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AAP

INDUSTRY GOALS AND PROGRESS FOR VACCINE BARCODING - PERSPECTIVE FROM AAP

"Reviewed April 2013"

Automated Identification of Vaccine Products

**Process and Partnerships to Improve Patient
Safety and Office Efficiency**

Presentation to the CDC

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Disclosure

I have the following disclosures:

- ▶ Consultant to RTI
- ▶ Merck Customer Solutions Advisory Board Member
- ▶ Clinical Research principal investigator:
 - a. Merck Vaccine Study
 - b. Novartis Vaccine Study
 - c. Mead Johnson Formula Study
 - d. Sanofi-Pasteur Vaccine Study
 - e. Med-Immune RSV Study
 - f. GSK Vaccine Study
 - g. B-D Strep Test Study

Immunizations and the AAP

- ▶ Pediatricians provide a majority of immunizations in the US
- ▶ Both vaccine safety and financing issues have been priorities for the Academy
- ▶ The Committee on Infectious Diseases writes immunization recommendations
- ▶ The Committee on Practice and Ambulatory Medicine deals with practice implementation issues

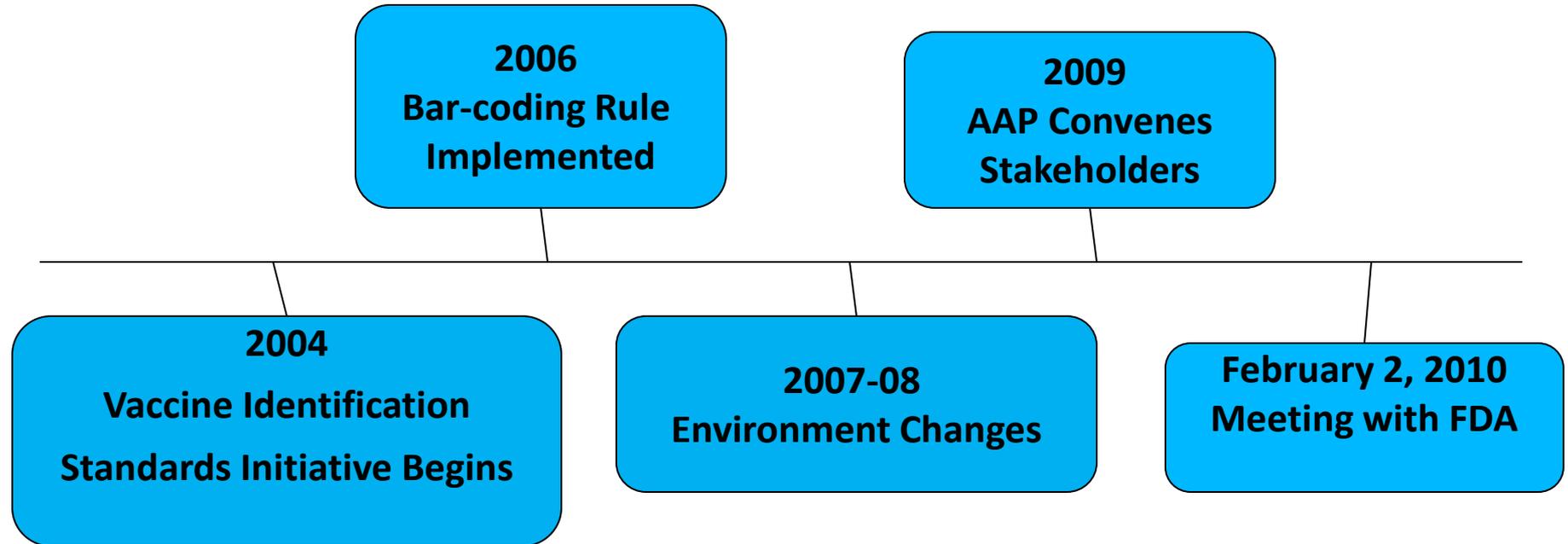
Bar-coding and the AAP

- ▶ Several pediatricians in practice and AAP leadership were interested in implementing bar coding on immunization vials and syringes
- ▶ Primary drivers:
 - ▶ Rapid uptake of technology
 - ▶ Vaccine safety and reporting of adverse events
 - ▶ Increased need for office efficiency
- ▶ AAP started to investigate feasibility

AAP Process: Learn History

- ▶ Discuss history with CDC and manufacturers
 - ▶ Gather previous bar coding experiences
 - ▶ Identify why desired outcome was not achieved
 - ▶ Learn from past leaders, create contacts with key movers and shakers

History



AAP Process: Identify Stakeholders

Originally included:

- ▶ Medical associations (AAP, AAFP, AMA, etc)
- ▶ Manufacturers
- ▶ CDC
- ▶ FDA
- ▶ Public health
 - ▶ ASTHO, [*Association of State and Territorial Health Officials*]
 - ▶ AIM [*Association for Automatic Identification and Mobility*]
- ▶ Standards group GS1
- ▶ AIRA [*American Immunization Registry Association*]

Think broadly:

- ▶ Distributors
 - ▶ Pharmacies
 - ▶ Pharma
 - ▶ NVPO [*National Vaccine Program Office*]
 - ▶ EHR and PMS
- Vendors

AAP Process:

Jan. 2009 Gather Information

- ▶ Convened stakeholders from government, public health, manufacturers and pediatricians to discuss feasibility and barriers
 - ▶ Bar coding Technology is ready but vials and syringes must have 2D barcodes to include GTIN, lot number, and expiration date to be useful to practices at the point of vaccine administration
 - ▶ Linear bar code on such a small vial or syringe cannot include sufficient information
- ❖ *Because of concurrent serialization efforts, primary focus was unit dose, not packaging*

AAP Process: Address Barriers

- ▶ Need permission from FDA - 2004 guidance dictated the use of linear barcodes
- ▶ AAP was identified as the lead for communications with FDA
- ▶ AAP, manufacturers, and GS1 met with FDA in February 2010 to discuss allowing 2D codes on the unit dose of vaccines
- ▶ With no major objections, FDA issued updated guidance in September 2010

AAP Process: Address Barriers

- ▶ Public comments were taken on the updated guidance
 - ▶ New stakeholders were identified
 - ▶ While guidance was positive and a step in the right direction, finalization of guidance took 11 months and certain public comments are still to be addressed

AAP Process: Develop Guidelines

- ▶ AAP provides a forum for industry competitors to discuss common issues with special attention to anti-trust laws
- ▶ Partnerships with standards groups and those using technology at the point of care are needed

AAP Process: Develop Guidelines

- ▶ Guidance is needed for uniform implementation by manufacturers
- ▶ Guidance is also needed for offices, registries, EMRs, etc.
- ▶ Two guidance manuals for 2D bar coding have been published by the AAP in collaboration with GS-1
 - ▶ **The manufacturer's guidance**
 - ▶ **The clinician's guidance**

Environment Changes

- ▶ Number of recommended vaccines has increased
 - ▶ Since 2004, several new vaccines (rotavirus, human papillomavirus, hepatitis A, MCV4 and 1 additional dose (varicella) have been added to the schedule
 - ▶ Influenza vaccine recommendations were also expanded to include children up to 18 years
 - ▶ Several combination products have been introduced (e.g., DTaP-IPV-HIB, DTaP-IPV-HebB)

Environment Changes

- ▶ Time to record data has increased
- ▶ National Childhood Vaccine Injury Act of 1986 requires recording of:
 - ▶ Vaccine identity (i.e., manufacturer and product), date administered, lot number, VIS information, and provider identity
 - ▶ CDC has announced plan to place 2D bar code on the VIS
 - ▶ AAP also recommends site, route, and expiration date

IMMUNIZATION ADMINISTRATION CHART - CHILD

Clinic Name/Address:

PATIENT'S SOCIAL SECURITY NO:

M F O

MOTHER'S MAIDEN NAME:

ADDRESS:

CITY:

STATE:

ZIP:

TELEPHONE NUMBER:

I.D. NUMBER:

"I agree to allow the health care provider giving vaccinations to release information about all vaccinations given to me, or to the person for whom I am authorized to consent, to the Kansas Immunization Information System (KIIS), other health care providers and schools in order to avoid receiving unnecessary vaccinations and to provide information about what immunizations have been received. I understand that I am not required to agree to the release of this information in order to receive the vaccinations I request."

"I have read or have had explained to me the information contained in the Vaccine Information Statements (VIS's) about the following disease(s) and vaccine(s): Polio, Diphtheria, Tetanus, Pertussis, Measles, Mumps, Rubella, Haemophilus Influenza type b, Hepatitis B, Hepatitis A, Varicella, Pneumococcal conjugate, and Influenza. I have had a chance to ask questions that were answered to my satisfaction. I understand the benefits and risks of the vaccine(s) and request that the vaccine(s) indicated on this form be given to me or the person named on this health record for whom I am authorized to make this request."

VACCINE (CIRCLE WHAT IS GIVEN)	DATE SHOT & VIS GIVEN	SIGNATURE OF RECIPIENT OF VACCINE OR PERSON AUTHORIZED TO REQUEST	VACCINE MANUF.	VACCINE LOT NO.	EXP DATE	SITE GIVEN	NAME/TITLE OF VACCINE ADMINISTRATOR	VIS PUB DATE	VFC CODE (below)
DTaP/DTP/DT1	SEP 05 2002	Kathleen	SAB	D10451A2	09/09/04	LD RD	[Signature]	11/30/11	
DTaP/DTP/DT2	NOV 08 2002	Kathleen	Aventis	C0810A07	3/25/03	LD RD	[Signature]	7/30/02	
DTaP/DTP/DT3	JAN 09 2003	Kathleen	Aventis	C09430A6	1/31/04	LD RD	[Signature]	7/30/01	
DTP/DT4 (DtaP)	OCT 04 2003	Kathleen	Aventis	C1386AA	10/16/04	LD RD	[Signature]	7/30/01	
DTP/DT5 (DtaP)	AUG 11 2006	[Signature]	Aventis	U1891CA	10/8/08	LD RD	[Signature]	7/30/01	
Td						LD RD			
Td						LD RD			
Polio 1	SEP 05 2002	Kathleen	Aventis	U11428	10/22/01	LSQ RSD/DVA	[Signature]	11/10	
Polio 2	NOV 08 2002	[Signature]	Aventis	W0013	1-11-03	LSQ RSD	[Signature]	1/100	
Polio 3	JAN 09 2003	[Signature]	Aventis	W0736	6/25/03	ORAL LSQ RSD	[Signature]	1/100	
Polio 4	AUG 11 2006	[Signature]	Aventis	V0991	10/29/07	ORAL LSQ RSD	[Signature]	1/100	
MMR 1	JUL 11 2003	[Signature]	Merck	02340	6/11/04	LSQ RSD	[Signature]	12/16/02	
MMR 2	AUG 11 2006	[Signature]	Merck	02310E	7/15/08	LSQ RSD	[Signature]	12/16/02	
Hib 1	SEP 05 2002	Kathleen	Merck	0283m	4/13/05	LD RD	[Signature]	12/16/02	
Hib 2	JAN 09 2003	Kathleen	Merck	0283m	6/27/05	LD RD	[Signature]	12/16/02	
Hib 3	JUL 11 2003	[Signature]	Merck	0281m	10/23/05	LD RD	[Signature]	12/16/02	
Hep A 1	JUN 09 2009	[Signature]	Merck	11025X	9/26/11	LD RD	[Signature]	3/21/09	
Hep A 2						LD RD			

DTAP/DTP/DT3	DATE	PROVIDER SIGNATURE	AGENT	PHONE	TIME	STATUS	RESULT	TIME
	JAN 0 9 2003	X K. W. Miller	Aventis	609488A	1:31:04	LD RD	OK	7:30:01
	OCT 0 4 2003	X K. W. Miller	Aventis	61386AA	10:51:04	LD RD	OK	7:30:01
	AUG 1 1 2006	X G. Blumest	Aventis	W1891CA	10:8:08	LD RD	OK	7:30:01
Td						LD RD		
Td						LD RD		
Polio 1	JUN SEP 0 5 2002	X K. W. Miller	Aventis	U1428	10:22:04	LSQ RSD	OK	11:10
Polio 2	NOV 0 8 2002	X K. W. Miller	Aventis	W0013	1-11-005	LSQ RSD	B	11:00
Polio 3	JAN 0 9 2003	X K. W. Miller	Aventis	W0760	6:25:05	LSQ RSD	B	11:00
Polio 4	JUN AUG 1 1 2006	X G. Blumest	Aventis	V0991	10:29:07	LSQ RSD	OK	11:00
MMR 1	JUL 1 1 2003	X K. W. Miller	Merck	0283m	6:40:04	LSQ RSD	B	12:16:04
MMR 2	AUG 1 1 2006	X G. Blumest	Merck	0283m	7:15:08	LSQ RSD	OK	12:16:04
Hib 1	CONV SEP 0 5 2002	X K. W. Miller	Merck	0283m	4:30:05	LD RD	OK	12:16:04
Hib 2	CONV JAN 0 9 2003	X K. W. Miller	Merck	0283m	6:27:05	LD RD	OK	12:16:04
Hib 3	HIB JUL 1 1 2003	X K. W. Miller	Merck	0283m	6:27:05	LD RD	OK	12:16:04
Hep A 1	JUN 0 9 2009	X K. W. Miller	Merck	W005X	9:26:11	LD RD	OK	3:21:00
Hep A 2						LD RD		
Hep B 1	7/3/02	X K. W. Miller	Merck	0283m	2:16:05	LD RD	OK	8/9/02
Hep B 2	CONV SEP 0 5 2002	X K. W. Miller	Merck	0283m	2:16:05	LD RD	OK	8/9/02
Hep B 3	CONV JAN 0 9 2003	X K. W. Miller	Merck	0283m	6:27:05	LD RD	OK	8/9/02
Varicella 1	OCT 0 4 2003	X K. W. Miller	Merck	0119N	2:19:05	LSQ RSD	OK	12:16:04
Varicella 2	AUG 1 1 2006	X G. Blumest	Merck	0283m	10:08	LSQ RSD	OK	12:16:04
Pneumo-conj 1	SEP 0 5 2002	X K. W. Miller	Merck	489-479	7:04	LVL RVL	OK	7:15:00
Pneumo-conj 2	NOV 0 8 2002	X K. W. Miller	Merck	485-989	9:03	LVL RVL	B	7:15:00
Pneumo-conj 3	JAN 0 9 2003	X K. W. Miller	Merck	441-173	9:04	LVL RVL	B	7:15:00
Pneumo-conj 4	OCT 0 4 2003	X K. W. Miller	Merck	493-248	7:05	LVL RVL	OK	7:15:00
Influenza 1	OCT 0 4 2003	X K. W. Miller	Merck	493-248	7:05	LVL RVL	OK	7:15:00
Influenza 2	OCT 0 1 2004	X K. W. Miller	Aventis	W1891CA	6:30:02	LVL RVL	OK	5:24:04

INCLUDE DATE AND PROVIDER OF PREVIOUS IMMUNIZATION

TB TEST	DATE GIVEN	PROVIDER SIGNATURE	DATE READ	RESULT

VACCINES FOR CHILDREN (VFC) CODES:
 1 = Medicaid, 2 = Uninsured, 3 = Native American or Alaskan Native,
 4 = Under Insured, 5 = HealthWave, 6 = Fully Insured

Environment Changes

- ▶ Number of private practices using electronic systems (e.g., registries, EMRs) continues to increase
 - ▶ Many private providers now enter data into a registry
 - ▶ mandated in some locales
 - ▶ Increasing numbers of ambulatory care settings use a basic electronic medical record
 - ▶ Recent stimulus funding has encouraged more widespread adoption
 - ▶ Although not necessarily among pediatric practices since this is primarily Medicare driven with some accommodations for practice that attend Medicaid patients

Environment Changes

- ▶ Technology has moved toward 2-dimensional barcodes as the standard, in retail, airlines, etc.
- ▶ Price of 2-dimensional readers have decreased
 - ▶ Can now be purchased for as low as \$150
- ▶ Manufacturers now have the ability to print NDC, lot number and expiration date on individual vials or syringes directly on the production line using 2D technology
 - ▶ Currently labels are pre-printed with NDC offline

Combination Vaccine Administration Concerns

When a vaccine has more than one vial that need to be combined for administration, there are special bar coding issues. Here are some suggestions:

- ▶ Each vial of the pair should be color coded and identifiable by distinct packaging that makes it clear that those vials SHOULD only be administered TOGETHER.
- ▶ Only one of the vials should have a 2D scannable bar code
- ▶ If one of the vials COULD be used as a stand alone vaccine for administration, it should have either NO 2D bar code in order to remind that this should never be administered as a stand alone vaccine or the 2D bar code must denote the combination vaccine.

Combination Vaccine Administration Concerns

It is the AAP committee's very strong concern that:

- ▶ If there are two vials with two separate 2D bar codes, that many end users would inappropriately scan only one of the vials which would compromise the documentation – including inventory, VAERS reporting, registry reporting, billing, etc.
- ▶ If there are two barcodes and both are scanned, then scanning could compromise documentation particularly billing of vaccine administration codes to third party payers.
- ▶ We feel that these situations need to be considered on a case-by-case basis

Opportunities

- ▶ Provide more accurate reporting of vaccine information
 - VAERS 30% error rate: 13-22% missing lot numbers; 10-15% inaccurate lot numbers
 - Eliminate extra or outdated doses with more automated recording of information
 - Improve accurate notification in case of recall
- ▶ Save the federal government millions of dollars
 - Improve accountability of the Vaccines for Children Program vaccine usage
 - Redirect \$26.4 million currently spent on phone-driven National Immunization Survey. This could be more accurate using registries

Our Goals for 2D Bar Codes

- ▶ Improve patient safety
- ▶ Reduce errors in record documentation
- ▶ Improve accuracy of reports regarding vaccine injuries [VAERS]
- ▶ Increase office efficiency
- ▶ Encourage use of vaccine registries
- ▶ Encourage use of EMRs
- ▶ Potentially save the federal government millions of dollars.

Conclusion

- ▶ We've made great progress.
- ▶ Despite this being “low hanging fruit” with general consensus, it still takes a while to implement.
[Weniger's publications are from 1994!!!!]
- ▶ Involvement and agreement of stakeholders is critical.
- ▶ Our ongoing task will be to educate stakeholders including vaccine administrators, software vendors, and immunization registries

Contact Information

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QUESTIONS?