

# MIROW Lot Number Validation Best Practices

## Validating Lot Numbers for Vaccine Doses

### Recommendations of the American Immunization Registry Association (AIRA) Modeling of Immunization Registry Operations Work Group (MIROW)

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### Introduction

The primary purpose of the Lot Numbers Validation Project is to improve the quality of a key Immunization Information System (IIS) data item – lot number for a dose of vaccine – by taking advantage of analysis, modeling, and group development techniques.

This report represents a set of best practice recommendations (micro-guide - in comparison with other, full-blown MIROW guides available at <http://www.immregistries.org/resources/aira-mirow>) for validating lot numbers for administered vaccine doses. These recommendations are expected to be shared among all IIS and other stakeholders as a vehicle to improve data quality, promote continuing dialogue and communication within the IIS community and with IIS partners, and facilitate standard-setting efforts. Recommendations are technology-neutral and can be implemented on a variety of technological platforms. The topic of validating (cleaning-up) lot numbers is within a framework for a general data quality assurance theme and will be associated with existing MIROW data quality assurance (DQA) guides [1, 2].

Expected benefits include:

- Higher efficiency and uniformity of data validation process for lot numbers.
- Improved accuracy and comparability of data by encouraging common processes and standards.
- Reduced cost because solutions can be shared among states and reporting sources.
- Reduced software development cost for IIS (a large portion of the cost for a successful software development project is in analysis and design).
- Improved data exchange between IIS and its partners.

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- Higher quality vaccination data.
- Reduced cost of training for IIS employees.

### Scope

The scope is validation of lot number data items (*lot number data item contains a string of characters that represents the lot number*) for administered vaccine doses from the IIS perspective.

From: When lot number data item is selected for validation. A typical trigger events are: lot number is recorded (automatically) or entered (manually) in the immunization record.

To: When validation process is completed, i.e., when the lot number data item is evaluated, edited (if necessary), and a record in the validation log is created.

### Including:

- Analysis of information needed to validate/clean up the reported alpha-numeric strings that represent lot numbers. That information can be very different in nature, coming from various aspects of practical knowledge about values and patterns for lot numbers. For example:
  - General manufacturers' coding schemes: patterns that applied to all manufacturers in general. For example:
    - A restricted set of characters for vaccine lot numbers: it should be represented only by alpha-numeric characters and dash (“-”)
    - Certain combinations of characters are valid, others are not valid.
  - Patterns of coding errors. For example, lot numbers should not start or end with certain combinations of characters, i.e., not to start with MED, SKB, LOT, etc., not to end with REAR, PENT, DTAP, etc.
  - A reference library/directory of vaccine lot numbers that were previously validated. That would include public and private lot numbers.
  - A reference library/directory of vaccine lot numbers from an inventory module. That reflects information on shipped vaccines, as well as current inventory distribution of vaccines between providers.

### Excluding:

- Any validations beyond cleaning-up alpha-numeric strings that represent lot numbers, for example, cross-fields validation in the immunization record, such as, validation of correspondence between lot number and lot number expiration date, or lot number and vaccine type.
- Use of manufacturer-specific coding schemes. This information could significantly enhance validation routines for lot numbers; however, close collaboration with vaccine manufacturers is needed to address this aspect of lot number validation. The MIROW Steering Committee recommends that such type of validation should be explored and developed in the future.
  - Note that lot number formats often vary by product for a vaccine manufacturer. This is caused by different systems in use at different production facilities.

### Limitations:

- Lack of manufacturers' involvement in this project
- Limited resources
- Incompleteness of the accumulated knowledge base

As a result, some of the developed recommendations are very generic, indicating just a strategic direction to take within this topic.

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### Validation Principles (Strategies)

**Table 1.** Principles (strategies) for lot number validation and editing.

ID	Principles (Strategies)	Remarks	X-ref
P01	<p><u>Reference a directory of known lot numbers</u> A directory of known lot numbers should be created, maintained, and referenced for lot number’s validation purposes.</p>	<ul style="list-style-type: none"> <li>• Such a directory should include two components:               <ul style="list-style-type: none"> <li>○ Lot numbers from the inventory module (e.g., from shipping logs); applies for publicly-purchased vaccine doses</li> <li>○ Previously validated and “manually” confirmed lot numbers; applies for privately- and publicly-purchased vaccine doses</li> </ul> </li> <li>• Every lot number under consideration should be checked (gauged) against a directory of known lot numbers.</li> <li>• As illustrated on the process model (Fig. 1, p.5), if the lot number under evaluation is known, i.e., it is in the directory of known lot numbers, then there is no need to evaluate the alpha-numeric string for manufacturer-specific or generic manufacturer coding schemes and patterns of errors. If the lot number is not known, when the validation checks need to be performed before accepting it as a new lot number.</li> </ul>	P04
P02	<p><u>Reference a directory of manufacturer-specific coding schemes for lot numbers</u> A directory of manufacturer-specific coding schemes for lot numbers should be created, maintained, and referenced for lot number’s validation purposes.</p>	<ul style="list-style-type: none"> <li>• This principle/strategy is not developed in this document. Close collaboration with vaccine manufacturers is needed to address this aspect of lot number validation. The MIROW Steering Committee recommends that such type of validation should be explored and developed in the future.</li> <li>• For example, it would be useful for lot number validation purposes to know that all lot numbers for a vaccine manufacturer always start with two letters, consist of a 10-character alpha-numeric string, end with a number.</li> <li>• Note that lot number formats often vary by product for a vaccine manufacturer. This is caused by different systems in use at different production facilities.</li> <li>• Manufacturers might have reasons not to share the information about coding schemes for lot numbers with the general public (e.g., to prevent counterfeits). One possible approach could be to attempt re-creating manufacturer-specific coding schemes from the retroactive analysis of IIS data.</li> <li>• Known expiration date can help to eliminate outdated schemes that are no longer in use or point to coding schemes that are currently in use.</li> </ul>	P04

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ID	Principles (Strategies)	Remarks	X-ref
		<ul style="list-style-type: none"> <li>Known vaccine type can help to further restrict a set of manufacturer-specific coding schemes.</li> </ul>	
P03	<p><u>Reference a directory of generic rules (for all manufacturers) for coding lot numbers</u> A directory of generic manufacturer rules for coding lot numbers should be created, maintained, and referenced for lot number validation purposes.</p>	<ul style="list-style-type: none"> <li>For example, restricted set of characters (lot number values should be represented only by alpha-numeric characters and dash, i.e., special characters like “/”, “,” etc. are not valid), patterns of coding errors (lot number values should not start or end with certain combinations of characters, i.e., not to start with MED, SKB, LOT, etc., not to end with REAR, PENT, DTAP, etc.),</li> </ul>	P04
P04	<p><u>Maintain reliability of reference directories</u> Reference directories (directory of known lot numbers, directory of manufacturer-specific coding schemes, directory of generic manufacturer rules for coding lot numbers) should be periodically reviewed and reconfirmed as reliable reference sources for validating lot numbers.</p>	<ul style="list-style-type: none"> <li>Objective: to maintain a level of confidence in the reference source.</li> <li>Note that coding schemes for lot numbers can be periodically changed by manufacturers. Therefore, some mechanism to maintain and update these coding schemes should be implemented.</li> </ul>	P01-P03

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## Process model

Revision date: 11-26-2013

### Lot numbers validation / clean-up

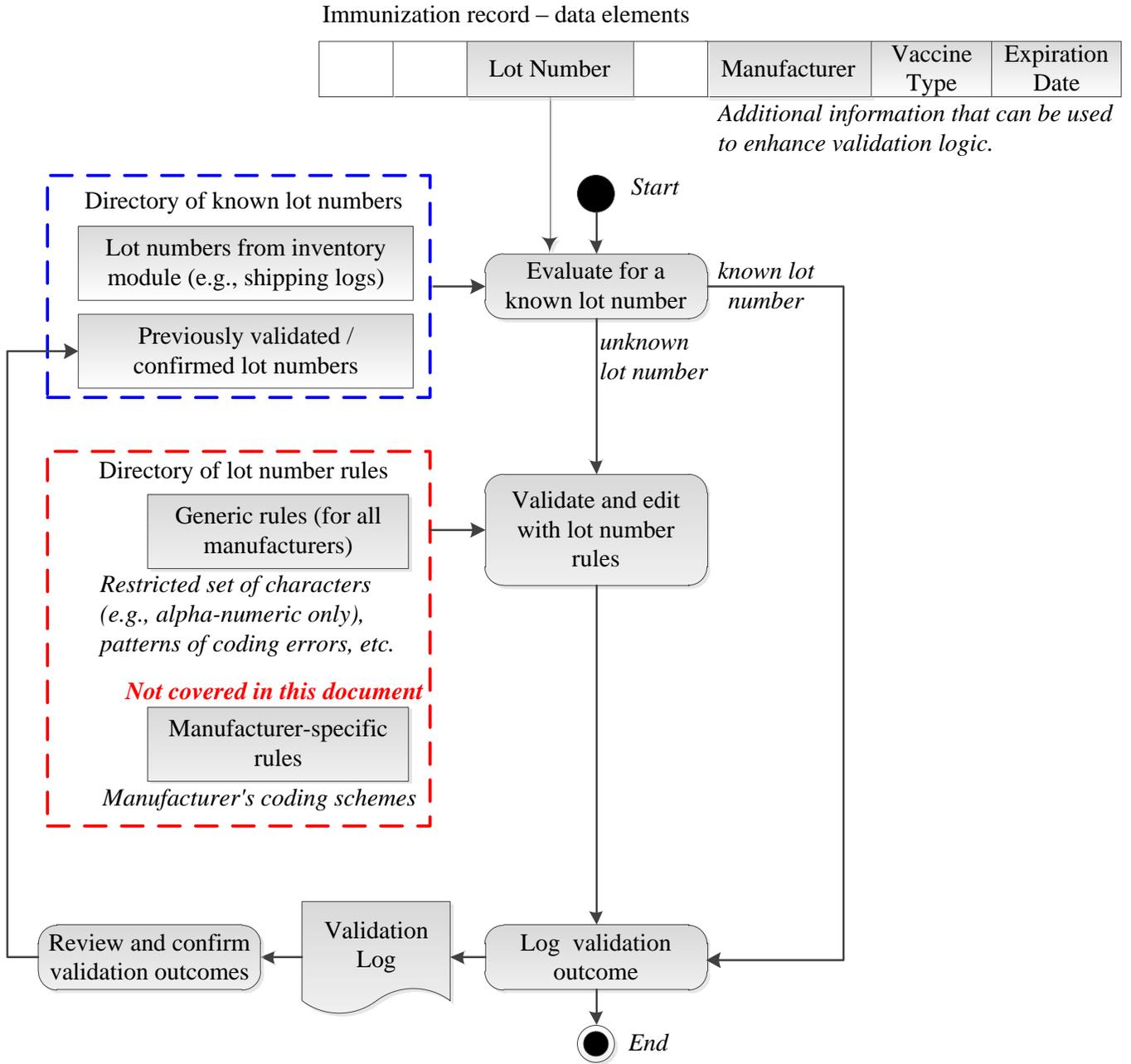


Figure 1. Process model

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### Validation rules

Validation rules can be applied at the different points of immunization tracking process: at the data source, prior to adding to the IIS database, and to clean-up data that is in the IIS already.

**Table 2.** Rules for lot number validation and editing.

ID	Rules	Remarks	X-ref
BR01	<p>Lot number data item should contain information about one and only one lot number.</p> <p>Action on BR violations: Identify, extract, and preserve in the same record information on second and all additional lot numbers for reference purposes.</p> <p>Note: Presented recommendation suggests that while the practice of submitting multiple lot numbers in one field is wrong and should be discouraged, the additional information on the second and all additional lot numbers – if submitted to IIS in violation of this recommendation - should not be wasted. An attempt should be made to utilize the information to advance completeness and accuracy of patients’ records. Note, that best practice recommendations reflect not only current capabilities of IIS, but also expected future advancements of IIS functionality.</p>	<ul style="list-style-type: none"> <li>• A helpful pattern to recognize rule’s violation: In some cases, when lot number data item contains information about two or more lot numbers (which is a violation of this business rule), these lot numbers are separated by “/” or “;”. Other forms of separation are possible, for example, second lot number may start from “AHBV” or another combination of characters.</li> </ul>	<p>IE07 IE08 IE09 IE10 IE11</p>
BR02	<p>Lot number should be represented only by combinations of the following characters:</p> <ul style="list-style-type: none"> <li>• Letters,</li> <li>• Numbers,</li> <li>• Dash.</li> </ul> <p>Action on BR violations: Remove characters other</p>	<ul style="list-style-type: none"> <li>• Lot numbers may contain no other special characters than a dash.</li> </ul>	<p>IE13 BR01</p>

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ID	Rules	Remarks	X-ref
	<p>than letters, numbers, and a dash. Determine if more than one lot number is present (BR01). Each lot number identified should be validated.</p>		
BR03	<p>Lot number data item should contain lot number information only.</p> <p>Action on BR violations: Remove additional characters/text. Determine if more than one lot number is present (BR01). Each lot number identified should be validated.</p>	<ul style="list-style-type: none"> <li>Lot number data item should not start from, end with, or contain any additional characters beyond characters that represent the lot number. See specific business rules BR05-BR08 for currently identified cases of this rule’s violations.</li> <li>Revision note 06-23-2015: Business rule BR09 [“Lot numbers for IPOL (Polio Virus Inactivated) should not be ended in -1 or -2”] has been deleted. There is a unique situation with the IPOL vaccine when “-1” and “-2”, appended to a lot number shown on the vial, constitutes a part of the lot number as printed on the packaging box.</li> </ul>	BR05 – BR08 IE04
BR04	<p>Lot number information should be reported for every vaccine dose administered.</p>	<ul style="list-style-type: none"> <li>Note that the lot number data item is included in the minimum/mandatory set of data items for administered vaccines in the MIROW DQA guide [<a href="#">1</a>, p. 72].</li> <li>If the validation process (Figure 1) does not result in a meaningful value for the lot number, a manual review/intervention is needed.</li> </ul>	
BR05	<p>Lot number should not start from any of the following strings of characters (currently identified cases):</p> <ul style="list-style-type: none"> <li>(P)</li> <li>MED</li> <li>SKB</li> <li>LOT</li> <li>PMC</li> <li>WSD</li> <li>WAL</li> </ul> <p>Action on BR violations: Remove string of characters at the beginning of the lot number. Determine if more than one lot number is present (BR01). Each lot number identified should be validated.</p>	<ul style="list-style-type: none"> <li>When present, these strings of characters can be considered as a source of information to inform other data elements of a vaccination record. For example, “(P)” can be used to provide a value for the Public/Private Indicator designation.</li> <li>Note that these strings of characters represent currently identified cases when extra characters added to a lot number. Each IIS may need to modify and expand currently identified cases to reflect its own specifics. It is possible that vaccine manufacturers might start using these characters at some point in the future in their coding schemes for lot numbers. See remarks for principle/strategy P04 in Table 1.</li> <li>In some cases there are leading/trailing spaces in lot number data items that come from HL7 transmissions.</li> </ul>	BR03 IE01



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ID	Rules	Remarks	X-ref
	<ul style="list-style-type: none"> <li>○ DTAP,</li> <li>○ IPV,</li> <li>○ MENA,</li> <li>○ ACTH,</li> <li>○ HIB,</li> <li>○ PFF,</li> <li>○ FLU,</li> <li>○ BOOST,</li> <li>○ HAV,</li> <li>○ GARDASIL,</li> <li>○ ROTATEQ,</li> <li>○ PEDVAX,</li> <li>○ VARIVAX,</li> <li>○ PNEU,</li> <li>○ PNEUMOVAX,</li> <li>○ MMR,</li> <li>○ MENVEO,</li> <li>○ MENACTRA,</li> <li>○ FLU ZONE</li> </ul> <p>Action on BR violations: Remove string of characters at the end of the lot number. Determine if more than one lot number is present (BR01). Each lot number identified should be validated.</p>		
BR07	<p>Lot number should not contain a dash with spaces (" - ") in the middle of the lot number.</p> <p>Action on BR violations: Remove a dash with spaces (" - ") in the middle of the lot number and text that follows it. Determine if more than one lot number is present (BR01). Each lot number identified should be validated.</p>	<ul style="list-style-type: none"> <li>● A dash with spaces (" - ") usually followed by text.</li> <li>● Note that these strings of characters represent currently identified cases when extra characters have been added to a lot number. Each IIS may need to modify and expand currently identified cases to reflect its own specifics. It is possible that vaccine manufacturers might start using these characters at some point in the future in their coding schemes for lot numbers. See remarks for principle/strategy P04 in Table 1.</li> </ul>	BR03 IE03

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ID	Rules	Remarks	X-ref
BR08	<p>Lot number should not be followed by "IC3" and additional text.</p> <p>Action on BR violations: Remove string of characters at the end of the lot number, starting from "IC3". Determine if more than one lot number is present (BR01). Each lot number identified should be validated.</p>	<ul style="list-style-type: none"> <li>Note that these strings of characters represent currently identified cases when extra characters have been added to a lot number. Each IIS may need to modify and expand currently identified cases to reflect its own specifics. It is possible that vaccine manufacturers might start using these characters at some point in the future in their coding schemes for lot numbers. See remarks for principle/strategy P04 in Table 1.</li> </ul>	BR03 BR06 IE05

Note: Business rules presented in this table are generic rules applicable for all manufacturers.

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### Illustrative examples for typical validation scenarios

**Table 3.** Illustrative examples for typical validation scenarios.

ID	Illustrative Example (Before → After)	Remarks	X-ref
IE01	(P)123AA → 123AA		BR05
IE02	123AA-P → 123AA		BR06
IE03	123AA – Note → 123AA		BR07
IE04	P123AA → 123AA		BR03
IE05	123AAIC3ZXY → 123AA		BR08
IE06		Revision note 06-23-2015: Example IE06 has been deleted.	
IE07	123AA/456BB →(1) 123AA, (2) 456BB	Two records are identified.	BR01
IE08	123AA,456BB →(1) 123AA, (2) 456BB	Two records are identified.	BR01
IE09	12AB,34BC,56CD → (1) 12AB, (2) 34BC, (3) 56CD	Three records are identified.	BR01
IE10	C1426AA C1894BB → (1) C1426AA, (2) C1894BB	Three records are identified.	BR01
IE11	123AAAHBV789 → (1) 123AA, (2) AHBV789	Two records are identified.	BR01
IE12	123AA PENTACEL →123AA	Vaccine name, together with preceding ““, is removed	BR06
IE13	123(AA): → 123AA	Characters “(, )”, and “:” are removed	BR02
IE14	U44889AA (36 MO+) → U44889AA	36 MO+ removed	BR03
IE15	UT2176KA- PF .25 → UT2176KA	-PF .25 removed	BR03
IE16	U3174CA P-FREE→U3174CA	P-FREE removed	BR03
IE17	1329Y STATE→1329Y	STATE removed	BR03
IE18	U4488EA (6-35) →U4488EA	(6-35) removed	BR03
IE19	*1206901*→1206901	Removed * at beginning and * at end	BR03
IE20	AVEN T0533-2→T0533-2	Removed AVEN	BR03
IE21	U3872CA(*)→U3872CA	Removed (*)	BR03
IE22	S/K ENG 1374A1→1374A1	Removed S/K ENG	BR03
IE23	1292Y-(2DOSE) →1292Y	Removed –(2DOSE)	BR03
IE24	VFC MERCK-1297Y→1297Y	Removed VFC MERCK-	BR03
IE25	(PRT) VFC U1188A→U1188A	Removed (PRT) VFC	BR03
IE26	P-V WYETH F51336→F51336	Removed P-V WYETH	BR03
IE27	ST 0611N→0611N	Removed ST	BR03
IE28	M12028 (OVER19) →M12028	Removed (OVER19)	BR03

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IE29	UH899AB(ST>6MO) →UH899AB	Removed (ST>6MO)	BR03
IE30	UT3575DA PREFLD→UT3575DA	Removed PREFLD	BR03
IE31	X12025/A12025→X12025 A12025	Removed / , two lot numbers are identified	BR03, BR01
IE32	U1830AA INFT PVT→U1830AA	Removed INFT PVT	BR03

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### References

1. AIRA Modeling of Immunization Registry Operations Work Group (eds). Data Quality Assurance in Immunization Information Systems: Selected Aspects. Atlanta, GA: American Immunization Registry Association. May, 2013.

[http://www.immregistries.org/resources/AIRA-MIROW\\_DQA\\_Selected\\_Aspects\\_best\\_practice\\_guide\\_05-17-2013.pdf](http://www.immregistries.org/resources/AIRA-MIROW_DQA_Selected_Aspects_best_practice_guide_05-17-2013.pdf)

2. AIRA Modeling of Immunization Registry Operations Workgroup (eds). Data quality assurance in Immunization Information Systems: Incoming Data. Atlanta, GA: American Immunization Registry Association. February, 2008.

[http://www.immregistries.org/AIRA\\_MIROW\\_Chap3\\_DQA\\_02112008.pdf](http://www.immregistries.org/AIRA_MIROW_Chap3_DQA_02112008.pdf)

### Appendix A: Some typical scenarios for lot number errors

- Confusion between NDC and lot number. Sometimes providers record the NDC as the lot number or add the NDC to the end of the lot (ex: 1234AA 49281-0545-05) – the multiple NDCs per vaccine package can make this issue more prominent.
- Provider forgets a letter (example: lot is actually 0079AA, provider will enter 0079A)
- Provider confuses letters (sometimes it is difficult to distinguish – main problems are: “Z” vs “2,” “1” vs “I” or “7,” “0” vs “O”). One of the awardees had a problem this past year with H0 vs. HO.
- Uppercase vs. lowercase letters in the lot numbers – some providers use this as a distinction between public and private doses.
- Vaccine vs. diluent – providers do not record diluent in an IIS. Sometimes they will combine the diluent lot with the vaccine lot.
- Some EHRs still make the user enter a combination vaccine (take Pediarix for instance) three times with the same lot number so that each antigen can be processed. It comes to the IIS all on the same day so the system just treats it as one vaccination. Specifically they enter it as DTaP and then choose the code for Pediarix and enter the lot number, the IPV - choose the code for Pediarix and enter the lot number, etc.
- Some EHRs have a function that the lot number is "remembered" from what the last user entered for that vaccine. If the EHR is shared across many locations this still applies. If the lot number is entered wrong the first time, it can be similar enough that subsequent users will just reuse it and then it is wrong many times over.

## **MIROW Lot Number Validation Best Practices**

### **Appendix B: List of Contributors**

#### **MIROW Steering Committee**

- Warren Williams, CDC, Co-Chair
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## MIROW Lot Number Validation Best Practices

### Appendix C: Revision History

Revision	Date	Location	Change	Implemented by
1.1	06-23-2015	p. 7  p. 10  p. 11	<ul style="list-style-type: none"> <li>• Note added to the business rule BR06: Business rule BR09 [“Lot numbers for IPOL (Polio Virus Inactivated) should not be ended in -1 or -2”] has been deleted. There is a unique situation with the IPOL vaccine when “-1” and “-2”, appended to a lot number shown on the vial, constitutes a part of the lot number as printed on the packaging box.</li> <li>• Business rule BR09 has been deleted.</li> <li>• References to BR09 have been deleted.</li> <li>• Example IE06 has been deleted.</li> </ul>	David Lyalin