

Assuring Correctness and Consistency in AFIX-IIS Coverage Implementation

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AIRA 2017 IIS National Meeting
April 11, 2017



Background

- **AFIX:** Assessment Feedback Incentives eXchange
- **Technical Guidance for AFIX-IIS Integration:**
Instructions for IIS Program staff on implementing AFIX Coverage Assessment report(s) in the IIS
- **Rhode Island KIDSNET:** Integrated Child Health Information System and IIS operating in Rhode Island since 1997



Agenda

- Review of AFIX-IIS Coverage Requirements
- Assessing AFIX Coverage in an IIS
- Testing Strategies
- Lessons Learned



Review of AFIX-IIS Coverage Requirements

- **Childhood** (2 year-olds; as of 24 months)
 - 4 DTaP
 - 3 Polio
 - 1 MMR
 - UTD Hib
 - UTD Hep B
 - 1 VAR
 - UTD PCV
 - UTD RV
 - 1 Flu (previously completed flu season)
 - 2 Hep A
 - 4:3:1:3:3:1:4 Series
- **Adolescent** (13-17 year-olds; as of today)
 - UTD Hep B
 - 2 MMR
 - 2 VAR
 - 1 Tdap
 - UTD Meningococcal
 - 1 HPV*
 - UTD HPV*
 - 1 Flu (previously completed flu season)
 - 2 Hep A
 - UTD Polio

Immunization Schedule

Source: <https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html> as of March 2017

Vaccine	Birth	1 mo	2 mos	4 mos	6 mos	9 mos	12 mos	15 mos	18 mos	19-23 mos	2-3 yrs	4-6 yrs	7-10 yrs	11-12 yrs	13-15 yrs	16 yrs	17-18 yrs	
Hepatitis B ¹ (HepB)	1 st dose	←-----2 nd dose-----→			←-----3 rd dose-----→													
Rotavirus ² (RV) RV1 (2-dose series); RV5 (3-dose series)			1 st dose	2 nd dose	See footnote 2													
Diphtheria, tetanus, & acellular pertussis ³ (DTaP: <7 yrs)			1 st dose	2 nd dose	3 rd dose				←-----4 th dose-----→			5 th dose						
<i>Haemophilus influenzae</i> type b ⁴ (Hib)			1 st dose	2 nd dose	See footnote 4		←-----3 rd or 4 th dose,-----→ See footnote 4											
Pneumococcal conjugate ⁵ (PCV13)			1 st dose	2 nd dose	3 rd dose				←-----4 th dose-----→									
Inactivated poliovirus ⁶ (IPV: <18 yrs)			1 st dose	2 nd dose	←-----3 rd dose-----→							4 th dose						
Influenza ⁷ (IIV)					Annual vaccination (IIV) 1 or 2 doses								Annual vaccination (IIV) 1 dose only					
Measles, mumps, rubella ⁸ (MMR)					See footnote 8		←-----1 st dose-----→					2 nd dose						
Varicella ⁹ (VAR)							←-----1 st dose-----→					2 nd dose						
Hepatitis A ¹⁰ (HepA)							←-----2-dose series, See footnote 10 -----→											
Meningococcal ¹¹ (Hib-MenCY ≥6 weeks; MenACWY-D ≥9 mos; MenACWY-CRM ≥2 mos)			See footnote 11												1 st dose		2 nd dose	
Tetanus, diphtheria, & acellular pertussis ¹² (Tdap: ≥7 yrs)														Tdap				
Human papillomavirus ¹³ (HPV)														See footnote 13				
Meningococcal B ¹¹													See footnote 11					
Pneumococcal polysaccharide ⁵ (PPSV23)											See footnote 5							

AFIX-1S: Child

Vaccine	Birth	1 mo	2 mos	4 mos	6 mos	9 mos	12 mos	15 mos	18 mos	19-23 mos	2-3 yrs
Hepatitis B ¹ (HepB)	1 st dose	←-----2 nd dose-----→			←-----3 rd dose-----→						
Rotavirus ² (RV) RV1 (2-dose series); RV5 (3-dose series)			1 st dose	2 nd dose	See footnote 2						
Diphtheria, tetanus, & acellular pertussis ³ (DTaP: <7 yrs)			1 st dose	2 nd dose	3 rd dose			←-----4 th dose-----→			
<i>Haemophilus influenzae</i> type b ⁴ (Hib)			1 st dose	2 nd dose	See footnote 4		←-----3 rd or 4 th dose, See footnote 4-----→				
Pneumococcal conjugate ⁵ (PCV13)			1 st dose	2 nd dose	3 rd dose		←-----4 th dose-----→				
Inactivated poliovirus ⁶ (IPV: <18 yrs)			1 st dose	2 nd dose	←-----3 rd dose-----→						
Influenza ⁷ (IIV)						Annual vaccination (IIV) 1 or 2 doses					
Measles, mumps, rubella ⁸ (MMR)					See footnote 8	←-----1 st dose-----→					
Varicella ⁹ (VAR)						←-----1 st dose-----→					
Hepatitis A ¹⁰ (HepA)						←-----2-dose series, See footnote 10-----→					
Meningococcal ¹¹ (Hib-MenCY ≥6 weeks; MenACWY-D ≥9 mos; MenACWY-CRM ≥2 mos)											
Tetanus, diphtheria, & acellular pertussis ¹² (Tdap: ≥7 yrs)											
Human papillomavirus ¹³ (HPV)											
Meningococcal B ¹¹											
Pneumococcal polysaccharide ⁵ (PPSV23)											

Assessment Cohort

UTD Hep B

UTD RV

4 DTaP

UTD Hib

UTD PCV

3 Polio

1 Influenza (previous season)

1 MMR

1 VAR

2 Hep A

Vaccine	Birth	1 mo	2 mos	4 mos	6 mos	9 mos	12 mos	15 mos	18 mos	19-23 mos	2-3 yrs
Hepatitis B ¹ (HepB)	1 st dose	←-----2 nd dose-----→					←-----3 rd dose-----→				
Rotavirus ² (RV) RV1 (2-dose series); RV5 (3-dose series)			1 st dose	2 nd dose	See footnote 2						
Diphtheria, tetanus, & acellular pertussis ³ (DTaP: <7 yrs)			1 st dose	2 nd dose	3 rd dose			←-----4 th dose-----→			
<i>Haemophilus influenzae</i> type b ⁴ (Hib)			1 st dose	2 nd dose	See footnote 4		←-----3 rd or 4 th dose, See footnote 4-----→				
Pneumococcal conjugate ⁵ (PCV13)			1 st dose	2 nd dose	3 rd dose		←-----4 th dose-----→				
Inactivated poliovirus ⁶ (IPV: <18 yrs)			1 st dose	2 nd dose	←-----3 rd dose-----→						
Influenza ⁷ (IIV)						Annual vaccination (IIV) 1 or 2 doses					
Measles, mumps, rubella ⁸ (MMR)					See footnote 8	←-----1 st dose-----→					
Varicella ⁹ (VAR)						←-----1 st dose-----→					
Hepatitis A ¹⁰ (HepA)							←-----2-dose series, See footnote 10-----→				

Assessment Cohort

- UTD Hep B
- UTD RV
- 4 DTaP
- UTD Hib
- UTD PCV
- 3 Polio
- 1 Influenza (previous season)
- 1 MMR
- 1 VAR
- 2 Hep A

4

:

3

:

1

:

3^U

:

3^U

:

1

:

4^U

DTaP

Polio

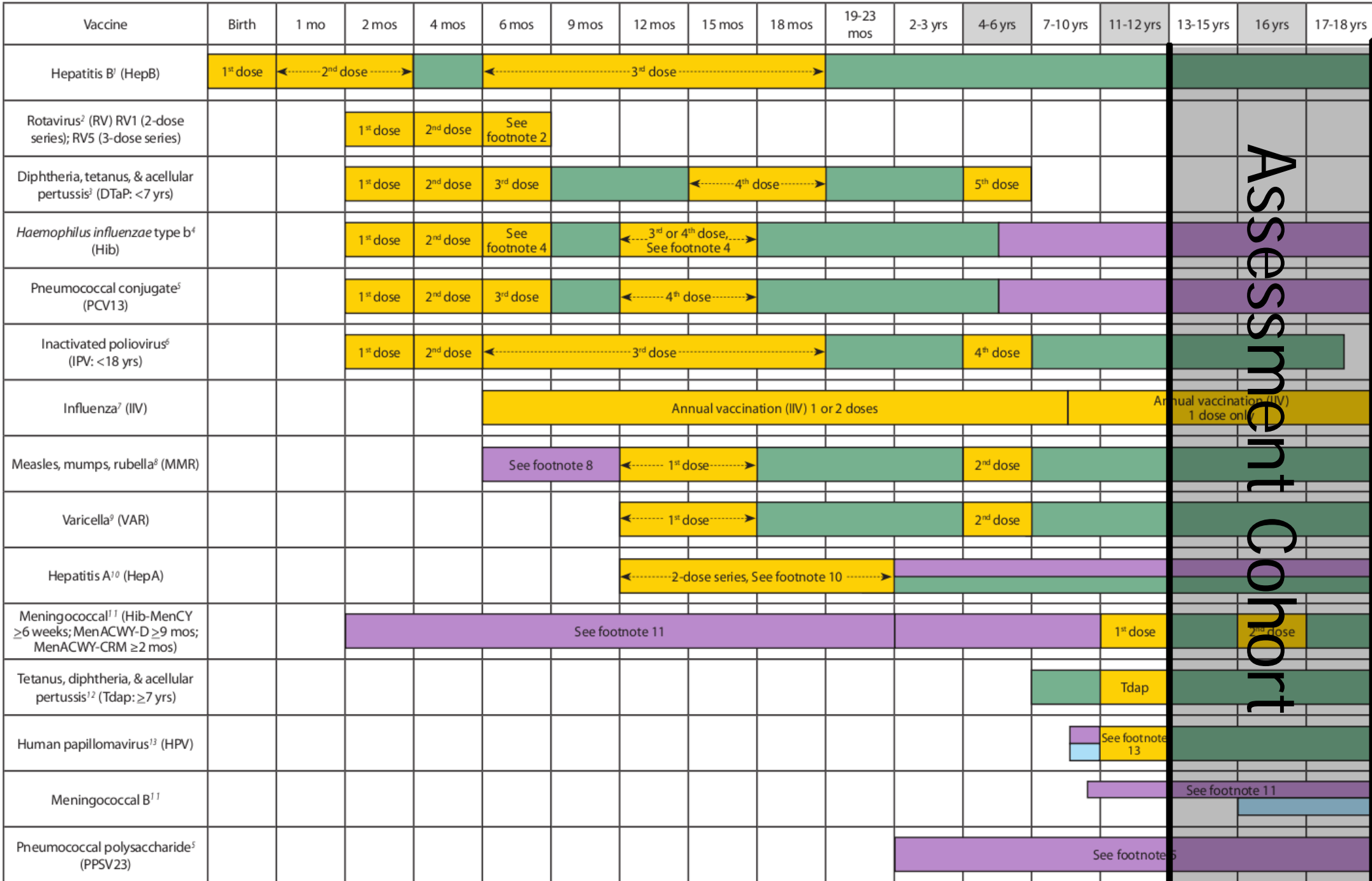
MMR

Hib

Hep B

VAR

PCV



UTD Hep B

UTD Polio

1 Flu
(prev. season)

2 MMR

2 VAR

2 Hep A

UTD Mening

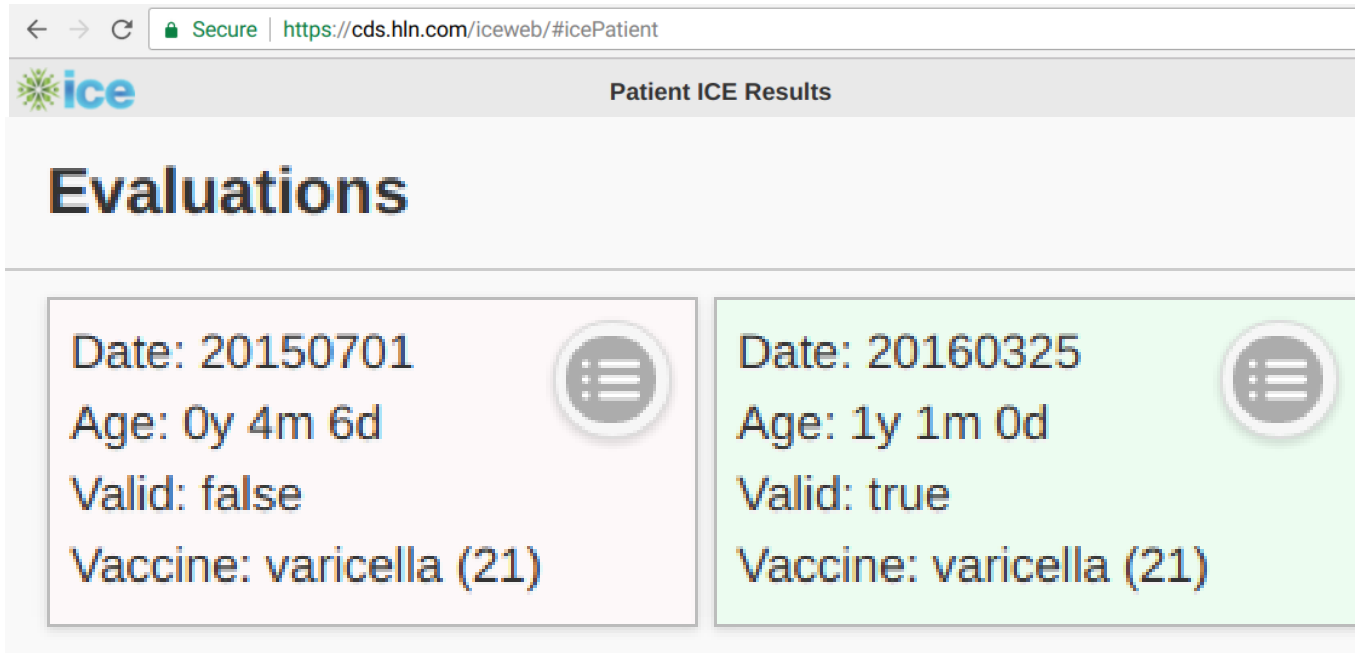
1 Tdap

1 HPV, UTD HPV*

Assessment Cohort

* Previous AFIX assessments 3 HPV, 2 HPV, 1 HPV; new 2-dose HPV series introduced in Dec. 2016; AFIX assessments now UTD HPV and 1 HPV

Assessing Fixed # of doses – Single Antigens



← → ↻ Secure | <https://cds.hln.com/iceweb/#icePatient>

ice Patient ICE Results

Evaluations

<p>Date: 20150701 Age: 0y 4m 6d Valid: false Vaccine: varicella (21)</p>	<p>Date: 20160325 Age: 1y 1m 0d Valid: true Vaccine: varicella (21)</p>
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Immunization Algorithm Output Example:
1 VAR (1 invalid, 1 valid)

- Examples: 3 Polio, 1 Flu, 1 VAR, 2 VAR, 2 Hep A, 1 HPV
- Utilize immunization algorithm evaluation output as of assessment date
- Count number of valid doses in series (i.e., valid doses towards series completion)

Assessing Fixed # of doses – Combination Vaccines

The screenshot displays a web-based interface for the Immunization Algorithm. On the left is a sidebar with navigation links: 'ice' logo, 'Nam', 'DOI', 'Gende', 'Evaluation Dat', 'Age @Evaluation', 'Patient Output G', 'Vaccine Group', and 'MMR'. The main content area is divided into two sections: 'Evaluations' and 'Recommendations'.

Evaluations

Date	Age	Valid	Vaccine
20160225	1y 0m 0d	true	measles (05)
20160225	1y 0m 0d	true	mumps (07)

Recommendations

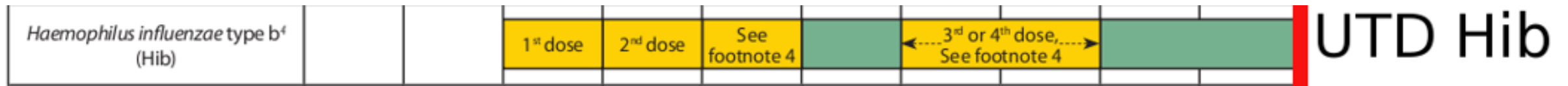
Date	Status	Message	Vaccine Group
20160324	RECOMMENDED	DUE_NOW	MMR

- Examples: 4 DTaP, 1 MMR, 2 MMR, 1 Tdap
- Utilize immunization algorithm output as of assessment date
- Depending on immunization algorithm functionality/output, may need to utilize evaluations *and/or forecasts* to ensure all antigens are included

Immunization Algorithm Output Example:
1 measles, 1 mumps does not meet 1 MMR requirement

Up-To-Date

- "... 'UTD' [...] is used in reference to vaccine measurements where a variable number of doses can be applied to achieve protection depending on patient age, date of first dose, and/or vaccine product licensure nuances."
- For example:





Up-To-Date

- UTD for AFIX is applied in accordance with the ACIP routine and/or catch-up schedules
- Appropriate number of doses to be considered compliant with the series
- Applies to both the individual vaccines and the 4:3:1:3:3:1:4 assessment



Which of these are Up-To-Date?

- Series Complete
- Waiting period for next dose
- Minimum age for next dose not yet reached
- Maximum age exceeded

Assessing AFIX UTD

Evaluations

Date: 20150425 Age: 0y 2m 0d Valid: true Vaccine: rotavirus, monovalent (119)	Date: 20150625 Age: 0y 4m 0d Valid: true Vaccine: rotavirus, monovalent (119)
--	--

Recommendations

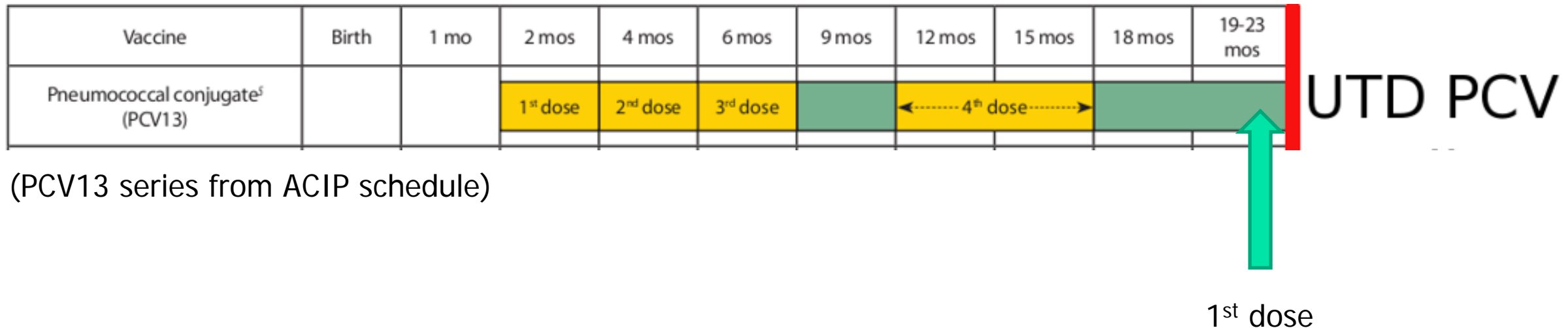
Date: N/A Status: NOT_RECOMMENDED Message: COMPLETE Vaccine Group: Rotavirus

- Examples: UTD Hep B, UTD RV, UTD Hib, UTD PCV, UTD Polio, UTD Mening
- Utilize immunization algorithm forecast output as of assessment date

Immunization Algorithm Output Example:
2 RV (2 Rotarix – 2-dose series)

Assessing AFIX UTD

- What if child receives 1st dose of PCV at 23 months?



UTD: Behind but in Waiting Period

Evaluations

Date: 20170125
 Age: 1y 11m 0d
 Valid: true
 Vaccine: pneumococcal conjugate PCV 13 (133)

Recommendations

Date: 20170322
 Status: FUTURE_RECOMMENDED
 Message: DUE_IN_FUTURE
 Vaccine: pneumococcal conjugate PCV 13 (133)

- Child only has one dose
- But second dose is not recommended until after 2nd birthday – past the cutoff point for the childhood AFIX assessment

Immunization Algorithm Output Example:
 1 PCV at 23 months results in future recommendation

Vaccine	Birth	1 mo	2 mos	4 mos	6 mos	9 mos	12 mos	15 mos	18 mos	19-23 mos
Pneumococcal conjugate ^s (PCV13)			1 st dose	2 nd dose	3 rd dose		←-----4 th dose-----→			

UTD PCV



UTD: Behind but in Waiting Period

- Initial guidance for KIDSNET:
 - This example is considered UTD for PCV at 24 month mark
 - UTD does not imply series completion
- Follow-up guidance:
 - AFIX-IIS Integration Guide requires “Series Complete” and remains unchanged

Assessing AFIX UTD

■ AFIX-IIS Integration Guidance: Use “Series Complete”

Table 13: Business Rules for Determining Patient Status: Childhood Assessment

Business Rules		Notes
9.A	For the following vaccine groups, the IIS should use Patient Series Status Complete from its forecasting/evaluation algorithm to determine if the child has completed the antigen series on or before age 24 months:	Hib PCV Rotavirus Hep B

Table 14: Business Rules for Determining Patient Status: Adolescent Assessment

Business Rules		Notes
10.A	For the following vaccine groups, the IIS should use Patient Series Status Complete from its forecasting/evaluation algorithm to determine if the adolescent has completed the antigen series on or before the compliance date:	Hep B Meningococcal Hep A Polio HPV

UTD for HPV

Evaluations

Date: 20160225 Age: 13y 0m 0d Valid: true Vaccine: HPV (HPV9-Gardasil 9) (165)	Date: 20160825 Age: 13y 6m 0d Valid: true Vaccine: HPV (HPV9-Gardasil 9) (165)
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Age @Evaluation: 14y 1m 17d

Patient Output Grid

Vaccine Group	Recommendations	Eva
Human Papillomavirus	Date: N/A Status: NOT_RECOMMENDED Message: COMPLETE Vaccine Group: Human Papillomavirus	Date: Age: Valid: Vaccine: HPV (HPV9-Gardasil 9) (165)

Recommendations

Date: N/A
 Status: NOT_RECOMMENDED
 Message: COMPLETE
 Vaccine Group: Human Papillomavirus

Example: 2 doses of HPV on 2-dose schedule; series complete

Evaluations

Date: 20170210 Age: 13y 11m 16d Valid: true Vaccine: HPV (HPV9-Gardasil 9) (165)	Date: 20170410 Age: 14y 1m 16d Valid: true Vaccine: HPV (HPV9-Gardasil 9) (165)
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Patient Output Grid

Vaccine Group	Recommendations	Ev:
Human Papillomavirus	Date: 20170810 Status: FUTURE_RECOMMENDED Message: DUE_IN_FUTURE Vaccine Group: Human Papillomavirus	Date: Age: Valid: Vaccine: HPV (HPV9-Gardasil 9) (165)

Recommendations

Date: 20170810
 Status: FUTURE_RECOMMENDED
 Message: DUE_IN_FUTURE
 Vaccine Group: Human Papillomavirus

Example: 2 doses of HPV on 3-dose schedule; waiting period for dose 3; not UTD for AFIX

- 3-dose series: Previous AFIX assessments were 3 HPV, 2 HPV, 1 HPV
- New 2-dose HPV series introduced in Dec. 2016
- AFIX assessments now UTD HPV and 1 HPV
- UTD HPV for AFIX requires series completion

UTD for Meningococcal

- Meningococcal is the only vaccine group that has a recommendation *inside* the assessment age cohort
- Can adolescent be considered UTD for Meningococcal without the 2nd dose?

Vaccine	11-12 yrs	13-15 yrs	16 yrs	17-18 yrs
Hepatitis B ¹ (HepB)				
Rotavirus ² (RV) RV1 (2-dose series); RV5 (3-dose series)				
Diphtheria, tetanus, & acellular pertussis ³ (DTaP: <7 yrs)				
<i>Haemophilus influenzae</i> type b ⁴ (Hib)				
Pneumococcal conjugate ⁵ (PCV13)				
Inactivated poliovirus ⁶ (IPV: <18 yrs)				
Influenza ⁷ (IIV)	Annual vaccination (IIV) 1 dose only			
Measles, mumps, rubella ⁸ (MMR)				
Varicella ⁹ (VAR)				
Hepatitis A ¹⁰ (HepA)				
Meningococcal ¹¹ (Hib-MenCY ≥6 weeks; MenACWY-D ≥9 mos; MenACWY-CRM ≥2 mos)	1 st dose	2 nd dose		
Tetanus, diphtheria, & acellular pertussis ¹² (Tdap: ≥7 yrs)	Tdap			
Human papillomavirus ¹³ (HPV)	See footnote 13			
Meningococcal B ¹¹		See footnote 11		
Pneumococcal polysaccharide ⁵ (PPSV23)	See footnote 5			

UTD for Meningococcal

The screenshot displays a web interface for patient vaccination management. It includes sections for 'Evaluations', 'Recommendations', and a table for 'Vaccine Group' and 'Recommendations'. The 'Evaluations' section shows a record for a patient with a meningococcal vaccine dose on 20130411. The 'Recommendations' section shows a future recommendation for the same vaccine group on 20180411. A table below summarizes the vaccine group and the next recommended date and status.

Evaluations

Date: 20130411
Age: 11y 0m 0d
Valid: true
Vaccine: meningococcal NOS (108)

Recommendations

Date: 20180411
Status: FUTURE_RECOMMENDED
Message: DUE_IN_FUTURE
Vaccine Group: Meningococcal

Vaccine Group	Recommendations
Meningococcal	<p>Date: 20180411 Status: FUTURE_RECOMMENDED Message: DUE_IN_FUTURE Vaccine Group: Meningococcal</p>

Immunization Algorithm Output Example:
15 year-old with 1 dose; next dose at 16 years



UTD for Meningococcal

- Initial guidance for KIDSNET:
 - 1 dose sufficient for UTD until past due on dose 2
- Follow-up guidance:
 - UTD requires series completion
 - *"For now and until further guidance..."*



Missed Opportunities

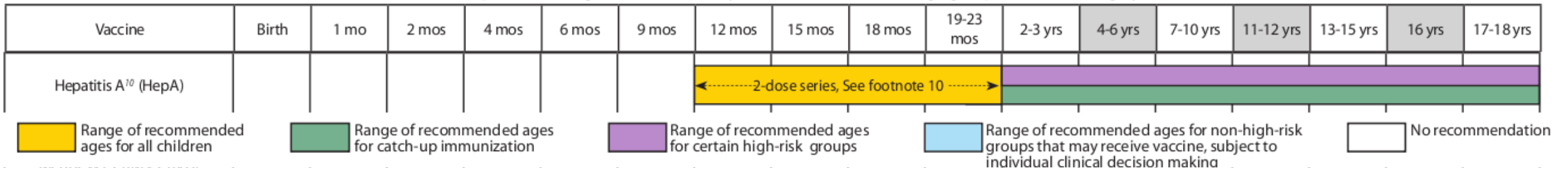
- Missed Opportunity on the Last Immunization Visit:
 - “On the patient’s last visit for an immunization he/she received a dose of a different antigen than the antigen in question, or there was a reason a different antigen was not given, and *at the time of that visit a valid dose of the antigen in question could have been administered in keeping with the patient’s age and the time interval from the previous valid or invalid dose.*”



Assessing AFIX Missed Opportunities

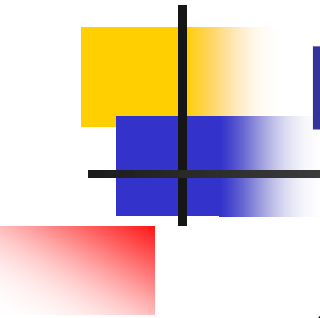
- Utilize immunization algorithm forecast output as of last immunization visit date
- Do not include any of the vaccinations given on that date in the algorithm input
- Compare the algorithm recommendations for that day with the vaccinations that were actually given

Missed Opportunity for “Category B” Recommendation



(Hep A series and series legend from ACIP schedule)

- Hep A for unvaccinated persons 2 years or older is a “Category B” recommendation: Individual clinical decision making
- For adolescents: Hep A is only assessed as a missed opportunity if the person has already received 1 dose – the IIS will forecast for the 2nd dose.
- But some IIS recommend Hep A even for unvaccinated adolescents (not KIDSNET though)



February 29, 2016 – AFIX Leap Baby!

- Children born on this leap day will be in the AFIX Childhood Cohort next year
- Assessment on 2nd birthday:
 - *February 28, 2018, or*
 - *March 1, 2018?*

February 29, 2016 – AFIX Leap Baby!

Date Calculation Rules

When calculating dates there are a few important rules to remember.

Calculation Type	Business Rule ID	Rule	Example
Adding years	CALCDT-1	Adjust only the year not the month and days.	January 1, 2000 + 3 years January 1, 2003
Adding months	CALCDT-2	Adjust only the month, and if necessary the year, but not the day.	January 1, 2000 + 3 months April 1, 2000
Adding weeks or days	CALCDT-3	Convert each week to 7 days, and add the total number of days to the date.	February 1, + 5 weeks (or 35 days) March 8
		Sometimes these rules can result in a date that does not exist. If this occurs, move to the first day of the following month.	July 31 + 2 months September 31 (October 1)

Assess as of March 1, 2018

Testing AFIX-IIS

- Like school entrance requirements, AFIX-IIS assessments are *based* on CDSi (Clinical Decision Support for Immunization) but add additional business logic on top of CDSi





Testing AFIX-IIS

- Challenges include:
 - Forecasts from the past (2nd birthday, last immunization visit)
 - Counting valid doses of combination vaccine
 - UTD for child assessments, HPV, Meningococcal
 - Missed opportunities for category “B” recommendations
 - Seasonal Flu
- Testing of AFIX-IIS coverage and missed opportunity decisions cannot be satisfied by CDSi test cases alone



Manual Testing

- Method 1: Test cases
 - Execute test cases by manually manipulating records in the IIS to trigger a switch in coverage result and monitoring output
 - Pros:
 - No test infrastructure required
 - No detailed test output required
 - Can target specific edge cases
 - Cons:
 - Tedious and time consuming
 - Low test coverage



Manual Testing

- Method 2: Random samples
 - Randomly select children in an AFIX coverage report and manually verify their AFIX coverage status
 - Pros:
 - Test cases not required
 - Cons:
 - AFIX coverage report must output detail at the child level
 - Tedious and time consuming
 - Low test coverage



Automated Regression Testing

- Compare results of large-scale IIS batch runs
- Pros:
 - Full coverage possible
 - Detect regressions
- Cons:
 - Test infrastructure required
 - Can only detect regressions, not pre-existing problems



Automated Testing Using Standard Test Cases

- Execute standard test cases and compare results
- Pros:
 - Potential for high quality, automated testing
 - Detect regressions and pre-existing problems
- Cons:
 - **There are no AFIX-IIS standard test cases at this time**
 - Test infrastructure required



Automated Testing against another AFIX-IIS engine

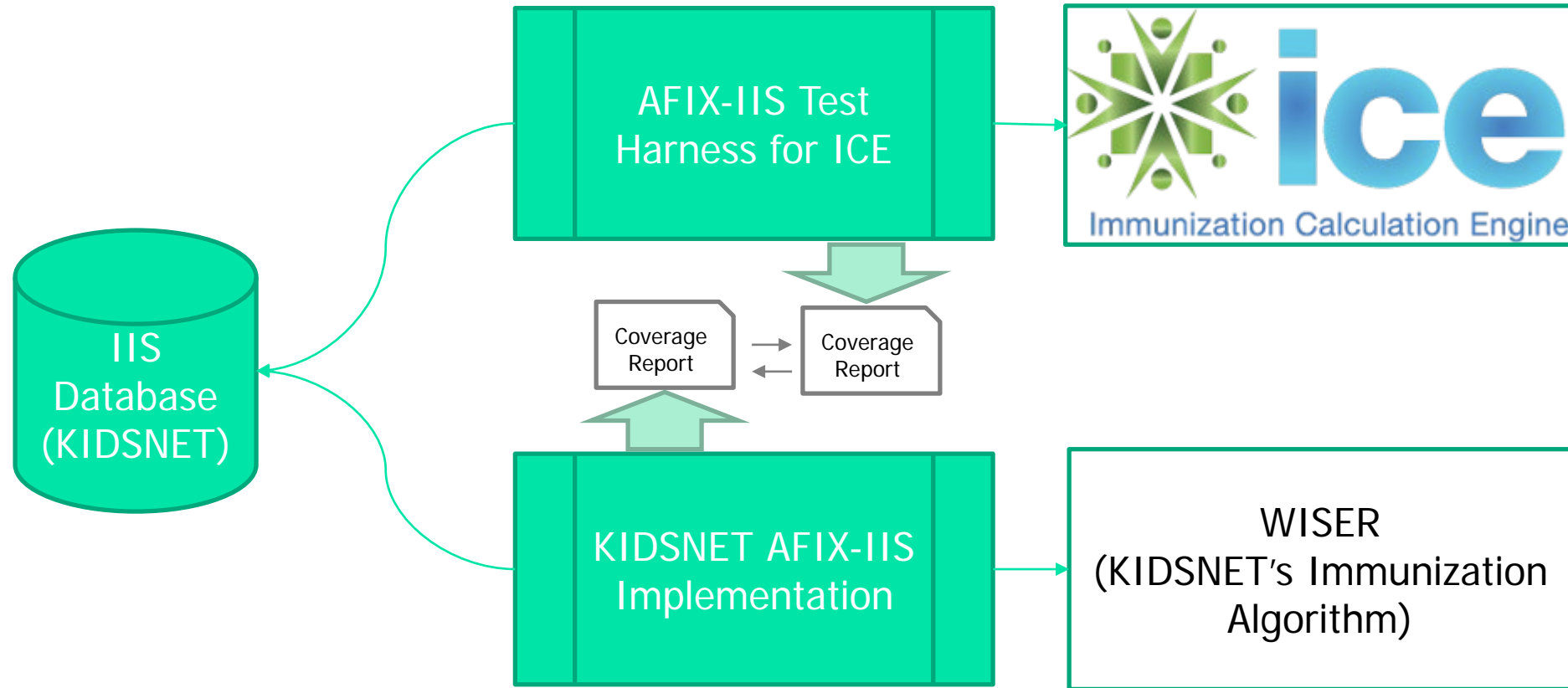
- Compare results of large-scale IIS batch runs against two *different* AFIX-IIS engines
- Pros:
 - A good alternative when no standard test cases are available
 - A good complement to standard test cases
 - High coverage possible
 - Detect regressions and pre-existing problems
 - Identify potential bugs or anomalies in both AFIX-IIS implementations
- Cons:
 - Test infrastructure required
 - Problems won't be revealed if *both* sources are wrong



Testing RI KIDSNET's AFIX-IIS against ICE

- Deployed open source Immunization Calculation Engine (ICE)
- Wrote AFIX-IIS test harness around ICE
 - Queries IIS for child/adolescent cohorts by practice
 - For each child in cohort:
 - Generates Virtual Medical Record (vMR) and makes ICE call
 - Parses vMR output and applies AFIX-IIS assessment logic
 - Outputs child/adolescent coverage summary and detail for practice

Testing RI KIDSNET's AFIX-IIS against ICE





Testing RI KIDSNET's AFIX-IIS against ICE

- Ran AFIX-IIS test harness
- Compared output with KIDSNET
 - Manually compared coverage numerators
 - Examined detailed output when numerators didn't match
 - Found and fixed issues with Rotavirus and Meningococcal that hadn't been detected using other testing methods



Lessons Learned

- Ensuring correctness and consistency requires:
 - Unambiguous interpretation of the guidelines
 - A high-coverage testing strategy
- Automated testing against an open source engine is feasible and effective



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