

AFIX

Assessment Feedback Incentives Exchange

AFIX-IIS Integration

Operational and Technical Guidance for Implementing
IIS-Based Coverage Assessment – Phase 1

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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 will be discontinued, and program awardees will be required to leverage their Immunization Information Systems (IIS) to support this key program activity in lieu of CoCASA. The date that CoCASA will be discontinued had not been determined.

Requirement: All AFIX awardees will leverage their Immunization Information Systems (IIS) to perform provider level assessment activities once CDC discontinues technical support for CoCASA.

Readers should pay special attention to the specific requirements and recommendations that have been noted throughout this document. Requirements have been identified through the use of bolding and a double underline, and Recommendations have been identified using a single underline. A complete summary of all requirements and recommendations has been provided in Appendix A. Summary of AFIX-IIS Integration Requirements and Recommendations.

Currently there are no technical specifications or operational guidelines to assist program awardees with the development or implementation of IIS-based coverage assessments. Expanding IIS functionality to accommodate AFIX (Assessment, Feedback, Incentives, and eXchange) Program needs following the discontinuation of CoCASA support could potentially overwhelm any one IIS program and result in unnecessary redundancy if all IIS programs tried to accomplish this task individually by investing resources in creating similar technical specifications, operational guidelines and modifications. Individual IIS would inevitably design and implement the AFIX functionality differently, thereby compromising the comparability of assessment results reported from jurisdiction to jurisdiction. For example, inconsistent usage of patient active/inactive status (PAIS) codes or cohort assessment age ranges in the IIS can adversely impact AFIX assessment outcomes at the clinic, jurisdictional, and federal levels.

An authoritative guideline for implementing AFIX functionality in IIS is needed in order to serve as a single reference source for all awardees, to save individual IIS resources, and to ensure consistent reporting of coverage assessment results across jurisdictions. This document will provide operational and technical guidance for AFIX programs and IIS to implement the operational and system modifications needed to support AFIX assessment functionality. This document is intended as a resource for members of the AFIX Community, IIS Community and Immunization Program Managers.

This document provides **CDC's requirements** and **recommendations** for incorporating AFIX assessment functionality in IIS. All requirements provided in this guide will need to be implemented by awardees in collaboration with IIS vendor/s, where appropriate, and designated CDC staff. This document was prepared as a collaboration between CDC, the American Immunization Registry Association (AIRA), the Association of Immunization Managers (AIM), and a number of AFIX and IIS

awardees selected to serve in an advisory capacity. For more information about this collaboration, refer to the section titled **Stakeholder Involvement**.

For more information about the requirements and recommendations contained in this document, please contact CDC at afixiis@cdc.gov.

Background

The following narrative provides general information about the AFIX Program, the role of CoCASA and rationale for retiring this application, and a discussion of IIS and why IIS are best positioned to take over the role of coverage assessments.

AFIX Program Overview

The AFIX Program, officially launched in 1995, is a continuous quality improvement process informed by research and used for improving immunization rates and practices at the immunization provider level. There is strong evidence that assessment and feedback, along with other elements such as incentives and exchange, are effective in increasing vaccination rates. The purpose of AFIX is to assist and support health care personnel by identifying low immunization rates, opportunities for improving immunization delivery practices, and ensuring that providers are:

1. Aware of and knowledgeable about their immunization rates and missed opportunities to vaccinate
2. Motivated to incorporate changes to their current practices
3. Ready to try new immunization service strategies
4. Capable of sustaining these new behaviors

This project specifically supports the “A”, or Assessment component, of the AFIX effort. Assessment is defined as the “assessment of the healthcare provider's vaccination coverage levels and immunization practices”. Data is currently assessed through either CoCASA or an IIS. Assessment of performance enables providers to determine how well they are doing through systematic, routine examination of client records. The data collected through these Assessments can then be used to diagnose potential problems relating to immunization service delivery and office policies. Results of individual AFIX provider assessments are reported to CDC through the AFIX Online Tool, a web-based interface maintained by the CDC POB for managing site visits, tracking provider performance over time, and generating the AFIX Annual Report (AFIXAR) for awardees.

The AFIX Program Objective for the current Cooperative Agreement funding period (2013 – 2017) is as follows:

Work with Vaccines for Children (VFC) providers on quality improvement processes to increase coverage levels and decrease missed opportunities using AFIX components as appropriate and move toward use of IIS as primary source of data for provider coverage level assessment by the end of the project period. (*Objective B3, Section B: Assessing Program Performance, Immunization Program Operations Manual [IPOM]*).

Healthy People 2020 has also established an objective related to AFIX assessments (IID-17), stated as follows:

IID-17: Increase the proportion of providers who have had vaccination coverage levels among children in their practice population measured within the past year.

IID-17.1 Target is 50% of public health providers

IID-17.2 Target is 50% of private providers

Note: The word “providers” in the written Healthy People 2020 objective does not specifically refer to VFC providers since quality improvement assessments can be applied to any type of provider. These objectives, however, are acknowledged and supported by the AFIX Program. For more information on the Healthy People 2020 objectives and targets, visit the following website:

<http://www.healthypeople.gov/2020/topicsobjectives2020/objectiveslist.aspx?topicId=23>.

Retiring CoCASA

CDC developed CoCASA at the inception of the AFIX Program for the purposes of assessing immunization provider coverage rates and performance indicators. CoCASA has immunization data entry screens and IIS data import capabilities. After immunization data is entered or imported into CoCASA, data analysis capabilities can be utilized for coverage assessment purposes providing a variety of different reports that can be utilized to pinpoint areas of strength and areas requiring improvement for an individual immunization provider. Some of the AFIX reports generated through CoCASA include but are not limited to adolescent coverage, invalid dose, missed opportunities, need one dose, not up-to-date, diagnostic childhood report, etc.

In an age of decreasing budgets and improving workflow efficiencies, CDC has reassessed the role of CoCASA in supporting AFIX activities. Each year, CDC allocates a considerable amount of resources to the support, development and maintenance of CoCASA. CDC has made the determination that IIS are better positioned to assume the role of AFIX Coverage Assessments. The exact timeline for this transition is still “to be determined”, but once a specific date has been set, support and maintenance of CoCASA will be discontinued, and reports generated from this system will no longer be accepted by the AFIX Program. Some awardees have already made the transition to IIS-based coverage assessments, while others have been awaiting the operational and technical guidance provided through this project.

Immunization Information Systems (IIS)

Immunization Information Systems, also known as immunization registries, are confidential, population-based, computerized databases that record all immunization doses administered by participating providers to persons residing within a given geopolitical area.

- At the *point of clinical care*, an IIS can provide consolidated immunization histories for use by a vaccination provider in determining appropriate client vaccinations.

- At the *population level*, an IIS provides aggregate data on vaccinations for use in surveillance and program operations, and in guiding public health action with the goals of improving vaccination rates and reducing vaccine-preventable disease.¹

IIS have served as a resource for consolidated patient immunization records since the early to mid '90s. IIS represent one of the most established and successful models of healthcare data sharing and exchange in the U.S. IIS collectively contain tens of millions of patient and vaccination records. These systems have evolved over the years into sophisticated data management systems with tools and processes to support the entire immunization workflow for vaccination providers, state/local immunization program staff, and other immunization stakeholders. In many jurisdictions, mandatory reporting laws have been passed requiring immunization providers to report all vaccinations administered to the IIS.

Due to advanced IIS feature functionality and the volume of available patient and vaccination data, IIS are best positioned to assume the role of provider coverage assessment activities when CoCASA is retired. With standardized guidance in the operational use of the IIS and defined technical requirements, IIS will be able to generate the required AFIX reports in a manner that is comparable to those previously produced using CoCASA.

An Opportunity for Partnership

The integration of AFIX assessment functionality into the IIS provides numerous opportunities to leverage this new partnership for the benefit of the entire immunization community. This partnership feeds a constant improvement cycle that involves AFIX, the immunization provider, and the IIS resulting in improved patient care and increased vaccination coverage rates against vaccine preventable diseases. Some of the primary benefits discussed in this document include:

Benefits to AFIX

- Access to an increased amount of data – ability to assess 100% of the provider records
- Time savings in generating reports directly from the IIS – no manual data entry or export/import step

Benefits to IIS

- AFIX interactions with providers to increase participation and reporting
- Improved data quality resulting from AFIX assessments

Benefits to Providers

- Ability to update patient lists and review missing data prior to official AFIX assessment
- Periodic informational assessments
- Improved clinical decision support through increased participation and reporting

¹ <http://www.cdc.gov/vaccines/programs/iis/about.html>

Document Overview

It has been determined that the AFIX-IIS integration effort will be accomplished over the course of two or more development phases. The first phase of the project will specifically focus on the coverage assessment data reported to the AFIX Online Tool for the purposes of generating the AFIXAR. This phase represents the minimum, mandatory reporting that an IIS must be able to perform. During the second phase (and beyond) the scope will be expanded to include other reports utilized by AFIX Program staff for the purposes of provider feedback and quality improvement, along with other priority areas that may be identified by the federal AFIX program and/or program awardees.

This document provides guidance on how to implement IIS-based coverage assessments for AFIX and ensure consistent results and reporting. Specifically this document provides the operational guidance (how the IIS will be used to support AFIX coverage assessment efforts) and technical guidance (how to incorporate the necessary functionality to produce the required coverage reports) for transitioning AFIX coverage reports from CoCASA to awardee IIS.

Requirement: IIS will be able to perform the minimum/mandatory reporting requirements to support the AFIX workflow.

The section titled AFIX-IIS Integration: CDC Operational Guidance is meant to be complementary to the CDC AFIX Policies and Procedures Guide (<http://www.cdc.gov/vaccines/programs/afix/standards.html>) and provides instruction to AFIX Program staff on the following items:

- Using the IIS to identify providers in need of a visit
- Using the IIS to identify the assessment cohort and ensure they are assessing the patients who most accurately reflect/represent those patients under the care of the provider
- Identifying what measures are being/will be assessed in the IIS
- Identifying who should be able to run these reports, how often these reports should be run, and how the results will be reported to the CDC'S AFIX Program

The section titled AFIX-IIS Integration: CDC Technical Guidance provides specific instructions intended for IIS Program staff on the following items related to implementing AFIX Coverage Assessment report(s) in the IIS:

- Selecting provider sites for assessment
- Selecting the assessment cohort
- Selecting vaccinations for the assessment
- Determining dose validity and antigen series completion
- Calculations for the Childhood and Adolescent Coverage Reports
- Calculations for the Childhood and Adolescent Missed Opportunities Reports

Export specifications for the AFIX Online Tool will be provided by CDC in a separate document.

A Technical Design Specification has also been included in Appendix H. It is provided as a resource for programs as they work toward building AFIX assessment functionality into the IIS, if they find it helpful.

However, it is not required that programs utilize this design specification as long as their system generates the required outputs according to the requirements, business rules and decision tables in this AFIX-IIS Integration Guide. The design specifications addresses the following topics:

- Required data inputs/data elements
- Report parameters/criteria
- Report format and access

Finally, this document includes additional discussion about best practices for implementing the transition of AFIX reporting to IIS and guidance for when an Immunization Program is ready to cease use of CoCASA and begin relying solely on the IIS for coverage assessment reports. The document concludes with a discussion of suggested future priorities/considerations for Phase 2 of the AFIX-IIS integration effort.

Stakeholder Engagement

On May 19-22, 2014, AIRA facilitated a three and a half day face-to-face meeting in Decatur, GA. A collaborative decision-making process was used to inform AFIX workflows, identify requirements for developing IIS-based coverage assessments for AFIX, and ensure consistent results and reporting practices across all awardees.

This process involved the identification of subject matter experts (SMEs) to serve in an advisory capacity and represent the perspectives of all critical stakeholders (federal AFIX and IIS programs, awardee AFIX and IIS representatives, IIS vendors, and public health consultants). The SMEs were 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.

Selected experts included 8 awardee projects (Florida, Kansas, Michigan, Minnesota, New York City, Oregon, Washington, and Wisconsin). Awardees were invited to participate in pairs with a representative from the AFIX Program and from the IIS Program to operate as a team during the facilitated discussions. In addition, representatives from the 3 largest IIS vendors (determined by number of project implementations) were also invited to participate (HP, STC, and Envision). Other participants included 5 CDC program experts (POB and IIS Support Branch staff), 2 representatives from the Association of Immunization Managers (AIM), 2 representatives from the American Immunization Registry Association (AIRA), and 3 project staff (independent contractors of AIRA).

A list of meeting participants can be found in [Appendix D: List of Meeting Participants](#) along with the primary discussion elements in [Appendix E. Consensus Meeting Questions](#).

Project Limitations

There are several limitations that should be noted as programs prepare to make the transition from CoCASA to IIS for AFIX Coverage Assessment activities:

1. Data in the IIS will only be as good as what has been reported by providers or other sources. This is impacted by two primary factors:
 - a. **Provider Participation:** In order for the AFIX assessments to be accurate, the provider being assessed must be reporting/recording data in the IIS. Assessments can only be performed on data included in the IIS. There are a number of strategies that can be employed to increase participation and reporting. See the section titled [Provider Participation](#) for operational best practices.
 - b. **Data Quality (DQ):** Factors such as data completeness, accuracy and timeliness contribute to the quality of the data available in the IIS. Many IIS have tools for identifying data quality concerns, and data quality improvement is an ongoing process. There are a number of strategies that can be employed to improve data quality in the IIS. See the section titled [Data Quality](#) for operational best practices.
2. Many providers are now using Electronic Health Records (EHRs) to manage patient records. Vaccinations are then transmitted to the IIS either directly or via Health Information Exchange (HIE) platforms. This practice introduces a number of issues that may not have been an issue with the previous AFIX chart-based workflows:
 - a. The EHR may not capture all of the fields required for AFIX assessments and/or may not transmit them in a standard way that allows them to be accepted into the IIS record (e.g. Patient Active/Inactive Status). In these situations, the provider may need to login to the IIS to manage these features manually through the IIS user interface in order to override a status automatically assigned by the IIS.
 - b. The onboarding process for establishing electronic data feeds between EHRs and IIS may be limited by available resources and occasionally results in a backlog. In this situation, the provider may have more complete and up to date patient/vaccination information that has not been reported to the IIS. This will make the provider's coverage rates appear artificially low.
 - i. Additionally, established data feeds may become inoperative or impaired over time for a variety of reasons (e.g., software upgrades or code set changes/updates). IIS resources are needed to actively monitor existing exchanges and identify these issues when they occur. Reestablishing these exchanges may also be subject to the same resource limitations/backlog that impacts new data exchanges.
 - c. Many of the larger EHRs have not yet implemented bi-directional data feeds with the IIS. Issues may be encountered when the EHR does not "consume" or incorporate the return data from the IIS. This contributes to incomplete records on the provider's side that may result in poor immunization decision support by the provider and be reflected in the assessment reports.

- i. Incomplete data on the provider side will also be an issue if the provider is not routinely entering all historic vaccinations into their EHR and transmitting that information to the IIS.
3. When assessing records using a manual chart pull, the assessor is provided with a full view of all immunization and non-immunization visits for assessing missed opportunities. A known limitation of the IIS is that only immunization visits are reported and therefore, only immunization visits can be assessed for missed opportunities through IIS-based assessment. Missed opportunities are addressed in the section titled [Assessing Missed Opportunities](#).
4. Each IIS product uses a unique set of terminology to describe the various levels of the organizational hierarchy and provider-patient relationships. In this document, an attempt has been made to cross-walk this terminology whenever possible and/or leverage vendor/platform-neutral terminology. Additionally, terms that exist in the AFIX community may be unfamiliar to those involved with the IIS and vice versa. A glossary of terms has been provided in Appendix B. [Glossary and Acronyms](#) in an attempt to define some of these terms in reference to their use in this project.

AFIX-IIS Integration: CDC Operational Guidance

The CDC AFIX Policies and Procedures Guide (2013-2017) is the primary guidance document for AFIX Program operations. The material in this document is intended to complement the AFIX Policies and Procedures Guide for programs that have made, or are in the process of implementing, the transition to IIS-based coverage assessments. The following AFIX-IIS Integration: CDC Operational Guidance is intended to inform AFIX Coordinators and staff on how the IIS should and could be used to support AFIX coverage assessment efforts and other program operations. This document specifically provides guidance on the following functions:

- Using the IIS to identify providers in need of a visit
- Using the IIS to identify the assessment cohort and ensure they are assessing the patients who most accurately reflect/represent those patients under the care of the provider
- Identifying what measures are being/will be assessed in the IIS
- Identifying who should be able to run these reports, how often these reports should be run, and how the results will be reported to the CDC'S AFIX Program

Provider Selection

According to the AFIX Policies and Procedures Guide:

CDC currently recommends selecting at least 25% of VFC-enrolled providers to receive annual AFIX visits. In selecting the number or percentage of providers to visit from the eligible priority list, programs are encouraged to consider CDC's recommendation to select at least 25% of VFC-enrolled providers to receive annual AFIX visits, as well as Healthy People 2020's AFIX objective (IID-17) with a target of 50% annual visits to public and private providers.

The IIS can help AFIX staff achieve or exceed these goals by differentiating VFC providers from other providers/provider types and generating analytics to help support provider selection decisions.

This section provides guidance on the following items:

- Using VFC Pin to uniquely identify and match a provider for AFIX purposes
- Using IIS to identify high volume providers
- Using IIS to identify low performers (low coverage rates, poor DQ, poor vaccine management)
- Ways to improve provider participation and data quality in the IIS

Defining a Provider

For the purposes of AFIX, the term "provider" references a VFC-enrolled *practice* identified through the assignment of a unique VFC Pin. The term "provider" has been used consistently throughout this document to correspond with the VFC Program's definition of the term. In this document, "provider" will not be used to refer to the individual clinician/practitioner/vaccinator.

Due to the numerous ways that a “provider” can be labeled and defined in the IIS community, this document will focus on the *attributes* of a “provider” in the IIS in order to establish a consistent identification of “provider” regardless of which IIS platform or product a jurisdiction may be using.

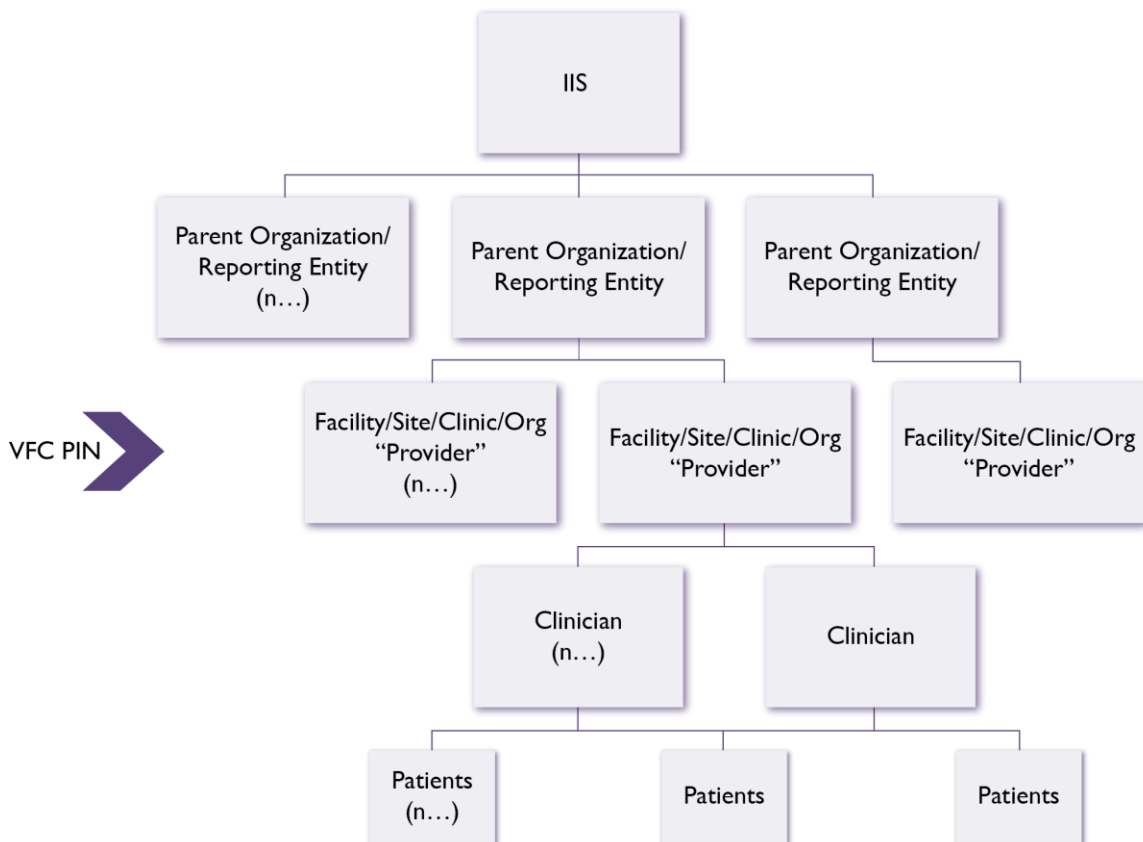
In the IIS, a “VFC provider” will be identified as having the following attributes:

- 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)

When providers are defined in the IIS, an organizational hierarchy is applied. In IIS hierarchy, the functional name for “provider” varies by IIS product type. Some terms used to define a “provider” in the various IISs include clinic, site, facility, or organization and are typically associated to a larger parent organization and/or reporting entity. For AFIX purposes, the most important aspect of identifying a “provider” is determining where in the IIS hierarchy the VFC Pin is being associated. This will then allow AFIX staff to appropriately select providers and generate assessment reports.

The following diagram illustrates an example of a common IIS hierarchy:

Figure 1: IIS Hierarchy



Additionally, the VFC Pin will be the primary identifier used for generating and reporting AFIX assessments to ensure a direct match between the provider in the IIS and the provider in the AFIX Online Tool. Within the IIS, there should always be a unique one-to-one relationship between the VFC Pin and the “provider”. During the consensus meeting, several unique scenarios were discussed, but all tested true to the attributes of a provider and the unique assignment of a VFC Pin.

Requirement: The VFC Pin number will be the primary identifier for linking the provider in the IIS with the provider in the AFIX Online Tool.

Selection Criteria

The AFIX Policies and Procedures Guide (2013-2017) recommends that awardees prioritize selection of providers for AFIX visits based on a list of proposed criteria to be applied as time and resources allow. Additionally, there is specific interest in targeting and improving vaccination practices among providers classified as “underperformers”. The CDC AFIX suggested criteria for prioritizing visits include:

- Practices serving a large population (e.g. ≥ 30 patients in the assessment cohort)
- Low immunization coverage rates
- Practices requesting an assessment
- Practices with new staff or high staff turnover
- Practices newly/recently enrolled in the VFC Program

The IIS can be used to help identify providers who meet the first two suggested criteria – large provider practices and providers with low immunization coverage rates. Tools in the IIS can also be applied to identify other “underperformance” measures. The following sections describe the processes for using the IIS to perform these functions.

Note: CDC currently recommends selecting at least 25% of a jurisdiction’s VFC-enrolled providers to receive an annual AFIX visit. AFIX awardees will be required to prioritize at least $\frac{1}{2}$ of the recommended visits 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. See the section titled Low Immunization Coverage Rates for additional guidance on identifying these providers². The remaining $\frac{1}{2}$ of the recommended 25% should be prioritized using any or all of the criteria listed in the bullets above.

Requirement: AFIX awardees will prioritize at least $\frac{1}{2}$ of their annually recommended AFIX visits from providers with coverage rates in the bottom quartile.

² This will be a new requirement once these guidelines have been officially released by CDC.

Large Practices/High Volume Providers

Most IIS contain basic functionality to generate reports that display the number of patients associated with a specified provider. The level of IIS sophistication varies on whether these reports can provide additional breakdowns by age/age group. Regardless, reports of this nature can help to identify providers who have a large patient population, or at least providers who have *reported* immunization data for a large number of patients.

Another measure that can identify large practices is the number of doses administered. Most IIS have existing reporting functionality that can identify high volume providers through the use of Doses Administered Reports. These reports typically provide a breakdown of vaccine type, dose number in series, and number of doses administered by specified age brackets spanning the entire lifecycle. Some IIS also have the ability to produce a report of overall dose counts as a line listing by provider. Either report option can provide valuable detail indicating the size of the practice and volume of doses being administered (or at least being *reported* to the IIS).

AFIX staff should work with their IIS counterparts to identify and gain access to the reports that will be most useful in providing practice size data.

Low Immunization Coverage Rates

Once the proposed functionality for Phase 1 has been developed into the IIS, AFIX staff will be able to leverage the new report(s) for identifying and prioritizing provider visits. As previously stated, AFIX awardees will be required to prioritize at least ½ of the annually recommended AFIX visits 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. Several IIS that have already implemented coverage assessment capabilities utilize these reports to plan annual AFIX visits. For more information about this requirement, refer to the AFIX Policies and Procedures Guide.

Recommendation: AFIX awardees should use a systematic approach to identify providers with low coverage rates after the new report functionality has been developed into the IIS.

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 visit³.

³ 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.

Some awardees also use this activity as an opportunity to provide “FYI” or courtesy assessment feedback to all VFC providers. The individual coverage assessment results are shared with the respective provider regardless of whether they will be receiving an AFIX visit in the current year. For example, the Citywide Immunization Registry (CIR) in New York City provides courtesy coverage assessments to all VFC providers in their jurisdiction on a quarterly basis⁴. AFIX Coordinators are encouraged to adopt periodic courtesy assessments as a best practice (exact timeframe to be determined by individual awardees).

Recommendation: AFIX awardees should conduct periodic courtesy assessments for providers in their jurisdiction and share the results with providers.

For those providers who are prioritized for an annual AFIX visit, a new assessment will be run prior to the actual visit in accordance with the process described in the section titled [Assessment Timelines](#).

Other Underperformance Indicators

Defining an underperformer can be based on a number of factors: high level of invalid doses, high level of duplicate vaccinations, low immunization rates, high rate of missed opportunities, low rates of data submission to the IIS, high number of patients associated with the provider that have not been seen for over 12 months, high staff turnover, other performance indicators that suggest a need for additional training and education.

The IIS can help identify some of these measures through the use of general provider, patient, inventory, and performance reports that already exist in the IIS. AFIX staff are encouraged to work with their IIS counterparts and help desk staff to identify and gain access to the reports/data that will be most useful in generating this information.

Role of Provider Participation and Data Quality

A noted limitation of transitioning AFIX to IIS-based assessments is the impact of provider participation and the quality of reported data. These issues have always been, and will continue to be, an ongoing struggle for IIS (or any electronic data repository). As with any assessment or survey, the results are only as good as the data that has been collected and/or entered. The following sections describe the impact, limitations and challenges these issues create, as well as best practices for minimizing their effect on AFIX assessment activities. Further, the integration of AFIX assessments with IIS creates an additional opportunity to improve provider participation and data quality in the IIS, which in turn benefits AFIX and the entire immunization community.

⁴ 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.

Provider Participation

For assessment purposes, an ideal scenario would assume that 1) every provider is participating in the IIS, and 2) every provider is consistently reporting all historical and administered immunization data to the IIS (whether through electronic interface or manual entry); however, this is not always the case. Incomplete data leads to an incomplete assessment with results that may or may not reflect what is actually happening at the practice. There are a number of strategies that AFIX-IIS awardees can employ for improving provider participation. Several of these options are described below.

Many jurisdictions have legislated mandatory reporting requirements for providers to report administered vaccinations to the IIS. In some areas this strategy has been very successful in increasing provider participation in the IIS and/or ensuring that doses are reported to the IIS within a specified timeframe (e.g. within 14 days of the administration date). For more information on which projects have implemented mandatory reporting, refer to resources located on the CDC IIS Policy and Legislation website⁵. Rates of participation in jurisdictions where reporting is mandated may or may not be higher than rates where participation is optional. The success of mandates may also depend on whether there are consequences for not reporting and whether participation/consequences are enforced. Regardless of whether a jurisdiction has a mandatory reporting requirement, challenges with provider participation continue to exist across all IIS projects.

Some jurisdictions include an IIS requirement as a condition of VFC Program participation. This option may be employed in conjunction with or in lieu of a legislated mandatory reporting requirement (described above). Relevant VFC Program language can be found in the VFC Program Operations Guide – Module 2 and the VFC Enrollment Overview Document:

Requirement: Immunization Information System requirement language described in the Awardee Provider Agreement Application (Attachment A). Awardee language should be a short statement about the requirement. Details related to the use of the IIS should be addressed in additional awardee communications. By including this language, the awardee is confirming that requiring VFC providers to use the IIS improves program accountability and prevents fraud and abuse of the VFC Program.

When requirement is added:

- *This requirement must be added to the Provider Agreement when the awardee has legal authority requiring use of the IIS.*
- *Awardees without legal authority requiring use of the IIS may choose to add this requirement to the Provider Agreement to increase VFC program accountability.*

⁵ CDC IIS Policy and Legislation Website (<http://www.cdc.gov/vaccines/programs/iis/policy-legislation.html>)

Provider Education Goals for this requirement:

By the end of the enrollment and VFC compliance site visit the provider and staff will understand:

The state or local statute, or awardee requirement, requiring the use of the IIS as a means to improve VFC program accountability.

During the SME meeting, participants shared examples of other strategies that have been successfully employed to increase provider participation without a formal requirement:

- Requiring online use of IIS Vaccine Ordering features for VFC Program participants and/or turning off access to IIS Vaccine Ordering if provider is not routinely submitting data (New York City⁶, Oregon, Washington)
- Running FYI provider assessments with IIS data “as is” – artificially low rates motivate providers to clean up data in the IIS (Michigan, New York City)
- Providing initial data entry assistance to providers who are new to the IIS and/or VFC Program (SME recommendation)
- Educating providers, in advance, about the transition towards IIS based AFIX assessments (Michigan)
- General marketing of the IIS and educating providers on the benefits of using the IIS and the tools it contains to support the clinical workflow (Oregon)

Other strategies include:

- Publicly recognizing (e.g., in a newsletter) providers that set a good example (e.g., those that consistently submit data or submit data in a timely manner)
- Displaying to providers at log on to the IIS the current practice level coverage rate (or alternatively, training providers to run practice level coverage rate reports and to monitor the results routinely)
- Partnering with providers in ongoing IIS planning and development to ensure that the system supports the practice as well as the public health mission
- Partnering with organizations (e.g., local chapters of AAP, schools, professional organizations)

Please direct questions on these and other strategies to afixiis@cdc.gov .

⁶ 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.

IIS are discouraged from developing special, rapid entry interfaces for AFIX in order to accommodate non-participating providers. Providers should utilize standard direct data entry and/or electronic data interfaces to report their data to the IIS. Providers choosing not to participate or routinely submit data should be educated on the value of using the IIS and how improved data reporting can improve their coverage rates. This is another example of how the AFIX-IIS partnership can be leveraged to improve provider participation for the benefit of the entire immunization community.

Recommendation: AFIX and IIS staff should work together to develop and apply strategies to increase provider participation in, and reporting of data to, the IIS.

Data Quality

There are three primary data quality challenges that impact data in the IIS – Accuracy, Completeness and Timeliness⁷.

Accuracy – *The data recorded in the IIS should match exactly what happens in a clinical encounter, whether or not it is clinically appropriate (e.g. Tdap administered to a 6 month old instead of DTaP).*

Completeness – *1) The information submitted to the IIS must contain the minimum/mandatory set of data items in order to be accepted by an IIS. 2) The data recorded in the IIS should reflect a complete history of all vaccinations ever administered to an individual, and 3) The IIS should contain complete histories for all individuals residing in the jurisdiction.*

Timeliness – *Data should be timely. Data should be reported and recorded in the IIS, as well as be available to users in a timely manner⁸.*

These issues impact all IIS to some degree or another and have been the focus of many expert discussions at the CDC, jurisdictional and vendor levels. Similar to provider participation, poor data quality leads to assessment results that may or may not reflect what is actually happening at the practice. Many jurisdictions have developed and implemented formal data quality improvement strategies supported by sophisticated IIS reporting tools and dedicated staff.

Note: AFIX awardees should make every attempt to ensure that provider data is as clean as possible prior to the actual visit to a provider's office (immunization records are complete and patient statuses are correct). Courtesy assessments as described in the section titled [Low Immunization Coverage Rates](#) or routine pre-visit assessments as described in the section on [Assessment Timelines](#) should be used as an

⁷ Modeling of Immunization Registry Operations Workgroup (MIROW) Data Quality Assurance in Incoming Data (2008).

⁸ Idem. Note: MIROW business rule 115 states, "for administered vaccinations, Report Submission Date should be within 30 days of Vaccination Encounter Date". Awardee legislation and/or program policy often establish more stringent requirements for the timeliness of data submissions (e.g. data must be reported to the IIS within 14 business days of administration). Awardees are encouraged to familiarize themselves with the laws and policies that govern reporting in their jurisdiction.

opportunity for providers to identify and correct data quality issues prior to an official AFIX visit. AFIX visits should not be used as a data cleaning opportunity.

Recommendation: AFIX awardees should leverage pre-visit assessment activities as an opportunity for providers to review active patient lists and address any data quality issues.

Projects looking for additional guidance on improving data quality in IIS are encouraged to refer to the MIROW resources posted on the AIRA website and the patient-level deduplication resources produced through the EHR-IIS Interoperability Expert Panel Project:

Modeling of Immunization Registry Operations Workgroup (MIROW): Best Practice Guidelines (<http://www.immregistries.org/resources/aira-mirow>)

- Vaccination Level Deduplication in IIS – 2006
- Data Quality Assurance in IIS: Incoming Data – 2008
- Data Quality Assurance in Immunization Information Systems: Selected Aspects – 2013

EHR-IIS Interoperability Expert Panel Project (<http://www.cdc.gov/vaccines/programs/iis/interop-proj/ehr.html>)

- Patient Deduplication Best Practices and Test Cases – 2013

In addition, CDC and AIRA have both developed tools to assist awardees in identifying and evaluating IIS data quality issues.

- CDC IIS-Trends in Immunization Practices System (TIPS)
- AIRA Data Quality Assurance Tool (2015 pilot)

Data quality improvement is an ongoing effort, and all awardees are encouraged to continue working towards improved data quality as resources allow.

Strategies for AFIX Staff

In addition to formal requirements for provider participation and reporting, and ongoing IIS data quality improvement efforts, there are a number of strategies that can be employed directly by AFIX staff to encourage provider participation and improve data quality in the IIS. With the launch of the AFIX Site Visit Questionnaire in January 2014, awardees are encouraged to refer to the section dedicated to provider participation, *Strategies to Improve Completeness and Accuracy of Immunization Information in the IIS*. This questionnaire and the accompanying answer guide should be used to educate providers about submitting their data to the IIS to ensure the most complete and accurate AFIX assessment possible.

To further support positive partnerships between AFIX staff and providers, the following strategies suggested in the AFIX Policies and Procedures Guide should be employed to improve provider assessments generated from the IIS:

1. Send the assessment data to the provider in advance of the visit. Request that the provider update the data in the IIS. Print a more accurate report to share/discuss during the visit⁹.
2. If a provider is not enrolled in the IIS, develop plans to get them enrolled and get their data submitted. For newly enrolled providers who don't have an EHR capable of submitting historical data to IIS, AFIX will initially only include newly submitted data until historical data can be manually entered or migrated.
3. If the program's IIS allows providers to generate their own reports to review their data, encourage providers to review these reports to ensure that the data they have submitted is complete and accurate. This check may be monthly or as frequently as the program determines necessary. These provider self-assessment reports should not be used in place of an annual AFIX assessment.

AFIX staff may also want to encourage providers to implement a "spot check" technique that has been utilized by IIS programs over the years. Spot checking involves having the provider pull a small selection of charts or select a sample of records in the EHR and compare the immunization record against what is reflected in the IIS. This allows providers to verify that data on paper charts or electronic health records matches what is displayed in the IIS and/or identify possible issues with their office workflow or data interface.

Recommendation: VFC providers should be given appropriate permissions in the IIS to generate their own periodic assessments.

Patient Selection

Another consideration of using IIS to perform AFIX assessments is patient selection. Unlike the historical practice of analyzing a *sample* of eligible charts, use of the IIS will facilitate the assessment of *ALL* eligible records. Patient selection will be driven by two primary factors: 1) defining the assessment cohorts, and 2) ensuring that the patients being assessed have been correctly associated with the provider's practice.

This section provides guidance on the following items:

- Defining assessment cohorts
- Identifying active patients of the selected provider
- Defining rules for patient inclusion/exclusion

⁹ Awardees should not print official assessment reports more than 7 days prior to the actual feedback session. When conducting the informational pre-assessment, providers should be informed of when the official report will be run and that any changes they intend to make should be done prior to that date. Changes made after the official coverage report is run will not be factored into the assessment results.

Defining the Assessment Cohorts

For the purposes of producing consistent AFIX coverage assessments from the IIS, all coverage report results reported to the AFIX Online Tool are required to be generated for the specified childhood and adolescent cohorts:

- Childhood: **24 through 35 months** (immunization status to be assessed at 24 months/2nd birthday)
- Adolescents: **13 through 17 years** (immunization status to be assessed on date of assessment)

Note: A determination was made to assess adolescents from 13 -17 years because of how some IIS laws/mandates are applied after an individual reaches their 18th birthday. In order to achieve consistency in the adolescent cohort assessments and to avoid any law/mandate limitations for 18 year olds, the go-forward age range for adolescent assessment will be 13-17 years of age.

Additional Note: The IIS will utilize the specified cohort age ranges and the “as of” date to derive a birthdate range for patient inclusion. Refer to the section titled [AFIX Assessment Dates](#) for additional information.

For AFIX guidance on when to conduct an adolescent visit in conjunction with a childhood visit, AFIX awardees should consult the AFIX Policies and Procedures Guide.

Some awardees that have already made the transition to IIS-based coverage assessments may offer the ability to select and analyze different age cohorts and assessment measures (e.g. 12-24 months by 12 months of age); however, for the purposes of required AFIX reporting, the IIS must be able to, at minimum, assess the cohorts specified above and apply the assessment measures detailed in the section titled [Assessment Measures](#).

Requirement: Assessment age ranges will be defined as 24 through 35 months for childhood assessments and 13 through 17 years for adolescent assessments.

A Note about AFIX vs. NIS Methodology and Cohorts

It has been reported that some jurisdictions compare AFIX results to those published by the National Immunization Survey (NIS). This practice is not recommended by CDC. AFIX and NIS use slightly different assessment measures and serve different purposes. A comparison of the primary differences between AFIX and NIS are described in Appendix F. [AFIX vs. NIS Comparison](#).

Identifying Active Patients

In addition to assessing the correct age cohorts, it is also important that the AFIX assessment include only the “active” patients of the selected provider. Patient status is a term used to describe a relationship between a patient and a provider, where that provider has responsibility for immunization of that patient if status is active, or does not have responsibility for immunization of that patient if status is inactive or deceased. In general, all patients with an “active” patient status in each age cohort

will be included in an AFIX assessment for the identified provider. To determine which patients are active with a provider and included in the AFIX assessment, IIS and AFIX staff should follow guidelines published in the AIRA Modeling of Immunization Information Systems (MIROW) document: *Management of Patient Active/Inactive Status (PAIS) in Immunization Information Systems: Replacement of 2005 Guidelines—2015*. The MIROW guidelines provide context for how patient status business rules can be applied consistently among IIS. For the purposes of reporting to the AFIX Online Tool, IIS can identify patients active with a provider on the “Assessment Date”, or, for those systems that maintain a historical record of patient status at the provider-level, IIS can identify patients active with a provider on the “As of Date”. AFIX staff should work closely with their IIS colleagues to understand the way that their specific IIS works to include and exclude patient records from AFIX assessments.

Requirement: The IIS will be able to identify active patients of the assessed provider.

There are two common approaches for indicating patient status in an IIS. Both approaches are acceptable for AFIX assessments and only one approach will be used by each IIS. The two approaches are:

- **One-to-One.** In the one-to-one approach, a patient can have a status of “active” with only one provider at any point in time. In general, for the one-to-one approach, patients who have a status of “active” with a provider will be included in an AFIX assessment for that provider. For further business rules on when a patient should be considered active please see the MIROW document referenced above.
- **One-to-Many.** In the one-to-many approach, a patient can have a status of “active” with more than one provider at the same time. In general, for the one-to-many approach patients who have a status of “active” with a provider will be included in an AFIX assessment for that provider; however, it also means that a patient could be included in multiple AFIX assessments (for different providers). For further business rules on when a patient should be considered active please see the MIROW document referenced above.

Patient statuses can be changed manually in many IIS user interfaces by staff in the provider’s office who have appropriate add/edit permissions. Status changes may also be done through some EHR user interfaces. If the change is made in the EHR interface, it must be communicated to the IIS through routine data submissions so that the IIS reflects the most current status. In many cases the EHR is not able to export (or capture) this information. In those cases, the provider must manually change the status in the IIS so that the status is correctly reflected in the IIS. If the status indicated in the IIS is “active”, the patient will automatically be included in the assessment cohort. A patient status of “inactive” or “deceased” will be excluded from the AFIX assessment.

Recommendation: Providers should have the ability to edit the patient active status value when needed.

Providers should not change patient status to “inactive” strictly for the purposes of improving their coverage assessment rates; appropriate criteria must be applied to inactivate a patient. It is up to the IIS and AFIX program awardees to provide guidance and/or enforcement on the use of patient status updates based on this Operations Manual and the MIROW patient status guidelines.

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. This step should be included as part of the pre-visit assessment described in the section on [Assessment Timelines](#). A new assessment will then be run prior to the actual visit to generate the official results that will be shared with providers during the visit and reported to the AFIX Online Tool.

Special Rules for Record Inclusion and Exclusion in an AFIX Assessment

When using the IIS for an AFIX coverage assessment, 100% of the patients in the specified age cohort with an “active” status for the selected provider must be included in the assessment. This includes all patients regardless of whether there is a patient-level exemption (medical, religious or philosophical) or global contraindication/precaution. Patients with no immunizations on their record should be assessed as not up to date for all measures. *(Note: Patients with history of disease or blood titer recorded for a specific antigen will be considered complete for that particular vaccine/series when the evaluation algorithms are applied.)*

Requirement: The assessment will include 100% of the patients in the specified age cohort that have an active status with the provider (denominator).

The only exception to this rule of inclusion is patients who have not consented or have opted out of participation in the IIS (applies to jurisdictions where participation in the IIS is optional). These patients should automatically be excluded from the AFIX assessment cohort. It should also be noted that opt out behavior is implemented in various ways depending on jurisdictional laws/policies and IIS functionality. In some implementations, the patient may continue to remain accessible and “active” with the provider for assessment purposes. The MIROW document (*Management of Patient Active/Inactive Status in Immunization Information Systems: Replacement of 2005 Guidelines*) provides additional guidance on handling the various opt-out scenarios with regards to assessment.

Assessment Factors

This section will describe the various elements that will be applied when analyzing the patient cohort against the various coverage assessment measures.

This section provides guidance on the following items:

- Confirming which vaccines and benchmarks to assess
- Defining how Missed Opportunities will be calculated in the IIS

- Applying IIS vaccine forecasting/evaluation algorithms to determine validity of doses and series completion
- Applying AFIX assessment date logic
- Describing operational aspects of running and managing reports (users, timelines, report management, reporting to CDC)

Assessment Measures

For the purposes of producing AFIX coverage assessments from the IIS, all coverage report results reported to the AFIX Online Tool must be based on the required assessment measures. This section provides details about what benchmarks to assess for children and adolescents and criteria to apply for determining vaccination coverage and missed opportunities. AFIX measurements have been designed to evaluate a provider on the number/percentage of patients within a specified cohort that meet the burden of protection according to ACIP recommendations, routine and/or catch-up schedules, for the defined assessment measures.

As previously stated, some IIS may offer the ability to select and analyze different age cohorts and assessment measures; however, for the purposes of required AFIX reporting, the IIS must be able to, at minimum, assess for the measures detailed in the following sections.

Childhood Assessment

As described in the section titled [Defining the Assessment Cohorts](#), childhood assessments will include patients aged 24-35 months. Vaccination coverage will be retrospective to assess vaccination status at 24 months of age (the child's 2nd birthday). Children adhering to both the routine and catch-up schedules will be included in the assessment.

Requirement: Patient compliance with the specified AFIX measurements will be assessed at 24 months/2nd birthday for childhood assessments.

The following vaccination/series benchmarks will be assessed as the primary indicators of whether a child has been immunized in a timely manner for the primary Advisory Committee on Immunization Practices (ACIP) recommended vaccines:

Note: Throughout this document, the term up to date (UTD) will be used in reference to vaccine measurements where a variable number of doses can be applied to achieve protection depending on patient age, date of first dose, and/or vaccine product licensure nuances. Where noted, use of UTD applies to both the individual vaccines and the 4:3:1:3:3:1:4 series.

- 4 DTaP (%)
- 3 Polio (%)
- 1 MMR (%)
- UTD Hib⁺ (%)
- UTD Hep B⁺ (%)
- 1 VAR (%)

- UTD PCV[†] (%)
- UTD RV[†] (%)
- 1 Influenza (%) (*note: previously completed flu season*)
- 2 Hep A (%)
- 4:3:1:3:3:1:4 (%) Series[†]

[†] See CDSi (<http://www.cdc.gov/vaccines/programs/iis/interop-proj/cds.html>) for more information on specific schedule guidance.

Requirement: IIS will assess patient compliance with the specified AFIX measurements according to the detailed calculation logic included in this document.

The specific logic and equations that will be utilized by the IIS to calculate these results are detailed in the section titled [AFIX-IIS Integration: CDC Technical Guidance](#) and [Technical Design Specification](#) (Appendix H).

Adolescent Assessment

As described in the section titled [Defining the Assessment Cohorts](#), adolescent coverage assessments will include patients aged 13-17 years. Vaccine coverage will be assessed for status on the date of the assessment. Adolescents adhering to both the routine and catch-up schedules will be included in the assessment.

Requirement: Patient compliance with the specified AFIX measurements will be assessed on the date of assessment for adolescents.

The following vaccination/series will be assessed and represent the vaccines recommended for adolescents by the ACIP:

Note: As previously stated, the term up to date (UTD) will be 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 product licensure nuances.

- UTD Hep B[†] (%)
- 2 MMR (%)
- 2 VAR (%)
- 1 Tdap (%)
- UTD Meningococcal[†] (%)
- 3 HPV (%) (assesses the number of adolescents that *complete* the series, include only adolescents with 3 valid doses)
- 2 HPV (%) (assesses the number of adolescents *in progress* for the series, include all adolescents with 2+ valid doses)

- 1 HPV (%) (assesses the number of adolescents that *start* the series, include all adolescents with 1+ valid doses)
- 1 Influenza (%) (*note: previously completed flu season*)
- 2 Hep A (%)
- UTD Polio[†] (%)

[†] See CDSi (<http://www.cdc.gov/vaccines/programs/iis/interop-proj/cds.html>) for more information on specific schedule guidance.

Requirement: IIS will assess patient compliance with the specified AFIX measurements according to the detailed calculation logic included in this document.

During the consensus meeting, it was recommended that AFIX consider adding Polio and Td coverage to the list and adding the second Meningococcal booster dose to the assessment. These suggestions were considered by the CDC'S AFIX Program, and the following decisions were made:

- Polio – Polio has been added to the routine Adolescent Assessment, and results will be reported to the AFIX Online Tool. The adolescent series may be complete with 3-4 doses depending on the age at which the 3rd dose of Polio was administered.
- Td – In 2006, the ACIP recommended routine use of Tdap as a single dose among adolescents 11 to 18 years of age, with preferred administration at 11 to 12 years of age. The primary goal of establishing the U.S. Tdap vaccination program in 2005 was to directly reduce the burden of pertussis among adolescents 11 to 18 years of age. CDC's AFIX requirement will remain to assess vaccination rates for Tdap and will not include Td.
- Meningococcal – AFIX currently assesses for 1 Meningococcal dose which should be received between 11 and 12 years of age. There is also a booster dose recommended at 16 years of age. Depending on the age of the adolescent assessed and the age at first Meningococcal dose, adolescents receiving either 1 or 2 doses of Meningococcal may be up to date according to ACIP recommendations. As a result, the measurement for Meningococcal has been updated to read "UTD" to account for ACIP recommendations and align with adolescent series completion per CDSi logic.

The specific logic and equations that will be utilized by the IIS to calculate these results are detailed in the section titled [AFIX-IIS Integration: CDC Technical Guidance](#) and [Technical Design Specification](#) (Appendix H).

A Note on Influenza Coverage

The current AFIX Policies and Procedures Guide describes the method CoCASA uses to assess influenza vaccine coverage. Presently, AFIX defines a flu season as July 1 through June 30, and coverage calculations are based on the most recently *completed* flu season – not a flu season in progress (e.g. 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). This measure was discussed during the consensus meeting to determine whether this is still the most appropriate measure to use in the transition to IIS-based coverage assessments. There was also discussion about whether influenza is a measurement that AFIX should be collecting based on numerous other surveys that already collect this information.

CDC'S AFIX Program considered the influenza discussion from the consensus meeting and made the following decisions:

- Influenza vaccine is a routine vaccination recommended by ACIP. Awardees are required to continue the assessment and reporting of influenza coverage rates to the AFIX Online Tool. The decision to continue measuring influenza coverage also supports the Healthy People 2020 objective of achieving a 70% influenza coverage rate. For more information about Healthy People 2020 please visit their [website](#).
- A flu season will continue to be defined as July 1 through June 30, and coverage calculations will continue to be reported for the most recently *completed* flu season using the existing coverage assessment methodology.
- Vaccination completion will be defined as "at least 1 valid dose of influenza vaccine for the prior completed season".

Requirement: AFIX awardees will assess and report coverage rates for influenza based on the previously completed flu season.

In addition to assessing influenza coverage rates for the most recently *completed* flu season, CoCASA also includes the ability to assess unvaccinated patients in a *current* season through a "quick count" report that includes a list of patients who have not completed the influenza vaccination series with either one or two doses, per ACIP recommendations, for the current season. In transitioning towards the use of IIS for assessing flu immunization coverage, awardees may want to consider producing a list of this nature from the IIS. It has been suggested that AFIX awardees utilize the existing reminder/recall features of the IIS to produce a list of patients who are due/overdue for influenza vaccine in the current/ongoing flu season. AFIX awardees should work with their IIS counterparts for training on how to use this feature. Providing an ongoing flu season report would alert the provider to the names of patients in the cohort that have yet to receive their annual vaccination, and this will enable the provider to take action to improve their immunization rate. A current-season influenza coverage report is not an AFIX reporting requirement.

Assessing Missed Opportunities

In addition to assessing coverage rates, both children and adolescents will be evaluated for missed opportunities. In general, a missed opportunity can be defined as anytime that a child/adolescent presents to their provider for services, is due for one or more vaccinations, and does not receive every vaccine they are currently due for at the time of that visit. Historically there have been four methods for reviewing and calculating missed opportunities as part of an AFIX assessment:

- Missed Opportunity on the Last Immunization Visit
- Missed Opportunity on All Immunization Visits
- Missed Opportunity on All Previous Visits (e.g. well child and sick child visits)
- Missed Opportunity on Only Non-Immunization Visits

A known limitation of using the IIS is that AFIX staff will lose the ability to assess non-immunization visits (e.g. sick visits or general screenings) previously assessed by manually reviewing patient charts. If AFIX staff still wants to review missed opportunities during all visits, program-level decisions will need to be made on how to operationalize and facilitate this review.

IIS conceptually could evaluate missed opportunities at the last immunization visit or retrospectively across all immunization visits. During the consensus meeting, however, it was decided that the standardized measure for AFIX will be based on the last immunization visit. This decision is supported by the following rationale:

1. Patients may have been seen by more than one provider, so evaluating the most recent visit ensures the most accurate reflection of the provider's vaccination practices.
2. Report performance in the IIS may be compromised due to the volume of data and system resources required to evaluate all immunization visits for each immunization record in the cohort, especially for large practices.

Therefore, for the purposes of reporting to the AFIX Online Tool, all IIS will be required to calculate missed opportunities based on the **last immunization visit**. The results of this assessment will then be reported directly to the AFIX Online Tool. For reference, "Missed Opportunity on the Last Immunization Visit" is defined as follows:

On the patient's last visit for an immunization he/she received a dose of a different antigen than the antigen in question, or there was a reason a different antigen was not given, and at the time of that visit a valid dose of the antigen in question could have been administered in keeping with the patient's age and the time interval from the previous valid or invalid dose.

Note: Parent refusals of one or more vaccines will be counted as a missed opportunity to vaccinate.

Requirement: Missed Opportunities calculations will be based on the last immunization visit.

The specific logic and equations that will be utilized by the IIS to calculate these results are detailed in the section titled [AFIX-IIS Integration: CDC Technical Guidance](#) and [Technical Design Specification](#) (Appendix H).

IIS Forecasting and Evaluation Algorithms

When assessing vaccination coverage, there are two approaches: 1) simple count of doses on the immunization record, or 2) applying ACIP guidelines for determining validity of doses and accepting only valid doses towards completion of the vaccination/series. Only valid vaccinations will count towards the UTD status determination for the AFIX measurements.

Requirement: Only valid vaccinations will be counted towards the up to date (UTD) coverage calculations.

In order for IIS to assess validity and calculate coverage and missed opportunity rates, the IIS should apply their full forecasting/evaluation algorithms. These algorithms provide the applied logic 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 dose¹⁰. Forecasting/evaluation algorithms account for most aspects and variations of the ACIP recommendations including but not limited to:

- Recommended Schedule
- 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

Recommendation: IIS should apply their full forecasting/evaluation algorithm for both the recommended and catch up schedules when making coverage/missed opportunity determinations.

A group of experts has been convened to develop the CDSi (Clinical Decision Support for Immunization) Logic Specification that provides guidance to developers of IIS forecasting/evaluation algorithms. For those interested in more information about these efforts/algorithms, please consult with your IIS counterpart and/or visit the CDSi website (<http://www.cdc.gov/vaccines/programs/iis/interop-proj/cds.html>).

Recommendation: IIS should leverage CDSi resources when defining forecasting/evaluation algorithms.

¹⁰ For more information on using target doses to determine validity, refer to the CDSi Logic Specification section 3.1.

AFIX Assessment Dates

In addition to defining the core measures to be evaluated, the IIS will also be used to establish the dates and parameters applied as assessment criteria for inclusion of patients and vaccinations in the assessment. AFIX assessment date concepts will be adopted by the IIS to emulate legacy CoCASA behavior. The primary assessment date parameters include Assessment Date, Feedback Date, Assessment Age Range, As of Date, Calculated Birthdate Range and Compliance by Age/Date.

Requirement: IIS will need to adopt and apply AFIX assessment date concepts for establishing report parameters used to derive the assessment cohort birthdate range and benchmarks/timeframes for vaccination status assessment.

Assessment Date – This field is informational and reflects the date the report is run (e.g. “today’s date”). The Assessment Date and the Feedback Date (date results are shared with the provider) should be as close as possible. The AFIX Policies and Procedures Guide recommends that “no longer than one week pass between assessment and feedback to ensure that the data generated presents an accurate picture of a provider’s coverage”. The Assessment Date does not directly impact any of the IIS calculations.

Feedback Date – This field is optional in IIS but must be reported in the AFIX Online Tool. This field is informational and reflects the date that the feedback session has been scheduled with the provider. This date should be ≤ 7 days from the “Assessment Date”. The Feedback Date does not impact any of the IIS calculations.

Assessment Age Range – This field is the same as the assessment cohort and may be reflected in months for childhood assessments (24-35 months) or years for adolescents (13-17 years). 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.

As of Date – This field will typically default to “today’s date” with the ability to be edited. The birthdate range for the assessment cohort should be calculated based on the age of the cohort as of the specified date. *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.* 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” that date in order to determine the assessment cohort. Individuals that have come of age after the “As of Date” will be excluded from the assessment cohort.

As a recommendation, the As of Date should be the same as the Assessment Date. Some projects reported routinely using an As of Date up to 14 days prior to the Assessment Date to allow for possible reporting delays for providers who submit data electronically to the IIS. This practice is acceptable, but the timeframe for standard assessments should never exceed 14 days as stated in the AFIX Policies and Procedures Guide

In addition, for projects using the IIS to identify providers with low coverage rates to be prioritized for an AFIX visit (see section titled [Low Immunization Coverage Rates](#)), a common As of Date may be applied as a point in time measure (e.g. 1st of the month or once a year). Some projects also use this approach for internal benchmarking and analysis. This approach should only be used for mass coverage comparisons and should never be used for generating assessments that will be reported to the AFIX Online Tool.

Calculated Birthdate Range – These dates will be automatically calculated by the IIS and displayed in the report header. The calculated birthdate range will be based on the criteria defined for the Assessment Age Range and the As of Date.

Compliance by 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)” in future phases of the AFIX-IIS integration effort.

These assessment criteria have also been described in the [AFIX-IIS Integration: CDC Technical Guidance](#) and [Technical Design Specification](#) (Appendix H). AFIX staff will define the various report parameters/criteria to be applied when running individual provider assessments.

Operationalizing IIS-based AFIX Coverage Assessment

This section will cover some of the operational aspects of IIS-based AFIX coverage assessments including who can run these reports, when assessments should be run, how reports are stored after they are run, and how results should be reported to the AFIX Online Tool.

User Access

Access to the AFIX Coverage Assessment Report(s) will be managed through IIS user roles and permissions. In general, these reports should be made available to any entity that will obtain value from having access to this information. AFIX staff should work directly with their IIS counterparts to determine which users/user types should be granted access. It is recommended that the following user types should be able to run the report:

- State IIS Staff
- State AFIX Staff
- Local Public Health IIS and AFIX Staff
- Staff at Parent Organizations/Reporting Entities
- Staff at Individual Clinics/Sites/Facilities/Organizations
- Contracted Designees (performing assessments on behalf of State/Local AFIX/IIS Staff)

User access will be managed in such a way that users will only be able to assess data directly within their purview. For example, a state level staff member can run an assessment on any provider in the state, whereas a local staff member will only be able to assess providers within their specified jurisdiction, and provider staff will only be able to assess their practice and/or practices within their Organization.

Recommendation: The new assessment report(s) should be made available to a variety of user types.

Assessment Timelines

In accordance with the AFIX Policies and Procedures Guide, when a provider is selected for an AFIX visit, there should be 1) an initial coverage assessment and 2) a follow up coverage assessment performed within 6 months following the initial visit. The initial assessment should include the childhood and/or adolescent assessment for immunization coverage and missed opportunities. These assessments should be run as close as possible to the feedback date. The follow up assessment does not require a physical visit to the practice, but the re-assessment report should be generated by applying the same standardized parameters/criteria used for the initial visit to determine whether AFIX interventions have resulted in improved practices and coverage rates. *Note: Use of the standard parameters/criteria to generate the follow up assessment report will result in a new birthdate range and new cohort group.* Results from both the initial and follow up assessments must be reported to the AFIX Online Tool.

Requirement: Providers prioritized for an annual AFIX visit should receive an initial assessment/feedback visit and a 6-month follow up assessment. Results of both the initial and the follow up assessment will be reported to the AFIX Online Tool.

As noted in previous sections, for those providers who are prioritized for an annual AFIX visit, AFIX awardees are advised to offer providers a pre-visit assessment so they can identify and correct data quality issues and have an opportunity to inactivate patients who are no longer receiving services at the practice prior to the official AFIX assessment and visit. AFIX awardees should make every attempt to ensure that provider data is as clean as possible prior to the actual assessment of a provider's office. AFIX visits should not be used as a data cleaning forum.

Recommendation: Prioritized providers should be provided with a pre-visit assessment to review the active patient list and address any data quality issues prior to the official assessment.

It was also noted in previous sections that some programs may run annual or quarterly assessments for all providers by using IIS-based coverage reports and then providing these reports to the providers as a courtesy/informational gesture. AFIX awardees are encouraged to adopt periodic courtesy assessments as a best practice (exact timeframe to be determined by individual awardees).

Recommendation: AFIX awardees should offer periodic courtesy assessments to all VFC providers within their jurisdictions regardless of whether they have been identified for a visit.

Table 1 (Assessment Summary Table) below summarizes the various assessment types, the timelines for when these assessments should be performed and whether this type of assessment is required by CDC's AFIX Program, and which results are required to be reported to the AFIX Online Tool.

Table 1: Assessment Summary Table

Assessment Type and Purpose	Timeline for running the assessment?	Assessment required by CDC's AFIX Program?	Required reporting to the AFIX Online Tool?
▪ Informational: Courtesy, FYI assessment	▪ Anytime or Common "As of" Date	▪ Recommended	▪ No
▪ Pre-Visit: Pre-assessment and active patient list to help provider prepare for upcoming scheduled visit by ensuring data is clean and complete prior to the official assessment	▪ Up to 1 month prior to the official assessment	▪ Recommended	▪ No
▪ Provider AFIX Visit: Initial provider assessment conducted prior to the feedback session	▪ Within 1 week prior to the visit	▪ Required ¹¹	▪ Yes
▪ Follow Up: Official follow up assessment to see if visit resulted in improved rates and immunization practices	▪ Within 6 months following the visit	▪ Required ¹²	▪ Yes

¹¹Assessment, Feedback, Incentives eXchange (AFIX): Program Policies and Procedures Guide; First Edition – 2013 (<http://www.cdc.gov/vaccines/programs/afix/downloads/standards-guide.pdf>)

¹² Idem.

Managing Reports

Once AFIX reports have been generated from the IIS, users should have the option to Print or Save (e.g. .pdf) the reports. These reports can then be used for the AFIX visit and manually reporting results to the AFIX Online Tool. IIS will not be required to store coverage assessment reports on behalf of AFIX. Report storage (manual or electronic) will be handled operationally by the AFIX program as determined by project-level policies and procedures.

Some IIS have existing capabilities to export results into an Excel (.xls) spreadsheet, store reports for a specified period (e.g. 10-30 days), and/or store the data in a data warehouse for future data mining. This functionality varies significantly from IIS to IIS, so AFIX staff should visit with their IIS counterparts to learn about what options are available through their particular IIS.

Ultimately, IIS will be encouraged to generate an export of the report data that can be uploaded directly into the AFIX Online Tool to minimize manual data entry. CDC is in the process of defining the export specifications to support this functionality. Once an interface for the AFIX Online Tool has been developed, export specification guidance will be provided to IIS awardees in a separate document.

Recommendation: The IIS should offer the ability to print, save and/or generate an export of the report results.

Reporting to the AFIX Online Tool

Until export specifications have been developed and implemented to facilitate electronic reporting, AFIX staff will manually enter the assessment results generated from the IIS directly into the AFIX Online Tool for both the initial assessment and follow up assessment. Providers in the IIS will be matched to providers in the AFIX Online Tool using the VFC Pin Number as described in the section titled [Defining a Provider](#). From this data the AFIX Online Tool will automatically calculate the percentage change in coverage rates between the two assessments. All provider level assessment data reported to the AFIX Online Tool will then be compiled on an annual basis by the CDC'S AFIX Program to generate the AFIX Annual Report (AFIXAR) for each awardee project.

As stated in the previous section, an export specification will be provided to IIS projects to facilitate electronic reporting of assessment results once the AFIX Online Tool import interface has been developed. The export will allow users to pull coverage results from the IIS and upload them directly to the AFIX Online Tool. This export will save time for AFIX awardees, eliminate the need for manual entry of coverage report results, and minimize potential data entry transcription errors when reporting assessment results to the AFIX Online Tool.

A Note about Report Performance

Reports that require multiple layers of logic tend to utilize a lot of IIS processing resources to generate the results, especially when the report is performed for a large provider. These reports compete for system resources that may be impacted by other resource intensive processes such as processing data imports and other large reports. As such, AFIX staff should discuss limitations of the IIS with their IIS

counterparts. Effective coding and hardware can improve some report performance issues; however, there are some best practices that can be universally applied by AFIX staff to ensure that reports will be ready and available when the reports are needed:

1. Avoid running reports during peak usage periods (e.g. Monday mornings, back-to-school, and peak flu season). IIS staff can provide guidance on when these heavy use periods occur.
2. Plan ahead! Avoid trying to run assessment reports right before heading out the door to an AFIX visit.
3. If the IIS offers a scheduling function, take advantage of this feature. Reports are scheduled and run during off hours. After reports have been generated they are either delivered by email or made available in a repository that can be accessed when the user is ready. IIS features vary, so AFIX staff should discuss these options with their IIS counterparts.

Recommendation: AFIX awardees should plan to run reports for assessment/feedback visits in advance of the visit (≤ 7 days) to avoid any possible IIS processing challenges that may be encountered when generating the large, complex reports.

AFIX-IIS Integration: CDC Technical Guidance

The following section is intended to inform IIS Coordinators of the CDC technical requirements for implementing the integration of AFIX coverage reports into IIS. This section will detail the following technical elements and is designed to ensure that queries are conducted consistently across awardees:

- Selecting provider sites for assessment
- Selecting the assessment cohort
- Selecting vaccinations for the assessment
- Determining dose validity and antigen series completion
- Calculations for the Childhood and Adolescent Coverage Reports
- Calculations for the Childhood and Adolescent Missed Opportunities Reports

In addition to this guidance, a *Design Specification* template has been provided in Appendix H, [Technical Design Specification](#) to inform IIS systems developers/vendors of what they need to know in order to develop the necessary functionality for producing the required report(s). The specification includes guidance on the following items:

- Required data inputs/data elements
- Report parameters/criteria
- Report format and access

Note: This document contains technical and key reference materials that are integrated and referenced in various sections, appendices and support documents. In order to maximize the effectiveness of these resources, the document should be reviewed in its entirety.

Requirement: IIS will be able to perform the minimum/mandatory reporting requirements to support the AFIX workflow.

Requirement: The IIS will apply all business rules detailed in this document for the purposes of identifying the assessment cohort (denominator), applying the assessment criteria (numerator), and performing the calculation logic.

Selecting Provider Sites for Assessment

AFIX Coordinators will use the newly developed coverage assessment report to identify which providers to prioritize for annual AFIX visits, as well as to generate individual provider reports for the AFIX visit, follow up assessment, and reporting of results to the AFIX Online Tool. AFIX Coordinators will use the VFC Pin as the primary identifier for generating and reporting AFIX assessments to ensure a direct match between the provider in the IIS and the provider in the AFIX Online Tool. Within the IIS, there should always be a unique one-to-one relationship between the VFC Pin and the assessed provider.

Requirement: The VFC Pin number will be the primary identifier for linking the provider in the IIS with the provider in the AFIX Online Tool.

For the purposes of AFIX, a provider is defined as an entity that includes all of 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)

CDC currently recommends that AFIX awardees select at least 25% of a jurisdiction's VFC-enrolled providers to receive an annual AFIX visit. AFIX projects will be required to prioritize at least ½ of the recommended visits 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. AFIX awardees will use the newly developed coverage report to help perform this prioritization. Refer to the section titled [Low Immunization Coverage Rates](#) for an explanation of how this process may be conducted.

Note: Some IIS and AFIX programs may choose to implement a master report that automatically calculates, prioritizes and lists all VFC provider coverage rates in a single report. Technical guidance for a master report of this nature will likely be prioritized for Phase 2 of the AFIX-IIS Integration effort. For projects that do not want to await this guidance for development of a master report, please ensure that all coverage calculations adhere to the current logic specified in this document for Phase 1, and that calculations for the master report are determined in the same way as they would be performed for individual provider assessments.

Selecting the Assessment Cohorts

Selection of the assessment cohort will be driven by two primary factors: 1) defining the birth cohort, and 2) ensuring that the patients being assessed have been correctly associated with the provider and are active clients of the provider's practice.

Defining the Birth Cohort

AFIX coverage assessments must be generated for the childhood and adolescent birth cohorts specified by the CDC Program Operations Branch:

- Childhood: **24-35 months** (have celebrated their 2nd birthday but have not yet turned 3 years)
- Adolescents: **13-17 years** (have celebrated their 13th birthday but have not yet turned 18 years)

Requirement: Assessment age ranges will be defined as 24 through 35 months for childhood assessments and 13 through 17 years for adolescent assessments.

Note: The exact birth cohort and birthdate range, are impacted by the "As of Date" specified when a user defines parameters for the report criteria. In general, the "As of Date" is typically the same as "today's date"; however, staff can define an alternative "As of Date". The birthdate range for the assessment cohort will 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, will have a cohort birthdate range between 1/1/2011 to 12/31/2011. Individuals that have come of age after the "As of Date" must be excluded from the assessment cohort. For more information on date criteria refer to the section titled [AFIX Assessment Dates](#).

The requirements/business rules below define the appropriate birth cohorts for AFIX assessments.

Table 2: Business Rules for Defining Birth Cohorts

Business Rules		Notes
1.A	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 1 day = 1/1/2012
1.B	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
1.C	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 1 day = 1/1/1997
1.D	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
1.E	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.

Business Rules	Notes
	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.

Patient Relationship with Provider

In addition to assessing the correct age cohorts, it is also important to ensure that the assessment includes all patients who are active with the selected provider in the IIS. There are two components that contribute to this determination: 1) the patient has been identified as having a relationship with the provider, and 2) the provider agrees that the patient is an active client of the practice.

Requirement: The IIS will be able to identify active patients of the assessed provider.

Table 3: Business Rules for Identifying Provider/Patient Relationships

Business Rules	Notes
2.A 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.
2.B 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 not consented or 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 <i>MIROW Best Practice Guidelines, Patient Active/Inactive Status – 2015</i> .

All patients that have been identified as having a birthdate within the defined cohort parameters and have an "active" status with the provider practice being assessed will be included in the provider assessment. These patients will represent the denominator for both the coverage and missed opportunities calculations described in the following sections.

Requirement: The assessment will include 100% of the patients in the specified age cohort that have an active status with the provider (denominator).

Defining Vaccination Assessment Criteria

Two tasks need to be completed to determine if and how to use each vaccination in the coverage and missed opportunity assessments: 1) determine if each individual vaccine dose is valid, according to ACIP recommendations, and 2) determine if the child has received all the required doses to be included in the calculation. It is recommended that IIS apply their full forecasting/ evaluation algorithms to make these determinations. It is also recommended that all IIS programs work towards implementing the Clinical Decision Support for immunization (CDSi) resources¹³ as the gold standard for defining and maintaining these algorithms in IIS. For additional information on CDSi, see Appendix G. [CDSi Usage for AFIX](#).

Recommendation: IIS should apply their full forecasting/evaluation algorithm for both the recommended and catch up schedules when making coverage/missed opportunity determinations.

Recommendation: IIS should leverage CDSi resources when defining forecasting/evaluation algorithms.

Selecting Vaccinations for Assessment

The following vaccinations will be assessed by AFIX for childhood and/or adolescent vaccination coverage and missed opportunities. Results of the assessed vaccinations will be reported to the AFIX Online Tool. The CVX codes that should be used to define these vaccine families in the IIS are provided on the CDC IIS Homepage and in the CDSi Supporting Data spreadsheets (see each Antigen Series Overview tab).

- DTaP
- Polio
- MMR
- Hib
- Hepatitis B
- Varicella
- Pneumococcal
- Rotavirus
- Influenza
- Hepatitis A
- Tdap
- Meningococcal
- HPV

¹³ <http://www.cdc.gov/vaccines/programs/iis/interop-proj/cds.html>

Table 4: Business Rules for Selecting Vaccinations

Business Rules	Notes
<p>3.A 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).</p>	<p>CVX Mapping Reference: http://www2a.cdc.gov/vaccines/iis/iisstandards/vaccines.asp?rpt=cvx</p> <p>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</p> <p>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).</p>

Determining Dose Validity

All vaccinations recorded on the patient's immunization record will be assessed for validity according to ACIP recommendations (and supported by CDSi logic). IIS should apply their full forecasting/evaluation algorithm logic 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 the specified target dose¹⁴. Vaccinations will be assessed for validity within the vaccine family, as well as against the entire record. Only valid vaccinations will count towards the UTD status determination for the AFIX measurements.

Requirement: Only valid vaccinations will be counted towards the up to date (UTD) coverage calculations.

Note: IIS that include functionality to support compromised dose flagging due to storage and handling incidents or manufacturer recalls are encouraged to apply compromised dose logic when determining dose validity. If a dose has been identified as compromised, the dose should be considered invalid.

¹⁴ For more information on using target doses to determine validity, refer to the CDSi Logic Specification section 3.1.

Table 5: Business Rules for Determining Dose Validity

Business Rules	Notes
<p>4.A The IIS must assess the validity of each vaccination administered to a child/adolescent included in an AFIX assessment.</p>	<p>Validity is determined by factors such as:</p> <ul style="list-style-type: none"> ▪ 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. <p><i>For IIS with compromised dose functionality, validity may also be determined by factors such as:</i></p> <ul style="list-style-type: none"> ▪ Storage and handling incidents ▪ Manufacturer recalls ▪ Inappropriate site/route administration ▪ Etc.
<p>4.B The IIS must assess the validity of each individual component contained in multiple antigen vaccines separately.</p>	<p>For the purposes of AFIX, this applies to:</p> <ul style="list-style-type: none"> ▪ Combination vaccinations (e.g. DTaP/HepB/IPV, HepB/Hib, MMRV) ▪ Multiple antigen vaccine families (e.g. DTaP and MMR) <p>More information about combination and multiple antigen vaccines is provided below.</p> <p>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</p> <p>A full listing of all CVX codes can be found at: http://www2a.cdc.gov/vaccines/iis/iisstandards/vaccines.asp?rpt=cvx</p>
<p>4.C The IIS must ensure that its evaluation (i.e. dose validity) algorithms provide results consistent with ACIP recommendations.</p>	<p>IIS can use the CDSi Test Cases to confirm dose validity determinations made by their evaluation/forecasting algorithms:</p> <p>(http://www.cdc.gov/vaccines/programs/iis/interop-proj/cds.html)</p>

Combination and Multiple Antigen Vaccines

Dose validity determinations by IIS should be antigen based. For example, a combination vaccine for HepB-Hib should be broken into its two antigenic components of Hep B and Hib to accurately validate both antigens separately. IIS must apply this same logic behavior to the multiple antigenic families of MMR and DTaP/DT/Tdap/Td (for more information on this process see CDSi guidance in Appendix G. [CDSi Usage for AFIX](#)). Further, for AFIX purposes, all components of MMR, DTaP and Tdap must be present for the patient to be considered as complete. Single antigen Measles, single antigen Mumps, single antigen Rubella, DT, Td or TT will not be counted towards completion of AFIX coverage measurements (unless the patient receives valid doses for all components of the AFIX vaccine measurement).

Awardees that have implemented, or are in the process of implementing, the CDSi Logic Specification guidance should refer to Appendix G. [CDSi Usage for AFIX](#) for additional suggestions on how an IIS may leverage this guidance to support vaccine validity determinations.

Determining Antigen Series Status

For the purposes of producing AFIX coverage assessments from the IIS, all coverage report results reported to the AFIX Online Tool must be based on the required assessment measures. These measures represent defined benchmarks for assessing vaccination coverage for children and adolescents. Results of these coverage assessments also identify potential issues with the vaccination practices of the provider being assessed (e.g. timely vaccination, series completion, missed opportunities).

In some cases the measurement is specified as an exact number of doses (e.g. 4 DTaP, 3 Polio, 1 MMR); whereas, for selected measures, "UTD" will mean that the patient has received the appropriate number of doses to be considered compliant with the series, in accordance with the ACIP routine or catch-up schedule, at the age of 24 months (childhood) or at the time of assessment (adolescent). For example, the AFIX measurement may depend on the age at first vaccination (e.g. Hib, PCV, RV), the vaccine product type administered (e.g. RotaTeq 3-dose vs. Rotarix 2-dose, PRP-OMP/Pedvax 3-dose Hib, Recombivax 2-dose or Pediarix 4-dose Hep B), and/or patient age (adolescent Meningococcal booster, RV). 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>).

All patients who have achieved compliance with the specified AFIX measurements will be counted as up to date (UTD) on the AFIX coverage report. Patients will also be considered UTD for certain measures when evidence of immunity is present. Immunity status will be counted towards completion for Hep A, Hep B, Varicella, or MMR (immunity must be present for all 3 components to count: Measles, Mumps and Rubella).

Patients who have not achieved the measurement or provided proof of immunity will be counted as not up to date per AFIX terminology. Patients with vaccinations that have a recorded

contraindication/precaution¹⁵ in the IIS will be counted as not UTD for the assessed measure to represent the most accurate reflection of coverage within the practice. In addition, patients who have “aged out” of a series prior to completing the series (specifically RV) will be counted as not UTD for the measurement.

Awardees that have implemented, or are in the process of implementing, the CDSi Logic Specification guidance should refer to Appendix G. [CDSi Usage for AFIX](#) for additional suggestions on how an IIS may leverage this guidance to support AFIX coverage determinations.

Note: the assessment of series status will be further impacted by the “Compliance by”/ “Evaluate at” Age/Date specified when a user defines additional parameters for the report criteria. This field will always be used for the Childhood Assessment when the criteria are set for “Compliance by” 24 months of age (the child’s 2nd birthday). This field will directly impact the antigen/series evaluation. Any vaccinations received after the “Compliance by Age/Date” are not counted towards compliance with the assessed measurements but may factor in to “Late UTD” in future phases of the AFIX-IIS integration effort. For example, if a child receives a vaccination at 24 months + 1 day, that vaccination will not be counted towards compliance with the specified AFIX measurement.

Requirement: IIS will assess patient compliance with the specified AFIX measurements according to the detailed calculation logic included in this document.

Requirement: Patient compliance with the specified AFIX measurements will be assessed at 24 months/2nd birthday for childhood assessments and on the date of assessment for adolescents.

¹⁵ References to contraindications/precautions as used throughout this document refer strictly to those specified in Table 6 of the ACIP General Recommendations (<http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6002a1.htm#Tab6>).

Table 6: Business Rules for Determining Compliance with Assessed Measurements

Business Rules		Notes
5.A	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.	
5.B	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. 1/1/2014). For more information on AFIX Date Concepts, see the section titled AFIX Assessment Dates .
5.C	For both the childhood and adolescent cohorts, UTD status must be based on valid doses only as defined by ACIP recommendations (and compromised dose flagging where enabled by the IIS).	See the section titled Determining Dose Validity for more information on valid dose determinations.
5.D	<p>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:</p> <ul style="list-style-type: none"> ▪ 4 DTaP ▪ 3 Polio ▪ 1 MMR ▪ UTD Hib ▪ UTD Hep B ▪ 1 VAR ▪ UTD PCV ▪ UTD RV ▪ 1 Flu (<i>note: previously completed flu season</i>) ▪ 2 Hep A ▪ 4:3:1:3:3:1:4 Series 	<p>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 product 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.</p> <p>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 Appendix G. CDSi Usage for AFIX.</p> <p>All patients who have achieved compliance with the specified AFIX measurements will be counted in the AFIX coverage report numerators.</p>

Business Rules	Notes
<p>5.E For the following vaccine groups, the IIS must determine if the adolescent achieved the specified AFIX measurement on or before the "Compliance by Date" for the following criteria:</p> <ul style="list-style-type: none"> ▪ UTD Hep B ▪ 2 MMR ▪ 2 VAR ▪ 1 Tdap ▪ UTD Meningococcal ▪ 3 HPV ▪ 2 HPV ▪ 1 HPV ▪ 1 Flu (<i>note: previously completed flu season</i>) ▪ 2 Hep A ▪ UTD Polio 	<p>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 product 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.</p> <p>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 Appendix G. CDSi Usage for AFIX.</p> <p>All patients who have achieved compliance with the specified AFIX measurements on or before the "Compliance by Date", will be counted in the AFIX coverage report numerators.</p>
<p>5.F HPV calculations for the various dose measurements should be inclusive.</p> <ul style="list-style-type: none"> ▪ 1 HPV (include all adolescents with 1+ valid doses) ▪ 2 HPV (include all adolescents with 2+ valid doses) ▪ 3 HPV (include only adolescents with 3 valid doses) 	<p>Include all adolescents (female, male, unknown and unspecified).</p> <p>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</p>
<p>5.G 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.</p> <p>A flu season is defined as July 1 through June 30. Vaccination completion will be defined as "at least 1 valid dose of influenza vaccine for the prior completed season".</p>	<p>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.</p>

Business Rules	Notes
<p>5.H For the following vaccine groups, the IIS must be able to collect and store evidence of immunity:</p> <ul style="list-style-type: none"> ▪ Hep A ▪ Hep B ▪ Varicella ▪ MMR (immunity must be present for all 3 components to count: Measles, Mumps and Rubella) <p>Evidence of immunity will be counted as complete/up to date for the measured series.</p>	<p>See Immunity Supporting Data Table – CDSi (http://www.cdc.gov/vaccines/programs/iis/interop-proj/cds.html) for more information.</p> <p><i>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.</i></p>
<p>5.I 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.</p>	<p>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</p> <p>See also CDSi Supporting Data Table for Contraindications: http://www.cdc.gov/vaccines/programs/iis/interop-proj/cds.html</p> <p><i>Note: CDSi will be addressing precautions in a future phase.</i></p>

Calculations for the Childhood and Adolescent Coverage Reports

This section provides guidance on determining the numerator for AFIX coverage rate calculations. Determining the number of patients who meet or exceed the coverage requirements for the various AFIX assessment measures can be identified using the criteria provided in Decision Table 1 below. This decision making process should be applied to each of the individual AFIX assessments measures (e.g. 4 DTaP, 3 Polio, 1 MMR...), as well as the specified childhood series: 4:3:1:3:3:1:4. See table in previous section for a full listing of all of the AFIX childhood and adolescent assessment measures to be calculated.

Note: Refer to the section titled [Selecting the Assessment Cohorts](#) for specific guidance on determining the denominator for Childhood and Adolescent Coverage Reports.

Decision Table 1. Coverage Assessment Numerator Determination

Condition	Numerator	
	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 UTD 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

Table 7: Business Rules for Coverage Assessment Calculations

Business Rules		Notes
6.A	Coverage for each vaccine group assessed is calculated by dividing the total number of patients identified for inclusion in the numerator per Decision Table 1 by the total number of children in the denominator (<u>Selecting the Assessment Cohorts</u>) and multiplying by 100.	<p>Example:</p> <p>Cohort Defined – 180 active patients (denominator)</p> <p>Assessment Measure – 4 DTaP</p> <p>Number with 4 valid doses of DTaP – 144 (numerator)</p> <p>Equation: $144/180 \times 100 = 80\%$</p> <p>Percentage Complete – 80%</p>

Calculations for the Childhood and Adolescent Missed Opportunities Reports

This section provides guidance on determining the numerator for missed opportunity calculations. For the purposes of AFIX Assessment, Missed Opportunities will be calculated based on the last immunization visit. A missed opportunity is identified as a vaccination that was due at the time of the last visit but was not administered by the provider. Specifically, a Missed Opportunity is defined as:

On the patient's last visit for an immunization he/she received a dose of a different antigen than the antigen in question, or there was a reason a different antigen was not given, and at the time of that visit a valid dose of the antigen in question could have been administered in keeping with the patient's age and the time interval from the previous valid or invalid dose.

Requirement: Missed Opportunities calculations will be based on the last immunization visit.

Determinations for missed opportunities should leverage the basic logic for vaccine forecasting and evaluation per ACIP recommendations (supported by CDSi logic specifications). If a vaccine was forecasted but was not administered, or the incorrect vaccine product was administered, a missed opportunity would be counted for the assessed measurement and the patient would be counted in the numerator for the missed opportunity calculation.

Note: there are a few unique scenarios where the last immunization visit may be identified by the administration of a single invalid dose or the administration of a non-traditional vaccine type. Examples of these scenarios are presented in the requirements table below.

Additional Note: Parent and religious refusals of one or more vaccines will be counted as a missed opportunity to vaccinate; however, a medical contraindication or precaution in effect on the date of the last vaccination visit will NOT be counted as a Missed Opportunity since vaccine administration would have been inappropriate.

Table 8: Business Rules for Determining Missed Opportunities

Business Rules	Notes
<p>7.A 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.</p>	<p>Standard Example:</p> <ul style="list-style-type: none"> 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. <p>Additional Examples:</p> <ul style="list-style-type: none"> 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 other vaccinations (e.g. a 2nd 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.

7.B	<p>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 (e.g. eligible to receive dose).</p>	<p>Example:</p> <p>Scenario A: Child's DOB is 01/01/2014</p> <p>DTaP 1 (valid dose) at 2 months (administered on 03/01/2014)</p> <p>DTaP 2 (valid dose) at 4 months (administered on 05/01/2014)</p> <p>DTaP 3 (valid dose) at 6 months (administered on 07/01/2014)</p> <p>Last immunization visit at 15 months (on 04/01/2015)</p> <p>Received MMR and Varicella on 04/01/2015 but did not receive 4th DTaP</p> <p>Determination: Missed opportunity for DTaP because recommended date for 4th DTaP is 04/01/2015 (on or before the last immunization visit date)</p> <p>Scenario B: Child's DOB is 01/01/2014</p> <p>DTaP 1 (valid dose) at 2 months (administered on 03/01/2014)</p> <p>DTaP 2 (valid dose) at 4 months (administered on 05/01/2014)</p> <p>DTaP 3 (valid dose) at 6 months (administered on 07/01/2014)</p> <p>Last immunization visit at 12 months (on 01/01/2015)</p> <p>Received MMR and Varicella on 01/01/2015 but did not receive 4th DTaP</p> <p>Determination: No missed opportunity for DTaP because recommended date for 4th DTaP is 04/01/2015 (after the last immunization visit date)</p> <p>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 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</p>
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		date" for vaccination, not the minimum age or minimum date."
7.C	An "incorrect vaccine administration" at the time of the last immunization visit should be counted as a missed opportunity.	<p>An "incorrect vaccine administration" is a vaccination which 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.</p> <p>Example:</p> <ul style="list-style-type: none"> ▪ Tdap given as a dose in the primary DTaP series. ▪ Td instead of Tdap without a medical contraindication/precaution.

IIS will employ the following decision logic from Decision Table 2 and calculations (numerators/denominators) to derive the results for Missed Opportunities that will be reported and/or exported to the AFIX Online Tool for the required measures. These calculations build on the concepts described in the previous sections.

Note: The denominator for calculating Missed Opportunities is the same as that used for the Coverage Reports. Refer to the section titled [Selecting the Assessment Cohorts](#) for specific guidance on determining the denominator for Childhood and Adolescent Missed Opportunities calculations.

Decision Table 2. Missed Opportunity Numerator Determination

Condition	Numerator	
	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. Eligibility is defined by the recommended date in the vaccination forecast.		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 (includes influenza). Eligibility is defined by the recommended date in the vaccination forecast.	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 of vaccine (includes influenza) that resulted in an "incorrect vaccine administration". Eligibility is defined by the recommended date in the vaccination forecast.	X	

5.	Patient has evidence of immunity for the specified vaccine (where allowed).		X
6.	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
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

Table 8: Business Rules for Missed Opportunities Calculations

Business Rules		Notes
8.A	Missed opportunities for each vaccine group assessed is calculated by dividing the total number of patients identified for inclusion in the numerator per Decision Table 2 by the total number of children in the denominator (Selecting the Assessment Cohorts) and multiplying by 100.	<p>Example:</p> <p>Cohort Defined – 180 active patients (denominator)</p> <p>Assessment Measure – 4 DTaP</p> <p>Number with 4 valid doses of DTaP – 144</p> <p>Number Incomplete/Not UTD – 36</p> <p>Number with Missed Opportunities at last visit – 9 (numerator)</p> <p>Equation: $9/180 \times 100 = 5\%$</p> <p>Percentage Missed Opportunities – 5%</p>

Export for AFIX Online Tool

Export specifications are being defined by CDC to support the import of assessment data directly into the AFIX Online Tool. Export specifications will be developed and provided to awardees as a separate document. IIS will ultimately be able to implement the export specification as the primary method for reporting assessment results to the AFIX Online Tool to minimize manual data entry.

Implementation/Next Steps

This section will provide guidance to AFIX and IIS staff related to transitioning from CoCASA to IIS-based assessments.

Transitioning from CoCASA to IIS

A number of AFIX programs have already implemented, or are in the process of implementing, IIS-based coverage assessments. For those that have already gone down this path, there have been a few barriers and challenges along the way. With those challenges, there have also been some lessons learned and the emergence of a few best practices. The following section provides some insight shared by the participants of the consensus meeting. Although CDC staff participated in the consensus meeting, the practices identified below do not represent official positions of CDC.

The barriers/challenges reported can generally be categorized as one of the following:

- Policy
- Resource
- Technical/System
- Data
- Communication

Policy

The software lifecycle can often present challenges. When system changes or bug fixes need to be made, they are subject to this process. A typical software lifecycle includes determining requirements, scheduling the work for a release, coding the changes, regression testing, test system evaluation and then production system utilization. If bugs or other issues are identified, the process starts again. Additional challenges may also be introduced by the IT workflow, especially for jurisdictions that have moved to Centralized IT operations, where the IIS is just one of many systems used to support jurisdictional operations, thereby extending the timeline for how quickly changes and fixes can be addressed.

Best Practices: Plan accordingly! AFIX Coordinators should become familiar with the IIS release cycles and timelines. All changes will need to be coordinated through the IIS Coordinator. AFIX staff should also become familiar with help desk processes for reporting bugs or issues that may be identified. Every program should have a good regression testing¹⁶ plan and process in place for evaluating releases.

¹⁶ Regression testing is a quality assurance process of testing and evaluating system changes to ensure that older code/programming still works as intended with the addition of new functionality.

Other policy challenges relate to patient and provider participation. Patient “opt in” requirements create additional administrative layers for providers by requiring patient consent before their vaccination histories can be included in the IIS. Some jurisdictions still have a few providers doing paper-based charting. In some of these cases, none of the data is being reported to the IIS.

Best Practices: Revisit existing policies and initiate change wherever possible or appropriate. Use every opportunity to educate providers on the changes to the AFIX assessment process and the general importance and value of reporting data to the IIS. Consider implementing the VFC requirement for participation in the IIS as described in the section titled [Provider Participation](#).

Resource

Resource limitations are a universal challenge for all programs. Limitations come in many forms, but most commonly relate to shortages in staffing and/or funding. For many programs, limited funding has made IIS-based coverage assessments and system changes a lower priority, especially with the availability of CoCASA. With this current project, funding for the necessary IIS enhancements and ongoing maintenance of the AFIX assessment functionality is a concern for awardees that have not yet started the transition to IIS-based coverage assessment.

Best Practices: Funding for this effort will be addressed by CDC’S AFIX Program to help awardees facilitate the necessary system changes. Timelines for these changes will be managed to allow for adequate planning and implementation. Current projects reported that using IIS-based coverage assessments has resulted in numerous efficiencies and time-savings when performing provider AFIX assessments.

Technical/System

Occasionally, the IIS itself may present technical challenges or limitations. Some projects reported that their system did not include appropriate user privileges to allow access for running coverage reports. It was also noted that some systems don’t provide access for providers to change the status of the PAIS indicator.

Best Practices: AFIX and IIS staff should work together to ensure that users are given appropriate access and permissions to participate in IIS-based coverage assessments, including allowing providers to perform periodic self-assessments. Awardees should use the technical guidance provided in the body of this document and in Appendix H (*AFIX-IIS Integration: CDC Technical Guidance and Design Specification*) to ensure that the appropriate functionalities and workflows are implemented in a consistent manner. Changes will be subject to the software lifecycles and funding allocations noted previously.

Meeting participants also stated that system reports with complicated logic and those running on large data sets occasionally are subject to performance issues due to system processing capabilities and/or other large processes that may be competing for system resources.

Best Practices: Volume and performance testing is critical. AFIX staff, IIS staff, and the IIS vendor / IT staff should work together to ensure that the IIS is appropriately powered and that the report functionality is implemented in such a way to optimize report performance. Awardees should also familiarize themselves with the volume and performance testing policies and practices employed for their specific project. Operationally, AFIX staff should plan to run reports during off-peak periods or utilize scheduling tools, if available (see section titled [A Note about Report Performance](#)).

Data

Initially, all projects reported concerns that the initial assessments would appear very low due to incomplete data in the IIS.

Best Practices: Don't wait until the IIS data is "fully populated" or "perfect" to use IIS for coverage assessments. By using the IIS for assessments, the data will improve and become more complete as a result of those efforts. Low rates have proven to be powerful motivators. Using a data comparison technique during the transition from CoCASA to the IIS helps to build provider confidence, ease the transition and implement data improvement strategies (see Case Studies below – [Awardee Experience Transitioning from CoCASA to IIS](#)).

Communication

There are numerous challenges that can be managed through appropriate communication!

Best Practices: AFIX staff should begin preparing providers now for the upcoming changes and new assessment methodologies. Getting buy-in from staff, providers and other stakeholders is critical to the success of the transition and should be obtained from the very beginning. Fact sheets, webinars, and local jurisdiction communications with providers have all been successfully employed. State/local chapters of the AAP and AAFP can also serve as valuable liaisons to garner provider support and participation.

Formal communication and training during the implementation process is also critical.

Best Practices: Develop a communication plan that addresses interactions between AFIX staff and IIS staff, IIS staff and developers, and AFIX staff and providers to ensure that the reports are generating as intended and that all stakeholders know the process for reporting issues and concerns. Formal training for staff and providers should also be implemented to promote understanding of how report results are calculated and how the results should be interpreted.

Awardee Experiences Transitioning from CoCASA to IIS

A number of projects have already completely transitioned away from CoCASA. Michigan and New York City are examples of awardees that fully utilize their IIS to perform AFIX coverage assessments. The following provides a narrative of their transition experiences.

Michigan – The total transition process took about three years. Year one focused on developing the reports in the IIS. Once the reports were developed and ready for use, the AFIX staff used reports from

both the IIS and CoCASA to compare results. This allowed the staff to assess any discrepancies and educate providers on ways to improve their data in the IIS, and ultimately their coverage rates. Indirectly, it also led providers to refer to the IIS more frequently to perform chart comparisons and obtain the most complete picture of a patient's immunization history.

New York City – In NYC, there was a top down decision to link up VFC and IIS efforts for improved accountability and completeness. As a result, completeness of data in the IIS improved significantly. The rollout was a gradual process. Initially, AFIX staff included IIS coverage results in addition to the manual AFIX chart review so that providers could compare the two results. Early efforts demonstrated to providers (and staff) that the data in the IIS was incomplete. As a result, NYC implemented an effort to improve data quality and add some fields to the IIS user interface. To increase success, NYC also recruited providers to “champion” and garner support for the effort from the provider community. Ultimately the transition, from start to finish, took about four years. The full transition to IIS-based coverage assessments was completed in 2010. As a result of all of these efforts, data in the IIS is now much more complete and reliable. NYC also learned that low IIS coverage rates are a powerful motivator for providers to clean up their data!

Phase 2

In addition to the basic coverage assessments for childhood and adolescents described in this document, CoCASA offers a number of other important reports that support the AFIX mission. The key reports offered by CoCASA include:

- Single Antigen Report (dose by age)
- Need One Dose (patient list)
- Invalid Doses (patient and reason list)
- Missed Opportunities (patient and reason list)
- Not UTD (patient list)
- Summary Report
 - Flow Chart
 - Pie Chart
 - Need One Visit (table)
 - Last Visit > 12 months
 - Late UTD
- Diagnostic Childhood (% complete + additional eval)
- Adolescent Coverage (% complete + UTD dose spread)
- Missing Immunizations (recall list)
- AFIX Site Visit Summary (for adolescents)
- HPV Report

Some projects that have already implemented IIS-based coverage assessments have developed reports that emulate existing CoCASA reports and also created a number of customized reports to support the AFIX effort. These customized reports are often hybrids of one or more of the CoCASA reports. They may also include measures of specific interest to the state/jurisdiction for other program/department

purposes. These custom reports frequently include graphical representations of the data or comparison displays (e.g. AFIX vs. Healthy People 2020 goals, single provider vs. all providers in jurisdiction).

Phase 1 of this project was specifically focused on the coverage assessment components required for reporting to the AFIX Online Tool and the AFIXAR. Phase 1 represents the minimum/mandatory reporting requirements that an IIS must be able to perform. Phase 2 will include a broader scope and guidance for developing additional reports into the IIS to support the AFIX workflow. The foundation established in Phase 1 (provider selection, cohort selection, and vaccination evaluation) will be leveraged by the IIS in the next phase(s) of the AFIX-IIS Integration Project.

The consensus meeting SMEs discussed which existing CoCASA reports were considered to be the most critical to AFIX program operations. This discussion also included a review of several customized hybrid reports that have been developed by some of the states already relying on IIS-based coverage assessments. The following CoCASA reports were identified as the most critical to AFIX program operations among those participating in the discussion:

- Single Antigen Report (dose by age)
- Invalid Doses (patient and reason list)
- Not UTD (patient list)
- Missing Immunizations (recall list)

Hybrid reports developed by Michigan (AFIX Basic Overview Report) and Minnesota (Immunization Summary Report) also received a lot of interest from the group for how data from several CoCASA reports had been combined into a single summary.

In addition to reviewing and discussing existing CoCASA reports, the team also had a brainstorming session to identify the basic report elements commonly leveraged during provider feedback sessions to help guide process improvement. The following list was created from that discussion and will be used to identify Phase 2 reporting priorities:

- Single Antigen Assessment
- Missed Opportunities (Patient Listing)
- Number/percent of patients UTD and number/percent of patients not UTD
- List of patients missing vaccines
- Not UTD (% and list)
- Late UTD (%)
- Invalid doses (% and list)
- Needs 1 dose (% and list)
- <12 months and >12 months (since last immunization visit) (% and list)
- Comparison over time to self
- Comparison to state/region/county/NIS/Healthy People 2020/other providers
- Comparison by size of provider, type of provider
- Reports based on various levels of organization/hierarchy
- Patient list (active status at practice level)
- History of disease/titer (list)
- Exemptions (list and reason)

In conjunction with the existing CoCASA reports and general feedback elements listed above, a number of other items that may not exist at this time but could/should be prioritized into a future phase of this project were suggested by the consensus meeting participants for potential consideration:

- Consideration of other output formats (besides .pdf) that can be manipulated – need flexible ways to use the data
- All report data should be exportable
- Consider more graphical displays and comparisons including Healthy People 2020 goals and state/regional rates
- Ability to look at trend data from year to year
- Ability to assess at different levels of granularity (e.g. by individual vaccinator within a practice)
- Add documentation reason for missed opportunity (e.g. refusal or medical reason)

The information gathered during these consensus meeting discussions will be reviewed and prioritized by the CDC's AFIX Program and the Awardee AFIX Workgroup. Input from the broader AFIX community may also be solicited in this decision making process. In Phase 2, awardees can expect to see additional guidance on commonly used reports from legacy CoCASA, additional reporting parameters and graphical displays, along with any other measures that may be requested by CDC.

In the meantime, many IIS already include numerous tools and reports that may be valuable to AFIX staff in the form of patient lists and summaries. AFIX staff are encouraged to work with their IIS counterparts to review existing reporting options. Further, all projects are welcome to design their own reports and hybrids to support AFIX operations as resources allow; however, required reporting elements of Phase 1 must follow the guidance and specifications established in this document. Additional phases of this project may be considered when or if needed.

Appendices

A. Summary of AFIX-IIS Integration Requirements and Recommendations

Table 9: Table of Requirements and Recommendations

Type	Requirement/Recommendation	Page #
Location: <u>Introduction</u>		
▪ Requirement	▪ All AFIX awardees will be required to leverage their Immunization Information Systems (IIS) to perform provider level assessment activities once CDC discontinues technical support for CoCASA.	1
Location: <u>Document Overview</u>		
▪ Requirement	▪ IIS will be able to perform the minimum/mandatory reporting requirements to support the AFIX workflow.	4
Location: <u>Defining a Provider</u>		
▪ Requirement	▪ The VFC Pin number will be the primary identifier for linking the provider in the IIS with the provider in the AFIX Online Tool.	10
Location: <u>Selection Criteria</u>		
▪ Requirement	▪ AFIX awardees will prioritize at least ½ of their annually recommended AFIX visits from providers with coverage rates in the bottom quartile.	10
Location: <u>Selection Criteria (Low Immunization Coverage Rates)</u>		
▪ Recommendation	▪ AFIX awardees should use a systematic approach to identify providers with low coverage rates after the new report functionality has been developed into the IIS.	11
▪ Recommendation	▪ AFIX awardees should conduct periodic courtesy assessment for providers in their jurisdiction.	12
Location: <u>Role of Provider Participation and Data Quality (Provider Participation)</u>		
▪ Recommendation	▪ AFIX and IIS staff should work together to develop and apply strategies to increase provider participation in, and reporting of data to, the IIS.	14

Location: Role of Provider Participation and Data Quality (Data Quality)

Type	Requirement/Recommendation	Page #
▪ Recommendation	▪ AFIX awardees should leverage pre-visit assessment activities as an opportunity for providers to review active patient lists and address any data quality issues.	15
Location: <u>Role of Provider Participation and Data Quality (Strategies for AFIX Staff)</u>		
▪ Recommendation	▪ VFC providers should be given appropriate permissions in the IIS to generate their own periodic assessments.	16
Location: <u>Defining the Assessment Cohorts</u>		
▪ Requirement	▪ Assessment age ranges will be defined as 24 through 35 months for childhood assessments and 13 through 17 years for adolescent assessments.	17
Location: <u>Identifying Active Patients</u>		
▪ Requirement	▪ The IIS will be able to identify active patients of the assessed provider.	18
▪ Recommendation	▪ Providers should have the ability to edit the patient active status value when needed.	18
Location: <u>Special Rules for Record Inclusion and Exclusion in an AFIX Assessment</u>		
▪ Requirement	▪ The assessment will include 100% of the patients in the specified age cohort that have an active status with the provider (denominator).	19
Location: <u>Assessment Measures (Childhood Assessment)</u>		
▪ Requirement	▪ Patient compliance with the specified AFIX measurements will be assessed at 24 months/2nd birthday for childhood assessments.	20
▪ Requirement	▪ IIS will assess patient compliance with the specified AFIX measurements according to the detailed calculation logic included in this document.	20
Location: <u>Assessment Measures (Adolescent Assessment)</u>		
▪ Requirement	▪ Patient compliance with the specified AFIX measurements will be assessed on the date of assessment for adolescents.	21
▪ Requirement	▪ IIS will assess patient compliance with the specified AFIX measurements according to the detailed calculation logic included in this document.	21

Type	Requirement/Recommendation	Page #
Location: <u>Assessment Measures (A Note on Influenza Coverage)</u>		
Requirement	AFIX awardees will assess and report coverage rates for influenza based on the previously completed flu season.	22
Location: <u>Assessment Measures (Assessing Missed Opportunities)</u>		
Requirement	Missed Opportunities calculations will be based on the last immunization visit.	23
Location: <u>Assessment Measures (IIS Forecasting and Evaluation Algorithms)</u>		
Requirement	Only valid vaccinations will be counted towards the up to date (UTD) coverage calculations.	24
Recommendation	IIS should apply their full forecasting/evaluation algorithm for both the recommended and catch up schedules when making coverage/missed opportunity determinations.	24
Recommendation	IIS should leverage CDSi resources when defining forecasting/evaluation algorithms.	24
Location: <u>AFIX Assessment Dates</u>		
Requirement	IIS will need to adopt and apply AFIX assessment date concepts for establishing report parameters used to derive the assessment cohort birthdate range and benchmarks/timeframes for vaccination status assessment.	25
Location: <u>Operationalizing IIS-based AFIX Coverage Assessment (User Access)</u>		
Recommendation	The new assessment report(s) should be made available to a variety of user types.	26
Location: <u>Operationalizing IIS-based AFIX Coverage Assessment (Assessment Timelines)</u>		
Requirement	Providers prioritized for an annual AFIX visit should receive an initial assessment/feedback visit and a 6-month follow up assessment. Results of both the initial and the follow up assessment will be reported to the AFIX Online Tool.	28
Recommendation	Prioritized providers should be provided with a pre-visit assessment to review the active patient list and address any data quality issues prior to the official assessment.	27
Recommendation	AFIX awardees should offer periodic courtesy assessments to all VFC providers within their jurisdictions regardless of whether they have been identified for a visit.	27

Type	Requirement/Recommendation	Page #
Location: <u>Operationalizing IIS-based AFIX Coverage Assessment (Managing Reports)</u>		
▪ Recommendation	▪ The IIS should offer the ability to print, save and/or generate an export of the report results.	29
Location: <u>Operationalizing IIS-based AFIX Coverage Assessment (Report Performance)</u>		
▪ Recommendation	▪ AFIX awardees should plan to run reports for assessment/feedback visits in advance of the visit (< 7 days) to avoid any possible IIS processing challenges that may be encountered when generating the large, complex reports.	29
Location: <u>AFIX-IIS Integration: CDC Technical Guidance</u>		
▪ Requirement	▪ IIS will be able to perform the minimum/mandatory reporting requirements to support the AFIX workflow.	30
▪ Requirement	▪ The IIS will apply all business rules detailed in this document for the purposes of identifying the assessment cohort (denominator), applying the assessment criteria (numerator), and performing the calculation logic.	30
Location: <u>Selecting Provider Sites for Assessment</u>		
▪ Requirement	▪ The VFC Pin number will be the primary identifier for linking the provider in the IIS with the provider in the AFIX Online Tool.	31
Location: <u>Selecting the Assessment Cohorts (Defining the Birth Cohort)</u>		
▪ Requirement	▪ Assessment age ranges will be defined as 24 through 35 months for childhood assessments and 13 through 17 years for adolescent assessments.	31
Location: <u>Selecting the Assessment Cohorts (Patient Relationship with Provider)</u>		
▪ Requirement	▪ The IIS will be able to identify active patients of the assessed provider.	32
▪ Requirement	▪ The assessment will include 100% of the patients in the specified age cohort that have an active status with the provider (denominator).	33
Location: <u>Defining Vaccination Assessment Criteria</u>		
▪ Recommendation	▪ IIS should apply their full forecasting/evaluation algorithm for both the recommended and catch up schedules when making coverage/missed opportunity determinations.	34

Type	Requirement/Recommendation	Page #
▪ Recommendation	▪ IIS should leverage CDSi resources when defining forecasting/evaluation algorithms.	34
Location: <u>Determining Dose Validity</u>		
▪ Requirement	▪ Only valid vaccinations will be counted towards the up to date (UTD) coverage calculations.	35
Location: <u>Determining Antigen Series Status</u>		
▪ Requirement	▪ Patient compliance with the specified AFIX measurements will be assessed at 24 months/2nd birthday for childhood assessments and on the date of assessment for adolescents.	37
▪ Requirement	▪ IIS will assess patient compliance with the specified AFIX measurements according to the detailed calculation logic included in this document.	37
Location: <u>Calculations for the Childhood and Adolescent Missed Opportunities Reports</u>		
▪ Requirement	▪ Missed Opportunities calculations will be based on the last immunization visit.	42
Location: <u>Appendix H. Technical Design Specification</u>		
▪ Recommendation	▪ IIS awardees and their vendors may leverage the Technical Design Specification that includes suggestions on implementation considerations for generating the required report(s).	72
▪ Requirement	▪ The IIS will apply all business rules detailed in this document for the purposes of identifying the assessment cohort (denominator), applying the assessment criteria (numerator), and performing the calculation logic.	72

B. 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, 1 MMR, 3 Hib, 3 Hep B, 1 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.

Accuracy (*Data Quality Principle*) – The data recorded in the IIS should match exactly what happens in a clinical encounter, whether or not it is clinically appropriate.

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 Age Range (*Age Range in Months or Age Range in Years*) – This field directly defines the cohort to be included in the assessment (e.g. 24-35 months or 13-17 years). Only one age range option may be selected at a time. The Assessment Age Range will be used to calculate the birthdate range. Age Range and the calculated birthdate range may be further impacted by the “As of Date” described above.

Assessment Date (*see also Run Date*) – This field is informational and reflects the date the report is run (e.g. “today’s date”).

Birthdate Range – Birthdate range automatically calculated by the IIS based on the criteria defined for Ages Assessed and As of Date.

Cohort – Part of the population (individuals) within a Jurisdiction or assigned to a Provider Organization/Facility.

Completeness (*Data Quality Principle*) – 1) The information submitted to the IIS must contain the minimum/mandatory set of data items in order to be accepted by an IIS. 2) The data recorded in the IIS should reflect a complete history of all vaccinations ever administered to an individual.

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)" in future phases of the AFIX-IIS integration effort.

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.

Exemption – Medical (e.g. contraindications and precautions) and non-medical (e.g. philosophical and religious) reasons a patient does not receive 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" (see also IIS Organizational Hierarchy, Parent Organization/Reporting Entity, and 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.

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.

IIS Organizational Hierarchy – A relational hierarchy established in the IIS for identifying organizational interrelationships. Typically includes jurisdictional associations, parent organizations/reporting entities, related facilities/sites/clinics/organizations, and the clinicians employed and providing vaccinations at those sites.

Missed Opportunity – This assessment will focus on the Last Immunization Visit. On the patient's last visit for an immunization he/she received a dose of a different antigen than the antigen in question, or there was a reason a different antigen was not given, and at the time of that visit a

valid dose of the antigen in question could have been administered in keeping with the patient's age and the time interval from the previous valid or invalid dose.

Parent Organization/Reporting Entity – An organization/entity that is “accountable” for one or more entities that provide vaccination services. Often comprised of a number of clinical offices/sites and physician groups (see also Facility, Site, Clinic, Organization).

Patient – An individual who is the actual or potential recipient of an administered dose of vaccine.

Patient Active/Inactive Status (PAIS) – A patient status indicator in the IIS. 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)

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.

Timeliness (*Data Quality Principle*) – Data should be timely. Data should be reported and recorded in the IIS, as well as be available to users in a timely manner.

Underperformer – A provider with low coverage rates or generally poor immunization or vaccine management practices (e.g. high level of invalid doses, high level of duplicate vaccinations, low immunization rates, high rate of missed opportunities, low rates of data submission to the IIS, high number of patients associated with the provider that have not been seen for >12 months).

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.

Table 10: Table of Acronyms

AAFP	American Academy of Family Physicians
AAP	American Academy of Pediatrics
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
CVX	Vaccine Administered
DQ	Data Quality
EHR	Electronic Health Record
HIE	Health Information Exchange
HP	Hewlett Packard
IIS	Immunization Information System
IIS ID	IIS Identifier
IISB	IIS Support Branch
IPOM	Immunization Program Operations Manual
MIROW	Modeling of Immunization Registry Operations Workgroup
MOGE	Moved or Gone Elsewhere
NCIRD	National Center for Immunization and Respiratory Diseases
NIS	National Immunization Survey
PAIS	Patient Active Inactive Status
POB	Program Operations Branch
SME	Subject Matter Expert

STC	Scientific Technologies Corporation
TIPS	Trends in Immunization Practices System
UI	User Interface
UTD	Up to Date
VFC	Vaccines for Children

Table 11: Table of Vaccination Abbreviations

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

C. Project Reference Documents

1. **AFIX Online Tool** (available to CDC awardees; requires secure login)
2. **AFIX Annual Report 2014** (available to CDC awardees; requires secure login)
3. **AIRA Data Quality Assurance Tool** – data analysis tool (summer 2014 pilot)
4. **Assessment, Feedback, Incentives, and eXchange (AFIX): Program Policies and Procedures Guide; First Edition – 2013** (<http://www.cdc.gov/vaccines/programs/afix/downloads/standards-guide.pdf>)
5. **CDC AFIX Website** (<http://www.cdc.gov/vaccines/programs/AFIX/index.html>)
6. **CDC IIS Website** (<http://www.cdc.gov/vaccines/programs/iis/index.html>)
7. **CDC IIS Policy and Legislation Website** (<http://www.cdc.gov/vaccines/programs/iis/policy-legislation.html>)
8. **CDC IIS-Trends in Immunization Practices System (TIPS)** – data analysis tool (available to CDC awardees)
9. **Clinical Decision Support for Immunization (CDSi): Logic Specification for ACIP Recommendations; Version 2.0** – June 2015
(<http://www.cdc.gov/vaccines/programs/iis/interop-proj/cds.html>)
10. **CoCASA Users Guide; Version 8.1** – February 2013; Chapters 3 and 4
(<http://www.cdc.gov/vaccines/programs/cocasa/users-guide.html>)
11. **CoCASA Algorithm Reference; CoCASA 8.0** – December 2012
(http://www.cdc.gov/vaccines/programs/cocasa/downloads/algorithm_reference_document.pdf)
12. **Epidemiology and Prevention of Vaccine-Preventable Diseases; 13th Edition**– May 2015; Appendix A and B (<http://www.cdc.gov/vaccines/pubs/pinkbook/index.html>)
13. **Healthy People 2020; Immunization and Infectious Diseases**
(<http://www.healthypeople.gov/2020/topicsobjectives2020/objectiveslist.aspx?topicId=23>)
14. **IIS Functional Standards 2013-2017; Appendix B: IIS Core Data Elements** – December 2012
(<http://www.cdc.gov/vaccines/programs/iis/func-stds.pdf>)
15. **IIS: HL7 Standard Code Set CVX – Vaccines Administered; May 2014**
(<http://www2a.cdc.gov/vaccines/iis/iisstandards/vaccines.asp?rpt=cvx>)
16. **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
17. **Patient Deduplication Best Practices and Test Cases – EHR-IIS Interoperability Expert Panel Project; June/July 2013** (<http://www.cdc.gov/vaccines/programs/iis/interop-proj/ehr.html>)

18. **Text File Import Specifications for Comprehensive Clinical Assessment Software Application (CoCASA);** Version 5.0 – December 2009
(http://www.cdc.gov/vaccines/programs/cocasa/downloads/cocasa_import_specs.pdf)
19. 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.
20. **Vaccines for Children (VFC) Operations Guide** (available to CDC awardees; requires secure logon)
21. **VFC Enrollment Overview Document** (available to CDC awardees; requires secure logon)
22. **VTrckS ExIS Integration: File Specifications & Additional Information; Revision D02** – 2010-2013 (<http://www.cdc.gov/vaccines/programs/vtrcks/topics/ExIS.html#specifications>)

D. List of Meeting Participants

Table 12: Table of Meeting Participants

Awardee	Participant	Email	Job Title
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Appendices

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E. Consensus Meeting Questions

Major Consensus:

- How to build IIS-based coverage assessments for AFIX and ensure standardized results and reporting.

Minor Consensus:

- Operational: How will the IIS be used to support AFIX coverage assessment efforts?
- Technical: What do developers need to know to be able to develop the necessary functionality to produce the coverage report(s)?

Sub Consensus:

Operational

- How do we use the IIS to identify providers in need of a visit?
- How do we use the IIS to identify the assessment cohort and ensure that we are assessing the patients who most accurately reflect/represent those patients under the care of the provider?
- What are we assessing, and are there any IIS (or AFIX) variations that may produce non-standardized results?
- Who should be able to run these reports? How often should they be run? Does the IIS need to store the results?

Technical

- What are the required inputs?
- What are the required parameters/criteria for running the assessment?
- What is the required output and output format?
- Does the IIS need to produce an export? If so, what is the spec and how often should the export be generated?
- What are the required calculations in the background needed to ensure a standardized result?

Other

- What should be the primary focus areas of the Phase 2 effort?
- Best Practices: How should/could the transition to the IIS coverage reports be facilitated? When is an Immunization Program ready to cease use of CoCASA and begin relying solely on the IIS for coverage assessments?

F. AFIX vs. NIS Comparison

Why do the AFIX Standards use “24-35 months, at 24 months” rather than the 19-35 months used by the National Immunization Survey (NIS)?

The CDC AFIX Standards use the assessment criteria “24-35 months of age at 24 months” because of its precision, its ease of interpretation, and its adherence to national standards.

Both the 19-35 and 24-35 month age ranges are valid and useful ways of looking at “two-year olds.” However, their usefulness depends on the purpose of the data and the situations in which they are applied. There are important reasons that the National Immunization Survey (NIS) uses a 19-35 month age range, but the purposes for doing a national survey are very different than the purposes of a clinic-specific assessment.

The use of the 24-35 month age range is a common measure in the field of immunizations. Similarly, it is well recognized that the 2nd birthday is a key milestone. A key message in yearly National Infant Immunization Weeks (NIIW) is to make sure that children are immunized “before age two,” and the timeliness of vaccines has been increasingly recognized as a critical part of immunization practice. The important HEDIS childhood immunization measurement (of the National Committee for Quality Assurance) assesses children at 24 months of age, and many publications are based on a 24-35 month age group or children at 24 months of age.

Including all children between the ages of 19-35 months in a clinic-based assessment creates great difficulty in interpreting the results. Since the age range spans a period of 16 months including the critical 24-month mark, it is not possible to know when, during that span, those children became up-to-date. Assessing this large time span provides no indication regarding the percent of children immunized early, on-time or late, yet knowing those details is important to understanding the system issues and clinical reasons that the children were or were not up-to-date. The timeliness of vaccine administration is critical and the difference between children receiving a vaccine at 19 months vs. 35 months is not unimportant. Assessing children at 24 months of age from a 24-35 month range provides a clear measurement at an important milestone, and it can be a starting point for greater dialogue about immunization practices.

The most common reason that people want to use the 19-35 month range in their AFIX assessments is to compare their rates to NIS rates. However, care should be taken when making comparisons between the NIS rates and CoCASA generated rates for AFIX. There are many methodological differences between the NIS and CoCASA, but two of the most significant are that NIS is a population-based survey while CoCASA is usually clinic-based. And, secondly, the NIS counts all doses while CoCASA looks only at valid doses.

G. CDSi Usage for AFIX

It is recommended to use the Clinical Decision Support for Immunization (CDSi) resources to assess dose validity in accordance with ACIP recommendations and to determine if the assessed child/adolescent has received the appropriate number of doses to be included in AFIX assessments. This appendix explores places where the CDSi resources can be leveraged. Specifically, this appendix will explore the following:

- Selecting Vaccinations for Assessment
- Determining Dose Validity
- Using Patient Series Status for AFIX measurements
 - Completion
 - Aged Out
 - Immunity
- Missed Opportunities

CDSi Background

The CDSi initiative was established by the Immunization Information System Support Branch (IISB) at the CDC to harmonize the outcomes of existing CDS tools and ensure evaluation and forecasting results were consistent with ACIP recommendations. It developed new clinical decision aids for each vaccine on the childhood and adolescent immunization schedule to:

- Make it easier to develop and maintain immunization evaluation and forecasting products
- Ensure a patient's immunization status is current, accurate, consistent, and readily available
- Increase the accuracy and consistency of immunization evaluation and forecasting
- Improve the timeliness of accommodating new and changed ACIP recommendations

CDSi resources include Supporting Data, which describes, by antigen, various factors and their accompanying sets of values to be considered when implementing ACIP recommendations, and Logic Specifications, which describe the functionality required to evaluate and forecast based on a patient's immunization history and the supporting data. CDSi also provides a representative set of scenarios and their expected outcomes (test cases) as dictated by the Logic Specification to help programs ensure their CDS algorithms are producing accurate results. All of the CDSi resources can be found on the CDSi home page at <http://www.cdc.gov/vaccines/programs/iis/interop-proj/cds.html>.

Selecting Vaccinations for Assessment

CDSi provides a supporting data spreadsheet called "CVX to Antigen Map" in the Supporting Data resource which provides all of the CVX codes of interest when performing clinical decision support. This same supporting data artifact can be used for AFIX measurements, as all CVX codes supported by CDSi must be included in AFIX measurements (Business Rule 3.A).

Determining Dose Validity

Use of CDSi resources, including the CDSi test cases, can help ensure that IIS evaluation and forecasting algorithms produce dose validity determinations that are consistent with ACIP recommendations, as required by BR 4.C. Only the components of the vaccine that meet the rules of validity will be counted towards compliance with the AFIX coverage measurement.

The supporting data and dose validity documentation in CDSi is antigen-based. For example, HepB-Hib is broken into its two antigenic components of Hep B and Hib to accurately validate both antigens separately. CDSi also applies this same logic behavior to the multiple antigenic families of MMR and DTaP/DT/Tdap/Td. Logic Specification Chapter 7 – Identify and Evaluate Vaccine Group – describes the logic necessary to evaluate and then join the individual antigenic components together into one measurement for each vaccine group. Further, for AFIX purposes, all components of MMR, DTaP and Tdap must be present for the patient to be considered as complete; single antigen M-M-R, DT, Td or TT will not be counted towards completion of AFIX coverage measurements unless the patient receives valid doses of all required antigens. For example, in order for single antigens of M-M-R to count towards the completion requirement, a patient would be required to receive a valid single antigen measles + a valid single antigen mumps + a valid single antigen rubella to equal a completed valid dose of MMR.

Using Patient Series Status

For the purposes of producing AFIX coverage assessments from the IIS, all coverage report results reported to the AFIX Online Tool must be based on the required assessment measures. These measures represent defined benchmarks for assessing vaccination coverage for children and adolescents. Results of these coverage assessments also identify potential issues with the vaccination practices of the provider being assessed (e.g. timely vaccination, series completion, missed opportunities).

In some but not all cases, the Patient Series Status, as defined in CDSi (see Table 3-3 Patient Series Statuses, CDSi Logic Guidance version 2.0), can be used to determine whether a child/adolescent meets the AFIX measurement. The relevant CDSi patient statuses, and when they can/cannot be applied to AFIX measurements, are described below. It is important to note that these tables represent the *current* ability of CDSi Patient Series Status Complete to meet *current* AFIX measurement requirements. Changes in ACIP recommendations or AFIX reporting requirements could change the requirements presented in this table. Additionally, programs that are not using CDSi resources for their evaluation and forecasting algorithms might have similar constructs that can be used in support of AFIX measurements.

Patient Series Status: Complete

CDSi defines “Complete” status to mean that “the patient has met all of the ACIP recommendations for the patient series”. For some of the AFIX childhood and adolescent assessments, this status (or its equivalent in an IIS’s evaluation/forecasting algorithm), can be used to determine if the child/adolescent has met the AFIX assessment measure. This is perhaps most relevant in cases where the AFIX measurement can be achieved with a range of the number of doses depending on the age at first vaccination (e.g. Hib, PCV), the vaccine product administered (e.g. RotaTeq 3-dose vs. Rotarix 2-dose, Recombivax 2-dose and Pediarix 4-dose Hep B), and/or patient age (adolescent Meningococcal booster). In other cases, the Complete status cannot be used to assess compliance with the AFIX measurement because the childhood/adolescent series is not complete at age 24 months or during the adolescent years included in AFIX measurements (e.g. a child who has received 4 valid DTaP doses will not be identified by CDSi logic as “complete” because additional diphtheria, tetanus, and pertussis containing vaccinations are recommended at a future date). In this case, the IIS would need to

specifically count 4 valid doses to identify those children who received the number of doses to meet the AFIX measurement. Lastly, there are additional cases where the IIS can elect to use either the Complete status from its evaluation/forecasting algorithm or the exact number of doses required by the AFIX measurement, as both approaches will produce the same result.

More information about when the CDSi Patient Series Status Complete can be used by IIS for AFIX purposes is provided in the table below. All patients who have achieved compliance with the specified AFIX measurements will be counted as up to date on the AFIX coverage report.

Note: Influenza is not represented in the following tables. CDSi currently only publishes current season flu guidance; whereas AFIX measurements focus on influenza vaccinations administered during the previously completed flu season.

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

Business Rules		Notes
9.A	For the following vaccine groups, the IIS should use Patient Series Status Complete from its forecasting/evaluation algorithm to determine if the child has completed the antigen series on or before age 24 months:	Hib PCV Rotavirus Hep B
9.B	For the following vaccine groups, the IIS cannot use Patient Series Status Complete to determine if the child meets the AFIX assessment measure on or before age 24 months. These AFIX measures must be based on the number of valid doses administered:	4 DTaP 1 MMR 1 Varicella 3 Polio
9.C	For the following vaccine groups, the IIS can elect to use Patient Series Status Complete from its forecasting/evaluation algorithm or count the number of valid doses administered to determine if the child has completed the antigen series on or before age 24 months, as both approaches produce equivalent results:	2 Hep A

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

Business Rules		Notes
10.A	For the following vaccine groups, the IIS should use Patient Series Status Complete from its forecasting/evaluation algorithm to determine if the adolescent has completed the antigen series on or before the compliance date:	Hep B Meningococcal Hep A Polio
10.B	For the following vaccine groups, the IIS cannot use Patient Series Status Complete to determine if the adolescent is up-to-date for the antigen series on or before the compliance date. These AFIX measures must be based on the number of valid doses administered:	1 Tdap 2 HPV 1 HPV
10.C	For the following vaccine groups, the IIS can elect to use Patient Series Status Complete from its forecasting/evaluation algorithm or count the number of valid doses administered to determine if the adolescent has completed the antigen series on or before the compliance date, as both approaches produce equivalent results:	2 MMR 2 VAR 3 HPV

Note: These tables represent the current ability of CDSi Patient Series Status Complete to meet current AFIX measurement requirements. Changes in ACIP recommendations or AFIX reporting requirements could change the requirements presented in this table.

Patient Series Status: Aged Out

Patients who have “aged out” of a series prior to completing the series (e.g. rotavirus) will be counted as incomplete/not up to date for the AFIX measurement. In CDSi this is determined when a patient has a patient series status of “Aged Out”.

Patient Series Status: Immune

Patients will also be considered up to date for certain measures when evidence of immunity is present. In CDSi, a patient with appropriate documentation per the Immunity table in the Supporting Data (<http://www.cdc.gov/vaccines/programs/iis/interop-proj/cds.html>) will have a Patient Series Status of “Immune”. It should be noted that Immunity to MMR, requires documentation of immunity to each disease (Measles, Mumps, and Rubella).

Missed Opportunities

The CDSi Logic Specification provides business rules to calculate the forecasted earliest, recommended, and latest dates for the next vaccination visit within each vaccine group. The recommended date (also referred to as the adjusted recommended date), which is defined as the later of the earliest date and the unadjusted recommended date (see Table 5-16 Generate Forecast Date and Recommended Vaccine Business Rules, CDSi Logic Guidance version 2.0) must be used to determine if an opportunity to vaccinate was missed (see BR 7.B).

H. Technical Design Specification

The following Design Specification is complementary to the material presented in the section titled [AFIX-IIS Integration: CDC Technical Guidance](#). The Design Specification template is intended to inform IIS systems developers/vendors of what they need to know in order to develop the necessary functionality for producing the required CDC AFIX Coverage Assessment Report(s). This specification includes guidance on the following items:

- Required inputs
- Parameters/criteria for running the assessment
- Required calculations for ensuring standardized assessment results
- Required output and suggested output format(s)
- Process for reporting results and other administrative considerations

Note: This document contains technical and key reference materials that are integrated and referenced in various sections, appendices and support documents. In order to maximize the effectiveness of these resources, the document should be examined and viewed in its entirety.

This specification provides baseline guidance and can be adapted to fit the specific change management process for each IIS. It is understood that there may be some variation in terminology and workflow that is unique to each IIS product; however, any modifications made to this specification should ensure that the basic integrity of the report(s) and the core Technical Requirements ([AFIX-IIS Integration: CDC Technical Guidance](#)) are maintained. Where appropriate, references are made to specific Business Rules (BR) in the Technical Guidance section that must be applied during the development effort.

Recommendation: IIS awardees and their vendors may leverage the Technical Design Specification that includes suggestions on implementation considerations for generating the required report(s).

Requirement: The IIS will apply all business rules detailed in this document for the purposes of identifying the assessment cohort (denominator), applying the assessment criteria (numerator), and performing the calculation logic.

Throughout the following Design Specification, a number of terms have been used to identify specific implementation considerations. User interface (UI), IIS, and output suggestions and recommendations are offered for programs that find them useful, but they are not express requirements. Term utilization can be interpreted as follows:

- Field Behavior – Provides an explanation of how the defined field impacts the generation of the report
- UI (or IIS) Suggestion – Represents an optional suggestion that IIS may want to consider when implementing the report
- Output Suggestion and Examples – These items are used to provide suggestions/models for how the report output may be formatted

Note: Phase 2 of the AFIX-IIS Integration Project will likely include guidance for additional assessment of the specified patient cohort and vaccinations (e.g. incomplete/not up to date, invalid doses), including a number of “patient list” style reports for provider feedback sessions. IIS should consider developing the backend architecture in such a way that this data can be further leveraged for the Phase 2 effort of this project.

Functional Overview

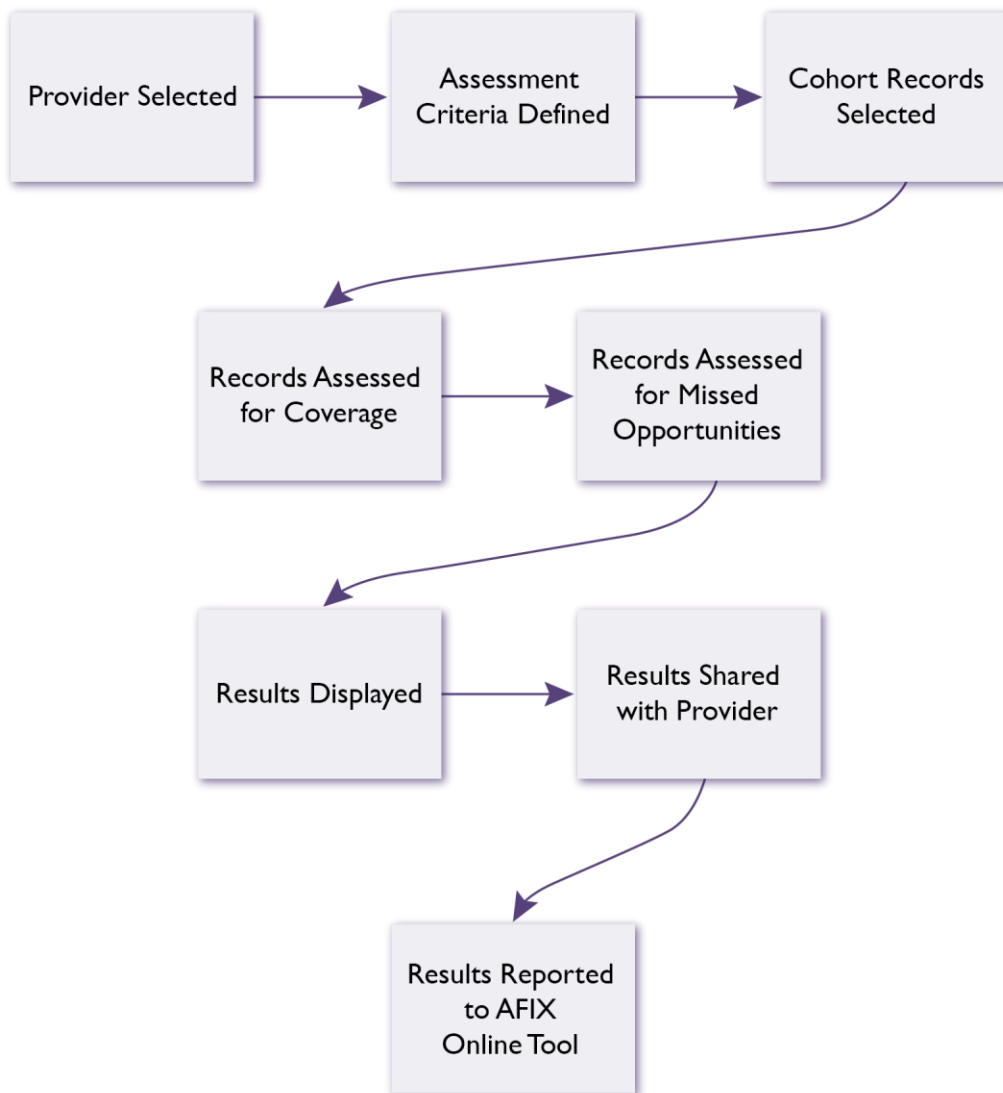
The purpose of this guidance is to create a new report (or modify an existing report) to assess VFC provider coverage levels for specific vaccines and/or vaccination series for a specified patient cohort. The following section provides an overview of the functional requirements for this effort. Detailed information on how to apply the requirements are then outlined in the subsequent sections.

1. IIS must be able to produce a report of coverage rates and missed opportunities for VFC provider assessments. The required reportable measures are defined by the CDC AFIX Program. There is a childhood and an adolescent component of the assessment.
2. The report must be developed according to universally applied technical guidance ([AFIX-IIS Integration: CDC Technical Guidance](#)) to ensure that report results are standardized across all awardees regardless of IIS product/platform.
3. The report should be made available to all user types/levels that may benefit from the information contained in the report.
4. The IIS must collect a minimum set of inputs/data elements when defining a provider, creating a patient record and recording/reporting a vaccination to the IIS.
5. A uniform set of reporting parameters/criteria should be applied for selecting the provider, identifying the assessment cohort(s), and assessing the vaccination records.
6. The IIS must be able to identify active patients of the provider within the specified age cohort for defining the assessment denominator.
7. Providers should have the ability to alter the Patient Active/Inactive Status (PAIS) indicator for associated patients to ensure that only active patients of the practice are being assessed.
8. The IIS must be able to distinguish the validity of a vaccination in relation to other doses in the series and other vaccinations on the immunization record by applying current ACIP recommendations.

9. The IIS must be able to evaluate the completeness of a vaccination record and apply special logic when needed in accordance with the ACIP routine and catch-up schedules.
10. The IIS must be able to assess missed opportunities on a vaccination record based on doses due/eligible but not received on the date of the most recent vaccination visit.
11. Users should have the ability to print, save or export the results of the assessment report(s).
12. New development efforts should apply best practice guidelines and the most current coding standards whenever feasible.

The following flow diagram illustrates the general process and workflow that will be supported by the proposed report.

Figure 2: AFIX-IIS Process Flow



Design Specification Overview

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 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

Report Headers:

- Provider Name
- VFC Pin Number
- Assessment Date
- Feedback Date
- Ages Assessed
- As of Date
- Birthdate Range
- Number of Records Analyzed
- Selected Series/Antigens
- Compliance by Age/Date

Report Options:

- Save
- Print
- Export (spec TBD)

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 indicator¹⁷ (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*
 - 1.) 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>

¹⁷ See AIRA MIROW: *Management of Patient Active/Inactive Status in Immunization Information Systems: Replacement of 2005 Guidelines – 2015* (in process; anticipated release in March, 2015); replaces *Management of Moved or Gone Elsewhere (MOGE) Status and Other Patient Designations in IIS – 2005*

- 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
 - vii.) Pneumococcal
 - viii.) Rotavirus
 - ix.) Influenza
 - x.) Hepatitis A
 - xi.) Tdap
 - xii.) HPV
 - xiii.) Meningococcal
- 2.) IIS Requirement: 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^{18*} (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.

1. 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)

¹⁸ Contraindication/precaution refers strictly to those specified in Table 6 of the General Recommendations (<http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6002a1.htm#Tab6>).

- 1.) *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 (see [Report Access](#)).*
- 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 suggestion – optional)
 - i. This field would offer users the option to select one of the following options:
 - 1.) 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

1 MMR

UTD Hib

UTD Hep B

1 VAR

UTD PCV

UTD RV

1 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 the "UTD" measurements could auto-populate as 4 Hib, 3 Hep B, 4 PCV and 3 RV; however, "UTD" calculations must be applied on the backend when returning AFIX coverage 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

1 Tdap

UTD Meningococcal

3 HPV

2 HPV

1 HPV

1 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 the "UTD" measurements could auto-populate as 3 Hep B, 1 Meningococcal and 4 Polio; however, "UTD" calculations must be applied on the backend when returning AFIX coverage 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.
 - 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.
 - iv. No default date should be offered. Only future dates \geq "today's date" through 7 days are acceptable values.
 - v. 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
 - vi. 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 Suggestion (optional): Labeling 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
 - vii. Age Range by Date of Birth
 - 1.) 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
 - viii. UI Suggestion (optional): consider implementing a toggle or button selector for "age range in months" and "age range in years".
 - ix. 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 will be 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 1.A – 1.E*)
- i. Date should default to “today’s date” with the ability to be edited. No future dates should be allowed.
 - 1.) 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 Suggestion (optional): 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”.

- b. 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.) 1 MMR
 - iv.) UTD Hib
 - v.) UTD Hep B
 - vi.) 1 VAR
 - vii.) UTD PCV
 - viii.) UTD RV
 - ix.) 1 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 Hep B, 4 PCV and 3 RV; however, "UTD" calculations must be applied on the backend when returning AFIX coverage 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.) 1 Tdap
 - v.) UTD Meningococcal
 - vi.) 3 HPV
 - vii.) 2 HPV
 - viii.) 1 HPV
 - ix.) 1 Influenza (previous season)
 - x.) 2 Hep A
 - xi.) UTD Polio
 - 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 3 Hep B, 1 Meningococcal and 4 Polio; however, "UTD" calculations must be applied on the*

backend when returning AFIX coverage 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:

Select Vaccines	Number of Shots
DTaP	<input type="text" value="0"/>
POLIO	<input type="text" value="0"/>
MMR	<input type="text" value="0"/>
HEP-B 3 DOSE	<input type="text" value="0"/>
VARICELLA	<input type="text" value="0"/>
PNEUMOCOCCAL	<input type="text" value="0"/>
MENINGOCOCCAL	<input type="text" value="0"/>
HPV	<input type="text" value="0"/>

- 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):
 - 1.) 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.
- 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](#)).

Report Calculations

For information on report calculations including the selection of provider sites for assessment, selection of assessment cohorts, vaccination assessment criteria, and coverage and missed opportunity calculations, please refer to the AFIX-IIS Integration: CDC Technical Guidance section of this document.

Report Format and Access

This section details the required report content, as well as suggested report headers, display and output types. This section also addresses what a user should be able to do with the report after it has been generated and which users should have access to the AFIX Assessment Report(s).

Report Headers

1. When the report displays, it should include the following headers:
 - a. Provider Name
 - i. Field should match the Provider Name specified in Report Criteria
 - b. VFC Pin Number
 - i. Field should match the VFC Pin Number specified in Report Criteria
 - c. Assessment Date
 - i. Field should always reflect "today's date".
 - d. Feedback Date
 - i. Field should display the date specified in Report Criteria.
 - e. Ages Assessed
 - i. Field should display the age range in months or age range in years selected in Report Criteria (e.g. "24 to 35 months" or "13 to 17 years").
 - 1.) See example in (f.) below
 - ii. If IIS is implementing the optional "Age Range by Birthdate", the IIS should calculate the ages of the assessed and display it here as months/years.
 - f. As of Date
 - i. Field should display the date selected in Report Criteria.
 - ii. Example:

Age range:	From	24	to	35	months	as of	12/31/2011
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- g. Birthdate Range
 - i. Field should display the calculated birthdate range based on Report Criteria selections for Ages Assessed and As of Date.
 - ii. If IIS is implementing the optional Age Range by Birthdate, the selected Birthdate Range should display here.
- h. Number of records analyzed
 - i. This field will display the total number of “active” patient records assessed for the selected provider within the defined age cohort.
- i. Selected series/antigens
 - i. Will reflect the antigens and number of doses assessed and/or series assessed as defined on the Report Criteria screen.
 - ii. This will display as a simple list (e.g. 4DTaP, 3Polio, 1MMR, etc.). Example:

Selected series/antigens: 4:3:1:3:3:1:4 (4DTaP, 3Polio, 1MMR, 3HIB, 3HepB, 1Var, 4PCV)
- j. Compliance By
 - i. Field should display the “Age” or “Date” assessment criteria defined in the Report Criteria.
 - ii. Example:

Compliance: ☐ By age: 0 months ☒ By date: 4/19/2012

Report Content

1. The output report should include the following required elements:
 - a. Separate row or column for each vaccine/antigen/series combination assessed
 - b. Completion: Results presented as a number (number of children/adolescents in the cohort that meet or exceed the specified number of doses) and percentage (number of children/adolescents meeting or exceeding the requirement divided by the total number of records analyzed in the cohort*100)
 - c. Missed Opportunities: Results presented as a number and percentage of individuals that were incomplete at the “Compliance by Age/Date”, AND could have received the assessed vaccination during their last vaccination visit, AND did not receive the assessed vaccination during that visit.
 - d. Output Suggestion (optional): The following example provides a suggestion for how the report display may be presented:
 - i. Columns
 - 1.) Vaccine (or Series)
 - 2.) Number of Doses
 - 3.) Number Complete
 - 4.) Percentage Complete
 - 5.) Number Missed
 - 6.) Percentage Missed
 - ii. Rows
 - 1.) Line listing of results for each vaccine/dose combo
 - 2.) Partial example:

<u>Coverage Levels:</u>	<u>#</u>	<u>%</u>
4 Doses of DTaP	37	79
3 Doses of Polio	42	89
1 Doses of MMR	40	85
3 Doses of Hib	42	89
3 Doses of HepB	43	91
1 Doses of Var	40	85
4 Doses of PCV	39	83

Report Options

1. Users should then have the option to “Save”, “Print”, or “Export” the report results.
 - a. Users will have the ability to save a copy of the report to their desktop or media device through the standard “save as” feature of selecting the file location and providing a file name.
 - b. Users will have the ability to print a copy of the report to a networked printer through the standard print feature.
 - c. Users will have the ability to export report results into an .xls or flat file format as defined in the Export Specification (TBD, to be provided under separate cover).
2. IIS Suggestion: Users should have the ability to schedule the report(s) to run during off hours or non-peak use periods. The report could then be retrieved via email or from the designated repository.
3. IIS Suggestion: Capable IISs may want to consider storage of report data in a Data Mart or Data Warehouse for future reference and/or trend analysis.

Report Access

1. It is recommended that this report be accessible to the following user types:
 - a. State IIS Staff
 - b. State AFIX Staff
 - c. Local Public Health IIS and AFIX Staff
 - d. Staff at Parent Organizations/Reporting Entities
 - e. Staff at Individual Clinics/Sites/Facilities/Organizations
 - f. Contracted Designees (performing assessments on behalf of State/Local AFIX/IIS Staff)
2. It is recommended that user access be managed in such a way that users will only be able to assess data directly within their purview.
 - a. For example, a state level staff member can run an assessment on any provider in the state, whereas a local staff member will only be able to assess providers within their specified jurisdiction, and provider level staff will only be able to assess their individual clinic/facility or practices associated with the Parent Organization.

Other IIS Tools and Resources

In addition to the AFIX Coverage Assessment report(s) described in this Design Specification, there are other IIS tools and resources that may be beneficial to AFIX program staff as they identify and prepare providers for AFIX visits. These tools are not required as part of the Phase 1 AFIX-IIS Integration effort;

however, most of these tools already exist in many IIS. IIS staff are encouraged to share available functionality with their AFIX colleagues.

Provider Selection:

- Generate a list of VFC Providers in the IIS (includes ability to differentiate between a VFC Provider and other providers/provider types in the IIS)
- Generate a patient count by provider
- Generate a doses administered and/or dose count report

Patient Selection:

- Generate a list of active patients for a selected provider

General AFIX Support Tools:

- Generate a variety of provider, patient, inventory, and performance reports