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Two-Dimensional (2D) Vaccine Barcoding Pilot Education Forum Report

The 2D Vaccine Barcoding Pilot is funded by the Centers for Disease Control and Prevention (CDC) and managed under contract by Deloitte Consulting, LLP (Deloitte). A contract to design and implement the barcoding pilot was awarded to Deloitte in September 2011.

"Reviewed November 2014"

Contents

Executive Summary

The 2D Vaccine Barcode Pilot's (Pilot) Education Forum (Forum) was conducted April 14-15, 2013, at the Intercontinental Hotel in New Orleans, LA. Seventy eight (78) immunization community stakeholders including vaccine manufacturers, immunization program awardees, public and private immunizing providers, and electronic medical record (EMR) vendors, Immunization Information System (IIS) staff, and 2D barcode scanner vendors met to discuss the lessons learned from the Pilot (to date), opportunities, challenges and next steps for the adoption of 2D barcoded vaccines.

The Forum was structured to provide information on critical topics for the industry, as suggested by the immunization community and Pilot participants. Discussion revolved around insights from the Pilot; early lessons learned and associated challenges, information to assist with clinical adoption and use of 2D barcodes and discussions regarding EMR and IIS maturity and capability to consume and use 2D barcoded data

The Forum opened with presentations that emphasized that, while indicators point to adoption of 2D vaccine barcoding, more work needs to be done including considering next pilot stages, future roadmap items, and strategies to move forward. The discussion progressed to an overview of 2D barcode history and progress presented by an American Academy of Pediatrics (AAP) representative.

The Forum included presentations on the 2D barcode technical foundation and an overview of the Pilot. Lessons learned and early findings from the Pilot were presented based on preliminary evaluations of Pilot data, which led to discussing the expanded application of implementing 2D barcodes on Vaccine Information Statements (VIS). Day 1 of presentations concluded with an overview and findings of a workflow study performed at a subset of Pilot provider sites.

The focus of Day 2 of the Forum was to connect the immunization stakeholders together and create an understanding of their individual roles, needs, and barriers to adoption that should be removed for 2D barcoded vaccine adoption. The second day of the Forum opened with two panel discussions, one focused on Inventory Management and Workflow, and the second panel, focused on EMR/IIS capability overview and progress. The panel discussions were followed by working group sessions with Forum attendees to discuss the benefits and impacts of 2D vaccine barcoding. Topics for the breakout working sessions were standards, adoption, and implementation.

Working sessions revealed a plethora of feedback, recommendations, and clarifications in understanding surrounding the adoption and use of 2D barcoding in the vaccine community. Key points gathered from the working sessions:

- Adding 2D barcodes to the vaccine product secondary package (saleable unit, i.e. carton) was a big topic of discussion. Doing so will benefit inventory management easing a path to adoption and implementation.

- The GTIN, lot number, and expiration date currently found in the 2D barcode on vaccine units of use should be aggregated at the secondary package level. In the future, also add serial numbers to the secondary and tertiary (unit of service/unit of sale) packaging.

- GTIN, NDC, and lot number crosswalks are needed to identify the relationships between primary and secondary packaging of vaccine products labeled with 2D barcodes.

- Reconstituted vaccines with one or more active components use unique NDCs for each component, which presents additional complexities when considering adding 2D barcodes to the outer or secondary package.

- Manufacturers, providers, and EMR/IIS solutions do not agree on a standard on which NDC and lot number should be encoded in the 2D barcode on a secondary or tertiary package. Further investigation and work are needed to establish standards and implementation guidelines.

- Data capture and processing standards are needed to guide EMR and IIS vendors how to process 2D barcodes currently found on vaccine product units of use as well as those 2D barcodes that may be found on secondary packaging in the future.

- The widespread adoption of scanning 2D vaccine barcodes should be promoted with a structured, national, organized approach. Clear initiative leadership, documented guidance, and cohesiveness between partners are needed in order to succeed.

- Practitioners and manufacturers are largely ready to adopt 2D barcoding.

The Forum concluded with a summary of progress to date and recognition of challenges remaining for full 2D barcoded vaccine implementation. Several points surfaced during Forum discussions were highlighted to emphasize the importance of 2D barcode implementation to the vaccination community. Meeting contributors were acknowledged and there was a general agreement that continued collaboration is required to facilitate 2D barcoded vaccine adoption.

Background

In September 2011, CDC initiated a 2D vaccine barcoding pilot project to assess the effect of 2D barcoding technology on the completeness and accuracy of immunization information.

The 2D Vaccine Barcode Pilot's Education Forum (Forum) was organized to bring together the immunization community stakeholders including vaccine manufacturers, immunization program awardees, public and private immunizing providers, and electronic medical record (EMR) vendors, IIS staff, and scanning vendors to discuss the lessons learned from the Pilot (to date), opportunities, challenges and next steps for implementing 2D barcoding on vaccine products. A full list of attendees is displayed in Appendix B.

Forum Objectives

The Forum was designed and structured to bring immunization community members together to discuss opportunities and challenges presented by the introduction of 2D barcodes on vaccine products. Forum objectives were to share insights from the CDC 2D Barcode Vaccine Pilot, early lessons learned and associated challenges, to provide information to assist with clinical 2D barcode adoption, and discuss Electronic Medical Record (EMR) and IIS functional applications of 2D barcode abilities. This was accomplished through speaker presentations and panel discussion. Attendees were engaged in working groups to determine where opportunities, gaps, and challenges to 2D adoption exist and determine how to best collaborate to move the industry forward.

Forum Agenda

Day 1 of the forum included presentations on 2D barcoding history, technology, and insights gained during the CDC 2D Barcode Vaccine Pilot. Day 2 was dedicated to collaboration, proving panel discussions and breakout working sessions. Panel discussions shared insight from immunization industry representatives experienced with 2D barcode vaccine application. Breakout working sessions facilitated discussion around 2D barcoded vaccine adoption, implementation, and standards.

Table 1 – Education Forum Agenda

Day 1: April 14, 2013		
Time	Description	Presenter
1:30-1:40 PM **10 minutes**	Welcome and Introduction • Welcome • Objectives of Forum • Agenda • Antitrust	Warren Williams, MPH CDC—NCIRD/Immunization Services Division, Informatics Team Lead, Immunization Information Systems Support Branch
1:40 – 2:10 PM **30 minutes**	The 2D Barcode History and Progress • History of barcoding at AAP –driving factors • AAP vision • How 2D barcoding supports AAP vision • Scanner guidance issued • Next steps for AAP	Elizabeth Sobczyk AAP
2:10 – 2:30 PM **20 minutes**	2D Barcode Technology • Overview of 2D barcode structure • Overview of scanners and capabilities • Other considerations	Paul Robinson Deloitte
2:30 – 3:00 PM **30 minutes**	2D Barcoding Pilot • Background and structure • Participants – Awardees, Immunizers, Manufacturers	Erin Kennedy, DVM, MPH CDC—NCIRD/Immunization Services Division, Medical Officer
3:00 – 3:15 PM	**Break 15 minutes**	
3:15 – 3:45 PM **30 minutes**	2D Barcode Pilot – Lessons Learned and Early Findings • Lessons learned – Scanners, Data entry models, EMRs, Linear barcodes, End to end supply chain • Early pilot findings - accuracy and completeness impact	Marshall Gaddis Deloitte
3:45– 4:00 PM **15 minutes**	VIS Overview • Overview of VIS • What is GDTI and how will placing on VIS be valuable • Progress in transitioning VIS statements • FAQs and Lessons learned • Where we go next? Vision?	Ken Gerlach, MPH, CTR CDC—NCIRD/Immunization Services Division, Health Scientist

4:00 – 4:20 PM **20 minutes**	Workflow Analysis • Workflow analysis • Overview of process • What were the challenges and what were the surprises • Key lessons learned that can be built upon	Andrew Sharpin Deloitte
4:20 – 4:30 PM **10 minutes**	Day 1 Close • Wrap up and overview for Day 2 – extend invitation to socialize at scanner booths	Warren Williams, MPH
Day 2: April 15, 2013		
Time	**Description**	**Presenter**
7:30 – 8:30 AM	Continental Breakfast	
9:00 – 9:15 AM **15 minutes**	Welcome - Day 2 • Welcome • Recap of Day 1 • Objectives and agenda for Day 2	Warren Williams, MPH
9:15 – 10:00 AM **45 minutes**	Inventory Management and Workflow Benefit discussion • Overview of the supply chain • Current practices in inventory management • Current workflow overview • Where are the opportunities and benefits • What is the real value and next step	Panel of 4 Jennifer Paster, Sanofi Pasteur Erika Jurrens, GlaxoSmithKline Tara Cullinan, Pediatrics for You Jan Hicks-Thomson, WA DOH
10:00 – 10:45 AM **45 minutes**	EMR/IIS Overview Progress and Updates • Role of EMR/IIS vendors in scaling and adoption • Current workflow overview • Where are the opportunities and benefits • What is the real value and next step	Panel of 4 Susan Stroud, Pediatric Health Mary Beth Kurilo, AIRA/Oregon Alert IIS Wes Baker, Cerner Maggie Griscom, Mitchell and McCormick
10:45- 11:00	Break 15 minutes	
11:00 – 11:15 AM	Breakout Group Instructions	

15 minutes	• Review objectives of breakouts • Assignment of people to groups – introduce facilitators and scribes • Overview of templates and review of questions • Readout format • Logistics	
11:15 AM –12:30 PM **75 minutes**	Breakout Groups Collaborative Sessions • Break into three (3) groups to discuss challenges to adoption and what is needed to accelerate acceptance • Review questions • Develop top needs to address in industry and what barcodes can and cannot do • Understand common practices and workarounds that may disappear • Discuss the benefits of barcoding from the perspective of providers and registries • Develop next steps	
12:30 – 1:00	Break for Lunch 30 minutes	
1:00 – 2:00 PM **60 minutes**	Breakout Groups Collaborative Sessions • Continuation of pre-lunch breakout session • Finalize materials for readout	
2:00 – 3:00 PM **60 minutes**	Group Readouts • Each group will provide details on what they discussed	
3:00 – 3:30 **30 minutes**	Day 2 Wrap up and Adjourn • Thank all participants • When materials will be available • Reference barcoding site for future questions and education needs • Help desk and web site resources available • Working together going forward • Questions • Feedback survey distributed	Warren Williams, MPH

Speaker Presentations

Speaker presentations are provided in Appendix A.

The 2D Barcode History and Progress
Elizabeth Sobczyk, AAP – Manager, Immunization Initiatives AAP

Elizabeth Sobczyk presented a historical and forward-looking overview of vaccine barcoding.

The key points presented by Ms. Sobczyk:

- Pediatricians provide the majority of immunization in the U.S.
- AAP partnered with CDC, vaccine manufacturers, and other immunization stakeholders to investigate the feasibility and barriers to implementing 2D vaccine barcoding.
- The GS1 DataMatrix 2D standard was agreed upon to barcode vaccine vials and syringes (units of use).
- AAP published clinician and manufacturer resources providing guidance on 2D vaccine barcode implementation.
- Sanofi Pasteur has rolled out seven 2D barcoded vaccine products. GlaxoSmithKline has rolled out one and committed to future products (as of the date of the Forum).
- Future clinician guidance is needed on workflow changes that can leverage decision support systems, such as scanning vaccines prior to instead of after administration.
- Next steps include measures to remove the linear barcode when 2D barcodes are present, completely integrate with registries, and roll out 2D barcodes into manufacturers' complete portfolios.

2D Barcode Technology
Paul Robinson, Deloitte

Paul Robinson provided a technical overview on the standards and structure of 2D barcodes, how they differ from linear barcodes, and barcode scanner hardware fundamentals.

The key points presented by Mr. Robinson:

- 2D barcodes offer higher density data storage than linear barcodes, 2335 alphanumeric characters capacity compared to 48 alphanumeric characters available in linear barcode, and requires less space, making 2D barcodes a logical choice to carry additional vaccine data elements such as product identifier, expiration date, and lot number, which are not stored on vaccine linear barcodes.

- Global Trade Item Number (GTIN) and Global Document Type Identifier (GDTI) are global standards developed by GS1 US Healthcare to identify vaccine products and VIS.

- Scanners typically must be configured by EMR vendors in order to interface with EMR solutions and process the 2D barcodes.

- Additional resources are available from AAP and GS1 for further 2D barcoding guidance and specifications. The links to these resources are found in Appendix F.

Table 2 - Technology Questions and Answers*

Question	Answer
Q1 Can you scan linear barcodes if your scanner also does 2D?	**[Paul Robinson, Deloitte]** Yes
	[**Bonni Kirkwood, Deloitte]** It will be important to think through how 2D barcoded vaccines not only affect EMR vendors but every other system that consumes data (payments, adjudication) - anything important to practices. So when you hear about 2D capabilities, think of other systems you work with today and how they will consume the data as well

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2D Barcoding Pilot
Dr. Erin Kennedy, CDC, NCIRD/Immunization Services Division, Medical Officer

Dr. Kennedy provided an overview of the 2D Vaccine Barcoding Pilot Project, including a description of the progress of 2D vaccine barcoding efforts since 2004.

The key points presented by Dr. Kennedy:

- The National Childhood Vaccine Injury Act requires documentation of data not available on linear barcodes and 2D barcodes can capture additional information like expiration date and lot number.

- Potential public health benefits of the 2D Vaccine Barcoding Pilot include improved accuracy of patient health records, consistency in information captured in IIS and VAERS reports, increased ability to identify safety concerns and a potential reduction in administration errors.

- The 2D Vaccine Barcoding Pilot's objectives are to examine the challenges of implementing 2D barcodes on vaccines and to evaluate the use of 2D barcodes via assessing data completeness, user experience, and process impacts, and to document best practices and lessons learned.

- The Pilot timeline began with manufacturer, IIS, and immunizer enrollment and provisioning from late 2011 through mid-2012, continued with immunization tracking through April 2013, and will conclude with a final report to summarize findings.

- Baseline and Learning data sets were collected from awardees and immunizers, and have been used to inform early findings. Additional data was collected through a user expectation survey, a mid-pilot user experience survey, and a workflow analysis. Additional data is still to be collected through a second user experience survey and a third data set, maturity data.

- The Pilot included 2 manufacturers, 10 awardees, and 217 immunizers. The immunizers included 145 private practitioners, 71 public health departments, and 1 commercial pharmacy.

- Specific EMR vendors were not targeted for Pilot participation. However, a total of 23 different EMR vendors and a number of provider sites entering directly into the IIS were used by participating immunizers during the Pilot.

Table 3 - Pilot Questions and Answers*

Question	Answer
Q2 Early in the slides on your history you talked about the FDA saying that manufacturers could request a waiver and it sounds like there was interest in that. Can you talk about if that is shifting—fewer manufacturers interested in a waiver/moving towards barcoding?	[Erin Kennedy, CDC] Vaccine manufacturers must request a waiver if they wish to remove the linear barcode from a product. I cannot speak to what manufacturers are planning. Both vaccine manufacturers in the Pilot are currently using linear and 2D.

Question	Answer
Q3 I thought that is what the waiver was— It is if you are carrying a linear code but you want to take it off?	[Erin Kennedy, CDC] Yes, the waiver is only required for replacing a linear with a 2D barcode.
	[John Roberts, GS1] Nowhere else is a manufacturer doing it beyond what they are doing in the Pilot. We do hope that they switch [to 2D barcodes] because of all of the benefits we know are there.
Q4 On the very last slide, it looks like there were 16 sites that did not have an EMR?	[Erin Kennedy, CDC] The 16 sites are public health sites, so they were entering data directly into their IIS.
Q5 Is there comparison data with those public health sites?	[Erin Kennedy, CDC] Right now we have just done the preliminary analysis, but that suggestion is great idea for future analyses.
Q6 Are all of the manufacturers on board with this; are they all in the process of doing it? Any timelines?	[Erin Kennedy, CDC]GSK and Sanofi are currently on board, but that is all I can tell you. [Bonni Kirkwood, Deloitte] We have heard in several industry events with other manufacturers that many are looking at applying 2D barcodes to other products (not just vaccines). My understanding of the waiver is if a manufacturer chooses to remove the linear barcode, they will need to apply for a waiver. At this time, the FDA has not applied this waiver to the broader Pharmaceutical markets, but expanding track and trace regulations may make this a possibility. Many manufacturers are interested in doing it just a matter of funding, priorities, etc. [Eric Metrokotsas (?), Merck]From the standpoint of using both linear and 2D on products, it was more of a marketing decision to accommodate practitioners that don't have 2D scanning capability - we don't want to limit their ability to use their current scanners. We just filed for (Varivax?) [Erin Kennedy, CDC] RTI interviewed seven vaccine manufacturers [during impact study], and all but one said they were going to move towards 2D barcodes. CDC was not told which these were. RTI report

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2D Barcode Pilot: Lessons Learned and Early Findings
Marshall Gaddis, Deloitte

Marshall Gaddis provided an overview of the preliminary lessons learned and early findings during analysis and evaluation of the baseline and learning data sets collected from the pilot immunization program awardees and immunizing providers.

The key points presented by Mr. Gaddis:

Lessons Learned

- Vaccination Data – Analysis of the baseline and learning data provided visibility to several vaccination recording practices that presented challenges for which controls were developed to enable analysis:
    - Data contained characters intentionally added by immunizers to the scanned lot number in order to assign attributes that are defined in separate fields on the user interface screen. Stripping out the erroneous characters from the lot numbers revealed increased accuracy rates. One example increased accuracy rate from 16% to 97%.
    - Data was transferred to the IIS in four different ways creating non-identical data sets.
    - Data entered free form yielded many variations of the same information. For example, when entering vaccine names instead of picking from a drop down list or other finite set of names, more than 100 unique names for the same vaccine appeared.
- User Experience – Measured with an online instrument:
    - The major concern was that a small percent of 2D vaccines were available in the pilot.
    - Scanning vaccines into inventory presented the additional concern of having to open the outer box to scan individual vaccine vials.
- Analysis Method – Completeness and accuracy are validated by first checking for a non-blank field to indicate completeness then comparing values to reference data comprised of distribution and manufacturing data.

Early Findings

- Approximately one million baseline and learning data records were received from provider sites and IIS. Of those, an upward trend in the availability of 2D barcoded records emerged as the pilot progressed and as more 2D barcoded products entered the Pilot supply chain.
- The EMR and IIS records received during the baseline and learning phases were compared and measured for completeness and accuracy. Both data sets increased in completeness and accuracy from the baseline to the learning phase. "EMR and IIS records received during the Baseline and Learning phases were compared and measured for completeness and accuracy. Both datasets increased in completeness and accuracy of lot numbers from Baseline to Learning. Baseline data for both EMR and IIS had over 250,000 records, and Learning data for each had over 650,000 records.
    - EMR Lot Number completeness went from 93% (Baseline) to 97% (Learning), and EMR Lot Number accuracy went from 97% to 99%.
    - IIS Lot Number completeness went from 66% to 83%, and IIS Lot Number accuracy went from 95% to 97%."

- IIS data increased even more from 289,000 complete baseline records to 816,000 complete learning phase records. Accuracy increased from 192,000 baseline records to 674,000 learning phase records.
- Additional analysis is needed to account for seasonality and other confounders such as technology gains or motivation levels of sites that are self-selected for this type of pilot study.

Table 4 - Pilot Findings Questions and Answers*

Question	Answer
Lessons Learned **Q7** On the side of the vial displayed in one of the slides, there is an L and E shown next to the human understandable information. Is that what you actually see?	**[Bonni Kirkwood, Deloitte]** That is the human readable - or human understandable - information. It is printed so that if there is no technology to read the bar code, providers can read the key product information. The L and E are there only in the human understandable representation to denote the L lot, and E expiry date. Manufacturers can vary on the human understandable approach they use and the field they use to indicate expiration, lot or batch etc.
Q8 Over time you would not need the human understandable?	**[Paul Robinson, Deloitte]**Manufacturers will still need to provide human understandable field for those who are not scanning barcodes. **[Bonni Kirkwood, Deloitte]** If you think about the variety of practices, there are some that are paper- based and they will not move to an e-system in the near future if ever. Also, need to think about global application as well.
Q9 Are the L and E in the barcode?	**[Paul Robinson, Deloitte]** No. The data is encoded in the barcode, but not the labels "L" and "E".
Q10 You mentioned some practices use a P before lot number to differentiate vaccines. When you found out a practice did it, did you ask why and what it captures?	**[Joe Durbin, McKing]** Some Pilot immunizers use "HOSP" as an indicator in their system for the private funded products as opposed to what is a VFC funded product. Different indicators are used by different practices, there is not a standard.
Q10 Did we ask the practices why they thought it was important to capture the "HOSP" or the "P" in the data cleansing lesson learned?	**[Paul Robinson, Deloitte]** Some practices use this indicator to differentiate sites, and some use the indicator to differentiate public or private purchase vaccines. **[Joe Durbin, McKing]**Practices told the team that they needed to keep the indicators for accounting purposes.
Q11 Was the variability seen in IIS and EMR?	[**Marshall Gaddis, Deloitte**]We have not looked at how many combinations in each. I can say for sure that unique values like this come in from EMR systems and IIS systems alike, it is not unique

Question	Answer
	to a specific data source.
Q13 Yes I understand that, but if they scan lot number then they have lost the ability to record that element that is important to their practice, so have to keep that into account.	**[Paul Robinson, Deloitte]** We have observed that, in some cases, an EMR has a variable to indicate if it was a private or public vaccine - but the variable wasn't selected. Instead, the immunizer entered the information in the lot number field.
Q14 Problems with the vaccine name was mentioned - is that because of NDCs?	**[Marshall Gaddis, Deloitte]** We used vaccine name as another validation point to identify the vaccine noted. NDCs themselves are prone to errors. Checking NDCs and the vaccine name resulted in a stronger match. What we found was a significant variability in vaccine names used. Standardization of product name is an area of opportunity.
Q15 Are lot codes specifically written for VFC vs. Private?	[Audience] No.
User Experience: **Q16** Are an equal number of pilot sites using 2D for vaccine administration and inventory?	**[Leslie Fierro, Deloitte]** No, the smaller number of responses could be due to number of sites using for each function.
Q17 Were there fewer practices scanning at inventory than administration? Could that be the fewer number?	**[Leslie Fierro, Deloitte]**Yes. Much fewer at inventory.
Analysis Methodology **Q18** Is there an opportunity to see how the data is exchanged between IIS and provider to see if that is a confounder?	**[Marshall Gaddis, Deloitte]** Yes we will look at the difference between IIS and provider transference methods to account for differences
Q19 Is there is an opportunity to look at the method of data exchange between the EMR and IIS- Struck between the completeness and accuracy of data that may seemingly be introduced because of the IIS specifically. Could that influence the data in some way? **Q20** Clarification, look at the transfer of data to the IIS to see if that could be why there is a difference from the EMR?	**[Marshall Gaddis, Deloitte]** I don't think I mentioned that earlier. We are going to evaluate EMR and IIS separately. We would expect similar trends, but we are going to evaluate them separately. We will have results for EMR and potentially separate results from IIS.

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VIS Overview

Ken Gerlach, CDC - NCIRD/Immunization Services Division, Health Scientist

Ken Gerlach provided an overview of the purpose for adding 2D barcodes to VIS, the data standards in use for VIS, and the 2D barcode VIS resources available.

The key points presented by Mr. Gerlach:

- 2D barcodes were implemented on VIS as part of the Pilot in order to achieve the benefits of increasing completeness of data elements, enhancing record keeping for providers, and promoting the use of barcoding technology.
- The CDC identified the GS1 Global Document Type Identifier (GDTI) to encode the VIS, added the 2D barcode VIS documents recently updated, developed guidance documents for users, and published the VIS lookup table online.
- Providers have an option to use either the multi-vaccine VIS or vaccine-specific VIS for DTap, Hepatitis B, Rotavirus, Hib, Polio, and PCV13.

Table 5 – VIS Questions and Answers*

Question	Answer
Q21 Are there plans to get all VIS updated? HIB hasn't been updated since 1998.	**[Ken Gerlach, CDC]** This is a good point. An argument could be made to update all of the VIS documents to include 2D barcodes without waiting for a different VIS update trigger.
Q22 Is language being captured? Sometimes a language other than English has a different date on the VIS.	**[Ken Gerlach, CDC]** The 2D barcode used on an English language VIS should be the same one used for the same VIS translated into other languages. If there is a discrepancy between for the same VIS in different languages, it sounds like an error of some type.
Q23 Is there a requirement that VIS must be delivered in hard copy?	**[Ken Gerlach, CDC]** There is no requirement that the VIS be paper based. Copies of the VIS are available in RTF file formats for use in electronic systems.
Q24 VIS barcodes are inside a black box, reading the barcode is not as snappy as reading a GS1 DataMatrix outside the little black box. Ease of reading the barcodes is important, is there a reason for the black box?	**[John Roberts, GS1]** CDC has actually changed the GS1 standard on the Data Matrix -they were one of the first US groups to use the GDTI
Q25 Wasn't the box put there to let people know this is a business type barcode and can't be used by trying to scan a QR code with their phone app?	**[Paul Robinson, Deloitte]** The black box surrounding the Data Matrix is potentially overlapping the quiet zone a little at the bottom of the barcode.

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Workflow Analysis
Andrew Sharpin, Deloitte

Andrew Sharpin presented a summary and key findings of the workflow analysis conducted at select pilot sites as part of the Pilot. The purpose of the workflow analysis was to develop a comprehensive view of each practice's immunization process to determine how 2D barcode utilization has impacted each practice's ability to accurately and efficiently manage vaccine inventory and administration. Two site visits were conducted for each provider site in the workflow analysis study: One visit was before the implementation of 2D barcodes and the other visit was after.

The key points presented by Mr. Sharpin:

- Limited supplies of 2D barcoded vaccines were available. Increasing the number of vaccines with 2D barcodes and ensuring that practices are aware of the products that can be scanned will improve scanning adoption and increase efficiency gains from scanning.
- The physical location in the provider's office where the vaccines are documented significantly impacts the adoption. Locations within the office, such as the vaccine prep station, the exam room, or moving throughout the office with a laptop, dictate proximity to the storage unit, scanner storage location and foot traffic, all of which impact scanner availability and user adoption.
- The timing of when vaccines are documented significantly impacts user adoption. Documenting administrations after vaccines have been given negates the value of using an EMR with clinical decision support, which increases the potential for medical errors. The delay in data entry also increases the possibility of entering incorrect information.
- EMR integration with 2D barcode scanning improves usability, which increases adoption.
- Data entry efficiency gains will be made by replacing manual data entry with scanner input and by reducing the need to correct errors that occur when manually entering product information. For example, entering NDC manually is a time consuming step. Scanning NDC would help promote the use of scanners.
- Efficiency gains are realized for inventory and administration. Practices using their EMR system for inventory management all saw efficiency improvements when scanning 2D barcodes. Improvements in vaccine administration efficiency were closely tied to a practice's experience scanning 2D barcoded vaccines.
- Practices are sometimes unaware they have received a product with a 2D barcode until that lot becomes active and they open the package. Adding 2D barcodes to the vaccine secondary package would expedite the inventory process.

Table 6 – Workflow Analysis Questions and Answers*

Question	Answer
Q26 Is using a phone or laptop camera as a way to scan possible?	**[Geoff Glaser, BARDA]** We have performed some testing with cell phones and were unable to get a read on 5mil X 5mil, but we could read the 7mil by 7mil. It appears to be related to the pixilation [**Paul Robinson, Deloitte**] The complication with using mobile devices is that the scan may work but there is no underlying application that will get the information back to the IIS or EMR. Unless you

Question	Answer
	have that application on your mobile device, the data is read but goes nowhere.
Q27 What about the gold standard practice of not documenting immunizations until after administered?	**[Andrew Sharpin, Deloitte]** There are two ways of thinking about this, if you scan before administration then you can validate that you are using the right vaccine, etc. However, there are also occasions in which the practitioner goes into the room and the parent decides to not to vaccinate. **[Elizabeth Sobczyk, AAP]** It would basically be a save in draft form, you are just giving the opportunity for clinical decision support to happen, and save as draft…that is something we are going through. **[Bea Salada, MI IIS]** This could affect inventory models. **[Elizabeth Sobczyk, AAP]** This is definitely an area we are looking into more. Draft form is only one means for making that happen.
Q28 I wonder about opening each box of vaccine to upload the inventory. Can you say a little about the process of manufactures who have barcode on the unit of use now – will they have to seek FDA approval and is that a barrier?	**[Geoff Glaser, BARDA]** When referring to serialized products there is a difference in the FDA requirements between the package and unit of use barcoding **[Erika Jurrens, GSK]** As the only company that puts 2D barcode on the vaccine box, we do not use serialization, we use NDC, we do encode lot number, expiry. You must understand that the NDC on the secondary package is different from the primary.
Q29 Are the inefficiencies with EMR receiving scanned data because the EMR was not set up to receive the information?	**[Andrew Sharpin, Deloitte]** Most likely but we cannot say "yes" across the board. Different EMRs process data in different ways.
Q30 Any discussion with McKesson about their processes and putting 2D barcode on the packing slip?	**[Paul Robinson, Deloitte]** We have not had that discussion. We are in the process of finalizing a report on the impact of 2D barcoded vaccine on supply chain participants that touches on this.
Q31 Focus on 2D barcode on outer package, why linear vs.2D barcode?	**[Andrew Sharpin, Deloitte]** The 2D incorporates lot number and expiration date. **[Max Peoples, RxScan]** Longer linear bar codes are more difficult for a scanner to read. **[Geoff Glaser, BARDA]** The linear bar code will become too big (note: linear barcodes grow in length as more data is added)
Q32 But on secondary and tertiary, is the size of the barcode an issue?	**[Geoff Glaser, BARDA]** 2D barcode use will be a global standard.

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Panel Discussions

Discussion Panel 1: Inventory Management and Workflow Benefit

Panel members:

- Jennifer Paster, Sanofi Pasteur
- Erika Jurrens, GlaxoSmithKline
- Jan Hicks-Thomson, Washington State
- Tara Cullinan, Pediatrics for You

Moderator: Paul Robinson
Note: The questions in **bold** are moderator questions. Italicized questions and comments came from the audience. Answers from panel members are indicated with the panelist's first name, answers from the audience are indicated the full name and organization. The questions and answers captured in this section were not captured verbatim.

1. **Jennifer and Erika, your companies' readiness to commit to implementing 2D barcodes on vaccines was vital to the feasibility of the 2D barcode pilot. Could you give us a better understanding of your experience with the regulatory process to gain approval for 2D barcode use on vaccines?**

    - Jen- For the regulatory process, we had to submit an FDA Post Approval Study (PAS) to apply a 2D barcode to a vaccine. Then we had to provide the rationale for the changes we were making, including a mock up. The FDA was a good partner; they reviewed our submission over a shorter timeframe so that we could get 2D vaccines out to the market in time for the Pilot. Our biggest issue was making the changes to the labeling—multiple products, multiple lines, and multiple countries. Communication was a key component in the success.
    - Erika- I agree with what you said. The 6-month PAS may be a hurdle going forward. That is a 6 month time period—so if you submitted today 4/15/2013- then you would have 6 months from today until you knew this was actually approved. First, there is a full six months before getting a green light, then you have all of the production concerns. Once the product is produced, then you have to work through existing inventory before the 2D product is to market. This is a much longer time to market than the regulatory 6-month review. I would echo that we were very happy to be a part of the Pilot. We really feel this is the best for patients and providers.

Q1.1- Beyond the pilot, are there any additional milestones? Or is this just a situation where you submit for FDA approval and just cross your fingers and wait?

- Erika-Yes, a bit but, because this was the Pilot, we were all learning together. There were some experiences we had where we went back and thought we would do it differently.
- Jen-There is prep work that goes into it, so you want everyone involved in the labeling process to be ready. Many of our 2D barcoded vaccines were approved internally prior to the 6-month approval coming through from FDA.

Q1.2 - Will this be the process for future requests, for future products?

- Jen- My understanding is 'yes'.

- Paul- We do not have FDA representation here. There has been no indication that it will be different.

Q1.3 - Do you anticipate continuing forward even though the pilot is nearly over?

- Erika- Yes we are 100% behind barcoding. We believe in its benefit and we understand there is a large ask from many. We are really committed to this.
- Jen- Yes. From Sanofi we have seven vaccines with 2D barcodes, and plan to have the pediatric portfolio with 100% 2D barcodes by the end of this year.

Q1.4 - Can you speak to how the barcodes are going to be put on the vials and syringes for those that you have to mix?

- Jen- At a high-level, the FDA did determine that the 2D barcode has to reflect the contents. You can either record the outside box or powder component.
- Erika- Ditto

2. **Costs and production impact are obvious considerations for vaccine manufacturers considering 2D barcodes. What are some of the not-so-obvious considerations?**

- Erika- There are more concerns than cap [capitalization] costs. There were a lot of line upgrades that were necessary, it can truly be difficult - Tom (attending GSK representative) can talk with you about that. I would also point out that we brought Chris (attending GSK representative) from an artwork perspective. There is very little living space for that barcode, so it is important that you can actually scan the barcode once as it is on the product and that the barcodes readable without taking up too much real estate. At GSK, we decided to put the barcode on the outer box as well as the vial. Barcoding on the outer box created some challenges, but we felt it would be important for inventory management. With all of the concerns aside, we do feel this is a benefit for patients.
- Jen- The only thing I might add is when it comes to production, it isn't just taking down the product lines. There is also a need to do a validation for quality for multiple countries; this can be a very big process.

3. **The increased data accuracy provided by 2D barcode scanning offers a clear benefit to practices that key-in vaccine inventory. Several practices have their vaccine inventories loaded by their state immunization registry. Jan's immunization registry in Washington is an example. Jan, would you please share about the impact 2D barcode vaccines have had on immunization registry vaccine inventory management and workflow?**

- Jan - It hasn't changed state-level inventory because we load that data in from VTrckS. But, from a provider perspective, if the lot scanned matches the lot number in inventory then the vaccination data it is more accurate. The process assures the correct lot number, correct expiration date and correct NDC are being pulled down from inventory.
- Tara- I agree. We get our vaccine information pre-populated. We don't have a lot of private vaccines in the office.

4. **Does 2D make the reconciliation process a more tightly coupled process?**

- Jan- From an overall business perspective, thinking about VFC in the state, there are many other benefits. For example, there are several data elements that are required that can be scanned in. If they are scanned in, it is accurate and clear. Also, yesterday there was a discussion about the VIS and recording the publication date of those with 2D scanning. If a practice is using 2D scanning to capture VIS data, you may have a higher likelihood that the data is accurate and complete so important from that perspective as well.

Q4.1 You mentioned the NDC number, which version do you use?

- Jan- We use the 5-4-2, the 11 digit version. We upload that data when we process orders.

Q4.2 Do you have trouble getting the 11 digit version in the system since what is barcoded is the 10 digit version?

- Mike Bin, Washington State - All of our NDCs are managed in a table, so as orders flow out of the system, the NDC stays with it. When an order is shipped from McKesson, we download the file from VTrckS and NDC is still tied.

Q4.3 Do you envision that being practical down the road when there might be overlap between lot numbers from manufacturers?

- Paul- That is something 2D barcode can help with
- Max Peoples, RxScan- But they are tracking the NDC
- Paul- There is potential for relationship tables to map the lot number/NDC combination if the information is available. This would be more dynamic than a straight NDC relationship table but would provide the NDC/Lot combination which would be unique.

Q4.4 With regard to inventory management, will there be an auto-trigger to McKesson that we are running low?

- Jan- I think that is beyond a scanning question. We have talked a lot and some states have a replenishment model that when inventory reaches a certain level an order is auto-generated. But in thinking about the role of scanning, it is more about if the inventory is valid, other pieces of the system would have to place the replenishment order.

Q4.5 For providers that have private and public vaccines, how are they indicating which are being used if they are just scanning the barcode?

- Jan- Washington is a universal purchase state, so we purchase all vaccines for all children under 19 years old in the state. With very few exceptions, they are publicly supplied.
- Tara- The only private purchase vaccine that we have is the flu vaccine. We don't scan the flu vaccine yet so I don't know how that is going to propagate.

Q4.6 Maybe someone from the audience has experience with this?

- Mary Beth, Oregon IIS - We use the lot number if there are two products from the same lot. From public and private lots, the system will use the dose-level eligibility code to break the tie.

5. **Patient safety is a recurring theme in 2D barcoded vaccine discussions. Would you share your thoughts on how 2D barcoded vaccine use may enhance patient safety?**
   - Tara- I think the most important items were covered yesterday. If we have recall, bad vaccine, or expired vaccine. Having that correct number in there makes it much easier for us to call that

patient and recall everyone who had that lot number. If you enter it manually, you might miss some folks.

- Jan- From a programmatic perspective, we manage all the returns in the state. Programs can return spoiled or expired vaccines for an excise tax. One challenge we have is matching the return to the product. If a digit is missed or something is hand written about the lot number then we have a very difficult time matching back to the product. If that product was one that could be returned, then we can't benefit from excise tax. So 2D scanning can be a real benefit at the program level.
- Jen- If you are thinking more future in terms of EMR and think about the pre-scan process. If the patient has allergies or if the product is expired, etc. think about the power of capturing that before the vaccine is administered to a patient.
- Erika—this is such a huge initiative. I just want to reiterate that we have had a great relationship with the partners and this really has been a learning initiative. I feel very fortunate to be able to say we really came together as a group. The manufacturers often get told that we work against each other, but we worked together here on patient safety. So we thank everyone. We have really enjoyed working together on this project.
- Jen- Agree.

Q5.1 If you were asked to respond to a pandemic influenza, how quickly could you respond with adopting a 2D barcode?

- Jen- It would depend. We have certain lines that are available and ready, assuming FDA worked with us on that, we probably could do it. It depends on the volume of product.
- Erika- Right, it is all about priority.
- Geoffrey Glaser, BARDA—everyone knows it is a priority. Could you work it into 8-12 weeks? I'm talking about using it across the board. It doesn't do much good to have it on the container if we can't use it throughout the system.
- Jan- I think this really goes back to some conversations yesterday about the potential value of having linear and 2D. Right now, in Washington State we have the ability to assign a linear barcode to a product and can use that so we already have that in IIS. So any clinic we have, that capacity is there. It isn't exactly what you are talking about because it is a specific assignment we would make. But if manufacturers can 't pursue a 2D barcode at the same time, as the public health system, we need to recognize that 2D is not a silver bullet and that it may not be the perfect answer for this.

Q5.2 I don't know much about McKesson, but I am wondering if you can speak to whether they are involved in this Pilot? (Role that McKesson played in the pilot)

- Paul- they didn't have a change in their role in the VFC vaccines. We were able to get source data from them that we are using as a reference. So that is their role in the Pilot, business as usual for them though.
- Warren Williams, CDC- We were not able to adjust their existing process as part of the Pilot because of large costs, etc.
- Jan- And I wonder since McKesson is a central distributor and we are talking about practice if that is necessary. I don't think we have to change McKesson's practice. At the state level, it is about how we assure the data is getting to IIS and decrementing inventories correctly for use in

returns, visible for site visits, etc. I don't really see a critical need for McKesson or other distributors to manipulate or change their processes to make this possible.

- Paul- I agree. There are aspects of their business that will likely need to change for serialization but not as much for 2D barcode application to vaccines.

- Mike Bin, Washington State - I think there may be an important step McKesson needs to play in this. When they are receiving bulk vaccines from the manufacturers, someone is hand-keying lot information into their system. There needs to be processes in place so they are entering the same exact number on the barcode because those are being used to pre-populate the IIS. We have a challenge with Sanofi because with IPOL there is a dash. **Note:** A *parking lot* was used to table points that would require more time to investigate than the agenda allowed. This item was added to the parking lot.

Q5.3 We spoke about inventory and reconciliation. Did you notice any improvement in your inventory reconciliation with 2D barcoded vaccines, and will you please tell everyone what you told me about how nurses felt about using scanners?

- Tara- Regarding inventory, I don't think there was a whole lot of difference. As far as nursing staff, we don't get a lot of 2D vaccines yet. We have two products with the barcode, so when one of them comes up, we fight over who gets to scan it.

Q5.4 Barcodes are great when they are scanned. But when you scan a UPC, and it isn't in database, it says "not found". How do you accurately get the information from vaccine manufacturers to get it into systems? This is the issue we run into; we don't get the info accurately.

- Paul- This is still in development. We are talking about having a common dataset that is published and available and can be pulled down to EMR and IIS systems.
- John Roberts, GS1- Right, for now folks do a work around, this is one you see at inventory and retail, etc. The work around is manual entry by clinicians.
- Jan- I think that really speaks to the need to have a holistic approach to that. You can't look at these processes in isolation to each other, must make sure that we have accurate inventory. If McKesson isn't scanning the lot number, then maybe they can improve that practice (if relying on IIS that is pre-populated); if doing your own inventory management at practice, you need to have 2D barcodes on the outer box so it can be quickly loaded into inventory.
- Max Peoples, RxScan - Possible solution to that ___ if you scan it and it isn't in your inventory; does the system just ask if you want to enter it?

Q5.5 This comes down to a trust issue, how do you get users to trust putting info into that main database?

- Erika- There are published reports of NDCs, for subscription purposes though. Not sure if that answers your question?
- John Roberts, GS1 - It does but someone pays for that. The easy answer is you give it to the FDA or the CDC to publish it, but they would have to pay for it. But what if the info goes up incorrectly? That is the biggest issue we have had on our side.
- Erika- your point is well taken.
- Paul- And we are considering this. There are data brokerage services that take data and then distribute it and charge a fee for it.
- John Roberts, GS1 - It gets even worse with serialization, which is going to be a nightmare. This is a tough nut to crack.

- Jan- The first entity that we trust is CDC, the second that we have to trust is our distributors (direct ship and shipped through McKesson); for other states that are not universal, they have to trust manufacturers. Also, trust for practices because they have to get data into system accurately. But these folks are all very vested in getting accurate information. Everyone wants to make sure patients get what they need. There is always going to be work to be done—if you can get to 98% accuracy that will be great. The standard cannot be any higher than we set for medical practice.

Discussion Panel 2: EMR/IIS Overview-Progress and Updates

Panel Members:

- Wes Baker, Cerner Corporation
- Mary Beth Kurilo, Oregon IIS/AIRA
- Susan Stroud, Pediatric Health/Ocean Health
- Maggie Griscom, Mitchell and McCormick

Moderator: Paul Robinson

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1. **What do you see as some of the key benefits 2D barcode functionality provides to immunizers?**

- Susan- When we were doing paper charting we didn't even know we had a problem, there were no red flags, etc. Then we stared online inventory management—we went all-in (we do private and public in our practice - more private than public actually in New Jersey). In NEW JERSEY, they were moving towards making inventory management required. Andrew touched well on efficiency—but efficiency in the reconciliation process is very important and wasn't mentioned. When we moved into online, it was an eye opener. What was on online was not what was in the refrigerator. So I started reconciling inventory every two weeks. I spent many, many hours reconciling, 2D has really improved this efficiency. Menactra was the first one. After a while I didn't have to look at Menactra anymore because it was correct in the inventory once 2D barcoding was introduced and used.
- Mary Beth- Just to underscore everything you say about accuracy, we have been watching data come in from about 1,000 providers in Oregon. The 2D plus paying attention to reconciliation helps so much with that.
- Susan- And it helps with accountability because you are accountable to that.

2. **What will it take to drive EMR vendors to incorporate functionality?**

- Wes- The government and stage 2 meaningful use requirements are key drivers to incorporate functionality we offer a full screen so you can use the PC with a tethered or blue tooth scanner. We also have an application with Honeywell and Motorola. Also working on Android application. There is a need to have mobile capabilities in the workflow. Streamlining is important

to making the process be accurate, etc. at point of care. I've heard a lot of nurses say I've never made an error—you don't know until you've seen it.

- Maggie-Barcoding cannot be intrusive into the process, it needs to be streamlined, and it needs to integrate into what we are already doing. Our folks have taken the barcoding and implemented it directly into inventory, it takes inventory and deducts when they give the vaccine. It triggers the fact that they need to give a particular VIS flyer, so they aren't seeing a new level of technology interfering with what they are doing when it comes to the patients.

Q2.1 Can you comment on the level of effort it took to get systems up in terms of handling vaccines?

- Wes- We are fully compliant. Once a 2D barcode is scanned, all information is extracted into the correct fields and available.

Q2.2 Any indication what the level of work is with 2D? How does it translate to sweat equity? Years?

- Wes- I wouldn't say years, probably a 6-month engineering effort. Not a lot of work.
- Maggie- For us, I would say it was fairly simple because we were collecting that information already (referring to data elements). Folks in health departments were used to collecting that information. It took one developer about one week. For us it was trying to do the same thing we do for our folks, just make it as simple as possible using existing processes.

Q2.3 When you say you are fully compliant and ready to go, does that mean you plug in 2D barcode scanners into a PC and your EMR just pulls the data in?

- Wes- Yes, that is correct. {Plug- and-play}
- Paul- I think that won't be the case with everything, there will be some configuration.
- Wes- once a scanner is configured it is seamless.

Q2.4 If it is not turnkey, how much time is it going to take? How long to get EMRs to be turnkey because no one is going to change their EMR. What about folks who don't have Cerner or M&M?

- Paul – the answer is "it depends" since this varies by product vendor. It also depends on their priorities. So many are focused right now on CMS requirements so it may not be at front of their list of enhancements.

Q2.5 Is there anything for outpatient yet?

- Paul- A very small number of vendors that specialize in outpatient solutions that have 2D barcode capabilities.
- Wes- those numbers are going to continue to grow.

Q2.6 How was the business decision made to prioritize barcoding? Was it based on meaningful use?

- Wes- No, we had been doing it for years.
- David Friedman, Deloitte- it depends on the vendor.
- Maggie- We have customers who wanted it and so we moved it through.
- Elizabeth Sobczyk, AAP – So if it is customer priority, then is it the customer who pays for it?
- Maggie- Our clientele is all public health departments.
- Elizabeth, AAP- Once built is it available to all other customers?

- Maggie- Yes.

3. Did you experience any push back from practices?

- Mary Beth - In Oregon, about 90% of data comes in electronically. Providers are very interested in 2D, but their concern is getting their vendors to make the change. It is an interesting process. We work with practices and vendors to try and triangulate solution. It is an issue of sequencing it in with priorities.
- Susan- I agree. We were ready before we heard about this pilot. We had actually discussed this idea. I think providers are ready, I have talked to other providers, and I think customer demand is there. When required to manage inventory electronically demand will definitely be there.
- Mary Beth- We heard from providers that they were concerned about having two workflows, having manual for some and scanning for some. But the providers who are in the practices in the pilot actually have said they appreciate 2D benefits even only having even a few vaccines barcoded.
- Paul- Maggie any pushback from practices?
- Maggie- No push back beyond cost of scanners. So it became a budgetary issue for them.
- Paul- I don't understand the degree of issue that poses. They are about $300 [scanners], so does it amount to a large expense?
- Maggie- It depends on the size of the practice. If you have five nurses giving vaccines all day every day, can become $1500 to $1600. That becomes a big concern at least for the public providers. Sue can probably talk to providers.
- Susan- I do have a take on that. The reconciliation process without the 2D is so challenging because of the time it takes. You know errors exist but you don't know what is wrong, there can be hundreds of errors that you have to find and it takes so much time. This is a cost, one that is largely removed when 2D is used.
- Wes- From the hospital perspective, cost is a major issue because many scanners are needed.

Q3.1 In one of yesterday's presentations, there was mention of a time study, pre and post. One of the larger practices that started the pilot and then declined to participate later noted that they would easily pay for a scanner because reconciliation takes so much time, so staff labor costs with respect to reconciliation was very high and scanners remove that.

Q3.2 Have any of you seen one barcode more challenging than others to scan (any variability)?

- Susan- I haven't noticed any differences between the five we have.

4. Mary Beth please put on your AIRA hat. Practices are ready they want to move forward but in some cases their registries aren't ready yet. Any guidance you would like to share?

- Mary Beth- For data coming across an e-feed, the data looks the same at the IIS end. We have some difficulties with providers entering into our e-system. We can currently bring in lot number and expiration date at inventory and administration. But we hit a stumbling block with NDC, developing and standardizing NDC at inventory with point of administration. Unless we are using the same clean cross walk when decrementing inventory and trying to reconcile in the end. But there is still room for disconnect, without the primary and secondary packaging labeled. As part of prevention, a public health fund grant exists where a few states are working on a first pass of the cross walk with CDC.

Q4.1 Do you support the notion of registries expanding or just focus on EMR side?

- Mary Beth- Great question,. Ninety (90%) of our data in Oregon is coming in from EMRs, but only 10% comes directly into the IIS. We have providers who say they will retire or die before they take on an EHR, so we probably have to do both to be responsive.

5. A couple of other questions, with some of the software being pushed out. For Wes and Maggie, what did you use for the guidelines for implementation, any standard?

- Maggie- We used the support from the scanner, how the scanner was reading the barcode. I don't know if we used GS1, we just took the information. The hard part for us was the translation from the barcode into the system to ensure the data went into the right places. But it was the developer who did this. He just took the codes he got from the scanner and plugged them in. Simplistic but that is basically what he did.
- Wes- Yes I think that was the hardest point on our side as well.

Q5.1 Is there a standard order for populating data into an e-record?

- Maggie- Mapping may have been lot number, bin, etc. the process for us was to take the process and make sure we mapped it to correct spot in the EMR.
- Further discussion concluded that there is not a specific standard sequence or order of data elements.

Q5.2 I'm interested in the level of change from a user's perspective. Was it a big change for them?

- Wes- Any introduction is a big change. But once they learn how to adopt it, they use it. It is a lot different than documenting on paper. If we had introduced it 10 years ago, then it would have been very difficult. But once they use it now, they see how much faster it is and they love it.

6. Similar to what we see as a commitment from the manufacturers, is there a way to toggle on and off at practitioner level?

- Wes- We do that, if they scan a barcode that is expired they get a notice from our system that it is expired.

Q6.1 Beyond the technical, you say you are changing the model, but do you offer training, customer support? Did you get calls from the customers?

- Wes- Yes, most use our consulting group. We usually train a set of super-users and then they go out and train others before implementation. Also, we have a support line and a front line group that manages those questions.
- Maggie- They have me on speed dial. For the pilot, we just went through a WebEx presentation; they picked it up very quickly. Because it didn't alter their workflow, it just added one step and eliminated many others. That was all the training they took.

Q6.2 For EHRs, do your systems have an inventory module? Is the inventory integrated into the process with the 2D scanner?

- Maggie- Yes they can scan directly into inventory from the 2D barcode and the same information is used to populate the immunization record as they go along. It deducts from inventory what they administer.
- Susan- Not the case with ours. We scan into the IIS and did not maintain any inventory.
- Wes- We are the same way, products get scanned into pharmacy [Cerner inventory application], once administered the inventory is adjusted.

Q6.3 This Pilot is all about vaccines, but did users ask about scanning other medicines?

- Maggie- Yes they did. They want to scan everything. So yes, and again in a public health department, they are programmatically structured so their medications are also structured by program. Even the people who weren't included in the vaccine pilot want to use the barcode.
- Max Peoples, RxScan – With your solution, were they able to do other meds?
- Maggie- They can do the others as long as there is a barcode on them.

7. We have heard a couple of discussion points on how to incentivize adoption by practices. Anything else we can do to motivate folks who are on the fence?

- Mary Beth- The biggest selling point is really that it is an opportunity to educate providers about how many places these data are used and build an understanding that those data are consistent and accurate. We just rolled out VTrckS in January of this year. The level of focus on the quality of that data has increased exponentially. Everything is all connected in a way that it wasn't before. It is really a perfect time to roll out 2D barcoding because we have a lot of providers understanding how important the accuracy of the data is.
- Wes- I agree with everything you said.

Q7.1 I want to make sure I understand what you are saying about providers. We want to motivate them to do this, but if there is an issue with the data quality, is it their [providers] office expending hours to work through the issue?

- Mary Beth- Yes, I think they are. This is my full time job, this is Jan's [Washington state program manager] full time job. It is such a small part of what providers do. When an error comes through it pulls away time from the other million things on their plate, so the added investment is important. They now see if they engage on a day-to-day basis they won't have to take so much time on reconciliation error checking, etc. It is very much on the providers' dime if there is inaccurate data that comes up.

Q7.2 Right, so that is dollars to them?

- Mary Beth- They understand the importance of data quality.

Q7.3 One thing we need to do is look at 2D barcoding with respect to medications in general. This is really about managing medications, vaccines are just a medication. If there is a way that barcoding can make managing meds an easier process, then that would be great. We can make this just about vaccines but it's good to keep in mind the bigger context in which these practices work. Are vaccines the only target or is it broader?

- John Roberts, GS1- Yes, when the FDA allows barcodes on the rest of pharmaceuticals. We keep asking them when they are going to rewrite the 2004 statement so that other meds can be managed this way. The California pedigree law only uses 2D DataMatrix barcode.

- Geoffrey Glaser, BARDA - California has mandated that every pharmaceutical must have a global trade identification number and serialization and the FDA stands behind this. Congress was to have FDA to take over this program at a national level but it didn't pass. The Pilot is a really good project to help the tail wag the dog on this issue.
- Max Peoples, RxScan- But will it actually be a 2D barcode? There is a stacked barcode as well. This meets FDA requirement and is available today, lots aren't using it though. There has to be some incentive for the manufacturers to use this barcode and I think it is California. Do you think everyone will switch over?
- John Roberts, GS1- I think they will all switch over. The stacked barcode has to be in alignment. The matrix is smaller, easier to print, the Europeans want it, and Asia Pacific wants it. Pfizer is using blister packs and I think they will switch very easily. It is so easy to print.
- Susan Ostroski, Pfizer- We are going to be 2D coding within six months.

Working Sessions

Prior to the Education Forum, the registrants were asked to identify three opportunities or challenges that the implementation of 2D barcoding presented for the vaccine immunization community. Three common themes emerged as the primary areas of interest:

1. **Standards** – The majority of challenges focused on the package level product identification and reconstituted vaccines. The 2D vaccine barcode currently uses a GS1 standard on the vaccine unit of use. The need exists to extend this industry-wide adoption to standardized product identifiers on the units of service and units of sale, or the secondary and tertiary packaging. Reconstituted vaccines also pose a challenge. Questions exist on how to provide unique product identifiers to each kit of multiple components and how to match the individually administered products back to the kit as it was recorded in inventory.

   Stakeholders are also concerned about the capability of EMR and IIS solutions to process and support 2D barcoding, and are looking ahead to the impact of serialization 2D vaccine barcodes.

2. **Adoption** – Adoption was defined as a balance between the value provided by 2D barcodes and the cost and benefits resulting from implementation. Primary concerns focused on the availability of 2D barcoded vaccine products, the financial considerations of purchasing hardware and software, the time commitments needed by clinical and IT staff, practice efficiencies to be gained, and the effectiveness in yielding complete and accurate data.

3. **Implementation** – Once adopted, many questions exist around how 2D barcoding is implemented by manufacturers, providers, IIS, and EMR/IIS solution vendors. Questions were presented regarding changes to inventory and administration workflow, office configuration, scanning, and training. Similar to the Standards group, reconstituted vaccines are major concern for implementation as well. How they are barcoded and the impact on current practice operations is a challenge.

The disproportionate number of submissions for these three areas made them the logical choice to be topics for the forum working sessions. Detailed responses received by attendees prior to the forum can be found in Appendix D.

The following section provides notes from each of the working sessions. Many of these notes are captured in bullet points or sentence fragments and are included to provide context and background for the opportunities and challenges summarized in Appendix D. A full listing of working session groups and their associated attendees can be found in Appendix C.

Group 1 – Standards

The focus of Group 1 was discussion of the benefits and the challenges of adopting and implementing GS1 standards for vaccine products. The questions asked of the group and the related discussion points are below:

1. **We know that 2D barcoding will extend beyond primary packaging to the secondary package. The AAP guideline applies only to unit of use. Other than GTIN, what data do you plan to include, e.g., lot numbers? What additional data elements are needed?**

The group agreed that the GTIN, lot number, and expiration date currently found in the 2D barcode on the units of use should also be aggregated at the package level. On the secondary and tertiary (unit of service/unit of sale) packaging, add the serial number.

- An example supporting serial numbers on units of use was presented: To expedite scanning of multiple vials from one package, nurses may scan one vial multiple times to account for quantity, which can cause a mismatch when scanning during administration if different information applied to the vials, e.g., different expiration date or dosage; To overcome, if each vial has serial number the EMR system can prompt the user to scan each individually.
- Manufacturers feel the track and trace regulation will exist at the package level so there is no need to put serial number on the primary unit of use.
- It might be good to have dosage information to help providers to enter inventory.
- Some information is publically available on FDA site, since NDC is part of GTIN, this information can be used to access the look up tables. The group agreed this is a good solution, although some advised against parsing the GTIN and others cautioned that the FDA website is not always current with vaccine data. A discussion ensued on the explanation of the evolution of the GTIN and data string components.

2. Should 2D barcoding expand beyond primary and secondary packaging to the tertiary level? Would it be helpful?

Relationships between primary and secondary packaging and what should be printed on those packages were discussed, which moved into details about vaccines and vaccine boxes. We broke vaccines into three groups and identified how the NDC, lot number, and expiration date should be presented on the primary and secondary packaging for each.

- Simple vaccine-1 component, no reconstitution required:
    - NDC will be different on primary and secondary packaging. It was noted that not all manufacturers use a different NDC between primary and secondary packaging. The FDA guidance is to use different NDCs and the FDA is working with manufacturers who do not comply with those regulations. In coming months, all manufacturers will be in compliance.
    - Lot number and expiration date should be the same on primary and secondary packages.
- Combination vaccines - Since there is no need to reconstitute, vaccines will come packaged in a vial or syringe and will have its own NDC; like the simple vaccine, the NDC, lot number, and expiration will be different on primary and secondary packaging.
- Reconstituted vaccines, which can have one or more active components, require further breakdown by the number of active components:
    - Reconstituted vaccines with one active component:
        a. Both the active component and diluent will have its own NDC
        b. The package (a kit containing the active component and the diluent) will have its own NDC (different from the one on the active component and the diluent)
        c. Lot number will be different for active component and the diluent
        d. The lot number on the kit should be the same as the lot number on the active component

e. The expiration date will be the earliest expiration date among the components.

- Reconstituted vaccines with one or more active components and one or more diluents:
  a. Each component will have its own NDC and the kit will have its own NDC
  b. The lot number for kits need to be **different** from the lot numbers of the active components of the kit
  c. Expiration date will be the earliest expiration date among the components

The state registries and EMR/IIS vendors disagree and view this approach as unworkable. They use both the lot number and expiration date **from the active component** to receive the kit into inventory (they ignore the diluent when scanning to administer vaccines). If the diluent has the earlier expiration, the kit would have an expiration date different from the active component and will not match when scanning for administration. The registries and EMR/IIS vendors also are concerned that HL7 messages will not accommodate using multiple lot numbers for reconstituted vaccines. The group discussed the infrastructure needed by EMR vendors to address issues resulting in the need to develop an NDC relationship matrix:

- For reconstituted vaccines, three NDCs are needed; one each for the kit, the active component, and the diluent. For each NDC, the EMR should be able to relate to the lot number and expiration date
- Alternatives were suggested to use an NDC with a package level indicator in a 14-digit GTIN. Two models were proposed.
  - The first model uses a GTIN where the NDC will not change and package indicator digits will change. The FDA already requires NDC to change when the presentation or package level changes, excluding the first model.
  - A second model was proposed that uses a GTIN where the NDC changes and the packaging level digits remain the same. The group agreed this model will work. This model requires an NDC relationship matrix to map NDC to lot number and expiration date.
- Further discussion is needed to determine how the matrix will be consolidated and maintained.

3. **The group also discussed the need for standards when using the lot number on the secondary packaging. Based on three different vaccine types (simple, combination, reconstituted), four different scenarios of using lot number and expiration exist. Should there be a universal standard for that?**

The group discussed the possibility of needing a lot number matrix. They agreed the matrix will be dynamic and carry a high cost of maintenance for all parties. The manufacturers, IIS, EMRs, and providers will all have to keep copies of the lot numbers. Currently, only the manufacturers have the lot numbers requiring them to publish it periodically and allowing it to be pulled by third party services or EMR/IIS vendors.

- The lot number should be the same as the unit of use.
- Currently, no one body owns the lots numbers (as FDA owns the NDCs for an NDC matrix), and manufacturers feel a lot number matrix solution is more cost than benefit.

4. **How do we ensure uniform capabilities within the EMR vendor community? What are the challenges and opportunities for EMR/IIS vendors to standardize 2D capabilities?**

   The HL7 messaging is intended to ensure that universal capabilities exist within the vendor community. However, standards are needed to guide EMR vendors on how to capture and process 2D barcodes currently found on vaccine product units of use as well as those 2D barcodes that may be found on secondary packaging in the future.

   - Incorporating logic into EMRs to use NDC mapping tables and an NDC matrix introduces challenges including EMR cost and time and an IIS burden to cross match to inventory. In addition to that, not all EMR solutions have an inventory module.
   - The EMR/IIS community needs a set of requirements for EMR capabilities.

Group 2 – Adoption

The focus of Group 2 was discussion of the benefits and challenges of adopting 2D vaccine barcoding by the cross functional groups represented at the Forum. The questions asked of the group and the related discussion points are below:

The widespread adoption of scanning 2D vaccine barcodes should be promoted with a structured, national, organized approach. We need for leadership to be determined, guidance documents to be written, and cohesiveness to exist between the partners.

1. **Financial considerations: What are the financial considerations of 2D barcode scanning? Equipment, implementation, and training for registries and providers?**
   - It would be great if there was a cost benefit assessment tool. Have to show the benefit and the value of that benefit. Where is the time saved? How much money is saved?
   - Cost of scanners; can CDC buy them for everyone? Can they be purchased in bulk at a reduced cost?
     - Suggestion of a trial program from scanner manufacturers to increase adoption. If they get a scanner for a "free trial", they may ultimately purchase more.
   - Could CDC or someone else develop a guidance tool? It would address a broad spectrum of topics and include recommendations from CDC for providers to use scanners. Ensure the tool includes information about the future state of scanning barcodes. Include information on who will assume the IIS upgrade costs? Who will assume the EMR upgrade costs?
   - EMR costs to the vendor as well as the private providers should be well documented
   - Create a grid that lists the scanners, attributes, costs, compatibility, scanner readiness, etc. Eliminate the need for each provider to do the research. Create the same type document to assist users in need of an EMR.
   - Remember that scanning adoption is not owned by pediatricians only. Other health care providers such as family practice, commercial immunizers, hospitals, and other specialized practices should be considered.

2. **What adoption incentives exist?**
   - Pharmaceutical and EMR companies are engaged and looking to be scanner ready.
   - Engage the professional communities and associations
   - The development of a cost assessment tool with time saving analysis would be an incentive to providers.

- Perhaps pull in insurance companies, align incentives?
- Standardization is very important. Prepare guidelines that people can use in making decisions. Don't want providers to put money forward only to be out of alignment with standards.
- Adoption psychology in intermediate phase where pilot is wrapping up but this is not a market standard yet. What to do to make sure 2D barcoding is not forgotten before the next interest is pushed to the forefront?
    - Have real user information of how scanning is helpful:
    - Record keeping (completeness, accuracy, inventory management)
    - Patient safety
    - Efficiency is higher
    - Someone to champion 2D
    - Helpful in meeting Meaningful Use criteria and perhaps other tasks.
- CE's (continuing education) as an incentive. Already an incentive in many states where licensure requires CE's. If so, have an organizing body to create CE's rather than 62 immunizer registries.
- Showing the public that by adopting the latest technology, health providers and others are committed to the latest and best in patient care. This could potentially increase reputation and business.

3. What other barriers to adoption exist?

- Resistance to change; attitude about change.
- Staff buy-in. This needs to make their life better immediately; otherwise, it will not be used. Change taking place from bottom-up might be best; peer-to-peer promotion. *Quote: If you can hear it from your peers that it is worth doing that goes a long way." Find champions.*
- Lack of support
- Costs are a barrier. Offices might cut costs and spend less on EMR or scanners. We need to communicate to providers what to look for when purchasing items/services. *Quote: "If we focus on what we see then we'll never get beyond where we're at."*
- IIS staff playing an increasingly busy role to troubleshoot provider challenges. Adding another layer of hardware and of software can be a barrier. There are great variations among awardees and their IIS capabilities.
- First intent is quality care, but there is dollar value attached to it. *Quote: "There is really a dollar value attached to it, it's a business."*

4. Benefits to Providers: Is there an immediate efficiency for the providers? Workflow? Other?

- Workflow impact is important. If it is too much effort, the providers will not use it. Need to be considerate of the workflow from vendor perspective to make it easier. Staff talks inside and outside the office and buy-in will decrease or be difficult if workflow is not worked out.
- Scanning before or after administration? Only one group member felt strongly about always scanning after administration with main concern being on inventory management.
- The group thought that having a computer at point of care will assist with compliance and workflow.

- Understanding the present changes and know how they will fit into the "why" aspect of changing impacts change. Providing underlying reasons may help acceptance.
- We need to answer "What's in it for me?" Figure out incentive and communication. Grassroots effort, use the carrot versus the stick.
- Concern with 2-year adoption timeframe. Small pilot involvement thus for, all for that with early implementers. *Quote: "Where is the support in 2-3 years from now to really manage who is going to get this? Free market? I'm worried we'll be on the next thing 2-3 years from now."*
- Transcription errors for nurses. Maybe position these technologies as stress relievers rather than adding stress for people in an already high stress role. More efficient to use this than writing numbers down, VIS statements, etc.
- This goes back to incentives. Financial incentive to keep coverage rates high. Could we attach an incentive to data quality?
- Need to decide if this is a public health initiative? What are the roles and responsibilities? Where is the expectation (if it is there) that an awardee will do something to promote this? Does CDC have a strategic plan on this, or are we just dabbling to get facts and information?
- *Quote: "Ultimately in the end, everything is for the good of the patient."*
- Completeness and accuracy
- Easier to review records. Assist with inventory and decrements then there should not be a problem with matching lots.
- Assist sites in when and how much vaccine to order.
- Assist awardees and sites to move toward a replenishing order model.

5. Benefits to manufacturers

- Accuracy and completeness would help business
- Actions could be seen as a good will gesture
- Global compatibility

6. Increase Immunizer Adoption: How can providers be convinced to invest in and embrace barcoding technology?

- Increase customer (patient/practice) satisfaction. Fewer errors when vaccines are scanned. Removes notion of visually inspecting records. Practitioners could use this as a marketing tool. *Quote: "We're really state of the art and we take your safety very seriously".* Could result in patient retention and increased business.
- *Quote: "This is about saving time. This is about making your office more efficient. Maintain your customer base. Time, efficiency, safety, accuracy, completeness."* Invest $xxx up front with xxx minutes of training, and the return on your investment is ____.
- Reconciliation time savings.
- Positive reports. Generate positive information from reports (versus recalls, not being involved in bad press)
  - VAERS
- Could make practices more technologically advance making them more attractive to some practitioners and patients.

- *Quote: "Am I driving? Riding shotgun and navigating? Sitting in the back seat watching the scenery? Or in the trunk with the rest of the baggage?"*

Group 3 – Implementation

The focus of Group 3 was discussion of the benefits and the challenges of implementing 2D barcoding within the various settings (e.g., manufacturing, immunizer provider sites, and IIS) represented by the breakout session participants. The questions asked of the group and the related discussion points are below:

1. **What needs to change in inventory and administration workflows in order to incorporate 2D barcode scanning?**
    - Having the 2D barcode on the exterior packaging would be helpful for the purpose of recording at inventory.
    - Introducing 2D barcoding into the workflow of immunization provider sites did not appear to present difficulties. Where scanners are located (e.g., next to fridge for scanning at inventory) may help with efficiency. In general, the 2D barcode scanning process should introduce minimal disruption to the current workflow.
    - Scanning of 2D barcodes appears to have strong benefits for inventory management.
    - No resolution was reached regarding when vaccine administrations should be recorded (before or after vaccination occurs), however, the potential negative impact of untimely recording of vaccine administrations by on-site staff was highlighted by the group.
2. **What technical support/training was put into place to support implementation?**
    - No significant training needs were identified among group members with respect to staff working at immunization provider sites. As long as the scanner was configured properly, the scanning process was easy to integrate. One caution mentioned is that several of the EHRs and IISs are only leveraging the lot number and expiration date from the 2D barcode, not the NDC/GTIN string, which may bring up additional training issues/needs in the future.
    - Training techniques mentioned by manufacturers included an intensive training ramp up for line operators when a new line was introduced. Additionally efforts were taken to inform various target audiences (such as wholesalers and health care providers) about 2D barcoding through mechanisms such as training operations groups and marketing representatives.
3. **What are some potential challenges and opportunities associated with having the 2D barcode on both primary and secondary packaging, particularly with respect to reconstituted vaccines?**

    The discussion about issues arising from differing lot numbers being included on the unit of sale and units of use for reconstituted vaccines comprised the majority of this breakout session. This was a very rich discussion that cannot be captured completely in a summary; as a result, only key issues are documented below.

    - The NDC and lot number represented on the unit of sale and the units of use differ. Although the lot number for the unit of sale and unit of use vial containing powder are linked by manufacturers, this is not the case within local immunization practices.
    - Immunization practices typically use the lot number to record inventory and vaccine administrations. If a practice scans the 2D barcode located on the unit of sale to record

inventory and later scans the 2D barcode on a unit of use when a vaccine is administered the inventory for the practice will not be appropriately adjusted.

- Some potential approaches for addressing this issue were brainstormed by the group, however, the group did not feel that any of the three identified were ideal.
    - Option 1: Scan the unit of sale barcode at administration
    - Option 2: Create a mapping table. However, ownership and maintenance of this table presents challenges.
    - Option 3: Introduce modifications to VTrckS.

4. **What are some potential future opportunities for using 2D barcoding?**
    - Mass vaccinations – The group felt that using 2D barcodes for mass vaccinations may be useful. The utility, however, may vary slightly based upon the type of mass vaccination as in some situations the product type, expiration date, and lot number would not vary significantly. Even in situations where this information did not alter significantly potential benefits of scanning 2D barcodes were seen by the group including improving the quality of records and potentially making it easier for individuals who do not typically work in immunization programs to provide assistance to mass vaccination efforts.

Summary and Recommendations

Summary

The Education Forum provided a platform to highlight the benefits offered, challenges remaining, and potential solutions to aid the adoption of 2D barcodes on vaccines. There was agreement that holistic 2D barcoded vaccine adoption will be eased through collaboration of immunization industry stakeholders. The tipping point has not been reached, although good indicators exist that early adoption is occurring. As the discussions continued throughout the Forum, several items emerged as themes and recommendations.

Themes

- Involvement from partners, including EMR, IIS, manufacturers, providers, and CDC, is key
- Manufacturer adoption is a driving factor for industry-wide 2D barcode adoption
- Practitioners and manufacturers are largely ready to adopt 2D barcoding
- Practitioners see clear benefits with inventory and reconciliation
- Examples of effective EMR implementation exist, but EMR functionality varies and so will the scanner configuration needed to implement 2D barcoding

Recommendations

Challenges	Recommendations	Next Steps
Packaging Hierarchy: Relating different levels of packaging is difficult due to the absence of a relationship reference. This challenge extends to the handling of reconstituted vaccines. Consider product identification sourcing to determine how to consolidate NDC data from the FDA and lot numbers from vaccine manufacturer sources	• Develop a NDC relationship matrix. Include GTIN and lot numbers.	• Develop a matrix for NDC hierarchy relationships and corresponding GTIN • Conduct additional discussion to confirm the need to include lot numbers. • Conduct additional discussion to determine how best to maintain reconstituted vaccine component relationships
Unclear Direction: A recurring statement was that there is not a central authority from which immunization industry stakeholders can obtain guidance on 2D barcode vaccine adoption.	• Create a roadmap to help set expectations and where stakeholders should go from here. • Develop and publish standardized requirements for EMR 2D barcode capabilities	

Challenges	Recommendations	Next Steps
	• Provide guidance on workflow best practices, specifically to scan vaccine units of use at administration	

A survey was distributed to all attendees in order to collect feedback on the Forum and what could be done to enhance the education and insight gained from the event. Results from the surveys are displayed in Appendix E.

Appendix A – Speaker Presentations

The 2D Barcode History and Progress
Elizabeth Sobczyk, AAP – Manager, Immunization Initiatives AAPAAP Guidance for Practitioners

2D Barcode Technology
Paul Robinson, Deloitte

2D Barcoding Pilot
Dr. Erin Kennedy, CDC, NCIRD/Immunization Services Division, Medical Officer

2D Barcode Pilot: Lessons Learned and Early Findings
Marshall Gaddis, Deloitte

VIS Overview
Ken Gerlach, CDC - NCIRD/Immunization Services Division, Health Scientist

Workflow Analysis
Andrew Sharpin, Deloitte

Breakout Session Overview
Paul Robinson, Deloitte

Appendix B – Attendees

Attendee	Organization	Role
Ambrose, Karita	Novartis Vaccines & Diagnostics Inc.	Sr. Medical Science Liaison
Bahukhandi, Ajay	Deloitte Consulting LLP	Manager
Baker, Belinda	Washington State Department of Health	IIS Technology Coordinator
Baker, Gene	MedChain Systems, Inc.	CEO
Baker, Wes	Cerner Corporation	RN, BSN
Bennett, Laurie	McKing Consulting Corporation	Consultant
Bin, Mike	Washington State Dept. of Health, Office of Immunization	Operations and Response Consultant
Callaghan, Don	Iowa Department of Public Health	Bureau Chief
Celfo, Christopher	GlaxoSmithKline	Manager
Charles-Rennie, Trisha	McKing Consulting Corporation	Meeting Coordinator
Clark-Gagne, Julie	Contractor to MI Dept. of Comm. Health	Public Health Consultant
Clason, Kristy	Motorola	Sales Director
Cox, Marietta	State of Florida Department of Health	Training Consultant
Cullinan, Tara	Pediatrics For You	CNA
Day, Michael	Oregon Immunization Program	Operations & Policy Analyst
DiVito, Daniel	Sanofi Pasteur	Business Planning
Doss, Jillian	New Jersey Department of Health	CDC Public Health Advisor/Assistant Program Manage
Durbin, Joe	McKing Consulting Corporation	PHA/Vice President
Fierro, Leslie	Deloitte Consulting LLP	Specialist Master
Flynn, Michael	NYS DOH NYSIIS	NYSIIS Technical Lead
Friedland, Leonard	GlaxoSmithKline	Vice President, NA Clinical/Medical Affairs
Friedman, David	Deloitte Consulting LLP	Principal
Gabor, Steve	Novartis Vaccines & Diagnostics Inc.	Associate Director Public Access
Gaddis, Marshall	Deloitte Consulting LLP	Analytics Consultant
Gerlach, Ken	CDC	Health Scientist
Glauser, Geoffrey	HHS/ASPR/BARDA	Program Manager
Gorman, Chrissie	Scientific Technologies Corporation	Public Health Advisor
Gowler, Jeremy	Novartis Vaccines & Diagnostics Inc.	Sr. Director, Marketing

Attendee	Organization	Role
Greene, Judi	Louisiana Immunization Program	Program Monitor
Griscom, Margert	Mitchell & McCormick	Sr. Analyst
Hartstein, Courtney	GlaxoSmithKline	Vaccine Futures Manager
Haupt, Kim	GlaxoSmithKline	Senior Director
Hicks-Thomson, Jan	WA Dept. of Health	Vaccine and IP Registry Integration Section Manage
Hoefer, Dina	New York State Immunization Information System	Program Manager
Hudson, Donna	MSDH/CDC	PHA
Jones, Rosemary	MSDH	VFC Coordinator
Jurrens, Erika	GlaxoSmithKline	Innovation Manager
Kennedy, Erin	CDC	Medical Officer
Kirkwood, Bonni	Deloitte Consulting LLP	Senior Manager
Kline, Thomas	GlaxoSmithKline	Packaging Area Engineer
Klipic, Ernad	DHHS Nebraska-Immunization Dept.	IT
Kurilo, Mary Beth	Oregon ALERT IIS	ALERT IIS Director
Laymon, Barbara	Deloitte Consulting LLP	Public Health Analyst
Le, Quan	LA DHH-OPH Immunization Program	Immunization Registry Program Manager
Lincicome, Susan	Florida DOH	IIS Manager
Listigovers, Charles	Sanofi Pasteur	Senior Director
Little, Tracy	ALERT IIS / Oregon Immunization Program	Data Exchange Analyst
Lynch, Jennifer	CPP Buying Group	Marketing Analyst
Metrokotsas, Eric	Merck & Co., Inc.	Project Manager
Mickle-Hope, Melissa	NYC DOHMH	MPH
Murchie, Steve	Envision Technology Partners, Inc.	CEO
Newland, Sophie	PATH	Program Officer
Ostroski, Susan	Pfizer	Sr. Director, Management Vaccine
Paster, Jennifer L.	Sanofi Pasteur	Deputy Director, New Products, U.S.
Peoples, Max	RxScan,Ltd.	President
Rak, Aaron	Novartis Vaccines & Diagnostics Inc.	Director, Immunization Policy
Roberts, John	GS1 US	Director healthcare
Robinson, Paul	Deloitte Consulting LLP	Manager
Salada, Beatrice	MCIR	MCIR Coordinator

Attendee	Organization	Role
Sathya, Bhavani	New Jersey Department of Health	NJIIS Coordinator
Schwartz, Pamela	Scientific Technologies Corporation	Senior Client Services Manager
Sharpin, Andrew	Deloitte Consulting LLP	Senior Consultant
Sobczyk, Elizabeth	American Academy of Pediatrics	Manager, Immunization Initiatives
Spencer, Tanya	Buffalo Pediatric Associates	Nurse Manager
Springer, Carmen	State of Alaska	Deputy Immunization Program Manager
Stroud, Susan	Pediatric Health PA	RN
Sturtz, Cynthia	Buffalo Pediatric Associates	LPN
Tichy, Kim	Iowa Department of Public Health	IIS Coordinator
Tippet, Andy	Zebra Technologies	Vertical Management
Tipple, Dayani	GlaxoSmithKline	Manager, Public Customer Marketing
Wall, Timothy	Pediatric Health Associates	President
Warf, Thomas	HHS/ASPR/BARDA	Director, Manufacturing, Facilities, and Engineering
Wells, Eron	Hewlett-Packard	Project Manager
Wheeler, Gary	Hewlett-Packard	IIS Executive
Wilkinson, John	Merck & Co., Inc.	Director, Vaccine Network Strategy
Williams, Warren	CDC	Health Analyst
Woinarowicz, Mary	North Dakota Department of Health	Sentinel Site Coordinator
Yett, Gerri	State of Alaska	Immunization Program Manager

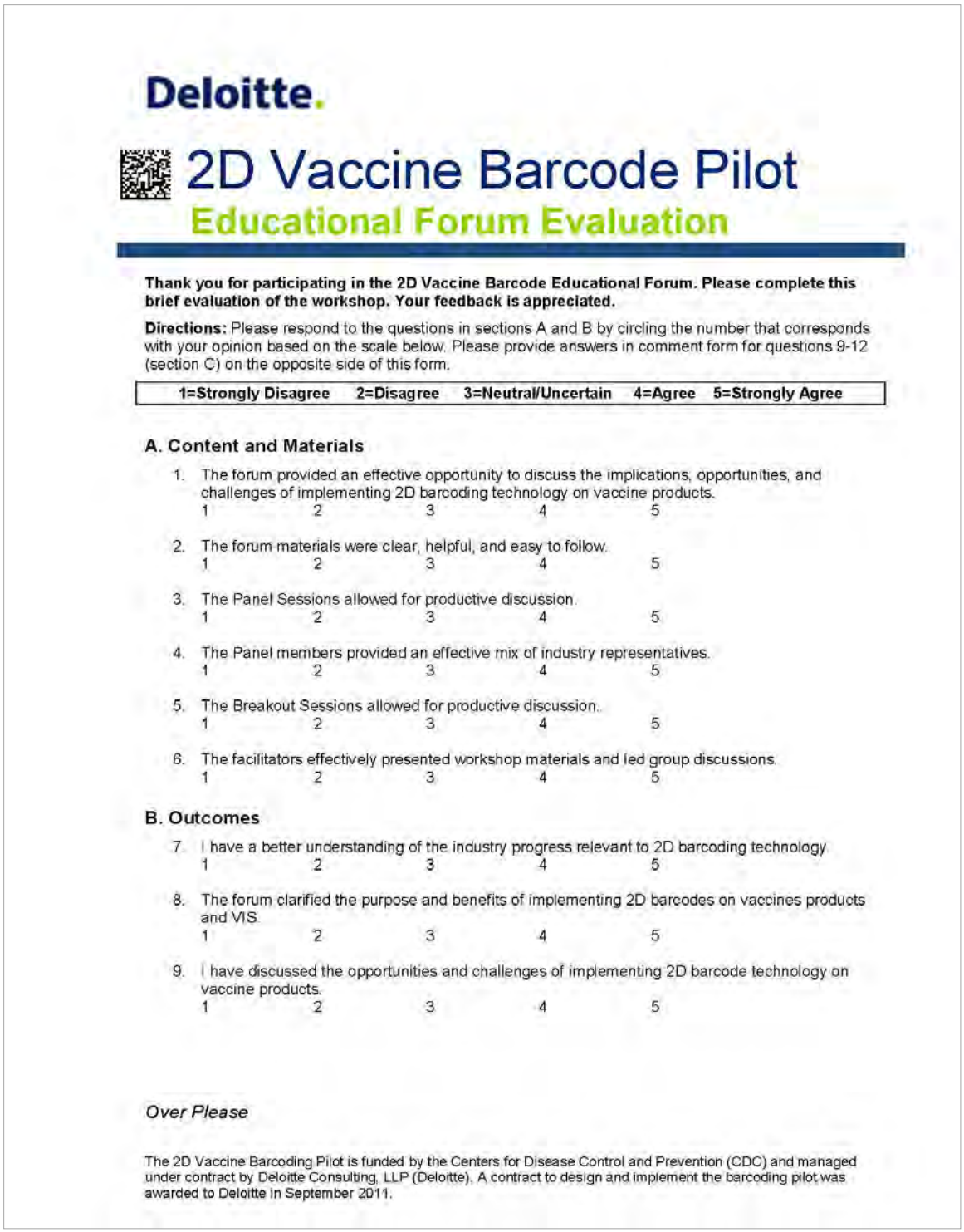
Appendix C –Breakout Groups

Standards	Adoption	Implementation
Belinda Baker, WA DOH	Wes Baker, Cerner	Christopher Celfo, GSK
Don Callaghan, Iowa DOPH	Dan DiVito, Sanofi	Julie Clark-Gagne, MI DOCH
Michael Day, OR Imm	Leonard Friedland, GSK	Marietta Cox, FL DOH
Joe Durbin, McKing	Kim Haupt, GSK	Tara Cullinan, Pediatrics For You
Michael Flynn, NYS DOH NYSIIS	Jan Hicks-Thomson, WA DOH	Jillian Doss, NEW JERSEY DOH
Chrissie Gorman, STC	Dina Hoefer, NY IIS	Ken Gerlach, CDC
Margert Griscom, M and M	Susan Lincicome, FL DOH	Geoffrey Glauser, HHS/ASPR/BARDA
Donna Hudson, MSDH/CDC	Tracy Little, ALERT IIS/OR Imm	Jeremy Gowler, Novartis
Erika Jurrens, GSK	Jennifer Lynch, CPP Buying Grp	Judi Greene, LA Imm
Thomas Kline, GSK	Sophie Newland, PATH	Courtney Hartstein, GSK
Ernad Klipic, DHHS NE Imm	Susan Ostroski, Pfizer	Rosemary Jones, MSDH
Charles Listigover, Sanofi	Pamela Schwartz, STC	Mary Beth Kurilo, OR ALERT IIS
Steve Murchie, Envision Tech	Tanya Spencer, Buf. Peds	Eric Metrokotsas, Merck
Max Peoples, RxScan	Timothy Wall, Ped. Health	Melissa Mickle-Hope, NYC DOHMH
John Roberts, GS1 US	Eron Wells, HP	Jennifer Paster, Sanofi
Carmen Springer, AK DOH	John Wilkinson, Merck	Aaron Rak, Novartis
Gary Wheeler, HP	Gerri Yett, AK DOH	Bhavani Sathya, NEW JERSEY DOH
Warren Williams, CDC		Elizabeth Sobczyk, AAP
		Susan Stroud, Ocean Health
		Kim Tichy, Iowa DOPH
		Dayani Tipple, GSK
		Mary Woinarowicz, North Dakota DOH
Facilitators and Scribes		
Laurie Bennett	Barbara Laymon	Andrew Sharpin
Ajay Bahukhandi	Marshall Gaddis	Leslie Fierro

Appendix D – Top Challenges Suggested by Forum Registrants

Standards	Adoption	Implementation
▪ **Impact of serialization on 2D barcodes** ▪ **Package-level GTIN considerations** ▪ **Reconstituted vaccine barcodes** ▪ **Standard capabilities of EMR/IIS solutions** ▪ **Use of both linear and 2D barcodes on the same product** ▪ **Location of 2D barcodes on packages and cartons**	▪ Financial considerations of equipment, implementation, and training for registries and providers ▪ Immediate provider efficiencies ▪ Balance between cost, effectiveness, and availability of barcoded data ▪ Increase adoption among immunizers ▪ Increase adoption ▪ EMR/IIS vendors ▪ Vaccine Manufacturers ▪ Practitioners ▪ Adoption incentives	▪ Workflow changes ▪ Package-level scanning ▪ Combination and reconstituted vaccines ▪ Office configuration ▪ Training and supporting state registry and provider scanning operations ▪ Future opportunities for 2D barcoding ▪ Mobile applications

Appendix E –Evaluation Feedback Results



Deloitte.

2D Vaccine Barcode Pilot

Educational Forum Evaluation

Thank you for participating in the 2D Vaccine Barcode Educational Forum. Please complete this brief evaluation of the workshop. Your feedback is appreciated.

Directions: Please respond to the questions in sections A and B by circling the number that corresponds with your opinion based on the scale below. Please provide answers in comment form for questions 9-12 (section C) on the opposite side of this form.

1=Strongly Disagree	2=Disagree	3=Neutral/Uncertain	4=Agree	5=Strongly Agree

A. Content and Materials

1. The forum provided an effective opportunity to discuss the implications, opportunities, and challenges of implementing 2D barcoding technology on vaccine products.
   1 2 3 4 5
2. The forum materials were clear, helpful, and easy to follow.
   1 2 3 4 5
3. The Panel Sessions allowed for productive discussion.
   1 2 3 4 5
4. The Panel members provided an effective mix of industry representatives.
   1 2 3 4 5
5. The Breakout Sessions allowed for productive discussion.
   1 2 3 4 5
6. The facilitators effectively presented workshop materials and led group discussions.
   1 2 3 4 5

B. Outcomes

7. I have a better understanding of the industry progress relevant to 2D barcoding technology
   1 2 3 4 5
8. The forum clarified the purpose and benefits of implementing 2D barcodes on vaccines products and VIS.
   1 2 3 4 5
9. I have discussed the opportunities and challenges of implementing 2D barcode technology on vaccine products.
   1 2 3 4 5

Over Please

The 2D Vaccine Barcoding Pilot is funded by the Centers for Disease Control and Prevention (CDC) and managed under contract by Deloitte Consulting, LLP (Deloitte). A contract to design and implement the barcoding pilot was awarded to Deloitte in September 2011.

A survey was distributed to all attendees in order to collect feedback on the forum and understand

the attendee perspective on what could be done to enhance the education and insight gained from the event. The survey document is included below:

C. Suggestions and Summary

10. How did you hear about the forum?

11. Did the registration process pose any issues? How could it be improved?

12. What part of the forum did you find most valuable?

13. What part of the forum would you change?

14. Are there areas of 2D barcoding implementation that you think require further investigation?

15. What other comments or suggestions do you have? Please provide any feedback that you think may be helpful as we continue to assess the use of 2D barcoding on vaccine products.

Thank you.

Your organization (optional): _____

Name (optional): _____

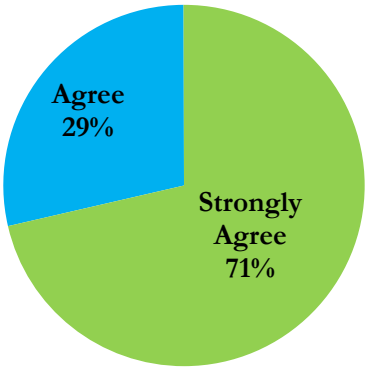
Results Summary: Forum Content and Materials

Thirty-five surveys were collected. Although this accounts for about half of the attendees, their responses demonstrate certain commonalities in the responses. The feedback from the surveys received has been aggregated.

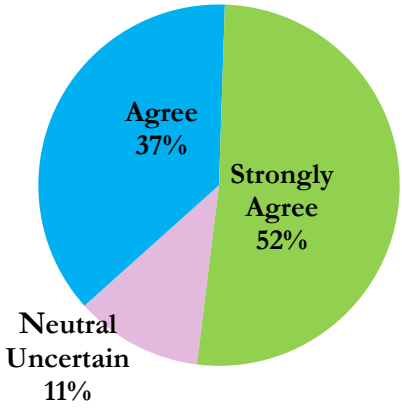
Quantitative Results

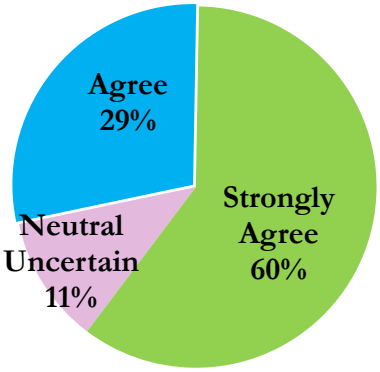
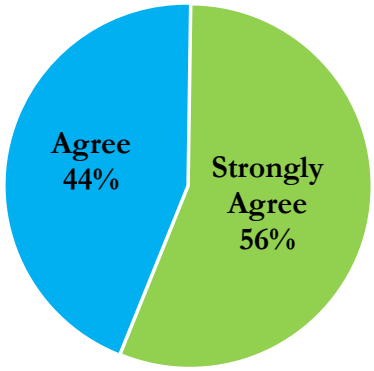
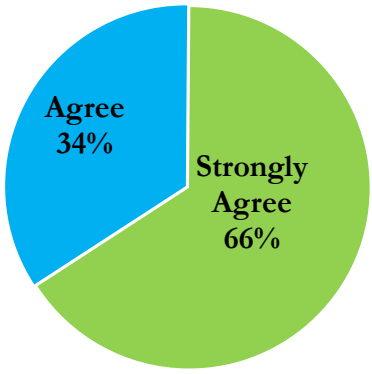
Survey results showed that overwhelmingly, the attendees were satisfied with the content and structure of the Forum. The panel discussions and breakout groups provided opportunities for effective discussions. Overall, the attendees felt that they gained a better understanding of opportunities and challenges around 2D Vaccine Barcoding from the Forum.

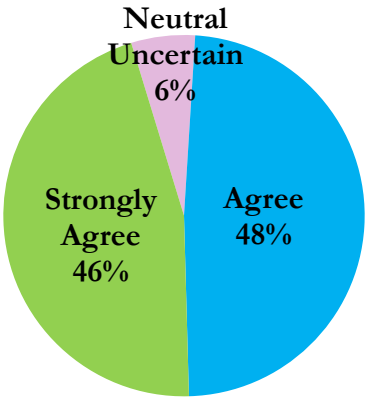
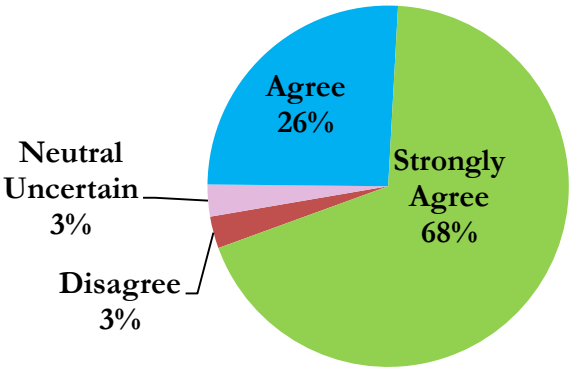
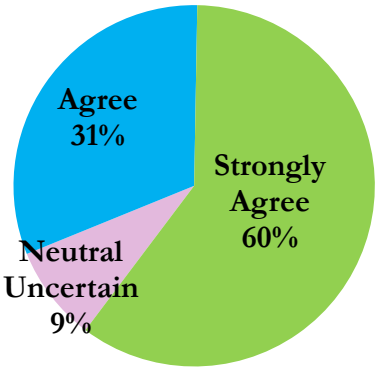
Question 1: This forum provided an effective opportunity to discuss the implications, opportunities, and challenges of implementing 2D barcoding technology on vaccine products.



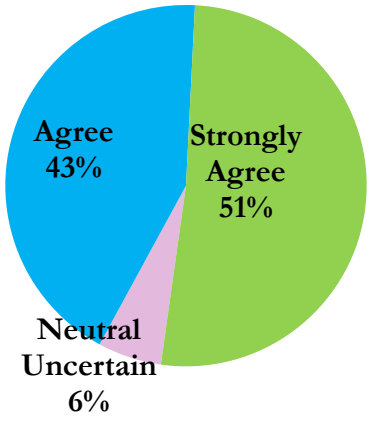
Question 2: The forum materials were clear, helpful, and easy to follow.



Question 3: The Panel Sessions allowed for productive discussion.	
Question 4: The Panel members provided an effective mix of industry representatives.	
Question 5: The Breakout Sessions allowed for productive discussion.	

Question 6: The facilitators effectively presented workshop materials and led group discussions.	
Question 7: I have a better understanding of the industry progress relevant to 2D barcoding technology.	
Question 8: The forum clarified the purpose and benefits of implementing 2D barcodes on vaccines products and VIS.	

Question 9: I have discussed the opportunities and challenges of implementing 2D barcode technology on vaccine products.



Qualitative Results

Most of the 35 surveys included additional free form responses capturing the benefits attendees saw from the forum as well as opportunities for improvement. The panel discussions, breakout sessions, and access to a diverse stakeholder attendance were universally acknowledged as the most useful aspects of the event. In terms of attendees' understanding of key concepts presented at the Forum, there is a fair amount of work to be done in the standards area, especially around the usage of NDC and lot numbers in barcodes on secondary and primary packaging, and on combination and reconstituted vaccines. There is significant expectation on a roadmap of next steps and on CDC guidance on EMR, IIS, and manufacturer implementation requirements. Overall, the attendees felt that the Forum provided useful and valuable information, it was well run, and they gained a better understanding of the cross-functional requirements and challenges experienced in the supply chain.

Questions	Responses (Out of 35)
Q10: How did you hear about the forum?	• N/A-4 • Pilot website-5 • CDC-2 • Pilot email invitation-7 • Deloitte contact-2 • Pilot newsletter-1 • AIRA email-3 • Colleague/coworker-6 • Pilot participant-5
Q11: Did the registration process pose any issues? How could it be improved?	• N/A-6 • No problems or issues-26 • Hotel registration/issues-3
Q12: What part of the forum did you find most valuable?	• N/A-7 • Panel discussions-5 • Breakout workgroup discussions-9 • Access to diverse group of stakeholders and resulting

Questions	Responses (Out of 35)
	conversations, varied perspectives-7 • Practical and/or useful information presented-6 • Q&A opportunities-1
Q13: What part of the forum would you change?	• N/A--18 • Next steps/future roadmap-4 • More technical details from manufacturers and EMRs-1 • More specific breakout groups-3 • Longer panel discussions-1 • Improve audio/acoustics/microphones-3 • Exclude weekend start time-3 • More technical information on barcodes-1 • Provide barcode glossary of terms-1
Q14: Are there areas of 2D barcoding implementation that you think require further investigation?	• N/A--9 • NDC and lot number on primary vs. secondary packaging, issues, and crosswalks-8 • Adoption incentives for EMR/IIS-3 • Pilot with more vaccines, participants-1 • Roadmap-2 • Standards guides for EMR, IIS, manufacturers-3 • Combination and reconstituted vaccines-issues, implementation, and impact on inventory in IIS-3 • Scanning prior to administering vaccines-1 • Ties to serialization-1 • User education on future vaccines availability-1 • Who should lead the initiative-2 • Collaboration with other initiatives, e.g., MU-1
Q15: What other comments or suggestions do you have? Please provide any feedback that you think may be helpful as we continue to assess the use of 2D barcoding on vaccine products.	• N/A-20 • Good forum, good opportunity for discussion-7 • Who owns this initiative and should lead-1 • Interagency collaboration, e.g., CDC, WHO, etc-1 • Funding for awardees to offer to providers-1 • AIRA position document on IIS guidelines and best practices-1 • NDC/lot numbers a major problem-2 • EMR/IIS functionality will influence provider adoption-1 • Improve audio, acoustics -1

Appendix F – Resources

AAP-Vaccine Barcoding:

http://www2.aap.org/immunization/pediatricians/barcoding.html

AAP Guidance for Practitioners:

http://www2.aap.org/immunization/pediatricians/BarcodingClinicianGuidance.doc

GS1 Implementation Resources:

http://www.gs1us.org/industries/healthcare/tools-and-resources/implementation-resources

RTI International Feasibility Study:

http://www.cdc.gov/vaccines/programs/iis/activities/downloads/2d-barcode-trkg-rpt.pdf

Barcodes on Vaccine Information Statements:

http://www.cdc.gov/vaccines/pubs/vis/vis-barcodes.htm