

AFIX-IIS Integration Operational and Technical Guidance for Implementing IIS-Based Coverage Assessment – Phase II



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Introduction

In 2013, the Centers for Disease Control and Prevention (CDC) Program Operations Branch (POB) announced that support for the software program developed and supported by CDC, Comprehensive Clinic Assessment Software Application (CoCASA), to perform provider level assessments would be discontinued. Therefore, immunization program awardees (hereinafter referred to as awardees) are encouraged to leverage their Immunization Information Systems (IIS) to support this key program activity in lieu of CoCASA.

Historically there have been no technical specifications or operational guidelines to assist awardees with the development or implementation of IIS-based coverage assessments. Expanding IIS functionality to accommodate AFIX (Assessment, Feedback, Incentives, and eXchange) program needs could potentially overwhelm any one IIS program and result in unnecessary redundancy of effort and expense. To mitigate the impact on awardees, CDC funded a two-phased approach to provide operational and technical specifications and guidelines that are IIS-platform neutral. The first phase resulted in the development and release of the document "AFIX-IIS Integration: Operational and Technical Guidance for Implementing IIS-Based Coverage Assessment — Phase I" (referred to as Phase I Guidance hereinafter). The second phase resulted in this document, which provides operational and technical guidance for additional report components of AFIX assessment and feedback functionality. Furthermore, this Phase II document is intended as a resource for members of the AFIX Community, IIS Community and Immunization Program Managers that have already implemented, or are in the process of implementing, the Phase I reporting requirements.

The project is a joint effort between CDC's POB-AFIX and the IIS Support Branch (IISSB), commissioned by the CDC and contracted to the American Immunization Registry Association (AIRA) through an existing cooperative agreement. Additionally, AIRA has partnered with the Association of Immunization Managers (AIM) for review and distribution of all final deliverables.

AFIX-IIS Integration Phases

The AFIX-IIS integration initiative was conducted through two primary development phases. Phase I guidance focused on the *required* coverage assessment measures assessed by CDC through the AFIX Online Tool. Awardees' AFIX staff enter results for individual provider assessments (coverage and missed opportunities) directly into the AFIX Online Tool. The AFIX Online Tool uses the reported information to calculate percentage change between a provider's initial visit and the follow-up assessment. Further, the AFIX Online Tool utilizes all data reported during the calendar year (CY) to tabulate results for each awardee's AFIX Annual Report (AFIXAR). Awardees were advised that the Phase I development effort would represent the minimum, mandatory requirements that an IIS must be able to perform in order to support awardees in meeting the POB reporting requirements.

Where Phase I focused on the reporting requirements of the POB, Phase II is geared towards the **optional** assessment/report components utilized during AFIX provider feedback sessions, as well as alternative ways of looking at coverage data. As used here, the term **optional** means that awardees may select the reporting components that are most useful for their AFIX provider feedback session and program policy. Although optional, these components provide important tools for the AFIX feedback process. Once the awardee has selected the report components they will use, they should adhere to the guidance provided in this document. This guidance represents feedback report components that were prioritized through the AFIX-IIS Community Input Process and the Phase II subject matter expert (SME) workgroup. This input was gathered from the AFIX-IIS Phase I SME workgroup and from awardees who participated in a web-based poll discussion. (Polling results and prioritization criteria have been included in Appendix C. Phase II Polling and Prioritized Report Components.)

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Document Overview

AFIX staff use a number of report components and tools during a provider feedback session to help raise provider awareness, improve office practices and workflows, and ultimately increase vaccination coverage levels. Although the intent of this document is to provide operational and technical guidance to support this process, guidance cannot be provided on every possible report component. Therefore, this document focuses on providing operational and technical guidance on components identified and prioritized by the AFIX-IIS community input process and Phase II SME workgroup. For purposes of Phase II, a report component is defined as one or more elements that can be used to measure a defined outcome or metric.

The report components included in this document are:

- Single Antigen Assessment
- Invalid Dose (Patient Listing)
- Not Up To Date/Missing Immunizations (Patient Listing)
- Missed Opportunities (Patient Listing)
- Detailed Report Component Options for Not Up to Date (UTD) Status and Missed Opportunities:
 - o Immunizations Up To Date
 - o Immunizations Late Up To Date
 - Immunizations Not UTD
 - Needs one dose to be UTD
 - Needs one visit to be UTD
 - With Missed Opportunity
 - With No Missed Opportunity
 - No Missed Opportunity & Eligible with last visit <12 months ago
 - No Missed Opportunity & Eligible with last visit >12 months ago
 - No Missed Opportunity Not Eligible for Immunization
- Provider Patient List
- Master Rate Comparison

Within each report component section the following can be found:

- An overview of how the report component is often used¹
- Standard Business Rules and Standard Decision Tables applicable to the report component (pulled from Phase I Guidance)
- Specific Business Rules and Decision Tables developed for the specific report component
- Other technical guidance including applicable standard data inputs, parameters, and calculations (pulled from Phase I Guidance), as well as deviations from the standard methods
- One or more samples of output formats

The document concludes with three sections that describe:

- Design suggestions for developing flexible user interfaces that allow for alternative coverage measurements
- · Principles of report component output and display that facilitate understanding and readability
- Suggestions and examples of trend and comparative analysis

¹ This document provides an overview on how the individual report components may be used with providers. For details on best practices of incorporation with provider visits, refer to the AFIX Policies and Procedures Guide.

Introduction

Additionally, the document refers to outside references (i.e., documents and/or websites) and instead of including those within the content of this document, the source references are located in Appendix G. Project Reference Documents.

Stakeholder Engagements

In May 2014, AIRA convened a group of SMEs for a face-to-face facilitated, collaborative decision-making meeting to inform AFIX workflows and identify requirements for developing IIS-based coverage assessments for Phase I of the AFIX-IIS Integration Effort. The SME group was composed of eight awardee projects selected based on IIS maturity, current abilities of IIS to prepare AFIX coverage assessment reports, geographic location diversity, variety of IIS vendors/platforms, and different legal/policy environments around IIS mandatory reporting. Other participants included representatives from the three largest IIS vendors, CDC, AIM and AIRA (see list of participants in Appendix D. <u>List of Meeting Participants (Phase I)</u>.

This group of SMEs also provided an initial list of prioritized assessment/report components for the Phase II effort. In order to ensure a representative view of AFIX feedback practices, AIRA hosted an interactive webinar on November 17, 2014. All awardees were invited to participate and encouraged to attend this opportunity to provide input on Phase II. A list of participating projects and polling results can be found in Appendix C. Phase II Polling and Prioritized Report Components.

On June 30 – July 1, 2015, AIRA convened a second face-to-face meeting with AFIX-IIS SMEs in Decatur, GA. The group of SMEs for Phase II included a subgroup of individuals convened for Phase I with some additions/substitutions. A list of meeting participants can be found in Appendix E. <u>List of Meeting Participants</u> (<u>Phase II</u>). The purpose of the face-to-face meeting was to 1) review draft operational and technical material prepared for the Phase II prioritized report components, and 2) resolve any discrepancies or points of contention. The meeting was conducted by a professional meeting facilitation group, Advanced Strategies.

Standard Business Rules and Standard Decision Table

For the report components described in this Phase II document, it is recommended that the IIS apply the same Business Rules (BRs) detailed in the Phase I Guidance. Specifically, most of the report components herein reference the BRs for "Selecting the Assessment Cohort" and "Defining Vaccination Assessment." Some of the report components reference the additional Phase I Business Rules for "Coverage Assessment Calculations," "Determining Missed Opportunities," and "Missed Opportunities Calculations," as well as the Phase I Decision Table "Coverage Assessment Numerator Determination."

All Phase I Business Rules are hereinafter referred to as the **Standard Business Rules**. The Phase I Decision Table is referred as the **Standard Decision Table** (see Appendix B. <u>Standard Business Rules and Decision Table</u> for a complete list). The following is a list of the topic areas contained in the Standard Business Rules:

- Defining the Birth Cohort (Standard BR I.A I.E)
- Patient Relationship with Provider (Standard BR 2.A 2.B)
- Selecting Vaccinations for Assessment (Standard BR 3A)
- Determining Dose Validity (Standard BR 4A-C)
- Determining Antigen Series Status (Standard BR 5A-5I)
- Coverage Assessment Calculations (Standard BR 6A)
- Determining Missed Opportunities (Standard BR 7A-7C)
- Missed Opportunities Calculations (Standard BR 8A)
- Coverage Assessment Numerator Determination (Standard Decision Table)

Technical Guidance: Standard Data Inputs/Parameters/Calculations

The following technical specifications may be helpful to those starting the design process. Full details on these specifications can be found in the **Phase I Guidance**: **Appendix H**, **Technical Design Specifications**. An excerpt from the Phase I Technical Design Specifications is included in this Phase II Guidance, in Appendix H. <u>Technical Design Specification Guidance</u> (Phase I Excerpt). Please note that these specifications are meant to be flexible so that each IIS can select the design approaches that are most appropriate for their needs.

Standard Table I. Standard Data Inputs/Parameters/Calculations

Data Inputs/Elements	Provider
	 Provider Name VFC PIN Number IIS ID (unique IIS identifier)
	Patient
	 First Name Last Name Date of Birth Gender/Sex Patient Active/Inactive Status (PAIS) Indicator
	Vaccination
	 Date of Vaccination Vaccine Type History of Disease/Titer (Immunity) Contraindication/Precaution
Parameters/Criteria See additional detail in Appendix H. Technical Design Specification Guidance (Phase I Excerpt)	 Provider Selection Assessment Date Feedback Date Assessment Age Range As of Date Compliance by Age/Date Series/Antigen Selection Active Patients Valid Vaccinations
Calculations	 Apply ACIP and/or CDSi logic for calculating validity and compliance with assessed measures

Note: This table is also contained in Appendix H. Technical Design Specification Guidance (Phase I Excerpt).

Each report component describes the Standard Data Inputs/Parameters/Calculations, deviations from the standards if any and specific considerations for the individual data element. These considerations are found in the "Other Technical Guidance" section for each report component.

Additional Considerations & Recommendations

The following items describe considerations and recommendations that should be understood and taken into account before implementing AFIX assessments within an IIS:

Clinical Decision Support for Immunizations (CDSi): The standard Business Rules developed in
Phase I, and used here in Phase II, reference the CDSi Logic Specification² for assessment of vaccine validity
and status. Specifically, the Standard Business Rules on Determining Dose Validity and Determining Antigen
Series Status are essential to many of the calculations needed in the report components of Phase II. While
many IIS have developed their own vaccine forecasting and evaluation tools, CDSi is now available for IIS to

² http://www.cdc.gov/vaccines/programs/iis/interop-proj/cds.html

use in testing and updating their own systems. According to CDC, CDSi "provides a single, authoritative, implementation-neutral foundation for development and maintenance of CDSi engines. It captures Advisory Committee on Immunization Practices (ACIP) recommendations in an unambiguous manner and improves both the uniform representation of vaccine decision guidelines, as well as the ability to automate vaccine evaluation and forecasting. The target audience for the Logic Specification for ACIP Recommendations includes business and/or technical implementers of immunization CDS engines. These implementers may support any system with an immunization evaluation and forecasting engine, including but not limited to IIS."

It is recommended that each IIS become familiar with the CDSi tools and use them to develop, test, review, and/or improve their own Clinical Decision Support systems. For report component results to be accurate, it is essential that the IIS have an up-to-date, accurate vaccine evaluation tool.

- Data Quality: Report results from the IIS are only as good as the data in the IIS. It is important for AFIX reviewers to be aware that there are a variety of data issues (i.e., completeness, accuracy, or timeliness) that may affect the report outputs. Some of the fields referenced in the report component parameters/outputs may be poorly populated in the IIS. Common examples include contraindications, exemptions, and substandard doses. The availability of certain data elements is frequently dependent on the capabilities of the Electronic Health Record submissions to the IIS, as well as on completeness and accuracy of direct data entry. Understanding that data quality is an on-going effort and becoming familiar with how data enters the IIS will benefit the AFIX reviewer.
- Patient Active/Inactive Status (PAIS) In 2015, AIRA's Modeling of Immunization Registry Operations Workgroup (MIROW) developed and published the document Management of Patient Active/Inactive Status in Immunization Information Systems: Replacement of 2005 Guidelines. Informally, this document is referred to as the PAIS (short for Patient Active/Inactive Status). The PAIS contains business rules for patient active and inactive status at both the provider level and the geographic level, with significant differences between the two. It is important that the AFIX reviewer and the providers being reviewed understand the definition of active and inactive status within their IIS, and that the IIS strive to achieve the PAIS best practices.
- **Denominators** When utilizing Phase II report components as a companion or follow up analysis to the Phase I coverage assessments, it is important to keep the cohort denominators the same to avoid confusion. However, there are business case scenarios where it is relevant to use different denominators. In these cases, it is helpful to document the denominator variations, so that data reviewers (such as AFIX staff or providers) understand apparent discrepancies.
- **Influenza Vaccine** Inclusion of the flu vaccine in the report components depends on the purpose and type of report. In the case of patient listing components, including flu may cause the outputs to be onerously long. However, if results need to match the AFIX required reports, flu vaccine should be included (see Denominator section above).

Single Antigen Assessment

Looking at coverage for single antigens, as opposed to a coverage assessment for a series such as 4:3:1:3:3:1:3, gives exact valid dose counts by age breakdown for each specified antigen. This approach can help to:

- Identify drop off patterns or late starts for various age groups,
- Provide a more accurate view of how patients completed a vaccine series, especially for those vaccines with variable numbers of doses equaling up-to-date status (due to aging out), such as Hib, PCV and RV,
- Develop targeted strategies for interventions or improved workflows,
- Illuminate opportunities for additional provider and/or patient education.

Note: Results of this report component are not reportable to CDC.

Standard Business Rules to Apply

Apply Standard Business Rules I through 4 from Appendix B. <u>Standard Business Rules and Decision Table</u>. Do <u>NOT</u> apply Business Rules 5A-5I for "Determining Antigen Series Status." IIS will apply a different set of business rules and calculations to determine compliance with each measurement and derive the results for this report component as described in Table I. Business Rules Specific to Single Antigen Assessment below.

Specific Business Rules

The following Business Rules and Decision Table should be considered in addition to the Standard Business Rules:

Table I. Business Rules Specific to Single Antigen Assessment

	Business Rules	Notes
I.A	Each age milestone should be viewed as a "Compliance by Age" measuring the number of valid doses administered by the specified age.	 Examples: Number of children that have received at least one dose of DTaP at 3 months of age. Number of adolescents that have received at least one dose of HPV at 14 years of age.
I.B	Childhood age milestones should be based on the routine ACIP vaccination schedule, although alternative age milestones may be chosen for specific program purposes.	Recommended childhood milestones (in months), up to and including the day of: • 3 rd month birthday • 5th month birthday • 7th month birthday • 13th month birthday • 16th month birthday • 19th month birthday • 24th month birthday Note: Birthday is defined as the first day the child turns the given age (i.e., same day and month as date of birth).
I.C	Adolescent age milestones should be based on the years of age specified in the cohort range (13-17 years), although alternative age milestones may be chosen for specific program purposes.	Recommended adolescent milestones (in years), up to and including the day of: I 3th birthday I 4th birthday I 5th birthday I 6th birthday I 7th birthday
I.D	Age should be defined as the specified age in months or years with each age bracket inclusive of the doses from the previous bracket.	 Examples: Childhood: "3 months" includes any doses administered at or before 3 months (i.e., between birth and the 3rd month birthday). Childhood: "5 months" includes any doses administered at or before 5 months (i.e., between birth and 5th month birthday).

	Business Rules	Notes
		 Adolescent: "13 years" includes any doses administered at or before 13 years (between birth and 13th year birthday).
I.E	The childhood measurements may include any/all of the following depending on how the report component criteria are defined: • DTaP-I, DTaP-2, DTaP-3, DTaP-4 • Polio-I, Polio-2, Polio-3 • MMR- I • Hib-I, Hib-2, Hib-3, Hib-4 • HepB-I, HepB-2, HepB-3 • VAR-I • PCV-I, PCV-2, PCV-3, PCV-4 • RV-I, RV-2, RV-3 • HepA-I, HepA-2	Dose number (such as DTaP-3) is a simple count of valid doses, not a measurement of patients' UTD status as in Phase I coverage assessments. Note: the single antigen report generally does not separate out those children that are on the Hib 3-dose PRP-OMP series versus 4-dose series, which would result in a lower count for the 4th dose of Hib.
I.F	The adolescent measurements may include any/all of the following depending on how the report component criteria are defined: • HepB-I, HepB-2, HepB-3 • MMR- I, MMR-2 • VAR-I, VAR-2 • Tdap-I • Meningococcal-I, Meningococcal-2 • HPV-I, HPV-2, HPV-3 • HepA-I, HepA-2 • Polio-I, Polio-2, Polio-3	See note above: a similar situation exists for adolescents receiving the 2-dose HepB series versus 3-dose series.
I.G	This report component will <u>NOT</u> include influenza since it is a seasonal measurement.	
I.H	The denominator for the childhood calculations will be static and will include the entire assessment cohort (Number of Records Analyzed).	Explanation: The childhood cohort includes children 24 through 35 months. All assessed measures occur at/before 24 months of age. As a result, all children assessed will be included in the denominator for each measurement.
1.1	The denominator for the adolescent calculations will change for each milestone to reflect only those adolescents that have reached the age of the specific milestone.	Explanation: Adolescents who are 13 years of age at the time of assessment will not be included in the denominator for the 14, 15, 16, or 17-year milestones. Those who are 14 years of age will be included in the denominator for the 13-year milestone, but not in the older age milestones. Conversely, a 17 year old will be included in ALL the milestones.

	Business Rules	Notes				
1.j	All patients that have achieved at least the specified number of age-appropriate valid doses ³ for the various measurements at the stated age milestones will be counted in the calculation numerators.	Example: DTaP2 includes all patients that have received 2 or more valid doses of DTaP by the stated age milestone.				
I.K	When "immunity" is present, the patient should be included in the maximum number of doses for that specified antigen at all age milestones.	Note: date of immunity is considered not to be a reliable data element at this time; therefore if child is immune, consider immunity to apply to all age milestones. It may be helpful to pull immune status into a separate count from vaccinated status.				

The following Decision Table I should be used to determine the criteria for which patients from the cohort will be included in the numerator for the report component calculations.

Decision Table I. Single Antigen Assessment Numerator Determination

		Nume	erator
Co	ndition	Include	Exclude
1.	Patient has received the number of valid doses for each specified measurement at the various age milestones.	Х	
2.	Patient has not received the specified number of doses to meet the particular measurement and/or has not reached the specified age milestone (adolescents).		X
3.	Patient has evidence of immunity for the specified vaccine (where applicable).	X	
4.	Patient has a contraindication/precaution (sometimes referred to as a medical exemption) for the specified vaccine per CDSi guidelines		X
5.	Patient has a religious or personal exemption noted for the specified vaccine.		X
6.	Patient has no recorded vaccinations.		X

Other Technical Guidance

Data Inputs - Standard

Parameters - Standard

Calculations – Use Specific Calculation Business Rules in Table 2 below.

³ From this point forward, use of the term "dose" or "doses" refers to "valid doses." Invalid doses are specifically called out as such.

Table 2. Calculation Business Rules for Single Antigen Assessment

	Business Rules	Notes				
2.A	This particular report component will NOT follow the more common "UTD" calculations for the various markers. Numerator will reflect only the patients that received the exact number of specified doses at the various age milestones and those who have been deemed immune.	Example: Child received a single dose of Hib at 15 months of age. In the output, this patient would be included in the numerator for Hib1 at 16 months, 19 months and 24 months. This patient would not be reflected in any of the numerators for Hib2, Hib3 or Hib4.				
2.B	Coverage for each vaccine assessed is calculated by dividing the total number of patients identified for inclusion in the numerator by the total number of children in the denominator and multiplying by 100.	Display as number and percentage of total denominator.				

Output - The output should be presented in a form that is easy for AFIX staff and providers to understand, and that contains the salient information. There is no single approach that is best for displaying the output. The following recommendations for output elements were developed from the IIS-AFIX community input process:

- 1. Separate table for each antigen type detailing dose by age
- 2. Age milestone depending on type of assessment (childhood or adolescent)
 - a. Childhood (in months)

3

5 7

13

16

19 24

b. Adolescent (in years)

13

14

15

16

17

- 3. Dose number breakdown for each vaccine type by age includes the following output elements:
 - a. Vaccine type and dose number in series for each measured antigen
 - b. Age milestone (defined above)
 - c. Denominator used for each age milestone
 - d. Calculated number and percentage for each age milestone
- 4. One option is to include a separate table containing the number with immune status:
 - a. For childhood ages (0-24 months), number with immune status for each antigen type
 - b. For adolescent ages (13-18 years), number with immune status for each antigen type

Sample of Single Antigen Assessment

Figure 1. Sample of Single Antigen Assessment (from CDC CoCASA)4

Months of Age		3		5		7		9	9		12		13			19		24	
		#	%	#	%	#	%	#	%	#	%	#	%	#	%	#	%	#	%
1	DTaP1	10	83	11	92	11	92	11	92	11	92	11	92	11	92	11	92	11	92
2	DTaP2			9	75	10	83	10	83	10	83	10	83	10	83	10	83	10	83
3	DTaP3					9	75	9	75	9	75	9	75	10	83	10	83	10	83
4	DTaP4													7	58	7	58	7	58
5	Polio1	10	83	11	92	11	92	11	92	11	92	11	92	11	92	11	92	11	92
6	Polio2			9	75	10	83	10	83	10	83	10	83	10	83	10	83	10	83
7	Polio3					9	75	9	75	9	75	9	75	9	75	9	75	9	75
8	MMR1											9	75	9	75	9	75	9	75
9	HepA1											9	75	9	75	9	75	9	75
	_											3	13	3	13	_		_	_
10	HepA2															8	67	8	67
)enc	minator	13	2	12	2	13	2	13	2	12	2	12	2	12	2	12	2	1:	2

Invalid Dose (Patient Listing)

The Invalid Dose⁵ Listing provides a list of all patients that have one or more invalid doses on record for the specified assessment measure(s). When defining the report component parameters, a user may be given the option to run this report component for "all patients" (UTD and Not UTD) or only those who are "not UTD" at the time the assessment is performed ("Assessment Date"). Determinations for validity will follow guidance provided in Phase I consistent with ACIP and CDSi assessment algorithms.

The Invalid Dose Listing can include detail on all vaccinations for the specified patient cohort that violated the rules of validity according to ACIP schedule/product licensure requirements. The list may include patient name, vaccine type, date of administration, and reason for violation (e.g., minimum age/minimum interval, maximum age, etc.). Additionally, IIS can add patient counts to a summary of Invalid Dose Patient listing. During feedback sessions, sharing this list with providers will help to:

- Identify patterns in invalid dosing as an opportunity to educate the provider and correct the behavior
- Allow the provider to conduct appropriate follow-up with the identified patients to bring them up to date
- · Identify data quality issues, such as miscoding
- Identify wastage

Note: Results of this report component are not reportable to CDC.

⁴ "This report does not necessarily reflect completeness (i.e., being up-to-date) and the percentages reflected on the single antigen report may differ from that on the summary report. The single antigen report is strictly a count of doses received at specified intervals and does not take into consideration scenarios in which a child could be considered up-to-date with fewer doses." From CoCASA Single Antigen Report Footnote, CDC.

⁵ CDSi uses the term "Not Valid" to indicate doses referred to here as "Invalid."

Standard Business Rules to Apply

Apply Standard Business Rules 1 through 5 found in Appendix B. Standard Business Rules and Decision Table.

Specific Business Rules

The following Business Rules and Decision Table should be considered in addition to the Standard Business Rules:

Table 3. Business Rules Specific to Invalid Dose Report Component

Business Rules	Notes
more invalid vaccinations recorded on their in the D Determ Addition between provide	s on list will be impacted by values defined Decision Table 2. Invalid Doses Numerator hination Criteria. nally, some IIS may choose to differentiate in doses administered by the assessed er and doses administered elsewhere, and clude non-attributed historical vaccines.

The following Decision Table 2 should be used to determine the criteria for which patients from the cohort will be included in the listing. Please note the two separate sections within the table: the first section is based on assessment of ALL patients whether or not they are UTD; the second section is based on assessment of only patients who are not UTD.

Decision Table 2. Invalid Doses Numerator Determination Criteria

	Condition	Include	Exclude
Parameter: For Assessment of A	LL Patients (whether UTD or not)		
1. Patient has no invalid vaccination	ons on their immunization record.		X
assessment measurement or re	er of valid doses specified in the AFIX eceived an appropriate number of valid doses selected measures BUT has at least one nunization record.	×	
	ropriate number of doses to meet the AFIX irements AND has at least one invalid ion record.	×	
Parameter: For Assessment of P	atients Not Up To Date Only		
4. Patient has no invalid vaccination	ons on their immunization record.		X
assessment measurement or re	er of valid doses specified in the AFIX eceived an appropriate number of valid doses selected measures BUT has at least one nunization record.		×
	ropriate number of doses to meet the AFIX irements to be UTD AND has at least one nunization record.	×	

Other Technical Guidance

Data Inputs - Standard

Parameters – Standard except Valid Vaccination parameter is not applicable. New parameters may also be added such as providing the option to run this report component for all patients (regardless of coverage status) or for only those patients considered to be Not UTD for the assessed measures. This selection will impact which portion of the cohort is assessed for invalid doses. When "All Patients" is selected, all records in the cohort should be assessed and displayed for invalid doses. When "Not UTD Only" is selected, only the records that meet the criteria for Not UTD should be assessed and displayed for invalid doses.

Calculations – Standard. The patient listing **(or** the numerator when doing a quantitative count) for the Invalid Dose report component will include all patients, depending on the specified parameters, with one or more invalid doses on their immunization record, per Decision Table 2 above.

Output – The output should be presented in a form that is easy for AFIX staff and providers to understand, and that contains the salient information. There is no single approach that is best for displaying the output. The following recommendations for output elements were developed from the IIS-AFIX community input process:

- I. Patient Name
- 2. Unique patient identifier(s) (with designation of ID source(s) such as IIS identifier and/or medical record number)
- 3. Date of Birth
- 4. Vaccine Type
- 5. Invalid Vaccine Series (the Antigen Series within which the invalid dose occurs e.g., Rotavirus 3 doseseries, Rotavirus monovalent 2-dose series, Hepatitis B 3-dose series, Hepatitis B 4-dose series.)
- 6. Trade Name
- 7. Date Administered
- 8. Historical or Administered Vaccine
- 9. Reason for invalid determination as derived from record. Choose those reasons that are of most value to the situation. Possible values include:⁶
 - a. Age: Too Young
 - b. Interval: Too Soon
 - c. Live Virus Conflict
 - d. Vaccine Type: Vaccine dose administered was not a preferable or allowable vaccine type
 - e. Vaccine Type: Vaccine dose administered outside of the preferred or allowable age range of the vaccine type
 - f. Vaccine Type: Vaccine dose administered was not the required trade name for the vaccine type⁷
 - g. Gender: Incorrect Gender
- 10. Optionally add counts of invalid doses if possible, by vaccine type and reason

⁶ The CDSi Logic Specifications lists attributes of a vaccine dose that lead to the determination of Not Valid. Besides age and interval requirements, there is a range of other common reasons why a dose might be invalid. In addition, there are attributes which are not called out as invalid in the CDSi, but which are deemed ineffective doses. One example is "age too old" which is considered an "extraneous" dose. Substandard doses comprise additional examples: though administered at the proper time, substandard doses (e.g., expired lot, partial dose administered, lot recall) do not count towards immunity. A program may want to include some of these attributes in their analysis if feasible and useful.

⁷ Applies where ACIP has a recommendation that is specific to a product, and vaccine type (CVX) is not sufficient. For example, there is a 2-dose Hep-B schedule for 11 through 15 year olds as long as Recombivax adult is administered 4 months apart. Only Recombivax can be used for this 2-dose series. Engerix would not be valid for this use.

Samples of Invalid Doses Patient Listing

Figure 2. Sample of Invalid Doses Patient Listing (from Envision Technology Partners)

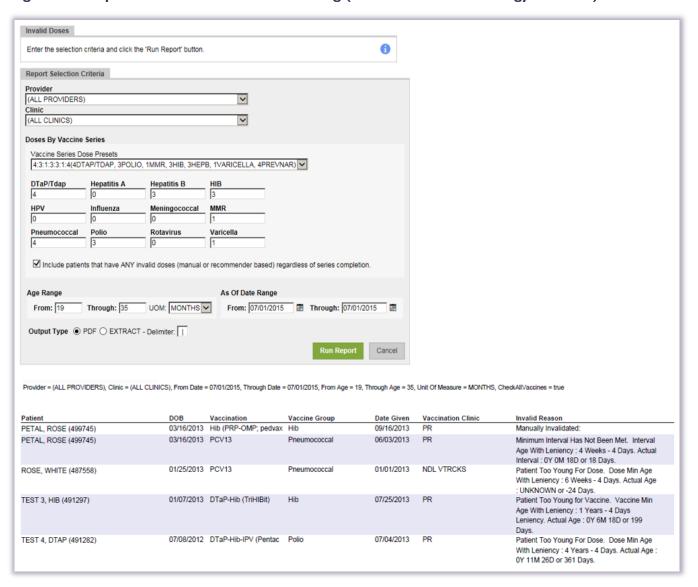


Figure 3. Sample of Invalid Dose Report (from CDC CoCASA)

Patient Name (Last, First MI)	DOB	Antigen	Date given	Reason not valid
Child, Six	07/01/2012	DTaP1	08/01/2012	Minimum age of 6 weeks not met
		Polio1	08/01/2012	Minimum age of 6 weeks not met
		HIB1	08/01/2012	Minimum age of 6 weeks not met
				_

Not Up To Date/Missing Immunizations (Patient Listing)

The Not Up-to-Date/Missing Immunizations report component identifies and lists patients in a cohort that were indicated as Not Up-to-Date (UTD) or missing immunizations at the time of the assessment. The Not UTD/Missing Immunizations list may include patient name, patient date of birth, missing vaccine type and number of doses missing, and (if desired and feasible) the reason as derived from the record. This report component can be used as a companion to the Phase I AFIX childhood and adolescent coverage assessment reports, providing further patient details on those patients not UTD. Providers often use this measurement as a way to:

- Identify immunizations that are part of their medical records but missing from the IIS.
- Identify patients that may need to be recalled back into the office for appropriate immunizations.

Note: Results of this report component are not reportable to CDC.

Standard Business Rules to Apply

Apply Standard Business Rules I through 6 found in Appendix B. Standard Business Rules and Decision Table.

Specific Business Rules

The following Business Rules and Decision Table should be considered in addition to the Standard Business Rules:

Table 4. Business Rules Specific to Not Up To Date/Missing Immunization

	Business Rules	Notes
4.1	Patient List will include all patients NOT Up to Date.	See Decision Table 3 for patients that should be included in the Not UTD/Missing Immunizations Patient List.
4.2	Patient List will include any patient that is missing one or more vaccinations. This includes a forecast status (or equivalent) of "overdue" (NOT UTD and eligible for vaccination based upon ACIP recommended ages and intervals) or "coming due" at any point in the future (NOT UTD and not yet eligible for vaccination as of the assessment date).	IIS should apply its full forecasting/evaluation logic (ACIP and/or CDSi) for these determinations as defined in Standard Business Rules 5. "Coming due" in the future applies to those who are missing a dose but are not yet eligible for it – often because of an insufficient interval from previous dose or a live virus conflict.
4.3	Including flu vaccine should be considered optional and up to each program.	This is an exception to the coverage assessment rules outlined in Standard BRs 3 through 5, which include influenza with stipulation "for previous season."

The following Decision Table should be used to determine the criteria for which patients from the cohort will be included in the numerator for the report component calculations.

Decision Table 3. Missing Immunization Determination Criteria

)	Condition	Include	Exclude
1.	Patient has received the number of valid doses specified in the AFIX assessment measurement or received an appropriate number of valid doses to meet the UTD criteria for selected measures ⁸ .		×
2.	Patient has not received an appropriate number of doses to meet the AFIX assessment measurement requirements.	X	
3.	Patient has evidence of immunity for the specified vaccine (where applicable).		X
4.	Patient has aged out for the specified assessment measure and did not receive the appropriate number of valid doses to be considered UTD before maximum age was reached.9	optional	
5.	Patient has a contraindication/precaution (medical exemption) for the specified vaccine. 10	optional	
6.	Patient has a non-medical exemption (such as religious, philosophical, or personal) noted for the specified vaccine.	X	
7.	Patient has no recorded vaccinations.	X	

Other Technical Guidance

Data Inputs - Standard

Parameters – Standard. IIS may want to consider adding the ability to select multiple categories regarding patient eligibility based on the AFIX program needs such as: patients who are currently eligible for vaccination and/or those not currently eligible for vaccination (allowing either option to be selected or both simultaneously).

Calculations – Standard. This report component will focus on all patients NOT included in the numerator for the coverage assessment calculations (for the basic AFIX Coverage Assessment report as established in the Phase I guidance).

Output – The output should be presented in a form that is easy for AFIX staff and providers to understand, and that contains the salient information. There is no single approach that is best for displaying the output. The following recommendations for output elements were developed from the IIS-AFIX community input process:

- I. Patient Name
- 2. Unique Patient Identifier

⁸ The program may choose to include or exclude "Late UTD" patients in the Not UTD listing. For the childhood series, "Late UTD" refers to patients were Not UTD as of the compliance date, but became UTD (received appropriate number of doses) by the **assessment** date. Late UTD does not apply to the adolescent series since the compliance date and assessment date are the same.

⁹ This is marked as optional because it depends upon how the information will be used. If the purpose of this Patient Listing is to recall patients who need vaccinations, this group should be excluded. If the purpose is to educate provider on their immunization practices, then it may be helpful to include.

¹⁰ This is marked as optional because there is no action the provider can take to correct the missing dose, but it may be of interest to the program or provider as an indicator of patients not protected from disease.

- 3. Date of Birth
- 4. Missing Immunizations (Vaccine Type and Dose Number)
- 5. Reasons for missing immunizations when able to be derived from record (optional). Possible values include:
 - a. Missed Opportunity
 - b. Contraindication/Precaution
 - c. Exemption (type of exemption may be determined by the program)
 - d. No Vaccinations on Record
- 6. Optionally add counts of missing immunization doses if possible, by vaccine type and reason

Samples of Not Up-to-Date/Missing Immunizations

Figure 4. Sample of Missing Immunizations (from CDC CoCASA)

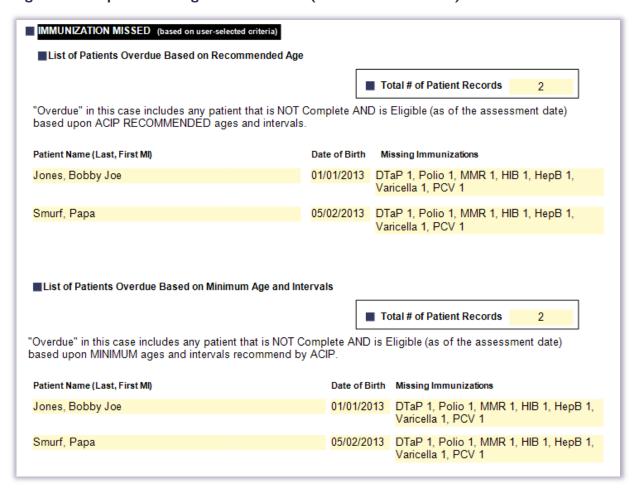


Figure 5. Sample of Patients Not Up-to-Date List (modified from New York City IIS)

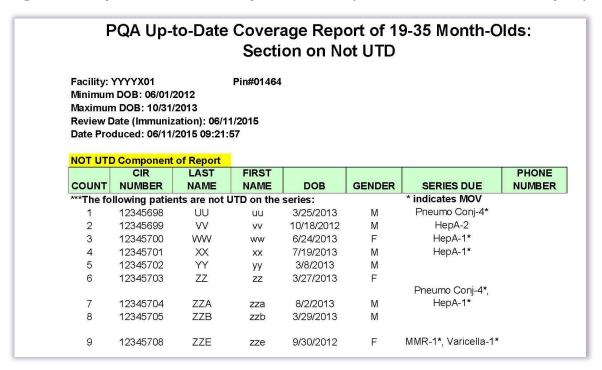
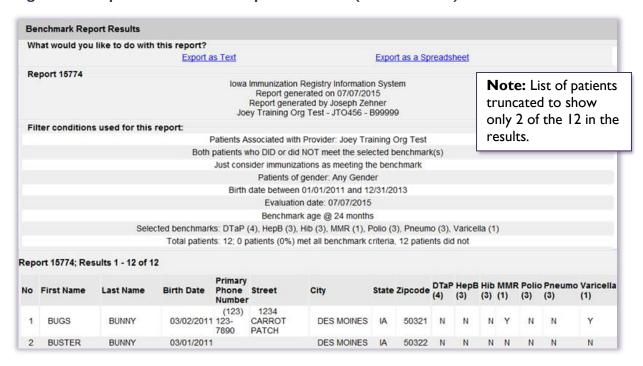


Figure 6. Sample of Patients Not Up-to-Date List (from Iowa IIS)11



¹¹ Note that in this sample, a number of filters can be selected, including the ability to filter on Not UTD doses only.

Missed Opportunities (Patient Listing)

Missed Opportunities can be identified in a number of ways. However, as defined here, Missed Opportunities are defined as patients in a cohort that were considered Not UTD at the Last Immunization Visit at which time they were eligible 12 for but did not receive one or more doses of vaccine. This report component is a companion piece to the Phase I Missed Opportunities (#/%) Coverage Assessment reported to the AFIX Online Tool. Instead of simply producing a number and percentage as in Phase I, this report component allows for the production of a patient listing of those that had a Missed Opportunity on the last immunization visit. It may be helpful to present the AFIX Phase I quantitative results along with the corresponding Patient Listing.

The patient list can include detail on the vaccine(s) and dose number(s) in a series that a patient could have received. The list may also include a reason for the Missed Opportunity, when available. During feedback sessions, sharing this list with providers will help to:

- Confirm the missing vaccinations against other available records,
- Identify the possible reasons that the forecasted vaccinations were not administered on the date of the last visit.
- Provide an opportunity to educate the provider and correct any pattern behavior, and
- Allow the provider to conduct appropriate follow up with the patients and administer any missing vaccinations.

Note: Results of this report component are not reportable to CDC.

Standard Business Rules to Apply

Apply all Standard Business Rules found in Appendix B. <u>Standard Business Rules and Decision Table</u>. Standard BRs 7 and 8 are specifically related to Missed Opportunity determination and calculation.

Specific Business Rules and Other Technical Guidance

The following Business Rules and Decision Table should be considered in addition to the Standard Business Rules:

Table 5. Business Rules Specific to Missed Opportunities

	Business Rules	Notes
5.A	Patient List will include all patients identified through application of the Standard Business Rules 7A – 7C.	See Decision Table 4 below for patients that should be included on the Missed Opportunities Patient List.

The following Decision Table should be used to determine the criteria for which patients from the cohort will be included in the patient listing. Note: This table is the same one used for the Phase I Missed Opportunities calculations — the only difference is the output, which will be reflected as a listing of patients versus a simple #/%.

¹² In this context, eligibility for a dose is based on the earliest recommended age, as opposed to minimum age or absolute minimum age. See CDSi: Logic Specification for ACIP Recommendations for definitions.

Decision Table 4. Missed Opportunities Patient Listing Determination Criteria

	Condition	Include	Exclude
1.	Patient has received the number of valid doses specified in the AFIX assessment measurement or received an appropriate number of valid doses to meet the "UTD" criteria for selected measures.		X
2.	Patient has not received the appropriate number of doses to meet the AFIX assessment measurement requirement and was NOT eligible to receive the vaccination on the date of the last immunization visit.		X
3.	Patient has not received the appropriate number of doses to meet the AFIX assessment measurement requirement and WAS eligible to receive the vaccination on the date of the last immunization visit.	X	
4.	Patient has not received the appropriate number of doses to meet the AFIX assessment measurement requirement, WAS eligible to receive the vaccination on the date of the last immunization visit, AND received an incorrect dose due to incorrect product use when administration of a different product could have resulted in a valid dose. ¹³	×	
5.	Patient has evidence of immunity for the specified vaccine (where applicable).		X
6.	Patient has aged out for the specified assessment measure and did not receive the appropriate number of valid doses to be considered UTD before maximum age was reached.		X
7.	Patient has a contraindication/precaution (medical exemption) for the specified vaccine.		X
8.	Patient has a religious or personal exemption noted for the specified vaccine.	X	
9.	Patient has no recorded vaccinations.		X

Other Technical Guidance

Data Inputs - Standard

Parameters/Criteria - Standard

Calculations - Standard

Output – The output should be presented in a form that is easy for AFIX staff and providers to understand, and that contains the salient information. There is no single approach that is best for displaying the output. The following recommendations for output elements were developed from the IIS-AFIX community input process:

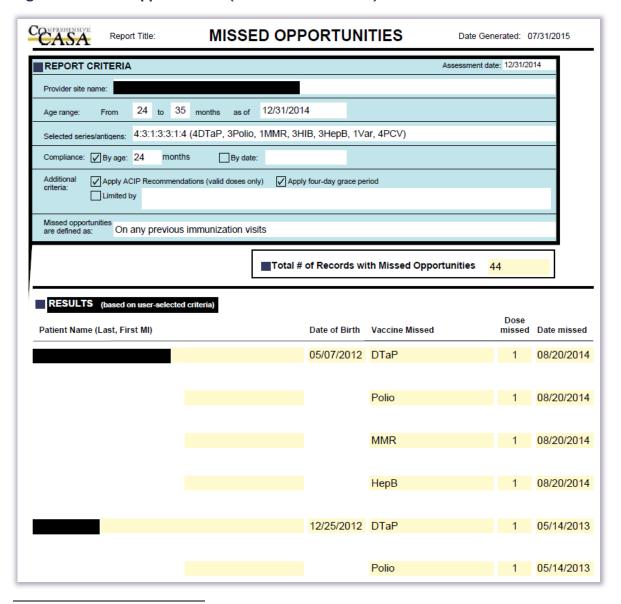
- I. Patient Name
- 2. Unique Patient Identifier
- 3. Date of Birth
- 4. Missing Immunizations (Vaccine Type and Dose Number)
- 5. Date of Last Immunization Visit

¹³ Examples: Tdap given as a dose in the primary DTaP series; Td given instead of Tdap without a medical contraindication/precaution.

- 6. Reason for missed opportunities when able to be derived from record (optional). Possible values include:
 - a. Null/Blank/Not Specified
 - b. Personal Exemption
 - c. Religious Exemption
 - d. Incorrect Vaccine Administration
 - e. Refusal14
 - f. Temporary Medical Exemption
 - g. Vaccine not available (e.g., out-of-stock, on back-order, ordering pattern change)
- 7. Optionally add counts of missing immunization doses if possible, by vaccine type and reason

Sample of Missed Opportunities

Figure 7. Missed Opportunities (from CDC CoCASA)



¹⁴ Refusal here means at the visit level – not a formal on-going personal exemption.

<u>Detailed Report Component Options for Not UTD Status and Missed Opportunities</u>

This section focuses on report components that can assist in drilling into reasons why patients are not UTD for their vaccines. It differs from the previous sections by providing a higher-level guidance rather than detailed rules and specifications. It is recommended that AFIX-IIS awardees use the **Standard Business Rules** in Appendix B. <u>Standard Business Rules and Decision Table</u> and the **Design Specifications** in Appendix H. <u>Technical Design Specification Guidance (Phase I Excerpt)</u> for consistency in methodology. However, the detailed components below may be tailored to specific needs.

Report Component Options

After first determining the number of patients who are UTD, Late Up to Date, and Not UTD, the assessment can analyze subsets of the Not UTD parameter. The Not UTD subsets can be calculated independently of each other or combined together into the same output. For example, the output could include those who are "eligible for immunization" AND who meet the criteria for "need one visit" to become UTD. Another "combination" output could combine three components and measure those whose last visit was less than 12 months ago AND who are eligible for immunization AND who need one visit to become UTD. These approaches may be helpful in producing a more manageable patient listing by focusing on those patients who could become UTD most efficiently and timely. Results can be displayed as a number and percentage of the total assessed cohort and/or as a patient listing using the general guidance concepts provided in the Patient Listing components above. Figure 8 illustrates the detailed report components described in this section. Results of these report components are not reportable to CDC.

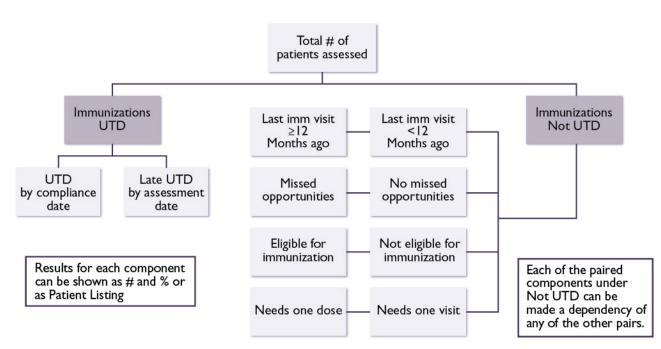


Figure 8. Detailed Report Components

Immunizations UTD:

Up to Date

Patients in cohort that were UTD for all assessed measures at the Compliance by Age/Date. **Numerator Guidance**: Refer to **Standard Business Rules I through 6** and **Standard Decision Table** in Appendix B. Standard Business Rules and Decision Table.

Up to Date but Late

Patients in cohort that were not UTD for assessed measures at the "Compliance by Age/Date," but were UTD as of the "Assessment Date." **Numerator Guidance:** Include all patients UTD for the assessed measures at the "Assessment Date" less the patients that were UTD at the "Compliance by Age/Date."

Immunizations Not UTD:

Patients in cohort that were Not UTD for the assessed measures as of the "Assessment Date." **Numerator Guidance**: Include all patients that were NOT included in the "Immunizations Up to Date" and "Immunizations Late UTD" numerators.

Subsets of Not UTD:

Needs One Dose

Patients in cohort that could be brought UTD for assessed measures with a single dose of vaccine.

Numerator Guidance: Include all patients that were Not UTD (per above definition and regardless of Missed Opportunity or Eligibility status) where the patient could be brought UTD with a single dose based on a current or future ACIP forecast. This component may be especially useful in the form of a patient listing when the number of patients Not UTD is quite large. It presents a more manageable number of patients for recall.

Needs One Visit

Patients in cohort that could be brought UTD for assessed measures with a single visit to the provider.

Numerator Guidance: Include all patients that were Not UTD (per above definition and regardless of Missed Opportunity or current eligibility status) where the patient could be brought UTD with a single visit based on a current or future ACIP forecast. This component may be especially useful in the form of a patient listing when the number of patients Not UTD is quite large. As with the Needs One Dose subset, it presents a more manageable number of patients for recall.

Missed Opportunities

Patients in cohort that were Not UTD at the Last Immunization Visit, could have been vaccinated, BUT did not receive all vaccinations due OR received a dose of an incorrect vaccine type. Numerator Guidance: Include all patients that were Not UTD at the Last Immunization Visit date and did not receive all vaccinations due at that time. See Missed Opportunities (Patient Listing) in previous section for technical guidance and business rules to apply.

NO Missed Opportunities

Patients in cohort that are Not UTD AND received all doses due at the Last Immunization Visit. **Numerator Guidance**: Include all patients that were Not UTD and were Not UTD included in the Not UTD-Missed Opportunity numerator.

Not Eligible for Immunization (No Missed Opportunities/Not Eligible)

Patients in cohort that are Not UTD at the "Assessment Date" but are not immediately eligible to receive one or more of the missing assessed vaccinations due to required scheduling per ACIP guidance (e.g., minimum intervals, age guidelines, brand licensure). **Numerator Guidance**: Include all patients that were Not UTD-No Missed Opportunity <u>not</u> currently due for a vaccination (e.g., forecast reflects a future due date).

Eligible for Immunization (No Missed Opportunities/Eligible)

Patients in cohort that are Not UTD at the "Assessment Date" but are immediately eligible to receive one or more of the missing assessed vaccinations. **Numerator Guidance**: Include all patients that were Not UTD-No Missed Opportunity currently due for a vaccination.

With Last Immunization Visit <12 Months Ago

Patients in cohort that are Not UTD but are eligible to be vaccinated where the last recorded vaccination date occurred within the past 12 months ("Assessment Date" minus 365 days). **Numerator Guidance:** Include all patients that are Not UTD-Eligible for Immunization where the Last Immunization Visit date occurred within the past 12 months.

With Last Immunization Visit ≥12 Months Ago

Patients in cohort that are Not UTD but are eligible to be vaccinated where the last recorded vaccination date occurred greater than 12 months ago ("Assessment Date" minus 366 days or more). **Numerator Guidance:** Include all patients that are Not UTD-Eligible for Immunization where the Last Immunization Visit date occurred at greater than 12 months ago.

Provider Patient List

The Provider Patient List is referenced in the Phase I Operational Guidance as it relates to helping providers prepare for an AFIX Assessment and visit. However, the technical guidance for generating the Patient List was not provided in Phase I and is thus provided here. The Provider Patient List will produce a list of all patients that are active with the selected provider within the specified cohort in the IIS. Refer to the glossary in Appendix A. Glossary and Acronyms for the definition of "provider." An optional parameter for "all patients" will include ALL patients associated with a provider in the IIS, including those that are inactive according to the current definitions of the MIROW Patient Active Inactive Status (PAIS). This patient list can be used to help a provider prepare for a visit and can be used during the feedback session. Sharing this list with providers will help the provider to:

- Confirm that the list of active patients in the specified cohort is correct, and
- Allow the provider to "inactivate" or "re-activate" patients according to appropriately applied criteria.

Note: Results of this patient list are not reportable to CDC.

15 "CDC recommends having providers run a list of active patients prior to conducting the AFIX assessment (this is a list that many IIS are capable of generating). This allows the provider the opportunity to identify patients who may have an incorrect "active" status indicated in the IIS that may need to be inactivated prior to the official AFIX assessment." (Phase I Guidance, p. 21)

Standard Business Rules to Apply

Apply the Standard Business Rules for **Defining the Birth Cohort** and **Patient Relationship with the Provider** (BR I and BR 2 in Appendix B. <u>Standard Business Rules and Decision Table</u>). Other Standard Business Rules regarding vaccinations and doses are not applicable.

Specific Business Rules

There are no specific business rules for the Associated Patients List. Standard Business Rules I and 2 suffice.

Note: This report component does not require special inclusion/exclusion logic for determining a numerator.

Other Technical Guidance

Data Inputs – Standard for Provider and Patient. Vaccination input is not required

Parameters/Criteria – Standard except the following parameters are NOT applicable:

- a. Compliance by Age/Date
- b. Series/Antigen Selection
- c. Valid Vaccination

The Active Patient standard parameter is critical. Per Standard Business Rule 2B, options should include Active, Inactive, All. Patient Status is determined by the MIROW PAIS indicator.

Calculations - N/A - This report component does not require any calculations.

Output – The output should be presented in a form that is easy for AFIX staff and providers to understand, and that contains the salient information. There is no single approach that is best for displaying the output. The following recommendations for output elements were developed from the IIS-AFIX community input process:

- I. Patient Name
- 2. Unique Patient Identifier
- 3. Date of Birth
- 4. Patient Status (MIROW PAIS indicator value for specific provider)
 - a. Values Include:
 - i. Active
 - ii. Inactive (optional)
- 5. Date of Patient Status Change in IIS (optional)
- 6. Date of Last Immunization Visit (i.e., date of last vaccine dose (optional)

Sample Provider Patient Listings

Figure 9. Sample of Patient Listing (from CDC CoCASA)

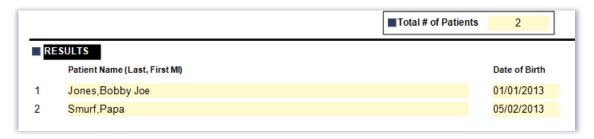


Figure 10. Sample of Patient Roster (from Envision Technology Partners)

se Reason	Close Date	Open Date	Status	Last Vac Date	Date of Birth	Age	First Name	Last Name	atient ID
		08/15/2013	ACTIVE	01/02/2015	07/04/2009	6Y 0M 23D	TINKER	BELL	87302
		02/18/2015	ACTIVE	02/18/2015	09/14/2001	13Y 10M 13D	DONATELLO	TURTLE	99784
		10/28/2014	ACTIVE	10/28/2014	10/18/1999	15Y 9M 9D	LEONARDO	TURTLE	99783
		10/28/2014	ACTIVE	10/15/2014	07/29/2000	14Y 11M 28D	RAPHAEL	TURTLE	99781
Patient Tot ve:									
ve: ve:	Rep								
ve: ve:tal: atient Tota	Rep Total								

Master Rate Comparison

The Master Rate Comparison report component is referenced in the Phase I Operational Guidance as it relates to helping awardees identify and prioritize VFC providers for annual AFIX visits. As stated in the Phase I Guidance, once the proposed functionality for Phase I has been developed into the IIS, AFIX staff will be able to leverage the new report component(s) for identifying and prioritizing provider visits. AFIX awardees will be required to prioritize at least ½ of the recommended 25% from the list of providers identified as having vaccination coverage rates in the **bottom quartile** when compared against all VFC enrolled providers within a program's jurisdiction.

A common recommended process is as follows:

- 1. On an annual basis, perform a coverage assessment for every VFC provider using the same "As of" Date.
- 2. Sort providers by a selected coverage measure (e.g. childhood 4:3:1:3:3:1:4 series or adolescent HPV coverage).
- 3. Based on the range of results produced by the IIS, identify low coverage rates.
- 4. Prioritize providers who fall in the bottom quartile for a visit. 16

This process can be conducted by running a separate report for each provider, entering the results into a sortable database (e.g., Excel), sorting on the selected variable such as the 4:3:1:3:3:1:4 coverage, and then identifying providers that fall below the specified threshold. However, such a process may not be feasible for all awardees, especially those with a very large number of providers and/or limited staff resources. Thus, this document provides guidance on developing a "Master" level report component capable of calculating and returning results for all providers within the jurisdiction.¹⁷

¹⁶ "Immunization rates may be skewed (artificially high or artificially low) for providers with a small number of patients in the defined cohort. AFIX awardees should also factor in provider size when evaluating which providers in the bottom quartile will be prioritized for a visit." From AFIX-IIS Integration Guide Phase I, p 12, footnote 3.

¹⁷ Note: the IIS system resources required to generate an output of this size may be significant. IIS staff should work closely with their vendor/development staff to minimize any potential impacts on performance.

Standard Business Rules

Apply all Standard Business Rules I through 6, Appendix B. Standard Business Rules and Decision Table.

Specific Business Rules

The following Business Rules and Decision Table should be considered in addition to the Standard Business Rules:

Table 6. Business Rules for Master Rate Comparison

	Business Rules	Notes
7.A	IIS will produce a master line listing of all VFC providers sorted by the calculated value for a specified measurement.	
7.B	Assessment will include only providers with a VFC PIN Number and an "Active" status if the IIS has implemented a VFC Program Status indicator.	AFIX Program can choose to include non-active or additional provider statuses.
7.C	IIS will apply the Standard Business Rules for "Selecting the Assessment Cohorts" (BRs 1A- 1E and 2A-2B) and "Defining Vaccination Assessment Criteria" (BRs 3A, 4A-4C, 5A-5-I).	A subset of vaccines listed in Standard BR 5D-5G may be selected. It is not necessary to run the full AFIX coverage assessment.
7.D	IIS will apply the Standard Business Rules for "Coverage Assessment Calculations" (BR6A) and the Standard Decision Table "Coverage Assessment Numerator" to derive the calculated values for the specified measure.	Limit the calculations to the selected subset of vaccines, if applicable.

Other Technical Guidance

Data Inputs - Standard

Parameters – Standard with the following exceptions:

- Provider Selection (this report component will run for ALL VFC-enrolled providers)
- Series/Antigen Selection may be defined by the AFIX-IIS awardee. To make the report technically
 feasible, users can choose to define a more restricted measure than the usual full coverage assessment.
 For childhood rates, a selected variation for the childhood assessment might be 4 DTaP only or 4 PCV
 only. For adolescents, a selected variation might be 2 Hep A or 3 HPV doses, or some combination of
 the recommended vaccines. I8 Although the selected measure may change from year to year, the same
 measure should be applied to all providers within a given year.

New Specific Parameter - "Sort Order" by coverage rate, with possible values of:

- High to Low
- Low to High

¹⁸ If the number of participating providers is low or the IIS is robust enough, a program may choose to run the full vaccine series. This is choice is at the discretion of the AFIX-IIS awardee.

Calculations - Standard

Output – The output should be presented in a form that is easy for AFIX staff to understand, and that contains the salient information. There is no single approach that is best for displaying the output. The following recommendations for output elements were developed from the IIS-AFIX community input process. For each provider, the output should include:

- I. Provider Name
- 2. IIS Identifier (IIS ID)
- 3. VFC PIN
- 4. Total Number of Patient Records Assessed
- 5. Calculated Rate for Selected Measure

Sample Master Rate Comparison

Figure 11. Sample of master rate comparison – mock-up based on output parameters

Parameters					
Date Report Run:	12/31/2014				
			Assess coverage		
	Age range	Age as of date	status as of:	Selected measure	Sort Order
			24 months		High to low childhood
Childhood	24-35 months	12/31/2014	of age	4 DTaP	measure
			Date of	1 Tdap + Meningococcal	
Adolescent	13-17 years	12/31/2014	assessment	(UTD for age)	

				#				
				childhood		#		
			# childhood	records		adolescent	# adolescent	
			records	UTD for	% UTD for	records	records UTD	% UTD for
Provider Name	IIS ID	VFC Pin	assessed	measure	measure	assessed	for measure	measure
Best Health Care	1052	85333	444	410	92%	300	280	93%
Public Health Immunizat	1050	84333	622	500	80%	401	305	76%
Westside Pediatrics	1049	83555	1125	882	78%	352	250	71%
Children's Clinic	1047	82846	333	251	75%	222	195	88%
ABC Clinic	1045	82838	45	30	67%	22	10	45%
Dr. Joe Smith	1046	82845	61	40	66%	35	15	43%
Mary's Health Center	1051	85322	135	60	44%	76	23	30%
Teen Clinic	1048	83847	0	0	0%	668	401	60%

Flexible User Interface Design

Awardees may also be interested in looking at alternative coverage measurements such as a 3:3:2:2 series (3 DTaP, 3 IPV, 2 Hib, and 2 HepB) at 12 months of age as early indicators for 24-month coverage, or assessing 4-6 year old compliance with school requirements. Assessing these alternative measurements can be accomplished if the IIS user interface is developed in such a way to support this additional flexibility. The Phase I Design Specification included recommendations for how this could be accommodated. In order to accomplish this flexibility, IIS should consider the following design implementations and apply the evaluation algorithms for ACIP and CDSi as described in the Phase I Technical Guidance.

Defining age cohort

The assessment age cohort is determined by the criteria defined by two primary data parameters: I) Assessment Age Range and 2) As of Date.

The "Assessment Age Range" can be defined in months (e.g., 24-25 months) or years (e.g., 13-17 years). This parameter directly defines the cohort to be included in the assessment based on a calculated birthdate range. Only one age range option (months or years) may be selected at a time. The calculated birthdate range is impacted by the "As of Date."

The "As of Date" should typically default to "today's date"; however, this field can be edited to reflect an alternative date in the past. The birthdate range for the assessment cohort should be calculated based on the age of the cohort 'as of' the specified date. For example, a Childhood Assessment (24-35 months) with an "As of Date" of 12/31/2013 would identify a cohort with a birthdate range between 1/1/2011 to 12/31/2011. The "As of Date" adds additional conditions to the Assessment Age Range parameters described above. When an "As of Date" is specified, the IIS must be able to calculate the birthdate range 'as of' that date in order to determine the assessment cohort. Individuals that have come of age after the "As of Date" would be excluded from the assessment cohort.

By using the Assessment Age Range and As of Date parameters, AFIX users can conduct assessments on a variety of defined cohorts (e.g., 12-23 months or 11-13 years), using logic similar to that presented in **Standard Business Rules IA-IE** in Appendix B. <u>Standard Business Rules and Decision Table</u>. Please note, however, that only official AFIX Coverage Assessments run with the applied Operational and Technical guidance provided in the Phase I Guidance will be reportable to the AFIX Online Tool and will serve as official coverage assessment results.

Defining vaccinations/dose numbers to assess

The assessed measurements are defined by two primary report component parameters: I) Compliance by Age/Date and 2) Series/Antigen Selection. By using the Compliance by Age/Date and Series/Antigen Selection data parameters, AFIX users can conduct assessments on a variety of vaccine benchmark measurements.

The "Compliance By" data parameter can be defined by either Age (e.g., 24 months) or Date (e.g., "today's date"). This parameter directly impacts the evaluation of series/antigen completion rates. Any vaccinations received after the "Compliance by Age/Date" are not counted towards completion but may factor into "Late UTD" (i.e., become UTD by Date of Assessment).

"Series/Antigen Selection" allows a user to determine which vaccines to assess and the number of doses to measure. Phase I Guidance provided details on assessed measures for the Standard Childhood and Standard Adolescent coverage assessments reported to the AFIX Online Tool. AFIX users, however, may be interested in

Flexible User Interface Design

assessing other measurements or a subset of the standard measurements. The Series/Antigen Selection parameter(s) offer users the flexibility to define a custom set of measurements based on any specified number of doses for the routine ACIP vaccines a user may be interested in assessing. These defined fields dictate the number of doses and vaccines that will be assessed to determine compliance with the various measurements. When the report component calculations are performed, individuals with fewer doses than specified would be considered incomplete or Not UTD (except where "UTD" logic is applied as detailed in Standard Business Rules 5D and 5E). Number UTD becomes the numerator for the assessed coverage measures.

Sample Flexible User Interface

Figure 12. Sample of flexible user interface design (from Arizona IIS)

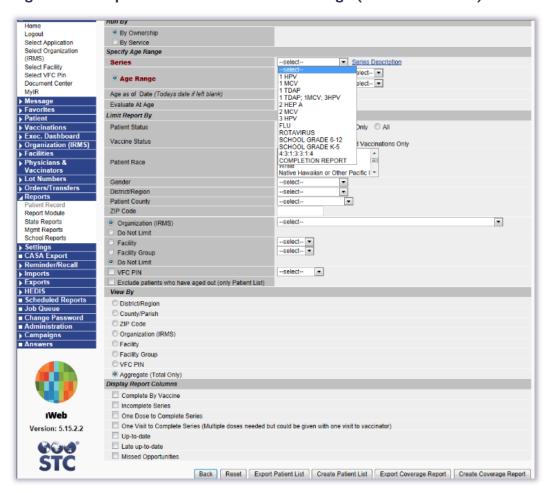


Figure 13. Sample of a flexible user interface design (from Envision Technology Partners)

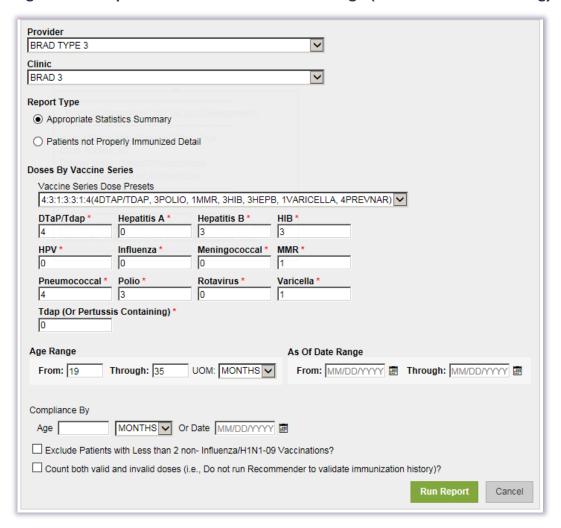
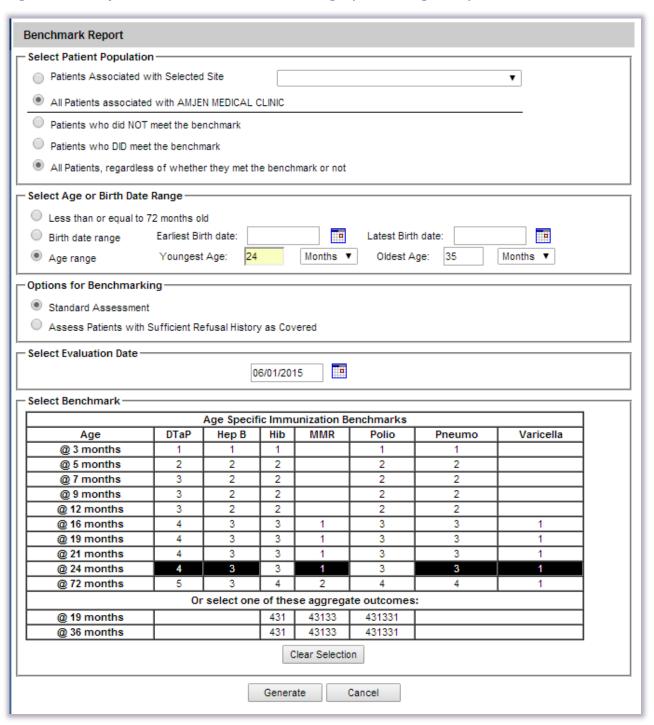


Figure 14. Sample of flexible user interface design (from Oregon IIS)19



¹⁹ Note: User can select the specific age and antigen for assessment as indicated by the dark shaded cells in the chart.

Guidance on Report Component Display

How information is formatted and displayed is often as important as the data itself. This document has focused on common report components used during AFIX provider feedback sessions. In addition to determining what data to share with providers, the report components themselves need to be formatted in a way that is easy for providers to understand and ultimately act upon by implementing strategies to increase coverage rates among their patient populations. This section provides suggested guidance for AFIX and IIS on how report components can be designed to have a user friendly and easily readable display.

The purpose of the report component will ultimately guide the decision on how best to display the data so that it is clear and concise - often "less is more." AFIX report components generated by the IIS should address a specific question or workflow and should not be over-complicated. Using appropriately applied filters/parameters, report components should contain only the most important data elements needed to address the report component objectives. Depending on the nature of the report component, AFIX-IIS partners may opt to present the data as a list, table, diagram, or graph. Regardless of the report component purpose and format selected for data presentation, a few common principles should be considered:

- <u>Accessibility</u>: Content that is viewed online should be accessible to people with disabilities. Guidelines for
 design of online documents, including use of PDF, Word, and Excel, can be viewed at
 http://www.hhs.gov/web/508/accessiblefiles/index.html
- **Headings**: It is useful to label the report with an appropriate title, state the cohort/selection criteria, and clearly define inputs such as date ranges, assessment date, compliance dates, and vaccine series evaluation.
- White Space: Report components with a lot of white space will draw the reader's eye to the important elements of the report component (this is a trick commonly used in advertising). If there is too much data to display on a single page, consider having multiple pages or, if needed, breaking the various elements of the report component into a series of individual report components. Too much text or too many visual elements on a report component may make the report component appear cluttered and cause the reader to lose interest.
- <u>Font</u>: For font type and size, consider maximum readability. Arial (san serif fonts) and Times New Roman (serif fonts) are ideal for printed materials. Verdana (san serif fonts) and Georgia (serif fonts) have been recognized as optimal for computer screen display. Font size is preferred at 14-point but should be no smaller than 10-point since it can be unreadable to the majority of users.
- <u>Line Spacing</u>: If data will be displayed contextually in a paragraph or sentence format, allow for adequate line spacing. A spacing of 1.5 or double-spaced is preferable to single spacing.
- <u>Page Numbers</u>: If the report component will span multiple pages, a page number should be included at the bottom or top of each page. Page numbers should be displayed as a number of the total pages (e.g., Page X of N).
- <u>Displaying Percentages</u>: If the data will include calculations of a percentage, the calculated value should be displayed as both a number and percentage. The denominator for the calculations should also be displayed in the report component header and/or data display (if variable).
- <u>Tables</u>: If the output will span multiple pages, a table may not be the best format. If a multi-page table cannot be avoided, however, pagination should be considered along with basic table properties. For pagination, consider where the page should break should hard page breaks or soft breaks be implemented to allow data to flow properly. Column headers should always be repeated at the top of additional pages to allow readers to more easily follow along with the data.

Guidance on Report Component Display

- **Graphs/Diagrams**: Sometimes graphical display is a preferable format for communicating information versus text or narrative. This is especially valuable for illustrating comparisons, trends over time or the flow of data. If the report component will utilize graphical or visualized data displays, it is wise to avoid color distinctions since not everyone has access to color printing. A good alternative is to use shading patterns to best illustrate the differences in data.
- <u>File Format</u>: If the dataset is large, consider using other report component output formats besides PDF (e.g., XML, CSV, and Excel). This will allow the user to either aggregate the data themselves or allow for the use of secondary analysis software (e.g., SAS).
- <u>Statement of report limitations</u>: Because there are different methodologies to create reports, it is highly recommended that report outputs include an explanation of limitations to the results. This could be in the form of a footnote or addendum to the report.

Trend and Comparative Analysis

AFIX staff often like to illustrate for a provider how their rates compare to common standardized measurements, how they compare to other providers within their jurisdiction, and/or how the provider has performed over time. Competition and goal setting are often powerful incentives. Some common examples of comparative analysis and trending include a comparison of the provider's assessed rates to the following assessments:

- State immunization rates^{20,21}
- Healthy People 2020 coverage targets
- Other providers within the same geographic jurisdiction (e.g., city, county or district) may be accomplished by comparing to specific providers of the same size/practice type or as an aggregation of all providers within the specified area possibly through the Master Rate Comparison report component
- The provider's own rates over a specified time period may be quarterly over the course of a year, or annually over a span of 2 or more years

At minimum, IIS should consider supporting a variety of capabilities for AFIX staff and providers to be able to make rate comparisons, retrieve data needed to compare results over time (trend analysis), and/or make data exportable so that users can leverage their own analysis tools if needed). Compiling data may be accomplished by leveraging the Flexible User Interface Design suggestions described previously in this document or by accessing data stored in the DataMart or data warehouse of capable IIS.

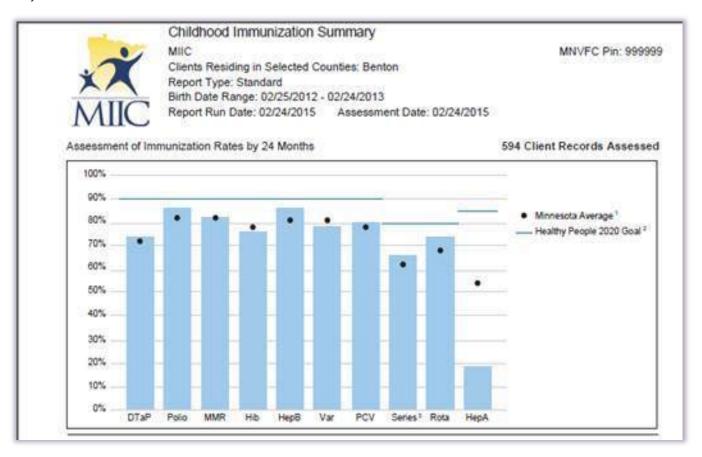
When displaying a comparative analysis or trend over time, a graph or chart is the optimal format. Limiting the number of comparisons to two or three may make the visual easier to interpret. The following figure provides an example of comparison and trend analysis produced by IIS.

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²⁰ State immunization rates can be calculated by various methods. If comparing one state to another, be sure the methodologies used are the same and comparable. Also note, a state rate is a geographical rate and uses different methodology than provider-based coverage assessments.

²¹ Comparing AFIX assessment measures and IIS-based data results to the National Immunization Survey (NIS) is problematic. NIS is NOT a comparable measure due to numerous differences in the methodology: cohort selection, compliance milestones, validity of assessed vaccinations and calculations applied to determine coverage. For additional information, refer to AFIX-IIS Integration: Operational and Technical Guidance for Implementing IIS-Based Coverage Assessment-Phase I, p. 74.

Figure 15. IZ rate compared to state average and Healthy People 2020 Goal (from Minnesota IIS)²²



- I. Minnesota average is based on MIIC records of children 24 through 35 months up-to-date by 24 months as of July 2014.
- 2. Healthy People 2020 is a set of science-based public health goals established by the U.S. Department of Health and Human Services.

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²² Note: Could be adapted to display provider rate instead of or in addition to region/county rate.

Appendices

Appendix A. Glossary and Acronyms

Definitions

- 4:3:1:3:3:1:4 Primary vaccination series for children, typically completed between 15 and 19 months of age. Series is comprised of 4 DTaP, 3 Polio, I MMR, 3 HIB, 3 Hep B, I VAR, and 4 PCV. For AFIX coverage assessment purposes, UTD logic will be applied to the component measurements for Hib, Hep B, and PCV where a variable number of doses can be applied to achieve protection based on date of first dose and/or vaccine product licensure nuances.
- **AFIX** AFIX (Assessment, Feedback, Incentives, and eXchange) is a continuous quality improvement process informed by research and used for improving immunization rates and practices at the immunization provider level. AFIX is a quality improvement program used by CDC awardees to raise immunization coverage levels, reduce missed opportunities to vaccinate, and improve standards of practices at the provider level.
- As of Date The "As of Date" adds additional conditions to the Assessment Age Range parameters. When an "As of Date" is specified, the IIS must be able to calculate the birthdate range "as of" that date in order to determine the assessment cohort. Individuals that have come of age after the "As of Date" must be excluded from the assessment cohort. Typically defaults to "today's date."
- Assessment Date (see also Run Date) This field is informational and reflects the date the report is run (e.g., "today's date"). It may also be used for determining Late Up To Date status for patients who were not Up To Date as of the Compliance by Age/Date.
- **Birthdate Range** Birthdate range automatically calculated by the IIS based on the criteria defined for Ages Assessed and As of Date.
- Clinical Decision Support for Immunization (CDSi): The logic, based on ACIP guidelines, applied for evaluating a single vaccine dose administered against a defined target dose to determine if the vaccine dose administered is valid or not valid for that specific target dose. Also includes the logic applied for determining past due status for vaccine doses and forecasting of dates for the next vaccine dose(s) to be administered. Forecast is based on a patient's immunization history, age, gender, and contraindications/precautions. See latest version of Logic Specification for ACIP Recommendations.
- **Cohort** Part of the population (individuals) within a Jurisdiction or assigned to a Provider Organization/Facility.
- Compliance by Age/Date (see also Evaluate at Age/Date) May also be labeled as "Evaluate at Age/Date." This field establishes the age or date at which vaccination compliance is assessed and directly impacts the evaluation of series/antigen completion rates. Compliance by Age is most appropriate for a Childhood Assessment (e.g., 24 months/2nd birthday), whereas Compliance by Date is most appropriate for an Adolescent Assessment (e.g., "today's date"). Any vaccinations received after the "Compliance by Age/Date" are not counted towards completion but may factor in to "Late Up To Date (UTD)."

- **Contraindication/Precaution** A patient medical condition that precludes a patient from receiving one or more vaccinations that may increase the chance of a serious adverse event.
- Evaluate at Age/Date An alternative labeling option for "Compliance by Age/Date."
- **Evaluation Algorithm** (see also Forecasting Algorithm) The logic applied for evaluating a single vaccine dose administered against a defined target dose to determine if the vaccine dose administered is **valid** or **not valid** for that specific target dose (and also may determine extraneous and substandard doses).
- **Exemption** Non-medical reasons, such as religious, personal, philosophical, that exclude a patient from vaccinations.
- **Facility, Site, Clinic, Organization** A sub-level designation of a Parent Organization/Reporting Entity. In most IIS, this level is where the VFC Pin is defined and is synonymous with "VFC Provider."
- **Feedback Date** This is the date that the feedback session has been scheduled with the provider and should occur within 7 days following the "Assessment Date."
- Forecasting Algorithm (see also Evaluation Algorithm) The logic applied for determining dates for the next vaccine dose(s) to be administered to a patient. Forecast is based on a patient's immunization history, age, gender, and contraindications/precautions. Logic is based on ACIP guidelines and the parameters defined in CDSi.
- **IIS Identifier (IIS ID**) Provider identifier uniquely assigned by the IIS. May also be called Facility/Site ID. Assigned to any Provider entity that has been defined in the IIS.
- **Late Up-to-Date** Patient was not UTD for assessed measures at the "Compliance by Age/Date," but became UTD by the "Assessment Date."
- Missed Opportunity This assessment will focus on the Last Immunization Visit. During the patient's last visit, he/she received at least one vaccination and one or more other vaccines were due but not administered. The non-administered vaccines are considered Missed Opportunities.
- **Patient Active/Inactive Status (PAIS)** A patient status indicator in the IIS. For AFIX purposes, identifies whether the patient is active or inactive with a provider and/or within a jurisdictional area.
- **Provider** (specifically VFC Provider) For the purposes of IIS-based coverage assessments, a VFC provider can be identified as having the following attributes:
 - Has a unique VFC Pin Number
 - Has a physical address where vaccinations are provided
 - Houses vaccine inventory
 - Employs one or more clinicians
 - Provides immunization services to patients and reports that data to the IIS
 - Is uniquely identified in the IIS (IIS identifier)

Appendices

Report Component – one or more elements that can be used to measure a defined outcome or metric.

Run Date - An alternative labeling option for "Assessment Date."

- **Target Dose** A target dose is a patient-specific dose required to satisfy the recommendations of ACIP. Until a target dose is satisfied, the patient is not allowed to move to the next target dose in the patient series. The patient remains on the "unsatisfied" target dose until the patient has a "valid" vaccine dose administered that satisfies the target dose.
- **Up-to-Date (UTD) -** Patient has received the number of valid doses specified in the AFIX assessment measurement or received an appropriate number of valid doses to meet the "UTD" criteria for selected measures.
- **User** An individual with authorized access to the IIS. User level and access permissions are managed directly through the IIS.
- **Valid Vaccination** Applying ACIP guidelines to the administration of vaccine in accordance with recommended schedules, minimum age, minimum intervals, maximum age, brand licensure, etc. Also includes factors such as proper vaccine storage and expiration dates (non-compromised). A valid evaluation status means the vaccine dose administered was administered according to ACIP recommendations.
- **VFC Pin** Provider identifier for the VFC program assigned and maintained by the CDC awardee. Every VFC Provider is assigned a VFC Pin. VFC Pin is used for vaccine ordering and accountability for all vaccine issued and administered as part of the VFC Program.

Acronyms

Table 7. Table of Acronyms

ACIP	Advisory Committee on Immunization Practices
AFIX	Assessment, Feedback, Incentives, and eXchange
AFIXAR	AFIX Annual Report
AIM	Association of Immunization Managers
AIRA	American Immunization Registry Association
CDC	Centers for Disease Control and Prevention
CDSi	Clinical Decision Support for Immunization
CoCASA	Comprehensive Clinic Assessment Software Application
IIS	Immunization Information System
IIS ID	IIS Identifier
IISSB	IIS Support Branch
MIROW	Modeling of Immunization Registry Operations Workgroup
MOGE	Moved or Gone Elsewhere
NCIRD	National Center of Immunization and Respiratory Diseases
NIS	National Immunization Survey
PAIS	Patient Active Inactive Status
POB	Program Operations Branch
SME	Subject Matter Expert
UI	User Interface
UTD	Up to Date
VFC	Vaccines for Children

Vaccine Abbreviations

Table 8. Table of Vaccination Abbreviations

DTaP	Diphtheria, tetanus, & acellular pertussis
Flu	Influenza
Нер А	Hepatitis A
Нер В	Hepatitis B
HIB	Haemophilus influenzae type b
HPV	Human papillomavirus
IPV	Inactivated poliovirus
MCV	Meningococcal
MMR	Measles, mumps, rubella
PCV	Pneumococcal
RV	Rotavirus
Td	Tetanus, diphtheria
Tdap	Tetanus, diphtheria, & acellular pertussis
VAR	Varicella

Appendix B. Standard Business Rules and Decision Table

Many of the feedback options described in this document start with the same five sets of Business Rules:

- I. Defining the Birth Cohort
- 2. Patient Relationship with Provider
- 3. Selecting Vaccinations for Assessment
- 4. Determining Dose Validity
- 5. Determining Antigen Series Status

Three additional sets of Business Rules apply to certain report components:

- I. Coverage Assessment Calculations
- 2. Determining Missed Opportunities
- 3. Missed Opportunities Calculations

One decision table applies to many of the report components: <u>Coverage Assessment Numerator</u> <u>Determination</u>. These Business Rules and Decision Table, with details listed below, have been copied directly from the **Phase I Guidance** for the required AFIX reports. They are listed below, and can be found with additional narrative in the Phase I CDC Technical Guidance section, pp 36-51.

Standard Table 2. Standard Business Rules from Phase I

Business Rules Notes		Notes
Defining the Birth Cohort		
IA	The start date of the birth cohort range for 24-35 month olds is determined by subtracting 36 months from the as of date and advancing one day.	Example: As of Date = 12/31/2014 Subtract 36 months = 12/31/2011 Advance I day = 1/1/2012
IB	The end date of the birth cohort range for 24-35 month olds is determined by subtracting 24 months from the as of date.	Example: As of Date = 12/31/2014 Subtract 24 months = 12/31/2012
IC	The start date of the birth cohort range for 13-17 year olds is determined by subtracting 18 years from the as of date and advancing one day.	Example: As of Date = 12/31/2014 Subtract 18 years = 12/31/1996 Advance I day = 1/1/1997
ID	The end date of the birth cohort range for 13-17 year olds is determined by subtracting 13 years from the as of date.	Example: As of Date = 12/31/2014 Subtract 13 years = 12/31/2001
IE	The birth cohort start and end dates are inclusive.	Example: The birth cohort for 24-35 month olds as of 12/31/2014 includes children born on 1/1/2012 through children born on 12/31/2012. The birth cohort for 13-17 year olds as of 12/31/2014 includes children born on 1/1/1997 through children born on 12/31/2001.

	Business Rules	Notes		
Patie	nt Relationship with Provider			
2A	IIS will apply their existing logic/rules of patient association (e.g., 1:1 or 1: many) with provider organizations to determine whether the patient has a relationship with the provider.	The nature of this relationship is further clarified by the Patient Active/Inactive Status (PAIS) Indicator as described in 2.B below.		
2B	The assessment cohort should include only patients with an "Active" status with the provider being assessed as indicated by the Patient Active/Inactive Status (PAIS) Indicator. Patients with a status of "Inactive" or "Deceased" should be automatically excluded from the cohort. Patients who have opted out of the IIS should also be excluded from the assessment cohort unless otherwise supported by IIS implementation and/or jurisdictional law/policy.	For more information on patient status, see MIROW Best Practice Guidelines, Patient Active/Inactive Status — 2015.		
Selec	cting Vaccination for Assessment			
3A	The IIS must include support for all active and inactive CVX codes for the vaccine families assessed by AFIX (individual and as part of a combination vaccine).	CVX Mapping Reference: http://www2a.cdc.gov/vaccines/iis/iisstandards/vaccines.asp?rpt=cvx See also CDSi supporting data tables for CVX to antigen mapping found on the CDSi website (Supporting Data Version 2.0): http://www.cdc.gov/vaccines/programs/iis/interop-proj/cds.html For example, when assessing rotavirus vaccination coverage or missed opportunities, the IIS should include all currently active CVX codes (e.g., Rotateq CVX = 116; Rotarix CVX = 119) and inactive CVX codes (e.g., Rotashield CVX = 74; Rotavirus, unspecified formulation CVX = 122).		

	Business Rules	Notes
Dete	ermining Dose Validity	
4A	The IIS must assess the validity of each vaccination administered to a child/adolescent included in an AFIX assessment.	Validity is determined by factors such as: • Minimum Age • Minimum Intervals and Catch Up Schedules • Maximum Age • 4-Day Grace Period • Special Licensure Allowances/Brand Specific Variations • Gender • Vaccine Interrelationships • Historical Recommendations and Licensure • Foreign/International Vaccine Accommodations • History of Disease/Titers • Etc. For IIS with compromised dose functionality, validity may also be determined by factors such as: • Storage and handling incidents • Manufacturer recalls • Inappropriate site/route administration • Etc.
4B	The IIS must assess the validity of each individual component contained in multiple antigen vaccines separately.	 For the purposes of AFIX, this applies to: Combination vaccinations (e.g., DTaP/HepB/IPV, HepB/Hib, MMRV) Multiple antigen vaccine families (e.g., DTaP and MMR) More information about combination and multiple antigen vaccines is provided below. Supporting data tables for CVX to antigen mapping can be found on the CDSi website (Supporting Data Version 2.0): http://www.cdc.gov/vaccines/programs/iis/interop-proj/cds.html A full listing of all CVX codes can be found at: http://www2a.cdc.gov/vaccines/iis/iisstandards/vaccines.asp?rpt=cvx
4C	The IIS must ensure that its evaluation (i.e., dose validity) algorithms provide results consistent with ACIP recommendations.	IIS can use the CDSi Test Cases to confirm dose validity determinations made by their evaluation/forecasting algorithms: (http://www.cdc.gov/vaccines/programs/iis/interop-proj/cds.html)
Dete	ermining Antigen Series Status	
5A	For children 24-35 months of age included in AFIX assessments, vaccinations administered on or before the child's 24-month birthday should be included in the assessment.	

	Business Rules	Notes
5B	For adolescents 13-17 years of age included in AFIX assessments, vaccinations administered on or before the "Compliance by" date should be included in the assessment.	The "Compliance by" date used for adolescent coverage assessments will typically reflect the same date as the "As of" date, which may be "today's date" or a specified point in time (e.g., I/I/2014).
5C	For both the childhood and adolescent cohorts, vaccination assessments must be based on valid doses only as defined by ACIP recommendations (and compromised dose flagging where enabled by the IIS).	See Standard Business Rule "Determining Dose Validity" for more information on valid dose determinations.
5D	For the following vaccine groups, the IIS must determine if the child achieved the specified AFIX measurement on or before age 24 months based on the following criteria: • 4 DTaP • 3 Polio • I MMR • UTD HIB • UTD Hep B • I VAR • UTD PCV • UTD RV • I Flu (note: previously completed flu season) • 2 Hep A • 4:3:1:3:3:1:4 Series	For the purposes of this project, the term "UTD," in the list of measurements at left, 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 licensure nuances. This determination is applied in accordance with the ACIP routine and/or catch-up schedules for children aged 24 months. Where noted, use of "UTD" applies to both the individual vaccines and their measurement in the 4:3:1:3:3:1:4 series. In general, if a child started the series on time and stayed on time, the benchmark measurement would include 3-4 doses of Hib (depending on which vaccine product was used), 4 doses of PCV, and 2-3 RV (depending on which vaccine product was used and when the series was started and completed). Awardees needing additional information on how to apply these alternative criteria are encouraged to refer to the resources available through CDSi (http://www.cdc.gov/vaccines/programs/iis/interop-proj/cds.html) and Phase I, Appendix G. All patients who have achieved compliance with the specified AFIX
5E	For the following vaccine groups, the IIS must determine if the adolescent achieved the specified AFIX measurement on the date of the assessment (or "Compliance by Date") for the following criteria: • UTD Hep B • 2 MMR • 2 VAR • I Tdap	measurements will be counted in the AFIX coverage report numerators. For the purposes of this project, the term "UTD," in the list of measurements at left, is used in reference to vaccine measurements where a variable number of doses can be applied to achieve protection depending on patient age and/or vaccine licensure nuances. This determination will be applied in accordance with the ACIP routine and/or catch-up schedules based on the age and vaccination status of the adolescent at the time of assessment. Awardees needing additional information on how to apply these alternative criteria are encouraged to refer to the resources available through CDSi

	Business Rules	Notes
	 UTD Meningococcal 3 HPV 2 HPV I HPV I Flu (note: previously completed flu season) 2 Hep A UTD Polio 	(http://www.cdc.gov/vaccines/programs/iis/interop-proj/cds.html) and Phase I, Appendix G. All patients that have achieved compliance with the specified AFIX measurements on or before the "Compliance by Date," will be counted in the AFIX coverage report numerators.
5F	HPV calculations for the various dose measurements should be inclusive. • I HPV (include all adolescents with I+ valid doses) • 2 HPV (include all adolescents with 2+ valid doses) • 3 HPV (include only adolescents with 3 valid doses)	Include all adolescents (female, male, unknown and unspecified). Product type used for vaccination must comply with licensure as it relates to the approved use by sex/gender. See CDSi supporting data for clarification: http://www.cdc.gov/vaccines/programs/iis/interop-proj/cds.html
5G	 Influenza calculations must be based on the most recently completed flu season (not a flu season in progress) regardless of whether an "As of Date" or "Compliance by Age/Date" is defined. A flu season is defined as July I through June 30. Vaccination completion will be defined as "at least I valid dose of influenza vaccine for the prior completed season." 	Example: if the assessment occurs between January and June 2014, the assessment would include the 2012-2013 season whereas, if the assessment occurs between July and December 2014, the assessment would include the 2013-2014 season.
5H	For the following vaccine groups, the IIS must be able to collect and store evidence of immunity: • Hep A • Hep B • Varicella • MMR (immunity must be present for all 3 components to count: Measles, Mumps and Rubella) • Evidence of immunity will be counted as complete/up-to-date for the measured series.	See Immunity Supporting Data Table — CDSi (http://www.cdc.gov/vaccines/programs/iis/interop-proj/cds.html) for more information. Note: Rules for evidence of immunity may vary by the different vaccine groups/families. Some may require lab evidence or confirmation of disease, whereas others may simple require provider verification of history of disease. Awardees should refer to their jurisdictional laws/policies regarding this issue and apply ACIP/CDSi recommendations as appropriate.

	Business Rules	Notes
51	Vaccinations that have a recorded contraindication/precaution (medical exemption) in the IIS will be counted as incomplete/not up to date for the measured series.	References to contraindications/precautions refer strictly to those specified in Table 6 of the ACIP General Recommendations (additional reasons supported by the IIS should not be recognized): http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6002a1.htm#Tab6 See also CDSi Supporting Data Table for Contraindications: http://www.cdc.gov/vaccines/programs/iis/interop-proj/cds.html Note: CDSi will be addressing precautions in a future phase.
Cov	erage Assessment Calculations	
6A	Coverage for each vaccine assessed is calculated by dividing the total number of patients identified for inclusion in the numerator per Decision Table I by the total number of children in the denominator (see Selecting the Assessment Cohorts) and multiplying by 100.	Example: Cohort Defined – 180 active patients (denominator) Assessment Measure – 4 DTaP Number with 4 valid doses of DTaP – 144 (numerator) Equation: 144/180*100 = 80% Percentage Complete – 80%
Det	ermining Missed Opportunities	
7A	The patient's last immunization visit date is the date at which the most recent vaccination event is recorded on or before the Compliance by Age/Date regardless of the vaccine type that was administered or whether the vaccine administration was valid or invalid.	Standard Example: Vaccinations were administered on 01/01/2010, 03/01/2010, and 05/01/2010. The patient's last immunization visit date is 05/01/2010. Additional Examples: Invalid Vaccination: The patient received a single dose of HPV on the last immunization visit. That dose was determined to be invalid; however, the patient was also due for one or more routine vaccinations (e.g., a 2 nd dose of MMR) on the date of that visit. As a result, the patient would be counted for a Missed Opportunity for the other vaccinations due but not received at the time the invalid HPV was administered (e.g., Missed Opportunity for MMR). Vaccine Type: The patient received a yellow fever vaccination and was due for a MMR vaccination but did not receive it. This would be counted as a missed opportunity for any of the AFIX vaccines due but not received.
7B	A vaccination that was due at the time of the last immunization visit includes any of the AFIX measurements where the patient had a vaccine forecast and the recommended date for the vaccination being assessed is on/before patient's last immunization visit date (i.e., eligible to receive dose).	 Scenario A: Child's DOB is 01/01/2014 DTaP I (valid dose) at 2 months (administered on 03/01/2014) DTaP 2 (valid dose) at 4 months (administered on 05/01/2014) DTaP 3 (valid dose) at 6 months (administered on 07/01/2014) Last immunization visit at 15 months (on 04/01/2015) Received MMR and Varicella on 04/01/2015 but did not receive 4th DTaP

	Business Rules	Notes
		 Determination: Missed opportunity for DTaP because recommended date for 4th DTaP is 04/01/2015 (on or before the last immunization visit date)
		 Scenario B: Child's DOB is 01/01/2014 DTaP I (valid dose) at 2 months (administered on 03/01/2014) DTaP 2 (valid dose) at 4 months (administered on 05/01/2014) DTaP 3 (valid dose) at 6 months (administered on 07/01/2014) Last immunization visit at 12 months (on 01/01/2015) Received MMT and Varicella on 01/01/2014 but did not receive 4th DTaP Determination: No missed opportunity for DTaP because recommended date for 4th DTaP is 04/01/2015 (after the last immunization visit date) NOTE: It is important to note that the use of "recommended date" in the definition and calculation of a missed opportunity is a change from the methods used by
		missed opportunity is a change from the methods used by CoCASA, which uses "minimum age" in the calculation. This change is highlighted in the example cases above. In CoCASA, a child who had an immunization visit at 12 months of age where the 4th DTaP was not administered would be included in the missed opportunity calculation because the child had met the minimum age requirement for the 4th DTaP, according to ACIP. However, this scenario will not be counted as a missed opportunity in these new requirements. Missed opportunities will only be counted if the child has met the "recommended date" for vaccination, not the "minimum age" or "minimum date."
7C	An "incorrect vaccine administration" at the time of the last immunization visit should be counted as a missed opportunity.	An "incorrect vaccine administration" is a vaccination that was determined to be not valid due to incorrect product use when the administration of a different product would have resulted in a valid dose. Examples: Tdap given as a dose in the primary DTaP series. Td instead of Tdap without a medical contraindication/precaution.
Miss	ed Opportunities Calculations	
8A	Missed opportunities for each vaccine assessed is calculated by dividing the total number of patients identified for inclusion in the numerator per Decision Table 2 (Phase I, p 50) by the total number of children in the denominator (see Selecting the Assessment Cohort, Phase I, p 35) and multiplying by 100.	Example: Cohort Defined – 180 active patients (denominator) Assessment Measure – 4 DTaP Number with 4 valid doses of DTaP – 144 Number Incomplete/Not UTD – 36 Number with Missed Opportunities at last visit – 9 (numerator) Equation: 9/180*100 = 5% Percentage Missed Opportunities – 5%

Standard Table 3. Standard Decision Table from Phase I for Determining Coverage Assessment Numerator

Coverage Assessment Numerator Determination		Numerator	
	Condition	Include	Exclude
1.	Patient has received the number of valid doses specified in the AFIX assessment measurement or received an appropriate number of valid doses to meet the "UTD" criteria for selected measures.	X	
2.	Patient has not received an appropriate number of doses to meet the AFIX assessment measurement requirements.		X
3.	Patient has evidence of immunity for the specified vaccine (where allowed).	X	
4.	Patient has aged out for the specified assessment measure and did not receive the appropriate number of valid doses to be considered complete before maximum age was reached.		X
5.	Patient has a contraindication/precaution (medical exemption) for the specified vaccine.		X
6.	Patient has a religious or personal exemption noted for the specified vaccine.		X
7.	Patient has no recorded vaccinations.		X

Appendix C. Phase II Polling and Prioritized Report Components

Poll Summary

The following list represents the grantees involved in the AFIX-IIS Project Status Conference Call. Each grantee answered at <u>least one</u> of the following poll questions but not necessarily all of them.

Grantees (41):

Alaska	Maryland	Oregon
Alabama	Michigan	Pennsylvania
Arkansas	Minnesota	Philadelphia
Arizona	Mississippi	Rhode Island
California	Montana	San Antonio
Colorado	North Carolina	South Carolina
Connecticut	North Dakota	South Dakota
Iowa	Nebraska	Tennessee
Idaho	New Hampshire	Texas
Illinois	New Mexico	Utah
Indiana	Nevada	Virginia
Kansas	New York	Vermont
Kentucky	New York City	Washington
Maine	Ohio	_

I. Are you currently using CoCASA to prepare some or all of reports used to support AFIX coverage assessments and provider feedback?

YES = 30/37 (81%) No = 7/37 (19%)

2. Which reports in CoCASA are you using on a routine basis?

Note: Respondents = 33

Report	Total	Percentage
Missing Immunizations (recall list)	27	82%
Invalid Doses (patient and reason list)	27	82%
Diagnostic Report Childhood (% complete + additional eval)	24	73%
HPV report	21	64%
Missed Opportunities (patient and reason list)	19	58%
Adolescent Coverage (% complete + UTD dose spread)	19	58%
Single Antigen Report (dose by age)	18	55%
AFIX Site Visit Summary (for adolescents)	16	48%
Summary Report - Flow Chart	15	45%
Summary Report - Late UTD	14	42%
Not UTD (patient list)	14	42%
Summary Report - Pie Chart	13	39%
Summary Report - Last visit >12 months	П	33%
Summary Report - Need One Visit (table)	8	24%
Need One Dose (patient list)	4	12%

3. What other reports in CoCASA are you using on a routine basis?

- Adolescent Coverage
- Adolescent coverage by assessment date and also by age
- Childhood summary, graph of UTD, LUTD, and total UTD
- NOTES Report. Allows for personalized information entered by the site visit reviewer.
- Sometimes Reviewers use Not UTD patient list, Summary Report Late UTD
- Summary Report, page I
- Summary Rpt-< 12 months list
- We leave lists of adolescent clients who are NUTD with providers and this has been very helpful. We plan to begin leaving NUTD client lists for young children—not only for two-year-old clients upon which the coverage reports are based, but for younger 12-23 or 18-23-month-olds as well.

4. What of the following report attributes do you consider to be the most critical to the AFIX provider process?

Note: Respondents = 36

Report Attribute	Total	Percentage
Coverage assessments for children (# and % of patients UTD for selected measures)	36	100%
Coverage assessments for adolescents (# and % of patients UTD for selected measures)	32	89%
Not UTD/Missing Immunizations (patient list plus missing vaccinations list)	27	75%
Missed opportunities calculation (# and % for selected measures)	24	67%
Not UTD/Invalid Doses (patient and vaccination reason list)	23	64%
Missed opportunities reason (patient and reason list)	21	58%
Not UTD (patient list)	20	56%
Rate comparison of provider to other measures (e.g., state rates, regional/county rates, NIS rates, HP2020 objectives)	20	56%
Not UTD (# and % for selected measures)	14	39%
Rate comparison of provider to self over time	14	39%
Full Patient Listing (practice level listing of all active patients in defined assessment cohort)	14	39%
Not UTD/Invalid Doses (# and %)	12	33%
Exemptions and contraindications (patient and reason list)	10	28%
Dose by Age Breakdown (# and % for each measure broken down by dose number and age)	10	28%
Rate comparison of provider to other providers in jurisdiction (e.g., comparison by size of provider or provider type)	10	28%
Late UTD (patient and reason list)	9	25%
Ability to run reports based on various levels of organizational hierarchy (e.g., individual providers, entire HMO)	8	22%

Report Attribute	Total	Percentage
Not UTD/Visit History - <12 months or >12 months since last immunization visit (patient list)	7	19%
Not UTD/Needs One Visit (# and %)	6	17%
Late UTD (# and %)	6	17%
History of disease/blood titer (patient and reason list)	6	17%
Rate comparison of provider to HEDIS score	6	17%
Not UTD/Needs One Visit (patient and vaccination list)	5	14%
Not UTD/Needs One Dose (patient and vaccination list)	5	14%
Rate comparison of provider to other providers in jurisdiction (line listing)	5	14%
Not UTD/Visit History - <12 months or >12 months since last immunization visit (# and %)	3	8%
Not UTD – Influenza, current flu season (patient list)	I	3%
Not UTD/Needs One Dose (# and %)	I	3%

5. Which other report attributes do you consider to be the most critical to the AFIX provider feedback process?

- Patient list with addresses (to be used for identifying patients that may have moved or gone elsewhere).
- Trends found in practice ex; tends to vaccinate 12 month MMR too early therefore invalid

6. Rate the following attributes on how important they are (or would be) to AFIX reports generated using an Immunization Information System: (5 being very important; I not important).

Note: Respondents = 36

Attributes	Average	5	4	3	2	1	No Answer
All reports/data should be exportable	4.8	32	2	I	0	I	0
Ability to run reports based on various levels of organizational hierarchy (e.g., individual providers, entire HMO, by jurisdiction – zip code, city, county, district/region, statewide)	4.1	17	9	8	I	I	0
Ability to account for changes in ACIP schedules over time to ensure patients are evaluated according to the schedule they were vaccinated under	4.1	23	6	2	ı	0	4
Ability to evaluate other vaccine coverage measurements at various age mile markers (e.g., 3:3:2:2 by 12 months)	4.0	17	8	7	3	I	0
Ability to view trend data from year to year	4.0	16	14	3	0	0	3

Attributes	Average	5	4	3	2	1	No Answer
Flexible report output types that can be manipulated to leverage the data in different ways	3.9	18	6	8	I	2	I
Ability to generate graphical displays of data and data comparisons	3.7	14	7	9	4	0	2
Reports generated by the IIS should looks the same or similar to those previously generated by CoCASA	2.6	4	5	9	7	11	0

Additional Question Added: Note: Respondents = 33

Question	Yes	No
Should select reports be made available	32	ı
for providers to run on their own?	(97%)	(3%)

7. Do you have any other suggestions for Phase II considerations?

- A list of patients that might be moved or gone elsewhere based on a last site visit.
- Consideration for awardees whose registries are not mature enough for AFIX and still rely on CoCASA.
 We miss CoCASA guidance.
- How much time will we have to reply to this? I have an MD conducting AFIX visits in 2015 and assume I will have more input from her perspective.
- Informal incentives resources
- List of patient that have been MOGE'd or inactivated in a time period
- Simultaneous administration prompt to provider to assess why doses were not given at the same time.
- Toolkit that explains all new AFIX processes. CDC emphasis on the mandated registry data in the states

Prioritization Breakdown

The AIRA AFIX-IIS Project Team Update conference call on November 17, 2014 confirmed a need for Phase II Report Prioritization from the AFIX-IIS Project. Of the 37 jurisdictions that participated, 81% (30) pronounced that they currently use CoCASA to prepare some or all of the reports used to support AFIX coverage assessments and provider feedback. Based on the additional feedback gathered during that call and taking into consideration previous Phase I SME feedback the following summarizes the recommendations for prioritization of AFIX-IIS Project Phase II.

A. Reports Selected Based on Route Basis Usage

Recommended for Inclusion:

Report	Justification
Missing Immunizations (recall list)	Selected reports that scored higher than 50% from poll results (actual was 82%).
Invalid Doses (patient and reason list)	Selected reports that scored higher than 50% from poll results (actual was 82%)
HPV report	Selected reports that scored higher than 50% from poll results (actual was 64%).
Missed Opportunities (patient and reason list)	Selected reports that scored higher than 50% from poll results (actual was 58%).
Single Antigen Report (dose by age)	Selected reports that scored higher than 50% from poll results (actual was 55%). Also included as part of Phase I SME discussions.
Not UTD (patient list)	This report had 42% of respondents request and in addition it was requested as part of the provider feedback section so should be included.
Summary Report - Late UTD	Included as part of SME requests even though results were 42%.

Recommended for Exclusion:

Report	Justification
Diagnostic Report Childhood (% complete + add. eval)	Included in Phase I
Adolescent Coverage (% complete + UTD dose spread)	Included in Phase I
AFIX Site Visit Summary (for adolescents)	Excluded since poll results indicated below 50% of participants requested (actual was 48%). However could be included to give an overall summarization of visit if desired.
Summary Report - Flow Chart	Excluded since poll results indicated below 50% of participants requested (actual was 45%).
Summary Report - Pie Chart	Excluded since poll results indicated below 50% of participants requested (actual was 39%).

Appendices

Report	Justification
Summary Report - Last visit >12 months	Excluded since poll results indicated below 50% of participants requested (actual was 33%).
Summary Report - Need One Visit (table)	Excluded since poll results indicated below 50% of participants requested (actual was 24%).
Need One Dose (patient list)	Excluded since poll results indicated below 50% of participants requested (actual was 12%).

Additional Comments Addressed:

Report	Justification
Adolescent Coverage	Included in Phase I
Adolescent coverage by assessment date and also by age	Included in Phase I
Childhood summary, graph of UTD, LUTD, and total UTD	Partial already included in list above to include.
NOTES Report. Allows for personalized information entered by the site visit reviewer.	Not included in overall listing for Phase II.
Sometimes Reviewers use Not UTD patient list, Summary Report Late UTD	Both reports indicated in above lists: Not UTD patient list will be included but Summary Report Late UTD will be included for Phase II.
Summary Report, page I	Listed in inclusion priorities above.
Summary Rpt-< 12 months list	Not included as priorities for Phase II based on attribute responses below.
We leave lists of adolescent clients who are NUTD with providers and this has been very helpful. We plan to also begin leaving NUTD client lists for young children—not only for two-year-old clients upon which the coverage reports are based, but for younger 12-23 or 18-23-month-olds as well.	Listed above as part of inclusion.

B. Report Attributes Deemed Most Critical to the AFIX Provider Process

Recommended Attributes for Inclusion:

Report Attribute	Justification
Coverage assessments for children (# and % of patients UTD for selected measures)	Selected attributes that scored higher than 50% from poll results (actual was 100%).
Not UTD/Missing Immunizations (patient list plus missing vaccinations list)	Selected attributes that scored higher than 50% from poll results (actual was 75%) AND noted from above as critical.
Not UTD/Invalid Doses (patient and vaccination reason list)	Selected attributes that scored higher than 50% from poll results (actual was 64%) AND noted from above as critical.
Missed opportunities reason (patient and reason list)	Selected attributes that scored higher than 50% from poll results (actual was 58%) AND noted from above as critical.
Not UTD (patient list)	Selected attributes that scored higher than 50% from poll results (actual was 56%) AND noted from above as critical.
Rate comparison of provider to other measures (e.g., state rates, regional/county rates, NIS rates, HP2020 objectives)	Selected attributes that scored higher than 50% from poll results (actual was 75%).
Full Patient Listing (practice level listing of all active patients in defined assessment cohort)	Included in Phase I but probably should revisit in Phase II (actual poll results was 39%).
Rate comparison of provider to other providers in jurisdiction (e.g., comparison by size of provider or provider type)	Included in Phase I but probably should revisit in Phase II (actual poll results was 28%).
Rate comparison of provider to other providers in jurisdiction (line listing)	Included in Phase I but probably should revisit in Phase II (actual poll results was 14%).

Recommended Attributes for Exclusion:

Report Attribute	Justification
Coverage assessments for adolescents (# and % of patients UTD for selected measures)	Included in Phase I
Missed opportunities calculation (# and % for selected measures)	Included in Phase I
Not UTD (# and % for selected measures)	Excluded since poll results indicated below 50% of participants requested (actual was 39%).
Rate comparison of provider to self over time	Excluded since poll results indicated below 50% of participants requested (actual was 39%).
Not UTD/Invalid Doses (# and %)	Excluded since poll results indicated below 50% of participants requested (actual was 33%).
Exemptions and contraindications (patient and reason list)	Excluded since poll results indicated below 50% of participants requested (actual was 28%).

Report Attribute	Justification
Dose by Age Breakdown (# and % for each measure broken down by dose number and age)	Excluded since poll results indicated below 50% of participants requested (actual was 28%).
Late UTD (patient and reason list)	Excluded since poll results indicated below 50% of participants requested (actual was 25%).
Ability to run reports based on various levels of organizational hierarchy (e.g., individual providers, entire HMO)	Excluded since poll results indicated below 50% of participants requested (actual was 22%).
Not UTD/Visit History - <12 months or >12 months since last immunization visit (patient list)	Excluded since poll results indicated below 50% of participants requested (actual was 19%).
Not UTD/Needs One Visit (# and %)	Excluded since poll results indicated below 50% of participants requested (actual was 17%).
Late UTD (# and %)	Excluded since poll results indicated below 50% of participants requested (actual was 17%).
History of disease/blood titer (patient and reason list)	Excluded since poll results indicated below 50% of participants requested (actual was 17%).
Rate comparison of provider to HEDIS score	Excluded since poll results indicated below 50% of participants requested (actual was 17%).
Not UTD/Needs One Visit (patient and vaccination list)	Excluded since poll results indicated below 50% of participants requested (actual was 14%).
Not UTD/Needs One Dose (patient and vaccination list)	Excluded since poll results indicated below 50% of participants requested (actual was 14%).
Not UTD/Visit History - <12 mo. or >12 mo. since last immunization visit (# and %)	Excluded since poll results indicated below 50% of participants requested (actual was 8%).
Not UTD – Influenza, current flu season (patient list)	Excluded since poll results indicated below 50% of participants requested (actual was 3%).
Not UTD/Needs One Dose (# and %)	Excluded since poll results indicated below 50% of participants requested (actual was 3%).

Additional Comments Addressed:

Report Attribute	Justification
Patient list with addresses (to be used for identifying patients that may have moved or gone elsewhere).	Included in Patient Detailed List above.
Trends found in practice ex; tends to vaccinate 12 month MMR too early therefore invalid	Already included in Phase II from list above.

C. Report Attributes Deemed Important to be generated by IIS (5 being very important; I not important).

Recommended Attributes for Inclusion:

Report Attribute	Justification
All reports/data should be exportable	Selected attributes that scored higher than 4 from poll results (actual was 4.8).
Ability to view trend data from year to year	Selected attributes that scored higher than 4 from poll results (actual was 4.0).
Flexible report output types that can be manipulated to leverage the data in different ways	Even though this one was below 4 felt it could be tied into the first one listed above (actual was 3.9).

Recommended Attributes for Exclusion:

Report Attribute	Justification
Ability to run reports based on various levels of organizational hierarchy (e.g., individual providers, entire HMO, by jurisdiction – zip code, city, county, district/region, statewide)	Included in Phase I
Ability to evaluate other vaccine coverage measurements at various age mile markers (e.g., 3:3:2:2 by 12 months)	Included in Phase I
Ability to generate graphical displays of data and data comparisons	This one will be hard to recommend since there are too many variations. Will handle as part of making data exportable (actual result was 3.7).
Reports generated by the IIS should looks the same or similar to those previously generated by CoCASA	Excluded since poll results indicated below 3 (actual was 2.6).

Additional Comments Addressed:

Question	Justification
Should select reports be made available for	Included in Phase I (results were 97% Yes)
providers to run on their own?	

Additional Suggestions for Phase II:

Comment	Justification
A list of patients that might be moved or gone elsewhere based on a last site visit. Date.	This could be considered as part of the patient list, showing date last vaccination.

Comment	Justification
Consideration for awardees whose registries are not mature enough for AFIX and still rely on CoCASA. We miss CoCASA guidance.	CoCASA will no longer used for AFIX assessments so this guide will be used for IIS to implement the needed changes to accommodate the AFIX assessments.
How much time will we have to reply to this? I have an MD conducting AFIX visits in 2015 and assume I will have more input from her perspective.	The poll closed during the conference and the results are being used for Phase II Prioritization.
Informal incentives resources	Out of scope for this project.
List of patient that have been MOGE'd or inactivated in a time period	Included as part of Phase I and will be emphasized for Phase II.
Simultaneous administration prompt to provider to assess why doses were not given at the same time.	This would be an individual IIS implementation request not standardized by the AFIX project.
Toolkit that explains all new AFIX processes. CDC emphasis on the mandated registry data in the states	This project will deliver recommendation documents for IIS implementation.

D. Overall Recommendations for Phase II:

Reports

Missing Immunizations (recall list)

Invalid Doses (patient and reason list)

HPV report

Missed Opportunities (patient and reason list)

Single Antigen Report (dose by age)

Not UTD (patient list)

Summary Report - Late UTD

Report Attributes

Coverage assessments for children (# and % of patients UTD for selected measures)

Not UTD/Missing Immunizations (patient list plus missing vaccinations list)

Not UTD/Invalid Doses (patient and vaccination reason list)

Missed opportunities reason (patient and reason list)

Not UTD (patient list)

Rate comparison of provider to other measures (e.g., state rates, regional/county rates, NIS rates, HP2020 objectives)

Full Patient Listing (practice level listing of all active patients in defined assessment cohort)

Rate comparison of provider to other providers in jurisdiction (e.g., comparison by size of provider or provider type)

Rate comparison of provider to other providers in jurisdiction (line listing)

All reports/data should be exportable

Ability to view trend data from year to year

Flexible report output types that can be manipulated to leverage the data in different ways

Appendix D. List of Meeting Participants (Phase I)

Table 9. Table of Meeting Participants (Phase I)

Awardee	Participant	Email	Job Title	
Florida-AFIX	Cristi Chambers	Cristi.Chambers@flhealth.gov	CDC Senior Public Health Advisor	
Florida-IIS	Baskar Krishnamoorthy	Baskar.Krishnamoorthy@flhealth.gov	Business Analyst, Florida SHOTS	
Kansas-AFIX	Patti Kracht	pkracht@kdhe.state.ks.us	AFIX/Education Manager	
Kansas-IIS	Deb Warren	dwarren@kdheks.gov	Project Manager, KS Immunization Information System	
Michigan-AFIX	Stephanie Sanchez	Sanchezs@michigan.gov	AFIX Coordinator	
Michigan-IIS	Therese Hoyle	therese.hoyle@gmail.com	Senior Public Health Advisor	
Minnesota- AFIX/IIS	Sudha Setty	Sudha.setty@state.mn.us	AFIX and Quality Improvement Coordinator	
New York City-AFIX	Karen Fernandez	kfernand@health.nyc.gov	Provider Quality Assurance Unit Chief	
New York City-IIS	Vikki Papadouka	vpapadou@health.nyc.gov	Director of Research and Evaluation	
Oregon-AFIX	Sara Beaudrault	sara.beaudrault@state.or.us	Immunization Policy Specialist	
Oregon-IIS	Jenne McKibben	jenne.mckibben@state.or.us	Oregon ALERT IIS Training Lead	
Washington- AFIX	Nicole Pender	Nicole.Pender@DOH.WA.GOV	AFIX Coordinator	
Washington-IIS	Belinda Baker	belinda.baker@doh.wa.gov	IIS Technology Coordinator	
Wisconsin- AFIX	Tracey Andrews	Tracey.Andrews@dhs.wisconsin.gov	Public Health Advisor	
Wisconsin-IIS	Stephanie Schauer	Stephanie.Schauer@dhs.wisconsin.gov	IIS Sentinel Site Epi	
STC	Kristi Siahaya	kristi_siahaya@stchome.com	Provider Services Manager	
HP	Katie Reed	catherine.reed@hp.com	Program Manager	
Envision	Brad Couse	bcouse@envisiontechnology.com	Software Developer	
AIRA	Rebecca Coyle	coyler@immregistries.org	Executive Director	

Appendices

Awardee	Participant	Email	Job Title
AIRA	Elaine Lowery	Lowery <u>elaine.lowery@comcast.net</u> Independent Consultant	
AIRA-Project Staff	Danielle Reader-Jolley	dreaderjolley@immregistries.org	Independent Consultant
AIRA-Project Staff	Ruth Gubernick	gubernrs@hln.com	Consultant/QI Advisor
AIRA-Project Staff	Sue Salkowitz	salkowit@mac.com	Health Information Systems Consultant
AIM	Beth Rowe-West	bwest@immunizationmanagers.org	Membership Services Director
AIM-Alaska	Gerri Yett	geraldine.yett@alaska.gov	Program Manager
CDC-AFIX	Hanan Awwad	wgn5@cdc.gov	Public Health Advisor, AFIX Lead – POB
CDC- Admin/IIS	Amanda Bryant	zmr1@cdc.gov	Program Analyst – IISSB
CDC-IIS	Laura Pabst	Inw9@cdc.gov	Health Scientist – IISSB
CDC-IIS	David Lyalin	dil8@cdc.gov	Public Health Analyst – IISSB
CDC-AFIX	Nathan Crawford	ngc7@cdc.gov	Public Health Advisor – POB

Appendix E. List of Meeting Participants (Phase II)

Table 10. Table of Meeting Participants (Phase II)

Awardee	Participant	Email	Job Title	
Arizona-AFIX	Alexandra Bhatti	alexandra.bhatti@azdhs.gov	Immunization Assessment Manager	
Florida-IIS	Baskar Krishnamoorthy	Baskar.Krishnamoorthy@flhealth.gov	Business Analyst, Florida SHOTS	
Iowa-AFIX	Kelly Rooney-Kozak	krooney@idph.state.ia.us		
Michigan-AFIX	Stephanie Sanchez	Sanchezs@michigan.gov	AFIX Coordinator	
Michigan-IIS	Therese Hoyle	therese.hoyle@gmail.com	Senior Public Health Advisor	
Minnesota- AFIX	Sudha Setty	Sudha.setty@state.mn.us	AFIX and Quality Improvement Coordinator	
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Appendix F. Other Related Sample Report Components

Below are additional sample report components provided by awardees and CoCASA that did not necessarily fit into one or more of the report component categories in the main document. However, they provide good information and samples of what can and is being done with the integration of AFIX into IIS.

Figure 16. AFIX Basic Overview Report (from Michigan IIS)

07/23/2014	AFIX	Basic Overv	iew MCIR	Report			Page 1	
People of age (months) Compliance by Select people by Patient Status Gender Missed Opportunities defined Total # of Patient Records As		2014 er Id	on visit	Tdap IPV MMR HIB HepB Varicella	$\frac{1}{3}$ $\frac{2}{2}$ $\frac{0}{3}$ $\frac{3}{2}$		0 0 0 0 0 0 1	
Note: UTD = Up-To-Date for rec	quested criteria							
Coverage Levels:	#	%						
1 Doses of Tdap	1852	89						
3 Doses of Polio	2038	98						
2 Doses of MMR	1962	94						
3 Doses of HepB	2007	96						
2 Doses of Var	1808	87						
1 Doses of MCV	1852	89						
Var Immunity	98	5						
Up-To-Date	1731	83						
Information for Feedback and the following in the followi	s not complete	:	ion: 40 346					
of Patients that need one vi	icit to be LITD:		270					
# of Patients that need only one dose to be UTD:		108						
of Patients not UTD that la	st immunizatio	on >= 12 mon	ths: 157					
of Patients not UTD with M	Missed Opportu	unity for simu	ltaneous ad	ministration:	177 / 8	%		
of Patients not UTD with p	atient status of	f Inactive Los	t to Follow	Up:	0			

Figure 17. Contraindication Report (from Arizona IIS)

Patient Name Bi	Birth Date	Sex SIIS Patient ID	Vaccination Influ split 36+ mos pres free Influ split 6-35 mos pres free	Contraindication Registered by SUNSET COMMUNITY HEALTH CENTER- YUMA - 48 Registered by ADELANTE HEALTHCARE PHOENIX - 2361	Permanent Y
			Varicella	Registered by ADELANTE HEALTHCARE PHOENIX - 2361	Y

Figure 18. Data Quality Report - Patient (from Arizona IIS)



Figure 19. Data Quality Report - Vaccination (from Arizona IIS)

Vaccination Data Quality Report July 09, 2015 This Vaccination Data Quality Report summarizes vaccinations outside of recommended administration age or administered vaccinations that were given from unspecified vaccine types. Birth Date Range: 07/09/2012 through 07/09/2013 ADELANTE HEALTHCARE - GILA BEND (0020) FACILITY UNDEFINED details HEP-B 3 DOSE Birth HepB with Pediarix or HepB Dose 3 prior to min. age requires four doses. HEP-B 3 DOSE This additional dose not required. HIB No schedule found for antigen based on age or intervals. POLIO DTaP-Hib-IPV Dose 4 administered at < 4 years of age does not satisfy the IPV dose 4 minimum age. Another IPV should be administered at >= 4 years of age.

Figure 20. Immunization Summary Report (from Florida IIS)

Immunization Summary Report

Organization: XXXXXXXXXXX Include Service Sites: All Assessment Date: 07/24/2015

Age Range: 24 to 35 months as of 07/24/2015 Base Complete on: 4:3:1:3:3:1 at 24 months Include only patients with WIC ID: No

Total patients selected: 1153

Patients moved or gone elsewhere before compliance age: 180

Patients with religious exemption: 36

Total patients assessed: 937

Patients moved or gone elsewhere after compliance age: 31

	Complete b	Complete by 24 months		Late up-to-date *		Complete by assessment date *	
	# of patients	% of patients	# of patients	% of patients	# of patients	% of patients	
Received 4 DTaP	830	89%	58	6%	879	97%	
Received 3 Polio	910	97%	11	1%	897	99%	
Received 1 MMR	906	97%	25	3%	906	100%	
Received 3 HIB	917	98%	14	2%	906	100%	
Received 3 HepB	912	97%	10	1%	897	99%	
Received 1 VZV	903	96%	26	3%	905	100%	
Received 4 PCV	888	95%	37	4%	903	100%	
Received 4:3:1	827	88%	61	7%	879	97%	
Received 4:3:1:3	826	88%	62	7%	879	97%	
Received 4:3:1:3:3	826	88%	62	7%	879	97%	
Received 4:3:1:3:3:1	823	88%	64	7%	879	97%	
Received 4:3:1:3:3:1:4	818	87%	66	7%	877	97%	

Of patients NOT complete, # of patients who could be be up-to-date for 4:3:1:3:3:1 with 1 additional visit:

Immunizations Needed	# of patients	% of patients
1	18	2%
2	0	0%
3	1	0%
4+	0	0%
Total patients up-to-date with 1 visit	19	2%

^{*} Patients that have moved after the compliance age and patients with permanent contraindications added after the compliance age will not be included in the and 'Complete by assessment date' columns.calculations for the 'Late up-to-date'

Figure 21. Recall for Inactivation (from Arizona IIS)

			Recall for i	Inactivation (by ow	nersnip)		
Report Criteria							Report Date: July 9, 20
			Number of Re	67 - ADELANTE HEALTHO Facility: All District / Region: All call Tries Greater than or E nge: 07/01/2012 through	qual To: 5		
otal Patients	Selected: 2						
atient ID	First Name	Middle Name	Last Name	Birthday	# of Recall Tries	Date	Туре
					5	08/16/2013	MAILING LABEL
						11/05/2013	PATIENT LISTING
						08/16/2013	PATIENT LISTING
						08/16/2013	PATIENT LISTING
					6	05/21/2014	PATIENT LISTING
						05/21/2014	PATIENT LISTING
						05/21/2014	PATIENT LISTING
						05/21/2014	PATIENT LISTING
						05/21/2014	PATIENT LISTING
						05/21/2014	PATIENT LISTING
						05/21/2014	PATIENT LISTING
						05/21/2014	PATIENT LISTING
						05/21/2014	PATIENT LISTING
						05/21/2014	PATIENT LISTING
						05/21/2014	PATIENT LISTING
						05/21/2014	PATIENT LISTING
						05/21/2014	PATIENT LISTING
						05/21/2014	PATIENT LISTING
						05/21/2014	PATIENT LISTING
						05/21/2014	PATIENT LISTING
						05/21/2014	PATIENT LISTING
						05/21/2014	PATIENT LISTING

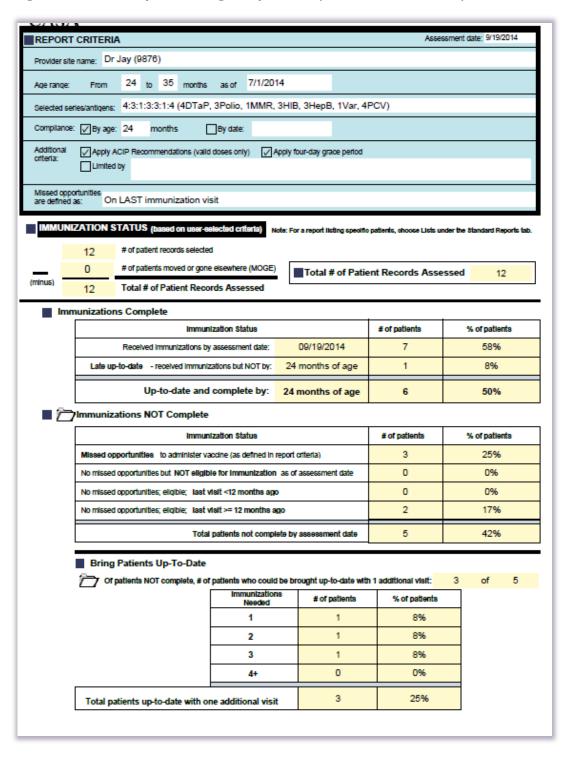
Figure 22. Recall Group Listing - Patient (from Arizona IIS)

			Patient Recall	Group Listin	ng by Ownership		
Report Criteria							Report Date: July 9, 2
Recall Date: 01/ Birth Date Rang- Include Inactive State: All High Risk Categ Deferred Vaccin	ory: All ations Only: No	2015	(PCV), POLIO, VARICEL	Physic Progra County Zip Co District	Plan: All ian: All m: All r/Parish: All		
Total Patients Se	elected: 3						
Datient TN	First Name	Middle Name	l act Namo	Rirthday	Guardian F N	Dhone Number	Chart Number
	Vaccine Family Nam	ne	Dose Number		Recommende	d Date	Minimum Date
	DTaP/DT/Td		4		05/18/201	15	05/18/2015
Patient ID	First Name	Middle Name	Last Name	Birthday	Guardian F.N.	Phone Number	Chart Number SIISCLIENT6147875
ratient 10							
radent 15	Vaccine Family Nam	ne	Dose Number		Recommende	d Date	Minimum Date
rudent ID	Vaccine Family Nan	ne	Dose Number		Recommender 08/05/201		Minimum Date 08/05/2014
	•	Middle Name		Birthday			
Patient ID	DTaP/DT/Td	Middle Name	4	Birthday	08/05/201	Phone Number	08/05/2014

Figure 23. Series-Specific Patient Forecast (from Arizona IIS)

				Series-Specific	Patient	Forecast		
Report Criteria					R	eport Date: 07/09/2015		
As of Date: Series:		07	7/08/2015	T/Td, 3 HIB, 3 POLIO, 3 F	A A	ge Range:	24 Months throu	igh 35 Months
State:			AZ	11/10, 3 HIB, 3 POLIO, 3 F	Pati	ent County:	Al	
District/Region: Organization		ADEL ANTE LIE	All	ID.		ip Code:	Al	
(IRMS): Patient Status:		ADELANTE HEA	LTHCARE - GILA BEN Active	ND		Facility: cine Status:	Al Valid Vaccina	
Evaluate At Age:	:	2	4 Months	Ex		ts who have aged out:	N	
				Patients	selected: 10)		
Patient ID	First Name	Middle Name	Last Name	Birthday	Age	Guardian F.N.	Patient Phone Number	Chart Number
	Vaccine Farr	ily Name		Dose Number		Recommende	ed Date	Minimum Date
Patient TD	DTaP/D	T/Td Middle Name	Last Name	4 Birthday	Δπe	05/18/20 Guardian E N	Patient Phone Number	05/18/2015 Chart Number
Patient TD	First Name Vaccine Fam	Middle Name	Last Name	Birthday Dose Number	∆ae	Guardian F N Recommende	Patient Phone Number	Chart Number Minimum Date
Patient ID	First Name	Middle Name	Last Name	Rirthday	Δαe	Guardian E N	Patient Phone Number ed Date	Chart Number
	First Name Vaccine Fam DTaP/D	Middle Name	Last Name Last Name	Rirthday Dose Number	Age	Guardian E N Recommende 03/18/20	Patient Phone Number ed Date	Chart Number Minimum Date 03/18/2015
	Vaccine Fam DTaP/D PNEUMO	Middle Name illy Name T/Td (PCV)	Last Name	Rirthday Dose Number 4 3	Age	Guardian E N Recommende 03/18/20 11/13/20 Guardian F.N.	Patient Phone Number ed Date 15 14 Patient Phone Number	Chart Number Minimum Date 03/18/2015 11/13/2014
Patient ID	Vaccine Fam DTaP/D PNEUMO	Middle Name illy Name T/Td (PCV)	Last Name	Rirthday Dose Number 4 3 Birthday	Age	Guardian E N Recommende 03/18/20 11/13/20 Guardian F.N.	Patient Phone Number ed Date 15 14 Patient Phone Number	Chart Number Minimum Date 03/18/2015 11/13/2014
Patient ID	Vaccine Fam DTaP/D PNEUMO First Name	Middle Name IIIy Name T/Td (PCV) Middle Name	Last Name Patient no longe	Rirthday Dose Number 4 3 Birthday er meets the age req	A ge uirements	Recommende 03/18/20 11/13/20 Guardian F.N.	Patient Phone Number ed Date 15 14 Patient Phone Number In the series Patient Phone Number	Chart Number Minimum Date 03/18/2015 11/13/2014 Chart Number

Figure 24. Summary Flow Diagram p. I of 3 (from CDC CoCASA)



SUMMARY REPORT Date Generated: 12/10/2014 Report Title: Series: 4:3:1:3:3:1:4 (4DTaP, 3Polio, Provider Site Name: Dr Jay Compliance: months 24 months 1MMR. 3HIB. 3HepB. 1Var. 4PCV) Total # Patient Records #= Number of patients %= Percent of patient records assessed 12 Patients Moved or Gone Elsewhere (MOGE) Total # Patient Records Assessed 12 0 Immunizations Complete up-to-date up-to-date but late Immunizations NOT Complete 50% 5 42% 8% No Missed Opportunities Missed Opportunities 2 17% 25% Eligible for Immunization Not Eligible for Immunization 17% 2 0 0% Last Visit >= 12 months ago Last Visit < 12 months ago 0% 17% 0 2

Figure 25. Summary Flow Diagram p. 2 of 3 (from CDC CoCASA)

v9.3

Department of Health and Human Services
Centers for Disease Control and Prevention
National Center for Immunization and Respiratory Diseases

4:3:1:3:3:1:4 (4DTaP, 3Polio, 1MMR, 3HIB, 3HepB, 1Var, 4PCV) Provider Site Name: Dr Jay Compliance: months 24 months Immunization Results 6 (50%) 1 (8%) 2 (17%) Legend Up-To-Date Missed Opportunity Not Eligible Last Immunization Visit < 12 Months Ago Last Immunization Visit >= 12 Months Ago

Figure 26. Summary Flow Diagram p. 3 of 3 (from CDC CoCASA)

Appendix G. Project Reference Documents

- 1. **AFIX Online Tool** (available to CDC awardees; requires secure logon)**AFIX Annual Report** 2014 (available to CDC awardees; requires secure logon)
- 2. **Assessment, Feedback, Incentives eXchange (AFIX)**: Program Policies and Procedures Guide; First Edition 2013 (http://www.cdc.gov/vaccines/programs/afix/downloads/standards-guide.pdf)
- 3. CDC AFIX Website (http://www.cdc.gov/vaccines/programs/AFIX/index.html)
- 4. CDC IIS Website (http://www.cdc.gov/vaccines/programs/iis/index.html)
- 5. CDC IIS Policy and Legislation Website (http://www.cdc.gov/vaccines/programs/iis/policy-legislation.html)
- 6. Clinical Decision Support for Immunization (CDSi): Logic Specification for ACIP Recommendations; Version 1.6 March 2014 (http://www.cdc.gov/vaccines/programs/iis/interop-proj/cds.html)
- 7. **CoCASA Users Guide; Version 8.1** February 2013; Chapters 3 and 4 (http://www.cdc.gov/vaccines/programs/cocasa/users-guide.html)
- 8. **CoCASA Algorithm Reference; CoCASA 8.0** December 2012 (http://www.cdc.gov/vaccines/programs/cocasa/downloads/algorithm_reference_document.pdf)
- 9. Epidemiology and Prevention of Vaccine-Preventable Diseases; 12th Edition Second Printing May 2012; Appendix A and B (http://www.cdc.gov/vaccines/pubs/pinkbook/index.html)
- 10. Healthy People 2020; Immunization and Infectious Diseases (http://www.healthypeople.gov/2020/topicsobjectives2020/objectiveslist.aspx?topicId=23)
- 11. **IIS Functional Standards 2013-2017**; Appendix B: *IIS Core Data Elements* December 2012 (http://www.cdc.gov/vaccines/programs/iis/func-stds.pdf)
- 12. **IIS: HL7 Standard Code Set CVX Vaccines Administered**; May 2014 (http://www2a.cdc.gov/vaccines/iis/iisstandards/vaccines.asp?rpt=cvx)
- 13. Modeling of Immunization Registry Operations Workgroup (MIROW): Best Practice Guidelines (http://www.immregistries.org/resources/aira-mirow)
 - a. Management of Move or Gone Elsewhere (MOGE) Status and Other Patient Designations in IIS
 2005 (to be superseded by the new PAIS document)
 - b. Vaccination Level Deduplication in IIS 2006
 - c. Data Quality Assurance in IIS: Incoming Data 2008
 - d. Reminder/Recall in Immunization Information Systems 2009
 - e. Data Quality Assurance in Immunization Information Systems: Selected Aspects 2013
 - f. Management of Patient Active/Inactive Status in Immunization Information Systems: Replacement of 2005 Guidelines 2015
- 14. Metroka A., Hansen M., Papadouka V., Zucker J. Using an Immunization Information System to Improve Accountability for Vaccines Distributed Through the Vaccines for Children Program in New York City, 2005-2008. *J Public Health Management Practice*. 2009; 15(5): E13-E21.
- 15. Vaccines for Children (VFC) Operations Guide (available to CDC awardees; requires secure logon)
- 16. VFC Enrollment Overview Document (available to CDC awardees; requires secure logon)
- 17. VTrckS ExIS Integration: File Specifications & Additional Information; Revision D02 2010-2013 (http://www.cdc.gov/vaccines/programs/vtrcks/topics/ExIS.html#specifications)

Appendix H. Technical Design Specification Guidance (Phase I Excerpt)

Design Specification Overview

Standard Table 4. Required Design Specification (excerpt from Phase I)

Required Data Inputs/Elements:

Provider

- Provider Name
- VFC PIN Number
- IIS ID (unique IIS identifier)

Patient

- First Name
- Last Name
- Date of Birth
- Gender/Sex
- PAIS Indicator

Vaccination

- Date of Vaccination
- Vaccine Type
- History of Disease/Titer
- Contraindication/Precaution

Report Component Parameters/Criteria:

- Provider Selection
- Assessment Date
- Feedback Date
- Assessment Age Range
- As of Date
- Compliance by Age/Date
- Series/Antigen Selection
- Active Patients
- Valid Vaccinations

Outputs:

- Assessed Measure
- Number Complete
- Percentage Complete
- Missed Opportunities Number
- Missed Opportunities Percentage

Data Inputs/Data Elements

This section defines the inputs/data elements that must be captured by the IIS in order to generate the required report. Fields are identified for provider detail, patient detail and vaccination detail. (Note: this section lists only the minimum/mandatory fields necessary to produce the required AFIX Coverage Assessment that is reported to CDC. CDC awardees may choose to collect additional fields for running the reports with optional parameters, but the list below represents the required data elements for CDC mandatory AFIX reporting.)

- 1. The IIS must be able to capture the following inputs/data elements:
 - a. Provider Detail when defining providers in the IIS, the IIS must capture the following:
 - i. Provider Name
 - ii. VFC Pin Number
 - iii. IIS ID (unique IIS identifier)
 - b. Patient Detail when defining patients in the IIS, the IIS must capture the following:
 - *Denotes a Required Core Data Element (2013-2017)
 - i. First Name*
 - ii. Last Name*
 - iii. Date of Birth*
 - iv. Gender/Sex*
 - v. Patient Active/Inactive Status indicator²³ (for patient status at Provider Site/Facility Level)*
 - 1.) Status options should include:
 - a.) Active
 - b.) Inactive
 - c.) Deceased
 - c. Vaccination Detail when recording/reporting a vaccination for a patient record, the IIS must capture the following:
 - *Denotes a Required Core Data Element (2013-2017)
 - i. Date of Vaccination*
 - ii. Vaccine Type*
 - I.) Each vaccine type must be appropriately associated to the correct CVX code in the IIS database for appropriate forecasting/evaluation.
 - a.) The most current list of vaccine types and CVX codes can be found at: http://www2a.cdc.gov/vaccines/iis/iisstandards/vaccines.asp?rpt=cvx
 - b.) The following vaccinations will be evaluated for the childhood and/or adolescent AFIX Coverage Assessment:
 - i.) DTaP
 - ii.) Polio
 - iii.) MMR
 - iv.) Hib
 - v.) Hepatitis B
 - vi.) Varicella

²³ See AIRA MIROW: Management of Patient Active/Inactive Status in Immunization Information Systems: Replacement of 2005 Guidelines - 2015

- vii.) Pneumococcal
- viii.) Rotavirus
- ix.) Influenza
- x.) Hepatitis A
- xi.) Tdap
- xii.) HPV
- xiii.) Meningococcal
- 2.) IIS Recommendation: Support all Vaccine Types that may have been licensed and/or recommended for children/adolescents over the past 18 years to account for correct up to date determinations and evaluation calculations from historical recommendations.
 - a.) Resources:
 - i.) CDSi: http://www.cdc.gov/vaccines/programs/iis/interop-proj/cds.html
 - ii.) Pink Book:
 http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/discontinued_vaccines.pdf
- iii. History of Disease/Blood Titer*
- iv. Contraindication/Precaution^{24*} (for calculating Missed Opportunities)

Report Parameters/Criteria

This section identifies and defines the report criteria that must be applied to produce the required AFIX assessment report(s). See AFIX-IIS Integration: CDC Operational Guidance for official guidance and best practices. For systems developers, each field has been defined with suggested defaults and specific field behavior. Where appropriate, UI suggestions have also been offered for consideration.

- I. The user interface should offer/apply the following parameters/selection criteria for the AFIX assessment report(s):
 - a. Provider Selection
 - i. Provider practice may be selected by name, by VFC PIN and/or by IIS ID* from providers previously defined/created in the IIS (*selection by IIS ID is optional and acceptable but not a preferred practice)
 - I.) Note: VFC PIN is the primary mechanism for uniquely identifying the provider practice in the AFIX Online Tool for reporting purposes.
 - a.) If provider is selected by name, VFC PIN should automatically populate and display.
 - b.) If IIS ID is used for provider selection, the provider name and VFC PIN should automatically populate and display.
 - 2.) Note: List of providers available for selection will depend upon defined user type and access level.
 - ii. Field behavior: This selection will determine the specific practice being assessed and ultimately which patients will be eligible for inclusion in the assessment cohort according to rules of "patient status" (See BR 2.A and 2.B).
 - b. Type of Assessment (UI recommendation optional)
 - i. This field would offer users the option to select one of the following options:

²⁴ Contraindication/precaution refers strictly to those specified in Table 6 of the General Recommendations (http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6002a1.htm#Tab6).

- I.) Childhood
- 2.) Adolescent
- 3.) Other
- ii. Depending on which option is selected, appropriate defaults will populate the other criteria fields/parameters to minimize data entry errors and improve standardized reporting
- iii. See text boxes for suggested defaults

Childhood Assessment Defaults

Assessment Date: "Today's Date" Age Range (in Months): 24-35 As of Date: "Today's Date" Compliance by (Age): 24 months Series Selection:

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

Note: for IIS that implement a flexible UI for Series/Antigen Selection by dose number, the default values for "UTD" could auto-populate as 4 Hib, 4 PCV and 3 RV; however, "UTD" calculations **must** be applied on the backend when returning assessment results (see BR 5.D).

Adolescent Assessment Defaults

Assessment Date: "Today's Date" Age Range (in Years): 13-17 As of Date: "Today's Date"

Compliance by (Date): "Today's Date"

Series Selection:

- UTD Hep B
- 2 MMR
- 2 VAR
- I Tdap
- UTD Meningococcal
- 3 HPV
- 2 HPV
- I HPV
- I Influenza (previous season)
- 2 Hep A
- UTD Polio

Note: for IIS that implement a flexible UI for Series/Antigen Selection by dose number, the default values for "UTD" could auto-populate as 3 Hep B, I Meningococcal, and 4 Polio; however, "UTD" calculations <u>must</u> be applied on the backend when returning assessment results (see BR 5.E).

c. Assessment Date

- i. UI Suggestion (optional): Labeling as "Run Date" is also acceptable.
- ii. Date should be hardcoded to "today's date" and will not have the ability to be edited.
 - 1.) Future date (\leq 5 days) is acceptable.
- iii. Field behavior: This field is informational and will reflect the date the report is run. Field will not be used for calculations but must be included in the report header.
- d. UI Suggestion (optional): Feedback Date
 - i. Implementation of this field is strictly optional.
 - ii. No default date should be offered. Only future dates > "today's date" through 7 days are acceptable values
 - iii. Field behavior: This field is strictly informational and will be used operationally to reflect the date of the scheduled visit to the provider. This field will not be used for calculations but will be included in the report header if used

- e. Assessment Age Range (see BR 1.A 1.E)
 - i. Age Range in Months
 - 1.) This field should behave as either/or with "Age Range in Years" (see below)
 - 2.) Range should include a "from" and "through" selection
 - 3.) UI Suggestion: When this option is selected, the Range should default to "24-35 months" but can be edited
 - ii. Age Range in Years
 - 1.) This field should behave as either/or with "Age Range in Months" (see above)
 - 2.) Range should include a "to" and "from" selection
 - a.) UI Suggestions (optional): Labelling of "from" and "through" is an acceptable alternative
 - 3.) UI Suggestion: When this option is selected, the Range should default to "13-17 years" but can be edited
 - iii. Age Range by Date of Birth
 - I.) Field behavior: This field is predominately informational and should display a calculated birthdate range for the values entered when "Age Range in Months" or "Age Range in Years" is defined.
 - a.) Alternative behavior: "Age Range by Date of Birth" provides an alternative approach to selecting the assessment cohort (selection by Date of Birth is optional and acceptable but not a preferred practice)
 - 2.) Range should include a "from" and "through" selection
 - 3.) No default should be offered
 - iv. UI Recommendation (optional): consider implementing a toggle or button selector for "age range in months" and "age range in years."
 - v. Field behavior: This field directly defines the cohort to be included in the assessment based on a calculated birthdate range. Only one age range option may be selected at a time. The age range and calculated birthdate range used for the assessment will be required elements of the report header. The calculated birthdate range may be further impacted by the "As of Date" described below.
 - 1.) 24-35 months: have celebrated their 2nd birthday but have not yet turned 3 years.
 - 2.) 13-17 years: have celebrated their 13th birthday but have not yet turned 18 years.
- f. As of Date (See BR I.A I.E)
 - i. Date should default to "today's date" with the ability to be edited. No future dates should be allowed.
 - I.) The birthdate range for the assessment cohort should be calculated based on the age of the cohort as of the specified date.
 - a.) Example: For a Childhood Assessment (24-35 months) with an "As of Date" of 12/31/2013, the cohort would have a birthdate range between 1/1/2011 to 12/31/2011.
 - ii. Field behavior: The "As of Date" adds additional conditions to the Assessment Age Range parameters. The IIS must be able to calculate the birthdate range "as of" the specified date in order to determine the assessment cohort. Individuals that have come of age after the "As of Date" must be excluded from the assessment cohort.
- g. Compliance By (Age/Date) (See BR 5.A and 5.B)
 - i. UI Option: Labeling as "Evaluate At" is also acceptable

ii. Age

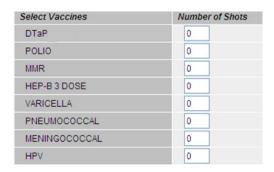
- 1.) This field should behave as either/or with "Compliance by Date"
- 2.) This should be the default selection when "Childhood Assessment" or "Age Range in Months" is selected
- 3.) This should be an open data entry field that can be edited
 - a.) UI Suggestion: When "Childhood Assessment" or "Age Range in Months" is selected, this field should default to 24 months
 - b.) UI Suggestion/Alternative: When "Childhood Assessment" or "Age Range in Months" is selected, this field could offer a set of hardcoded options (e.g., 12 months, 24 months, 72 months) as long as the default option is set to 24 months.

iii. Date

- 1.) This field should behave as either/or with "Compliance by Age"
- 2.) UI Suggestion: This should be the default selection when "Adolescent Assessment" or "Age Range in Years" is selected
- 3.) Date should default to "today's date" but can be edited to reflect a date in the past.
- iv. Field behavior: This field directly impacts the evaluation of series/antigen completion rates. Any vaccinations received after the "Compliance by Age/Date" are not counted towards completion but may factor in to "Late UTD" in future phases of the AFIX-IIS integration effort.
- v. UI Suggestion (optional): consider implementing a toggle or button selector for "Compliance by Age" and "Compliance by Date."
- h. Series/Antigen Selection (See BR 3.A, 5.D and 5.E)
 - i. UI Suggestion: Users could be given 3 options to select from. (Note: This parameter can be used instead of or in addition to "Type of Assessment" described above.)
 - 1.) Standard Childhood (24-35 months)
 - a.) This option will automatically prepare results for the following:
 - i.) 4 DTaP
 - ii.) 3 Polio
 - iii.) I MMR
 - iv.) UTD HIB
 - v.) UTD Hep B
 - vi.) I VAR
 - vii.) UTD PCV
 - viii.) UTD RV
 - ix.) I Influenza (previous season)
 - x.) 2 Hep A
 - xi.) 4:3:1:3:3:1:4 (series)
 - 1. Note: for IIS that implement a flexible UI for Series/Antigen Selection by dose number, the default values for the "UTD" measurements could auto-populate as 4 Hib,3 HepB, 4 PCV and 3 RV; however, "UTD" calculations must be applied on the backend when returning assessment results (See BR 5.D).
 - b.) If "Type of Assessment" is implemented as noted above, these selections would be automatically defaulted as noted above.

- 2.) Standard Adolescent (13-17 years)
 - a.) This option will automatically prepare results for the following:
 - i.) UTD Hep B
 - ii.) 2 MMR
 - iii.) 2 VAR
 - iv.) I Tdap
 - v.) UTD Meningococcal
 - vi.) 3 HPV
 - vii.) 2 HPV
 - viii.) I HPV
 - ix.) I Influenza (previous season)
 - x.) 2 Hep A
 - xi.) UTD Polio
 - Note: for IIS that implement a flexible UI for Series/Antigen Selection by dose number, the default values for the "UTD" measurements could auto-populate as 3 Hep B, I Meningococcal, and 4 Polio; however, "UTD" calculations must be applied on the backend when returning assessment results (See BR 5.E).
 - 2. Additional Note: for HPV, a single entry for number of doses may be entered as 3 HPV, but the calculations and returned results must list 1 HPV, 2 HPV and 3 HPV separately (See BR 5.F).
 - b.) If "Type of Assessment" is implemented as noted above, these selections would be automatically defaulted as noted above.
- 3.) Custom Selection (optional)
 - a.) This option will allow the user to specify any number of doses for any of the ACIP vaccines that they are interested in assessing.
 - b.) List of vaccines may include any/all vaccines supported by the database, but at minimum must include:
 - i.) DTaP
 - ii.) Polio
 - iii.) MMR
 - iv.) HIB
 - v.) Hep B
 - vi.) Varicella
 - vii.) Influenza
 - viii.) Hep A
 - ix.) Rotavirus
 - x.) Pneumococcal
 - xi.) Tdap
 - xii.) HPV
 - xiii.) Meningococcal
- ii. UI Suggestion (optional): IIS should offer the full list of ACIP vaccines with a data entry box for each vaccine where a user can specify the number of doses to assess. When the childhood or adolescent assessments are selected, these fields would automatically populate based on the requirements noted above.

Partial example:



- iii. Alternative UI Suggestion (optional): IIS should offer the full list of ACIP vaccines with a data entry box for each vaccine where a user can specify the number of doses to assess. Where a variable number of doses could be applied to achieve protection in accordance with the ACIP routine and/or catch up schedules (i.e. use of "UTD" for AFIX coverage assessments), users should be presented with an option to select "UTD" in place of specifying a specific number of doses. When the childhood or adolescent assessments are selected, these fields would automatically populate based on the requirements noted above.
- iv. Field behavior: These fields dictate which vaccines will be assessed and number of doses that will be used to determine compliance with the various measurements. Individuals without the appropriate number of doses would be considered incomplete (except where "UTD" logic is applied as detailed in the section titled Determining Antigen Series Status). Number completed becomes the numerator for the assessed coverage measures.
- i. Active Patients (See BR 2.A and 2.B)
 - i. For AFIX purposes, the assessment must always be run using only "Active" patients of the selected provider. Patient status is determined by the PAIS indicator.
 - ii. UI Suggestion (optional):
 - For projects using this report for other purposes, there may be a desire to implement the ability to run the report for other patient statuses. If so, a parameter could be added to allow additional flexibility.
 - a.) This field should offer a selector with the following options:
 - i.) Active
 - ii.) Inactive
 - iii.) All
 - b.) For AFIX purposes, this field must always default to Active.
 - iii. Field behavior: This field directly impacts which individuals are included in the assessment cohort by confirming a patient's active association with the assessed provider. All patients with a status of "Active" should be included in the assessment cohort. Patients with a status of "Inactive" and "Deceased" will be excluded from the assessment. Patients who have not consented or who have opted out of the IIS should also be excluded from the assessment cohort unless otherwise supported by the IIS implementation and/or jurisdictional law/policy.

Appendices

- j. Valid Vaccinations (See 4.A 4.C)
 - i. For AFIX purposes, the UTD status must always be run on "Valid" vaccinations only. Vaccination validity should be determined by the application of IIS forecasting/evaluation algorithms. Guidance on defining these algorithms is provided in the section titled Determining Dose Validity.
 - ii. UI Suggestion (optional):
 - 1.) For projects using this report for other purposes, there may be a desire to implement the ability to run the report for ALL vaccinations (i.e. by count includes both valid and invalid vaccinations). If so, a parameter could be added to allow additional flexibility.
 - a.) This field should offer a selector with the following options:
 - i.) Valid Vaccinations Only
 - ii.) All Vaccinations
 - b.) For AFIX purposes, this field must always default to Valid Vaccinations Only.
 - iii. Field behavior: This field directly impacts which vaccines on a patient's record are counted towards compliance for the specified measures.
- 2. After user has defined the assessment criteria, user will execute report generation. Report calculations will be based on the algorithms defined in the following section (Report Calculations).