of Alternate Coding System (ID)> ^ <Coding System Version ID (ST)> ^ <Alternate Coding System Version ID (ST)> ^ <Original Text (ST)>

Description: This field indicates the volumetric unit associated with RXA-23 Administered Drug Strength Volume.

HL7 RXA-25 Barcode Identifier

Definition: This field contains the pharmacy system's assigned barcode number for the give occurrence. For IV orders, many pharmacy systems generate a barcode number to identify a specific bag/bottle of the order. This number can be an instance identifier—unique for the patient, drug combination, and schedule instance, or it may be just a drug identifier.

The composition and use of the barcode number depend on application negotiation. An example of this field follows: The barcode number is in the following format: 9XXXXXXX000. The number '9' is a constant, XXXXXXX is seven (7) characters for a unique identifier assigned or derived from the patient account and order ID, and 000 is the zero-filled three (3) character IV bottle number.

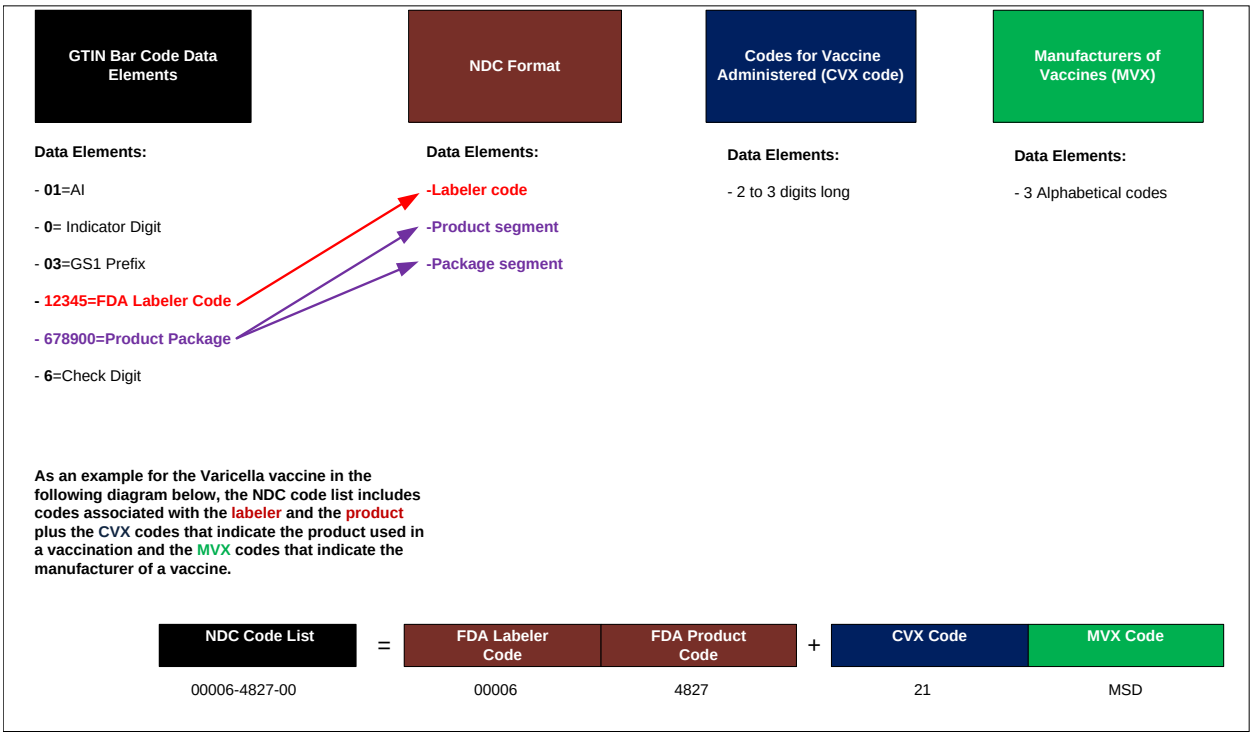
The maximum length of the first component of this field is **40 characters** to allow for the maximum existing barcode length in use today. The second component contains the description of the item being coded and the third component may define the barcode type.

Example: 12345678901^IV bottle^3X9

The implementation guide should be updated to reflect the following:

- Sending systems may use the RXA-25 (barcode) to hold the intact GTIN.
- Receiving systems should store the GTIN.
- Sending systems will use the GTIN and a mapping table to get the CVX and MVX and will get lot number and expiration date from the rest of the code.
  - Sending systems that know the GTIN will send the CVX, MVX, lot number, and expiration date.
- Sending systems will send the CVX in RXA-5.
- Sending systems may send the NDC in RXA-5 (in addition to the CVX).
- Sending systems should send the MVX in RXA-17.
- Sending system should send the lot number in RXA-15.
- Sending systems should send the expiration date in the RXA-16.
- Figure G-2 outlines the relationship between the GTIN, NDC, CVX, and MVX to demonstrate how mapping tables might work.

Figure G-2. Diagram: Mapping GTIN to NDC, CVX, and MVX



Health Care-GS1-128

This table summarizes the application identifiers used in the GS1 standard.

Application Identifier (AI) or Header	Data Attributes
Header	Organization name, corporate logo and GLN number of the producer
Header	Product description (e.g., brand/quality/age ref/size/number in case/% ABV)
(00) Mandatory	Identification of a logistic unit—serial shipping container code (SSCC)
(02) (Strongly Recommended)	Identification of a trade item (i.e., the case of bottles [GTIN])
(37) (SR)	Count of trade items contained in a logistic unit (i.e., number of cases on the pallet)
(10) (SR)	Batch/lot number
(15) (SR)	Minimum durability date (quality) (YYMMDD) (i.e., best before date if it appears on the label on the packaged goods)
(17)	Expiration date
(21)	Serial number

Data attributes recommended for the health care GS1-128.

Source: GS1. (2009, February). GS1 Standards Document, Business Process and System Requirements for Supply Chain Traceability, Global Traceability Standard for Healthcare. Retrieved from http://www.gs1.org/docs/gsmp/traceability/Global_Traceability_Standard_Healthcare.pdf, p. 56.

X12 Formatting Example

An EDI X12 Formatting Example

The following is an example of an EDI document. EDI documents are typically sent in a format similar to the following code, except that the code shown has been broken into multiple lines for display, while the real document is a single long line of text.

```
ISA* * * * *ZZ*SENDER *ZZ*
RECEIVER *041201*1200*U*00305*000000101*1*P*^!GS
*PO*SENDER*RECEIVER*041201*1200*101*X*003050!ST*850
*000000101!BEG*22*NE*101**041201*123456!FOB*DF*ZZ*JM
J!DTM*037*041205!DTM*038*041215!DTM*002*041218!TD1*
CNT90*1!TD5****JJ*X!TD3*40!N1*OB**92*7759!N3*111 Buyer
St!N4*Conyers*GA*30094*US!N1*SE*Foo Bar Sellers!N4****US
!REF*DP*101!PO1*100*1*EA***ZZ*BL47*HD*100!PID*F****
Widget!PO4**1*EA!N1*CT**38*CN!N4****CN!CTT*1*100!SE*22
*000000101!GE*1*101!IEA*1*000000101!
```

Here is the same document "unwrapped" at the segment level and indented to show the looping structure:

```
ISA* * * * *ZZ*SENDER *ZZ*RECEIVER *041201*1200*U*00305*000000101*1*P*^!
GS*PO*SENDER*RECEIVER*041201*1200*101*X*003050!
ST*850*000000101!
BEG*22*NE*101**041201*123456!
FOB*DF*ZZ*JMJ!
DTM*037*041205!
DTM*038*041215!
DTM*002*041218!
TD1*CNT90*1!
TD5****JJ*X!
TD3*40!
N1*OB**92*7759!
N3*111 Buyer St!
N4*Conyers*GA*30094*US!
N1*SE*Foo Bar Sellers!
N4****US!
REF*DP*101!
PO1*100*1*EA***ZZ*BL47*HD*100!
```

EDI comes in a variety of standard definitions such as ANSI X12, EDIFACT, and TRADACOM. The example documents shown above are of the X12 variety.

EDI documents are text files that are delimited into segments (in this example by the "!" character), and each segment is further delimited into elements (by the "*" character). Elements may also (rarely if ever) be subdivided into subelements (by the "^" character). In the "unwrapped" example above, each segment is on a line by itself. The first position in a segment is the segment identifier. For example, the first segment is an "ISA" segment and the last is an "IEA" segment. Each segment is made up of a number of elements. The first element in the "GS" segment is "PO." (Note that segment identifiers are not considered elements.)

The order and content of the segments create various levels of enveloping. The outermost level (from "ISA" to "IEA") makes up the interchange. The next level (from "GS to "GE") makes up the functional group. The last level (from "ST" to "SE") contains the transaction set. Each interchange may contain multiple functional groups and each functional group may contain multiple transaction sets. The ISA, IEA, GS, GE, ST, and SE segments are all enveloping headers. Transaction sets are the data payloads in an EDI message. The example above is a purchase order. It is distinguished as a purchase order by the "PO" in the first element of the GS segment and the "850" in the first element in the ST segment.

Looping occurs when a looping segment is encountered. Looping segments are not obvious by looking at the document itself. If the second example above were not provided, it would be impossible to determine correctly which segments were looping segments and which

were not. A looping structure ends when no more segments that belong in the loop are encountered. There is no explicit end to the looping mechanism.

Example for Drugs

Example 10—Drug Examples

The examples in this section have been created with a mixture of uppercase and lowercase letters. This demonstrates that this is an acceptable representation.

Drug Example 1—Drug Administered in the Physician's Office

Example of service in a physician's office, which includes the billing for a drug administered in the office.

Subscriber/patient	Steve R. Vaughn
Address	236 Diamond St., Las Vegas, NV 89109
Sex	M
DOB	5/1/1943
Subscriber identification #	MBRID12345
Group #	GRP01020102
Destination receiver	XYZ Receiver
ETIN	369852758
Destination payer	R&R Health Plan
National plan identifier	PLANID12345
Billing provider/sender	Associates in Medicine
Address	1313 Las Vegas Blvd., Las Vegas, NV 89109
TIN	587654321

This table is an example of an X12 claim. Drugs are used here as an example because the NDC code is used, as it will be for vaccines.

Contact person and phone number	Bud Holly (801) 726-8899
Pay-to provider	Associates in Medicine
Rendering provider	Jim Hendrix
National provider identifier	1122333341
Taxonomy identifier	208D00000X
Patient account number	CLMNO12345
Diagnosis	0359.1
Case	The service provided on 7/11/2004 is that the patient received an injection of immune globulin during an office visit. The service is billed with procedure code 90782.

Coding for the drug is accomplished with an HCPCS procedure code of J1550 (injection, gammaglobulin, intramuscular, 10 cc). And the drug is also coded with an NDC of 00026-0635-12 (BayGam® SDV, PF 10 ML).

Place of service is an office. Total billed charges are $103.37. Sales tax is $3.37.

This example demonstrates how drugs are billed along with services when provided by a physician's office. Billing for the drug is found in segments #25 through 30.

Abbreviations

Abbreviation	Definition	HL7/X12	GS1
SEQ	Sequence: Order in which the field appears	●	
LEN	Length devoted to the field	●	
DT	Data type that is in the field	●	
SI	Sequence ID (where field is in sequence)	●	
NM	Numeric	●	
TS	Point in time or time stamp	●	
CE	Coded element	●	
XCN	Extended composite ID number and name	●	
CM	Composite	●	
ST	String	●	
XAD	Extended address	●	
ID	Processing mode	●	
CWE	Allows user to send a term from an arbitrary coding system	●	
CNE	Primary code must be from a specified value set	●	
Format	How field must appear (numbers, letters, characters)		●
Item #	Catalogue item in standard		●
Application identifiers	Identifier that is part of the GS1 general specification		●

Summary Table

This is a summary mapping table as outlined in Chapter 6.

GS1	HL7—Vaccine Administration	HL7—Barcoding Message Segment	2.5.1 Implementation Guide	X12—837 P Transaction	HITSP Immunization Messages	NCPDP
Global Trade Item Number (GTIN)	Substance manufacturer name	Administered code	Substance manufacturer name	Labeler code	Substance manufacturer	Labeler code
	Administered code	Substance manufacturer name	Administered code	Product segment	Administered code	Product segment
	Administered drug strength volume	Administered barcode identifier	Administered drug strength volume	Package segment		Package segment
	Administered drug strength volume units		Administered drug strength volume units			
Expiration date (YYMMDD)	Substance expiration date	Substance expiration date	Substance expiration date			
Batch or lot number	Substance lot number	Substance lot number	Substance lot number		Substance lot number	

Note: The GTIN has the NDC embedded within it and the information in the NDC is what provides the information in the yellow-coded fields across standards.