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Prospective cost–benefit analysis of a two-dimensional barcode for vaccine production, clinical documentation, and public health reporting and tracking☆

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ABSTRACT

In the United States recording accurate vaccine lot numbers in immunization records is required by the National Childhood Vaccine Injury Act and is necessary for public health surveillance and implementation of vaccine product recalls. However, this information is often missing or inaccurate in records. The Food and Drug Administration (FDA) requires a linear barcode of the National Drug Code (NDC) on vaccine product labels as a medication verification measure, but lot number and expiration date must still be recorded by hand. Beginning in 2011, FDA permitted manufacturers to replace linear barcodes with two-dimensional (2D) barcodes on unit-of-use product labels. A 2D barcode can contain the NDC, expiration date, and lot number in a symbol small enough to fit on a unit-of-use label. All three data elements could be scanned into a patient record. To assess 2D barcodes' potential impacts, a mixed-methods approach of time–motion data analysis, interview and survey data collection, and cost–benefit analysis was employed. Analysis of a time–motion study conducted at 33 practices suggests scanning 2D-barcoded vaccines could reduce immunization documentation time by 36–39 s per dose. Data from an internet survey of primary care providers and local health officials indicate that 60% of pediatric practices, 54% of family medicine practices, and 39% of health departments would use the 2D barcode, with more indicating they would do so if they used electronic health records. Inclusive of manufacturer and immunization provider costs and benefits, we forecast lower-bound net benefits to be $310–334 million between 2011 and 2023 with a benefit-to-cost ratio of 3.1:1–3.2:1. Although we were unable to monetize benefits for expected improved immunization coverage, surveillance, or reduced medication errors, based on our findings, we expect that using 2D barcodes will lower vaccine documentation costs, facilitate data capture, and enhance immunization data quality.

1. Introduction

Accurate lot numbers in immunization records are imperative for identifying individuals having received recalled vaccine lots [1]. In the United States, the National Childhood Vaccine Injury Act requires recording lot numbers [2], and the American Academy of Pediatrics (AAP) recommends also recording expiration dates [3]. Yet 45% of immunization information systems (IIS) reported that lot number data elements are incomplete [4]. A 2011 review by the Centers for Disease Control and Prevention (CDC) found that lot numbers were missing from nearly one quarter of reports in the Vaccine Adverse Event Reporting System [5].

The US Food and Drug Administration requires vaccine product labels to have a linear barcode with the National Drug Code (NDC).[1] The rule is intended to improve patient safety by supporting barcode scanning to prevent medical errors [6]. However, few immunization providers are thought to use linear barcodes because lot number and expiration date must still be recorded by hand [8]. Thus, for vaccines, linear barcodes do not fulfill their intended purpose. Children's immunization records reveal transcription errors, administration of incorrect look-alike or sound-alike products (e.g., DTaP, Tdap, DT, Td), sibling confusion, and extraimmunization [7].

☆ *Disclaimer*: The findings and conclusions in this report are those of the authors and do not necessarily represent the views of the Centers for Disease Control and Prevention.

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[1] The NDC is a 10-digit number generated by manufacturers following FDA specifications that uniquely identifies the manufacturer, the specific drug or vaccine type and formulation, and the packaging of every pharmaceutical product.

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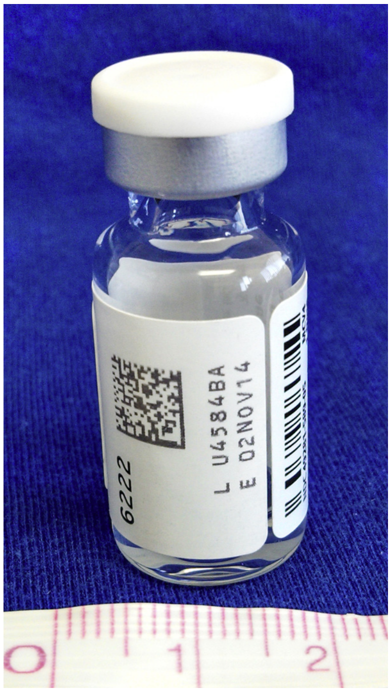

Fig. 1. Example linear and 2D barcodes.

In 2009, consensus emerged among AAP, several manufacturers, and CDC that lower technology costs, increasingly complex immunization schedules, and electronic health record (EHR) adoption likely made two-dimensional (2D) barcodes containing NDC, expiration date, and lot number cost-effective (Fig. 1) [9]. The accuracy and efficiency of documentation could be improved because handwritten or typed information instead could be entered electronically. Linear barcodes containing the same information are too large for labels appearing on 0.5-mL single-dose containers. Indeed, 2D barcodes were recommended by the Vaccine Identification Standards Intiative launched in 1997 [10], but a 2003 analysis performed for FDA concluded that available technologies were cost-prohibitive [11].

In 2011, FDA concluded that technologies had matured sufficiently and issued guidance to permit vaccine manufacturers to apply for a waiver to use 2D barcodes instead of linear barcodes or to use both barcodes without a waiver [12,13]. This paper reviews stakeholder perceptions and presents a prospective economic analysis of the manufacturing, clinical documentation, and public health reporting and tracking impacts of using 2D barcodes on unit-of-use vaccine product labels [14].

2. Methods

A mixed-methods approach of interview and survey data collection, secondary data analysis, and cost–benefit analysis was employed because of the diversity of stakeholders and the breadth of potential impacts. Supplemental information about our methods is provided in our accompanying web appendix.

2.1. Time–motion study analysis

A time–motion study performed by the Verden Group (Nyack, NY) tabulated activity-specific time–motion estimates for the administration of 724 vaccines to 302 patients at 30 pediatric and 3 family medicine practices with and without EHRs across 17 states [15]. Each piece of immunization documentation was a discrete measurement, and the results served as the baseline from which we estimated time savings from using 2D barcodes. Controlling for the administration of multiple doses to one patient during a visit, record keeping was disaggregated into documentation that is not expected to be affected by using 2D barcodes (e.g., chart notes, parental signatures) and documentation that could be affected (e.g., logbooks, product data transcription) to estimate time savings.

2.2. Interview data collection

Interviews were conducted with key stakeholder groups to assess knowledge, attitudes, and beliefs about 2D barcodes; identify cost–benefit variables; and prepare a survey instrument for immunization providers. Providers were represented by AAP, American Academy of Family Physicians (AAFP), American Congress of Obstetricians and Gynecologists (ACOG), American College of Physicians, American Medical Association (AMA), American Pharmacy Association, American Hospital Association, Convenient Care Association, CDC, Association of Immunization Managers, American Immunization Registry Association, National Association of County and City Health Officials (NACCHO), Visiting Nurses Association of America, Maxim Healthcare, and Walgreen's.

Of the 11 manufacturers with licensed products on the US market in 2011, 7 manufacturers that collectively produce 90% of FDA-licensed vaccines participated in telephone interviews and site visits between November 2010 and April 2011. Interviews were also conducted with 18 IIS, 5 software vendors, and 10 subject matter experts in medical outpatient practice management and immunization data exchange.

All interviews were scripted; interview guides were developed based on previous research experience, literature review, informal stakeholder discussions, and observation of immunization practice in a pediatric setting. RTI International's Institutional Review Board determined that our protocols were exempt from review.

2.3. Survey data collection

An Internet survey of primary care providers (defined as pediatric, family medicine, ob-gyn, and internal medicine practices) and local health officials (e.g., local health departments [LHDs]) was fielded between April and June 2011. These providers were selected for the survey because they were assumed to administer the majority of immunizations. We constructed a large convenience sample with the assistance of AAP, AAFP, ACOG, NACCHO, and 38 VFC Program coordinators who distributed promotional materials to their membership in these provider categories. The promotional materials included emails, blast faxes, newsletter articles and blurbs, and image files with the slogan "Take 10 to Enhance Vaccine Barcodes." Our survey partners were requested to issue communications up to 3 times at regular intervals; however, each promoter issued communications between 1 and 3 times at their discretion. Because survey response was voluntary, to encourage participation, respondents were entered into a raffle to receive one of 10 Apple iPads.

Survey topics included immunization volume, staffing by labor category, immunization workflow, office layout, information technology use and adoption, and inventory management. Respondents were also provided with detailed descriptions of expected costs and benefits and were asked whether they were likely to use 2D barcodes. Draft surveys were reviewed by AAP, manufacturers, and medical practice management experts; pretested with 14 pediatric practices and 1 ob-gyn practice; and revised based on their feedback.

Data collected through the survey were identifiable only by zip code of the respondent, except where the respondent volunteered contact information raffle entry. An algorithm was applied to raw data that reviewed respondents' contact information, zip codes, number of staff, and immunization volume to identify and exclude duplicate records and extreme responses to the number of doses administered per physician. If respondents did not provide their specialty or their practice's physician count, their responses were excluded.

Response was compared to the US population of practices meeting the same specialty and size criteria using the Group Practice Database in the AMA Physician Masterfile Data Collection [16] and the percentage of practices by specialty from the latest Physician Practice Information Survey [17]. The NACCHO Directory of Local Health Departments was used for LHDs [18].

2.4. Cost–benefit analysis

2.4.1. Manufacturer costs

Manufacturers provided data on their capital equipment, labor, and materials requirements, either in dollar terms or in physical units that we 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 for the Canadian Automated Identification of Vaccine Products Advisory Task Group [19].

Manufacturer responses were aggregated using data on affected packaging and labeling lines, doses (discrete units of an administrable vaccine product) produced for the US market, label media, and container types. Quantifying cost savings from changing label media required forecasting total US doses administered. Forecasts were developed for 2013–2023 using 2010 distribution data provided by CDC and manufacturers, the Advisory Committee on Immunization Practices' recommended immunization schedule as of February 2011 [20], immunization and series completion rates from the 2009 National Immunization Survey [21], and US population forecasts by single year of age for 2013–2023 [22,23].

2.4.2. Provider documentation benefits and adoption costs

Provider benefits were quantified as the estimated cost savings from scanning 2D barcodes relative to recording product, lot, and expiration date information by hand. Benefits were calculated for each combination of provider specialty (pediatrics, family medicine, internal medicine, ob-gyn), practice size (1–1.5, 2–9, 10 or more physicians), and EHR usage (yes/no). Within each combination, adoption rates were estimated based on survey respondents' stated preferences to use 2D barcodes and their expected timing of EHR adoption. Respondents who stated they planned to adopt an EHR before 2015 were treated as having an EHR in place in their expected year of adoption. Respondents who were unsure whether they would use the barcode were assumed to be non-adopters. Respondents who expected to adopt an EHR system after 2015 were assumed not to adopt one.

Time savings for each dose were monetized using weighted-average fully burdened wage rates for staff positions that prepare and administer vaccines. Mean hourly wage and cost of employment data for labor positions (e.g., physicians, registered nurses, medical assistants) were obtained from the Bureau of Labor Statistics (BLS) [24].

Provider adoption costs were one-time expenditures for staff training, workflow redesign, and scanner purchase and ongoing costs for scanner maintenance and replacement. (Software-related updates were expected by software vendors to be included in annual licensing agreements.) To estimate scanner costs for a practice, the unit cost was multiplied by the number of expected installation locations within a provider's office (collected in the office layout portion of the survey). Each scanner was assumed to cost $300, have a 5-year useful life, and cost 7% per year to maintain [19]. Total annual costs were calculated by summing costs for the estimated number of immunization provider practices that would use 2D vaccine barcodes for that year.

Workflow redesign and training time was estimated to be 1 h based on interview responses from information technology (IT) systems vendors and IIS that have implemented barcode and signature pad systems analogous to those needed for 2D barcode scanning. This estimate was multiplied by the number of staff requiring training and weighted-average fully burdened wage rates. Staff time for workflow redesign was monetized using the 75th percentile mean wage rate for registered nurses because IIS staff expected senior supervisory nurses to direct 2D barcode implementation [25].

To ensure that estimates were not biased by over- or under-representation of specific provider groups in our sample, results for each combination of specialty and size were the weighted average for all respondents falling within the size category. Respondent profile data were used to extrapolate survey responses to the US population of practices meeting the same specialty and size criteria.

2.4.3. Net benefits

Net benefits were the sum of benefits and costs for providers, manufacturers, AAP, and the Federal Government. Net present value and a benefit-to-cost ratio were calculated using the Office of Management and Budget's specified 7% social discount rate for nonregulatory initiatives [26]. The internal rate of return was also calculated. All monetary values are in real 2010 terms.

2.5. Key analysis assumptions

Several assumptions were necessary to quantify the impact of 2D barcodes alone. Survey respondents within the same specialty-size immunization provider category were assumed to be representative of all practices in that category. It was assumed that no new products or container types would be introduced and that there would be no changes in the relative proportion of products across container types or to manufacturers' market shares or unit-level costs. It was also assumed that there would be no changes in number of practices, ACIP-recommended immunizations, or series completion rates – only in the US population by single year of age.

3. Results and discussion

3.1. Stakeholder perceptions of costs and benefits

Professional associations and manufacturers believe that scanning 2D barcodes will improve patient safety by confirming that the vaccine to be administered matches doctors' orders and by recording lot numbers accurately through electronic means. They expect four additional advantages: (1) lower cost of immunization via fewer record-keeping steps; (2) automated data capture that populates patients' EHRs, adjusts inventory, interfaces with billing systems, and sends data to IIS; (3) lower vaccine wastage through better inventory management; and (4) lower extraimmunization through better records in IIS. Barcode scanning aligns with trends in EHR adoption and may improve what are currently disparate inventory management practices.

Five manufacturers reported that they plan to implement 2D barcoding, one was undecided, and one had no plans to implement. Implementation is expected to be a one-time expense, with ongoing costs unlikely to be appreciably different from those for linear barcodes. Manufacturers emphasized market demand, especially from large purchasers, as a motivator for investing in new printing systems.

Of 4568 provider survey responses received, 3669 met the inclusion criteria – 2816 from private practices and 853 from LHDs. 1442 responses were received from pediatric respondents, approximating a survey coverage rate of 29% of an estimated population of 4937 pediatric practices in the United States, and 968 responses from family practices, approximating a 10% coverage rate of 9561

Table 1
Survey results for information systems use and expected barcode use.

Survey question	Pediatrics ($n = 1304$)	Family medicine ($n = 879$)	LHDs ($n = 806$)
Average number of locations in offices where vaccines may be prepared for administration or documentation performed			
Nurses' stations	1.4	1.7	2.2
Dedicated rooms for immunization or laboratories	1.7	2.1	4.8
Examination rooms	4.4	6.2	4.4
Other locations	0.1	0.1	13.0
Responding practices' and LHDs' current use of computer systems			
Electronic health record system	58.9%	69.3%	35.7%
Practice management and billing system	87.6%	86.9%	67.5%
Automated input devices, such as weight scales or blood pressure devices	27.6%	32.0%	27.5%
Barcoding or barcode scanning of any type	11.5%	12.6%	7.6%
Other computerized systems	24.1%	20.9%	45.1%
Responding practices and LHDs without EHR systems currently expected time frame for EHR adoption			
By the end of 2011	11%	10%	5%
By the end of 2012	13%	9%	8%
By the end of 2013	4%	4%	4%
By the end of 2014	1%	1%	2%
By the end of 2015	0%	1%	1%
After 2015	1%	0%	1%
Not sure or no plans to adopt	11%	6%	42%
Responding practices' and LHDs' use of systems to monitor vaccine product inventory levels			
Registry or internet-based inventory system	43.0%	50.5%	69.3%
Inventory software system installed in your practice	14.1%	12.6%	29.2%
Computerized system that is part of your practice management and billing system	39.3%	36.9%	44.5%
Spreadsheets or similar files maintained by your staff	31.3%	23.4%	32.6%
Paper-based systems, such as a ledger	58.5%	53.4%	52.3%
None; we simply order when the stock looks low	37.7%	43.5%	27.3%
Other	13.2%	9.2%	9.9%
Responding practices' and LHDs' likelihood to use 2D barcodes			
Yes, my practice would likely use the barcode	60.0%	53.5%	39.2%
My practice would likely use the barcode if we had an EHR system	19.5%	16.3%	26.3%
No, my practice would not likely use the barcode	4.0%	7.0%	3.6%
I do not know if my practice would use the barcode	16.5%	23.2%	30.9%
Responding practices' and LHDs' average number of doses administered per year (2010/11)			
1–1.5 physicians	2735	936	6070
2–9 physicians	8891	2632	
More than 10 physicians	38,126	8874	

Private practices and LHDs provided data on office layout, current and expected systems usage, and stated preference for using 2D barcodes. These data later informed economic models estimating adoption costs and likely 2D barcode usage among providers administering the majority of noninfluenza immunizations
EHR, electronic health record; LHD, local health department.

Table 2
Estimated change in immunization documentation time from scanning 2D barcodes.

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

A time–motion study tabulated activity-specific time–motion estimates for the administration of 724 vaccines to 302 patients at 33 practices with and without EHR systems across 17 states. Average time for immunization was 221 s, consisting of reviewing the chart (2.9 s), counseling the patient (48.1 s), ordering vaccine administration (8.0 s), preparing the vaccine (59.9 s), administering the vaccine (33.9 s), cleaning up (5.5 s), and documenting vaccine administration (62.9 s).
EHR, electronic health record; VFC, Vaccines for Children program. Analysis of time–motion study data acquired from the Verden Group [16], except for barcode scan time, which was from Pereira et al. [27].

Table 3
Manufacturer cost–benefit analysis results.

	Value
Number of manufacturers with 2D barcode implementation plans	5 of 11 firms
Number of packaging and labeling lines to be converted	25 lines[a]
Expected implementation time per line	12–24 months
Expected time frame of barcode first appearance[b]	2012–2013
Average implementation cost per packaging and labeling line	$1.22 million
Capital budget component	25–40%
Labor budget component	60–75%
Total implementation costs	$31 million
Weighted average savings per dose from elimination of peel-off labels[c]	$0.057 per dose
Estimated of doses produced for the US market (2013)[f]	346.7 million
Estimated of doses produced for the US market (2018)	363.7 million
Estimated of doses produced for the US market (2023)	381.1 million
Total benefits from peel-off label elimination, 2013–2013	$54 million
Net benefits for manufacturers, 2013–2013	$23 million
Net present value at 7% real social discount rate[d]	$5 million
Net present value at 10% real industry working cost of capital rate[e]	$0.2 million

Five of 11 manufacturers with FDA-licensed vaccine products have 2D barcode printing implementation plans. One additional firm is considering whether to implement.
[a] Ten lines are located outside of the United States. Two additional lines had preexisting 2D barcode printing capabilities.
[b] Actual time was late 2011.
[c] Weighted by volume of single-dose vials and syringes.
[d] Per OMB Circular A-94 [26].
[e] Per Harrington and Miller [29].
[f] Excludes defense, traveler, and other products not included on the ACIP immunization schedule as of March 2011.

practices [16]. Internal medicine and ob-gyn were excluded from the final analysis because of poor survey response (fewer than 100 responses each).

Survey results suggest that 60% of pediatric and 54% of family medicine practices would use the 2D barcode (Table 1). An additional 20% and 16%, respectively, indicated they would use the barcode if they had an EHR system in place. Adoption decision factors presented to primary care providers rating above 3.5 (using a Likert-type scale where 4 = very important and 0 = unimportant) were increased records accuracy, decreased time spent recording vaccine information, barcode reliability, barcode scanner usability, more efficient and accurate management of inventory, and readability of the barcode.

3.2. Time–motion study

Time required for vaccine administration averaged 221 s, with a range among immunization encounters of 92–427 s. The longest process step was documentation, which took a mean of 63 s, accounting for 28% of total time. 2D barcode scanning could reduce documentation time by 44 s per dose at practices with EHRs and 41 s per dose at practices without EHRs. It takes 4 s on average to scan a vial [27]; therefore, we expect that practices with EHRs could save approximately 39 s per dose and practices without EHRs will save about 37 s per dose, equating to a reduction in documentation time of 58–63% per dose (Table 2).

3.3. Cost–benefit analysis

3.3.1. Manufacturers

Manufacturers currently outsource production of their product labels, which arrive at plants fully printed except for the final human-readable expiration date and lot number. These last two items are printed in a production step that coincides with affixing the label to the product container ("online printing"). In 2D barcoding, the symbology will contain static NDC data and variable expiration and lot data, precluding the option of having the 2D barcode printed by outside vendors who print and supply labels because of operational and regulatory risks. Manufacturers must, therefore, install 2D barcode printing systems to print barcodes online at sufficient quality while maintaining production speeds of 400 units per minute or more. Printing and assembling peel-off labels at the quality level required is not possible in this production environment. Consequently, peel-off labels will be eliminated from those containers that currently have them; however, the AAP believes these labels are not often used [28].

One-time costs were estimated to be $31 million, averaging $1.22 million for each affected production line (Table 3). Benefits from peel-off label elimination for some manufacturers were

Table 4a
Unit costs underlying provider benefits and costs.

Variable	Parameter estimate	Notes
Scanners		
Purchase cost, per scanner[a]	$300	Scanner specifications and costs were reviewed in January 2010, and the maintenance costs and expected useful life were provided by vendors [19]. Scanners would be expected to be installed at nurses' stations and in labs because these areas tend to have refrigerators already, which will allow immunizers to scan each dose as it is removed from storage
Cost of annual scanner maintenance	$21 (7%)	
Expected life of scanner	5 years	
Labor positions ($/h)		
Licensed practical nurse (LPN)	19.66	Labor rates were the mean national wage rates available from the BLS Occupational Employment Statistics (OES) for positions [24]. 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
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 h 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 RN and the cost-of-employment multiplier
Cost of workflow redesign, practices with at least 10 physicians, at 24 h of senior RN time	$1103.42	
Training time, per employee[a]	1 h	

Wage rates and other unit-level costs were obtained to monetize adoption costs and documentation benefits.
[a] In comparison, in the 2003 analysis for FDA, scanner cost was estimated at $750 and training time was estimated at 8 h per employee [30]. BLS, Bureau of Labor Statistics; IIS, immunization information system; IT, information technology; VFC, Vaccines for Children program.

Table 4b
Estimated provider adoption cost and time savings per dose.

Specialty	Size	*n*	Average number of staff requiring training						Weighted average hourly rate	Training cost	Workflow redesign	Equipment expense	Estimated adoption cost
			LPN	MA	NP	PA	MD	RN					
Pediatrics	1–1.5 physicians	408	0.38	1.37	0.03	0.15	0.50	0.38	$44.47	$124	$437	$455	$1016
	2–9 physicians	889	1.64	3.11	0.02	0.18	0.61	1.90	$37.76	$282	$437	$924	$1643
	More than 10 physicians	145	9.53	10.81	0.79	2.11	4.20	56.30	$45.19	$3785	$1310	$2736	$7831
Family medicine	1–1.5 physicians	408	0.46	1.43	0.09	0.18	0.34	0.38	$39.96	$115	$437	$708	$1260
	2–9 physicians	889	1.61	3.91	0.07	0.20	0.40	1.24	$33.22	$247	$437	$955	$1639
	More than 10 physicians	145	8.47	14.31	0.40	0.63	1.99	8.29	$35.62	$1215	$1310	$3591	$6116
Health departments		853	0.58	0.31	0.06	0.33	0.11	5.79	$42.65	$444	$479	$1927	$2736

Specialty	Practice size	*n*	Percentage of immunization by occupation						Weighted average hourly rate	Without EHR		With EHR	
			LPN (%)	MA (%)	NP (%)	PA (%)	MD (%)	RN (%)		Time savings per dose (s)	Cost savings per dose	Time savings per dose (s)	Cost savings per dose
Pediatrics	1–1.5 physicians	408	11	56	1	4	17	12	$42.37	36.47	$0.4293	39.42	$0.4639
	2–9 physicians	889	23	43	0	2	6	26	$35.44	36.47	$0.3591	39.42	$0.3881
	More than 10 physicians	145	28	44	1	1	2	24	$31.92	36.47	$0.3234	39.42	$0.3495
Family practice	1–1.5 physicians	408	12	58	3	6	9	11	$36.66	36.47	$0.3714	39.42	$0.4014
	2–9 physicians	889	21	53	1	2	4	19	$32.02	36.47	$0.3244	39.42	$0.3506
	More than 10 physicians	145	33	42	2	3	1	19	$31.07	36.47	$0.3148	39.42	$0.3402
Health departments		853	9	5	0	3	1	81	$45.20	36.47	$0.4580	39.42	$0.4950

Adoption costs for 2D barcoding encompass training, scanner purchase, and workflow redesign. Software updates for 2D barcode reading functionality were expected by EHR vendors to be included in annual license agreements at no additional cost. Documentation benefits were higher for those practices with EHR systems in use.
LPN, licensed practical nurse; MA, medical assistant; NP, nurse practitioner; PA, physician assistant; MD, physician; RN, registered nurse; EHR, electronic health record.

Table 5
Cost–benefit analysis results.

	Scenario 1, provider adoption rate set by survey results	Scenario 2, provider adoption rate slowed by 50%	Scenario 3, provider adoption rate slowed by 67%
Pediatric and family medicine practices and LHDs			
Benefits ($ million)	393	375	357
Costs ($ million)	75	56	62
Net benefits ($ million)	318	319	295
Manufacturers' net benefits (million)	23	23	23
Costs incurred by AAP and CDC (million)	8.5	8.5	8.5
Summary			
Benefits ($ million)	447	429	411
Costs ($ million)	114	95	101
Net benefits ($ million)	333	334	310
Measures of economic return			
Net present value (3% real discount rate)	261	259	238
Net present value (7% real discount rate)	190	187	169
Benefit-to-cost ratio (3% real discount rate)	3.6	4.0	3.6
Benefit-to-cost ratio (7% real discount rate)	3.2	3.5	3.1
Internal (social) rate of return	53%	50%	45%

Cost–benefit analysis results are lower-bound estimates. Clinical documentation benefits only for a subset of immunizers were quantified and compared with all known adoption costs. Benefits for inventory management (including wastage reductions) and reduced extraimmunization are expected; however, data to quantify them were unavailable.
AAP, American Academy of Pediatrics; CDC, Centers for Disease Control and Prevention; LHD, local health department.

$54 million, resulting in industry-level net benefits of $23 million over the entire period of analysis of 2011–2023. Manufacturers had stated during interviews that implementation would be a one-time capital expense. To reconcile forecasted benefits with the seeming discrepancy, the biopharmaceutical industry's real average working cost of capital of 10%, which can be interpreted as the minimum rate of return necessary to make an operations project a prudent expenditure of funds [29], was compared to the 10.12% internal rate of return on manufacturers' net benefits. The similarity corroborates interview findings that manufacturers view the initiative as a one-time cost.

3.3.2. Providers

One-time costs for practices were expected to range between $1016 and $7831, depending on practice size (Tables 4a and 4b). Savings on clinical documentation is $0.34–0.49 per dose with an EHR or $0.31–0.46 per dose without one. When per-dose savings are aggregated over the volume of doses administered annually, benefits are significant. For example, at 10,000 doses, the savings could be $3400 or $4600 per year on more efficient documentation alone.

Given respondents' stated preferences for 2D barcode use, we would expect that by the end of 2015, 75% of pediatric practices, 67% of family medicine practices, and 49% of LHDs would use it. Their net benefits would be $318 million through 2023. However, even if the rate of adoption were slowed by 50%, net benefits would remain largely unchanged at $319 million.[2] If the rate slowed by 67%, net benefits would be $295 million.

3.3.3. Summary

For all stakeholders between 2011 and 2023, net economic benefits were forecasted to be $310–334 million, inclusive of AAP and Federal Government costs of $8.5 million for coordinating and preparing for implementation (Table 5). The benefit-to-cost ratio is 3.1:1–3.2:1, indicating that for every $1 expended at least $3.10–3.20 is expected to accrue.

[2] The slight increase in net benefits for providers under this scenario is attributable to changing the relative timing and magnitude of benefit and cost accrual over time. Slowing the adoption rate pushed some scanner-related costs outside of the period of analysis.

This work also suggests that impact analyses that conclude that emerging technologies are immature or cost prohibitive should be revisited when reliable evidence of technological progress and/or cost reduction accumulates. For example, when the FDA regulatory impact analysis was completed in 2003 the cost per 2D barcode scanner was $750 but the price had fallen to $300 in 2010 [30].

4. Limitations

A benefit-to-cost ratio greater than 3:1 is encouraging, especially when only documentation time savings are compared with a comprehensive cost basis; however, our study had several limitations. We did not quantify benefits for expected reduced extraimmunization [31], reduced vaccine wastage [32], or improved inventory management [33]. Available data were also insufficient to project improvements in immunization coverage, surveillance, reductions in medication errors, and potential changes in health outcomes. Because of the opt-in survey sample, we were unable to make reliable estimates for net benefits for internal medicine and ob-gyn practices. Our estimates also do not include consideration of complementary immunization providers such as pharmacists and retail-based clinics. Finally, our survey sample was not systematic; however, the survey was focused on immunization workflow, which is expected to be more consistent than attitudinal information within each unique combination of specialty, size, and EHR use. We believe the benefit-to-cost ratio is conservative.

5. Conclusion

2D barcodes, if adopted by manufacturers, EHR vendors, and providers, could be a significant step forward in immunization safety, enhancing three of the "five rights" [34] – right patient, right product, right time (the others are right dosage, right route) – through the yes/no functionality of barcode scanning while electronically populating data fields for product, expiration date, and lot number. Since this study was initiated, 2 manufacturers have implemented 2D barcodes on 7 vaccine products [35,36]. Scanning 2D barcodes will enhance the accuracy of vaccine data in information systems, lower the burden of documenting immunizations or reporting immunizations, and increase the probability of being able to locate a patient should a recalled vaccine lot have been administered.

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Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at http://dx.doi.org/10.1016/j.vaccine.2013.04.073.

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