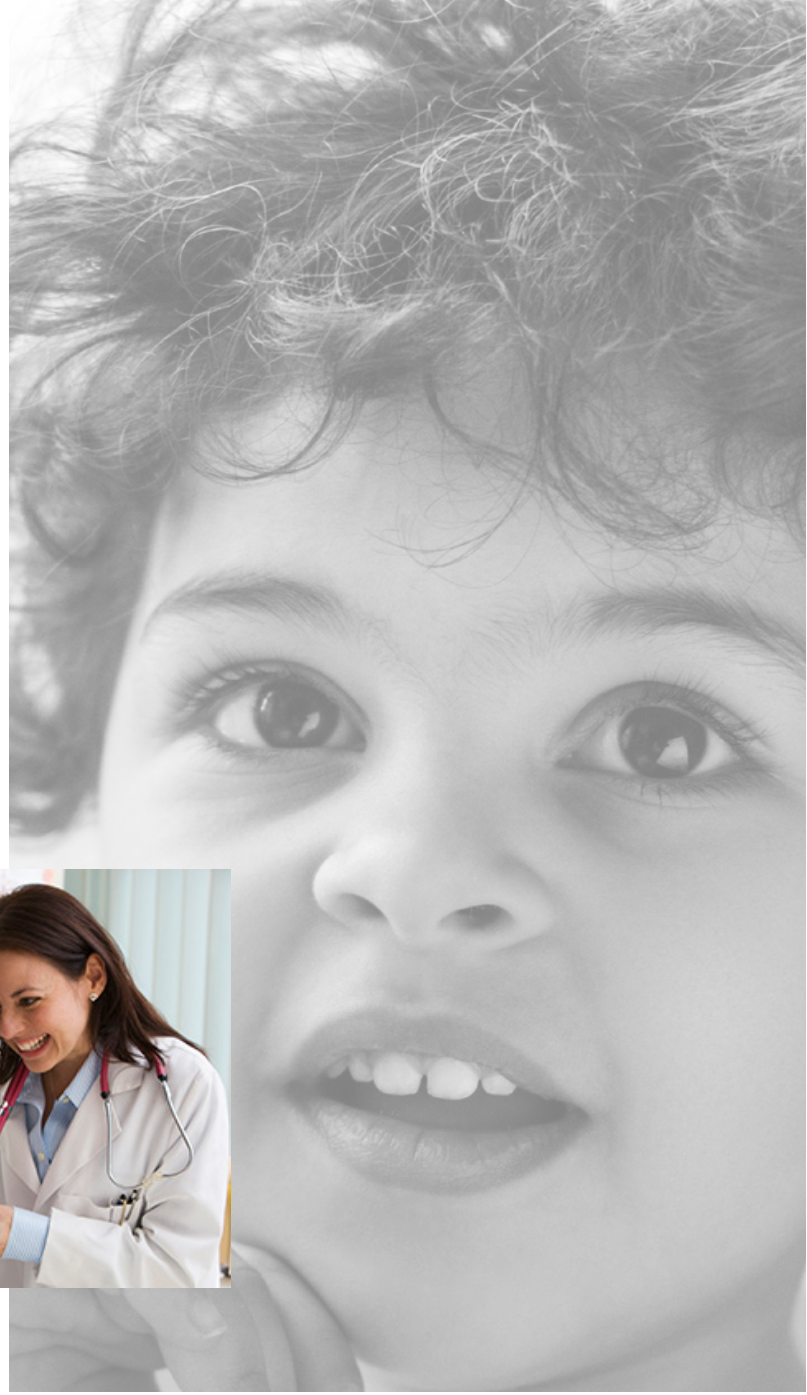
ANALYTIC GUIDE

For Assessing Vaccination Coverage Using An IIS

Practical considerations and decision points in designing a population-based coverage assessment.



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AIRA AMERICAN IMMUNIZATION REGISTRY ASSOCIATION

Immunization Information Systems for a New Era

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Purpose

The purpose of the ***Analytic Guide for Assessing Vaccination Coverage Using an IIS*** (hereinafter referred to as the "guide") is to assist Immunization Information System (IIS) staff and other interested parties in using IIS data to do population-based coverage assessments. The guide describes practical considerations and key decision points in designing a population-based assessment using an IIS.

Target audience

The target audience is IIS and immunization program staff at the state and local level. The intent is for the guide to be accessible and understandable to staff with a variety of roles and backgrounds, such as program managers, quality improvement specialists, and epidemiologists.

Background

In early 2014, AIRA's Assessment Steering Committee (ASC) oversaw a survey of the IIS community on use of the IIS for immunization coverage assessment. The resulting white paper (*Clark et al. 2014*) provided a list of recommendations for AIRA to pursue. The recommendations included two that relate specifically to this guide:

1. AIRA should provide support for IIS-based childhood immunization coverage assessments by updating and disseminating guidance on generating and interpreting assessment results, considering desired variation.

2. AIRA should provide support for high-value programmatic areas with currently low IIS use by developing strategies for using alternative denominator information to compensate for IIS data limitations, when needed.

Under AIRA's Cooperative Agreement with the Centers for Disease Control and Prevention (CDC), a 2015 objective was to develop a standard methodology for conducting IIS population-based immunization coverage assessments, with a guide as the output. After much consideration, the ASC decided to develop a guide that would be immediately useful and offer practical strategies and recommendations to IIS. The ASC views the guide as a stepping-stone to future initiatives that support the development, testing, and dissemination of IIS-based vaccination coverage best practices. Such initiatives can help ensure comparability of assessment results across programs. The guide may also contribute to the use of IIS data to estimate standardized national and state/local vaccination coverage, serving as a complementary source of information to other coverage estimates (e.g., *National Immunization Survey*).

Process of developing guide

AIRA contracted with a technical consultant to assist the ASC in developing and writing the guide. With input from the ASC and AIRA staff, the consultant convened a small workgroup composed of Subject Matter Experts (SMEs) – primarily epidemiologists with extensive experience using IIS data for research and coverage assessments.

The consultant and the workgroup met monthly by phone, gathered and reviewed relevant materials and resources, and shared real-life experiences in using IIS data. The guide was developed over a six-month period with iterative feedback on the document from the workgroup. See Appendix C and Appendix D for a list of resources and documents reviewed.

Important related documents

A number of existing resources provide important guidelines and recommendations that informed the development of this guide. Foundational documents are listed and described below, and along with other resources, are also found in Appendix C.

1. *AFIX-IIS Integration: Operational and Technical Guidance for Implementing IIS-Based Coverage Assessment - Phase 1.*
   In 2013, CDC's Immunization Services Division/Program Operations Branch (POB) announced that support for the provider-level assessment software developed and supported by CDC, *Comprehensive Clinic Assessment Software Application* (CoCASA), would be discontinued. Program awardees would be required to leverage their IIS to support this key program activity. (CoCASA is a part of the overall provider-level quality assurance activity called AFIX – "Assessment, Feedback, Incentives, and eXchange.") For this transition to occur, IIS would need operational and technical guidance to meet the CDC requirements. To that end, CDC contracted with AIRA to produce guidance to assist IIS in the implementation of AFIX coverage assessments. The AFIX work focused solely on provider-level assessments – not geographic or population-based assessments – that specifically meet the CDC's AFIX requirements. While there are many differences between provider-level and population-based coverage assessments, the AFIX guide includes elements that contribute to this guide. Readers are advised to become familiar with the AFIX-IIS Integration documents.

2. *Management of Patient Active/Inactive Status in Immunization Information Systems: Replacement of 2005 Guidelines – 2015*.
   In 2015, AIRA's Modeling of Immunization Registry Operations Workgroup (MIROW) updated the Patient Active/Inactive Status best practices document. Informally, this document is referred to as the PAIS (short for Patient Active/Inactive Status), and we will use this acronym throughout the guide. The PAIS contains business rules for patient active and inactive status at both the provider level and the geographic level, and there are differences between the two. It is essential that researchers understand if and how their IIS has implemented PAIS rules since their use can have a substantial impact on coverage assessment results.

3. Three additional MIROW Guides (http://www.immregistries.org/resources/aira-mirow) also provide a good foundation for implementing data quality best practices that are critical to the usefulness of IIS as an accurate source of coverage information:

   a) *Vaccination Level Deduplication in IIS* – 2006

   b) *Data Quality Assurance in IIS: Incoming Data* – 2008

   c) *Data Quality Assurance in Immunization Information Systems: Selected Aspects* – 2013

4. **Clinical Decision Support for Immunization (CDSi) Logic Specification**.
   The CDSi is another document of high relevance referred to several times in this guide. An IIS must have a strong and up-to-date CDSi (also known as "evaluation and forecasting") algorithm and tool in order to run coverage reports efficiently and accurately. Interpreting the recommendations of the Advisory Council on Immunization Practice (ACIP) into a logical, programmable algorithm is a huge challenge, one that each IIS or IIS vendor has dealt with individually in the past. To assist IIS with this challenge, CDC convened a group of experts to work with ACIP. They then clarified evaluation and forecasting rules for each vaccine, standardized interpretation of the vaccine schedule, and developed tools to guide developers of IIS forecasting/evaluation algorithms. ACIP recommendations for children birth to 18 years of age, as well as for adults and special populations, have now been converted into computable logic for a Clinical Decision Support engine:

   The CDSi Logic Specification provides a single, authoritative, implementation-neutral foundation for development and

maintenance of CDS engines. It captures ACIP recommendations in an unambiguous manner and improves both the uniform representation of vaccine decision guidelines, as well as the ability to automate vaccine evaluation and forecasting. The target audience for the Logic Specification for ACIP Recommendations includes business and/or technical implementers of immunization CDS engines. These implementers may support any system with an immunization evaluation and forecasting engine, including but not limited to IIS. (*http://www.cdc.gov/vaccines/programs/iis/interop-proj/cds.html*)

It is highly recommended that each IIS become familiar with these tools and use them to develop, test, review, and/or improve their own CDSi system.

Limitations of guide

This guide is not prescriptive but intends to offer practical considerations and approaches that may be tailored to the needs of a particular assessment and to the functionality of each IIS. We hope this document will provide a foundation for further discussion and sharing of ideas about best practices in the use of IIS for population-based immunization coverage assessments.

Definitions and Acronyms used in this document can be found in Appendix B.

Vaccination coverage can be defined as a rate describing the frequency at which immunization events occur in a defined population. The components of a vaccination coverage rate are the numerator, the denominator, and the specified time period in which immunization events can occur. The numerator is derived from counting the members of the cohort (population group) that meet certain criteria related to age, vaccinations, and period of time. Immunization rates are proportions in which the numerator is a subset of the denominator. IIS data is sometimes the best source for the denominator. Other times, external denominators such as the United States Census provide more accurate results. This guide will help you make decisions on how to calculate the numerator and how to determine the best denominator.

The purpose of a coverage assessment drives many of the decisions made in defining the assessment criteria. We will briefly review the two most common purposes below. More details related to purpose and criteria can be found within the cohort-related and vaccination-related sections of the guide (Sections 3.1 and 3.2).

One common purpose of a coverage assessment is to determine the percentage of the population that is immune, or protected, from disease. We will refer to these types of assessments as "protection-based." Protection might be acquired through vaccination or through the immunity conferred after infection. In a protection-based assessment, investigators would include in the numerator not only vaccinated children, but also children with history of disease or laboratory evidence of immunity. Investigators might also consider counting only valid doses, with the assumption that invalid doses do not confer an adequate immune response to protect the child from disease.

A second common purpose of coverage assessment is to determine the percentage of the population that has been vaccinated appropriately among those that were eligible for vaccination. We will refer to these assessments as "performance-based." This purpose implies assessing the adherence of a provider, program, or region to administering all ACIP-recommended doses. In this case, investigators might choose to include any administered vaccine, valid or invalid, in the analysis. Investigators might also remove from the denominator (if the denominator is IIS-derived) children who have a history of disease, laboratory-confirmed immunity, or a true medical contraindication, since they would not be eligible for vaccination.

It is crucial to determine the purpose of your coverage assessment and clearly state your hypothesis before selecting any analysis parameters. Deciding on your purpose early in the process will make this guide most useful to you as your purpose/hypothesis should guide your decision-making at each decision point discussed in this guide.

Deriving an accurate numerator requires a clear delineation of the population you wish to study and the immunization events you wish to assess. This includes consideration of the appropriate birth cohort, patient exclusion criteria, the period or point in time being measured, vaccine types, use of valid versus all doses, and if/when to censor vaccinations. Your purpose – whether related to performance, protection, or something entirely different – will drive how you handle a variety of issues. This section describes processes and reasons for selecting and limiting the study population (Section 3.1.Cohort-Related), considerations for including or excluding vaccination events (Section 3.2. Vaccination-Related Criteria), and a review of pros and cons in selecting your denominator source (Section 3.3. Selecting the Denominator).

3.1. Cohort-related

Identifying Patient Exclusion Criteria

In order to determine who is in your cohort, you first need to decide who is "out." Whom will you exclude from your analysis? Defining the geographic area of analysis will determine the first exclusion criteria. Limit your cohort by excluding everyone who is NOT in the target area. For example, you might limit the population to those within a particular county and exclude everyone else. Target areas you might select include:

- State
- County/Parish/Boroughs
- Zip Code
- Census Tract
- District/Region
- City
- Zip Code Tabulation Area (see Appendix C-11)

Once the target area is determined, you should exclude anyone who has an address outside the area. Next, you will usually exclude anyone who is deceased and consider the active/inactive status of patients. Specific rules for deeming a record "inactive" may be found in Appendix A. Make sure to note that determination of patient status at the geographic level differs from the provider level according to PAIS recommendations.

TIP: Age range statements are often ambiguous and subject to interpretation. One thing that can help avoid confusion, is to use the word "through" as in 19 through 35 months of age, rather than 19 to 36 months which is ambiguous. "Through" indicates the intent to include every person from the starting age up through the entire ending age – either in months or years as appropriate. For the 19 through 35-month assessment, this means including children from the day they turn 19 months old through their entire 35th month – that is, up to and including the day before their 36 month (3rd year) birthday. Be clear and precise in your age range definitions, using extra words and examples to clarify your intent.

Choosing the Assessment Age Range

The next step is to determine the assessment age range, hereinafter referred to as age range. The age range may be stated in months – usually for early childhood – or in years for older children and adults.

Choosing the Time Period of Assessment

TIP: You can use an online age calculator to confirm the birthdate ranges you arrive at. See an example at: *http://www.calculator.net/age-calculator.html*.

You can choose to conduct your assessment with the age range as of a point in time or with the age range over a period of time. Subcategories of the latter will either allow or not allow aging in and out of the assessment cohort during the period (i.e., be younger or older than X or Y months/years at some times during the period of assessment). Once you have determined the age range and the time period or point of assessment, you can calculate the birthdate range. You now have what is often referred to as the assessment birth cohort or simply the assessment cohort. Below is a description of the three time period methods with details on when to use them, pros and cons of each, and examples of birthdate range calculation. (See Appendix E-1 for more examples of birthdate calculations and Appendix E-3 for a visual comparison of birthdate ranges among the three methods.)

Method 1: Point in Time Assessment

Purpose: To assess coverage in persons aged from X through Y months or years of age as of a certain point in time (i.e., a particular date).

When to Use: This is a good approach when you plan to compare your results to other assessments that use a common as-of date for the birthdate range. For example, CDC's Immunization Information Systems Annual Report (IISAR) uses the last day of the previous calendar year as the as-of date. Point in time is also a good method to use when you want to track coverage rates over time, as it allows you to hold your cohort to the same age range from one period to the next. Note that birthdate range changes in alignment with the as-of date, but the assessment age range remains constant.

Pros: Because this method focuses on an age group as of a particular day, there is no "aging in or aging out" to consider. In addition, this method is used in CoCASA/AFIX and many other assessments, making it a good one for comparison of results.

Cons: This method does not always allow each person in the age range the same opportunity to be vaccinated. It is not a good method if you need to assess coverage in an age group that is being actively vaccinated. For example, you would not use this method to assess Hepatitis A coverage among 12 through 23 month olds since these children are being actively vaccinated through most of this age range. Children in the cohort would not have an equal opportunity for vaccination since they would have anywhere from one day to 12 months to receive their Hepatitis A vaccinations. The youngest would have limited opportunity to contribute to the numerator, yet would still contribute fully to the denominator, resulting in underestimates of coverage.

Birthdate Calculations for Point in Time Assessment

EXAMPLE: Assess children who are 19 through 35 months of age as of 12/31/2014

Earliest date of birth: subtract 36 months from "as of" date of 12/31/2014 = 12/31/2011 and advance 1 day = 1/1/2012

Latest date of birth: subtract 19 months from "as of" date of 12/31/2014 = 5/31/2013

Birthdate range = 1/1/2012 through 5/31/2013, a 17-month wide cohort

Method 2: Period of Time Assessment – Not Allowing Aging In or Out

Purpose: To assess coverage in persons who are aged X through Y months or years of age and who are within that age range throughout a given period of assessment (i.e., a person cannot age in or age out).

When to Use: This is a good method to use when the period of eligibility for the vaccine is limited, such as for influenza season or for a specific event/counter-measure. This method is appropriate when the measurement pertains to an age group that is being actively immunized.

Pros: Not allowing aging in or out during the assessment period ensures that all children have an equal opportunity for vaccination during the period of assessment if you are only assessing vaccinations administered during the time period of interest. However, if you are assessing vaccinations administered before or "before-and-during" the time period of assessment, then children have an equal minimal opportunity for vaccination – i.e., with some variability in opportunity but a guaranteed minimum opportunity. Other methods may not have this advantage, and thus, you may want to consider this method first to see if it meets your needs.

Cons: When a period of assessment is long (such as flu season), this method may result in a very small number of individuals that are eligible for the cohort – potentially too small for meaningful results. Another unique limitation of the method occurs when the number of months or years in the period of assessment is approximately equal to the number of months or years in the birth cohort. The result can leave you with a one-day cohort. See Appendix E-2 for an example of this.

Birthdate Calculations for Period of Time Assessment Without Aging In/Out:

EXAMPLE: Assess children who were 19 through 35 months throughout the period 1/1/2014–12/31/2014

Earliest date of birth: subtract 36 months from 12/31/2014 = 12/31/2011 and advance 1 day = 1/1/2012

Latest date of birth: subtract 19 months from 1/1/14 = 6/1/2012

Birthdate range = 1/1/2012 through 6/1/2012, a 5–month wide cohort

Method 3: Period of Time Assessment – Allowing Aging In and Out

Purpose: To assess coverage in persons who are aged X through Y months or years of age at any point during a specified period of assessment, understanding that some will age in or age out.

When to Use: This method might be appropriate when you are assessing coverage after the period of vaccination and when you would expect little impact from catch-up vaccination (or when you are able to exclude doses administered after a certain time to eliminate the impact of catch-up vaccination). Care must be taken to censor/exclude vaccinations administered after an individual has turned the maximum age of the cohort even if still within the assessment period. Likewise, immunizations received after the last date of the assessment period should be excluded even if the person remains within the designated age group. It is worth noting that this approach does not appear to be used very often, as it is not mentioned in any of the published literature reviewed for this guide. It is included here because it might be an option that fits with a specific need.

Pros: This method expands the number of individuals in the cohort since it allows a range of time rather than a point in time for persons to fall in the appropriate age group. This may be of value in situations where the population is small to begin with. It is best to use when the expected vaccination age (or compliance age) is at the beginning of the age cohort, allowing adequate time for vaccination to occur before the individuals age out.

Cons: This method is generally not appropriate when you are assessing coverage in an age group that is being actively vaccinated at the time of assessment (e.g., when assessing flu coverage during the flu season). Persons who are aging in have a more limited opportunity to contribute to the numerator (be vaccinated), but they would contribute fully to the denominator, which can result in underestimates of coverage.

Birthdate Calculations for Period of Time Assessment Allowing Aging In/Out:

EXAMPLE: Assess children who are 19 through 35 months of age at some time between 1/1/2014 and 12/31/2014

Earliest date of birth: subtract 36 months from 1/1/2014 = 1/1/2011 and advance 1 day = 1/2/2011

Latest date of birth: subtract 19 months from 12/31/2014 = 5/31/2013

Birthdate range = 1/2/11 through 5/31/13, a 29–month wide cohort

3.2. Vaccination-related Criteria

To determine immunization events for the selected birthdate range, a number of vaccination-related questions must be answered. These questions are listed below, followed by a detailed section on each question.

1) Which vaccines do you want to assess?

2) Are you interested in completion of vaccinations from the routine schedule only (requiring a particular number of doses administered for each vaccine) and/or from the catch-up schedule (could be up-to-date with fewer doses)?

3) Are you interested in valid doses only or all doses (both valid and invalid)?

4) Do you want to look at immunization status as of a particular age or date (the compliance age/date)?

5) How will you handle immune status (laboratory evidence/history of disease)? Will it qualify a patient as "immunized"?

6) Will you consider contraindications in your analysis? Will you exclude patients with contraindications from the numerator?

7) Will you consider exemptions in your analysis? Will you ignore them or include them?

Details on vaccination-related criteria

1) Which vaccines do you want to assess?

For the most accurate coverage results, you usually should include in your query any product that ever contained the particular antigen. To do this, you must include outdated CVX and/or CPT codes, as well as non-specific codes. (CDC webpages with vaccine codes are listed in Appendix C.) The rationale for including all codes is that many systems – billing and Electronic Health Records (EHRs) – lag behind in updating their vaccine code sets, forcing clinic users to choose incorrect vaccine types/codes. In addition, users entering data directly into the IIS might select an outdated vaccine or simply err in selecting the wrong product/code. If you exclude outdated vaccine codes, you risk underestimating your coverage rates.

For example, measurement of Hepatitis A vaccine coverage in 2 year olds should include the following vaccines:

CPT Code	CPT Description	CVX Short Description	CVX Code
90632	Hepatitis A vaccine, adult dosage, for intramuscular use	Hep A, adult	52
90633	Hepatitis A vaccine, pediatric/adolescent dosage-2 dose schedule, for intramuscular use	Hep A, ped/adol, 2 dose	83
90634	Hepatitis A vaccine, pediatric/adolescent dosage-3 dose schedule, for intramuscular use	Hep A, ped/adol, 3 dose	84
90730	Hepatitis A vaccine	Hep A, unspecified formulation	85
90636	Hepatitis A and hepatitis B (HepA-HepB), adult dosage, for intramuscular use	Hep A-Hep B	104
N/A	Hepatitis A pediatric, NOS	Hepatitis A pediatric, NOS	31

Sources: "CPT Codes Mapped to CVX Codes" from http://www2a.cdc.gov/vaccines/iis/iisstandards/vaccines.asp?rpt=cpt and "IIS: HL7 Standard Code Set Mapping CVX to Vaccine Groups" from http://www2a.cdc.gov/vaccines/iis/iisstandards/vaccines.asp?rpt=vg

There are exceptions to this general rule: if you want to measure uptake or coverage for a specific vaccine product, you will need to apply constraints to your vaccine type selection. An example is measuring uptake of PCV13 during the period that vaccine supply and recommendations transitioned from PCV7. If you want to know PCV13 uptake, you should not include PCV-unspecified or PCV7 in your data pull. However, considering the lag in updating CVX/CPT codes as described above, PCV13 may continue to be erroneously coded as PCV7 long after there is no PCV7 vaccine in the pipeline. This will bias your results. Until you are sure there is no more PCV7 in the system, it will be difficult to compensate for this issue although there are ways to do so. One option might be to filter doses by manufacturer and lot number to determine the likelihood that the dose truly is PCV13. Another option is to use sensitivity analyses to assess the potential impact of misclassification. White describes use of this method in assessing the potential misclassification of Hib in a study published in Pediatrics. (White et al.)

2) ***Are you interested in using the routine schedule only or the catch-up schedule?***

In this guide, we assume that you will use your IIS evaluation/forecasting (CDSi) tool to determine vaccination status. Alternatively, dose validity can be determined by an external analysis program that calculates coverage. You may choose to use the routine childhood schedule as your standard with or without the catch-up schedule. The decision about which standard to use depends on the purpose of your assessment. For example, if you are assessing protection rates, you should use both the routine and catch-up schedules. It allows those who are behind on their immunizations to "catch-up" without having had all the recommended doses in the routine schedule, and thus be included as up-to-date. However, if you are more interested in performance and on-time vaccination, you will probably choose the routine schedule only. With the routine schedule as your criteria, your assessment will include children who have received the correct number of doses for each vaccine series. Children who age out of certain vaccine doses (e.g. Rotavirus) will NOT be included as complete.

3) ***Are you interested in valid doses only or all doses?***

When measuring coverage levels, you have a choice of including only valid doses or including both valid and invalid doses. If your IIS has the capability of identifying sub-potent or partial dose administrations, you may also choose to count those as invalid doses. Restricting the numerator to valid doses only will usually provide a more accurate reflection of true coverage in terms of protection against disease. On the other hand, including invalid doses may give you a measurement of performance and/or uptake, helping identify problems with clinical practice or data entry. If you are comparing results to another assessment that uses "all" doses, you may want to use both "valid" and "invalid" doses in your calculation for consistency and comparability of results.

4) ***Do you want to look at immunization status (compliance) as of a particular age or date?***

"Compliance by" is sometimes referred to as "Evaluate at Age (or Specific Date)". It establishes the age or date at which immunization status (i.e. completeness or up-to-date status) is assessed, and directly impacts the evaluation of series/antigen completion rates. Any vaccinations administered after the Compliance by Age or Date are not counted towards completion. This is referred to as "censoring doses." If an IIS has reporting delays (as many do), allowing too short a time between the end of the reporting period and the analysis can bias the coverage rate downward.

AFIX assessments provide

TIP: Allow enough time for data to enter your system. Most IIS experience some delays in reporting. Work with IIS staff to determine timeliness of incoming data in order to find the appropriate amount of time to wait. Allowing too short a time between the end of the assessment period and the assessment date can bias the coverage rate downward.

a good example of constraining vaccinations to those administered by a certain compliance age or compliance date. With AFIX, coverage is assessed among children aged 24 through 35 months with a compliance age of 24 months – that is, only those doses administered on or before the child's 24-month birthday are included in the assessment. On the other hand, the AFIX adolescent assessment, which measures vaccine coverage in 13 through 17 year olds, has a compliance date equal to the date of the assessment. That is, adolescent immunization status is determined on the date of assessment rather than as of a common age. In sum, choose the Compliance by Age or Date that best meets your assessment needs – whether it is today's date, the last day of the previous year, or some other date that makes sense for your purpose.

5) ***How will you handle immune status (laboratory evidence/history of disease)?***

Immune status – such as history of disease or lab evidence of immunity – can be included as vaccine-equivalent in protection level assessments and sometimes in performance-based assessments depending on the question. Immunity status should be used with care since there are limited circumstances where ACIP rules allow it to be equivalent to immunization. For example, provider-documented history of varicella is sufficient as evidence of immunity, but provider-documented history of measles is not —measles must have a lab test for sufficient evidence of immunity. (See Appendix C-5a for links to official definitions/uses of immune status.)

6) ***Will you consider contraindications in your analysis?***

True medical contraindications and precautions as defined by ACIP and documented by CDSi might be considered, depending on the assessment. However, since contraindications do not indicate immunity, an immune-based (protection) assessment should not include them. If you do want to include contraindications as part of an analysis (perhaps with a performance-based assessment), be aware that many IIS are poorly populated with contraindication data. (See Appendix C-5b for link to official definitions/uses of contraindications and precautions.)

7) ***Will you consider exemptions in your analysis?***

Be cautious in including exemption status in your analysis. Personal or religious exemptions are generally not considered reasons to exclude someone from a coverage analysis. A good rule of thumb is to NOT include exemptions. If you want to analyze the impact of "exemptors" on your rates, that is another question which you may consider separately from your overall coverage rates. True medical exemptions are contained within the definitions of contraindications and precautions, and should be dealt with as described in the previous paragraph.

3.3. Selecting the Denominator

The two main sources of denominator data for IIS-based coverage assessments are the IIS itself and the United States Census. You also can pull your denominator from birth statistics, school census data, and possibly other population-based data sources. Your choice of denominator depends on a variety of factors. In general, your denominator source should match the population selection parameters for your numerator. You should be able to describe why the denominator you choose is the best one for the purpose of the assessment. In this section, we discuss the pros and cons of several denominator sources including:

- IIS-based denominators
- Non-IIS-based denominators
- Other denominator options

IIS-based Denominators

IIS have the potential to provide up-to-date population numbers that are more accurate than any other source. In reality, most IIS have a number of challenges to overcome before reaching this ideal (*Clark et al. 2014*). One major challenge is keeping track of individuals who move in and out of a jurisdiction. Many IIS experience "denominator inflation."

This is the combined result of in-migrants – especially children – having records quickly entered into the IIS by providers upon immunization, while former residents (out-migrants) who moved away are not so easily identified. Strategies to deal with this are out-of-scope for this guide, but suggestions for determining active and inactive patient status can be found in the PAIS Guide. Identifying and inactivating records of deceased individuals can also be a challenge, which sometimes can be addressed by linking the IIS with vital statistics. Unidentified and unresolved duplicate patient records also contribute to population overestimates. Unmerged records often exist as record fragments that fail to meet merging standards, and for which one or more fragments will appear as a highly under-immunized child. Duplicate records may be as much of a challenge as keeping track of individuals who have moved out of the jurisdiction. Thus, it is important to have good patient deduplication processes in place.

> **TIP:** Use **MIROW's PAIS guidelines** to determine when patient records should be inactivated. The PAIS recommends that patients with "active" and "unknown" status be **included** in geographic assessments, and patients with inactive and deceased status be **excluded**. Make sure that inactive status of patients is determined at the jurisdiction-level (not provider-level) for these assessments. (See Appendix A.)

IIS-based denominators may be best for mature IIS with excellent processes in place for deduplication and address updating. The ability to track individuals' latest addresses and appropriately flag their inactive status at the jurisdictional level makes it more likely that an IIS denominator will reflect the truly active population. In addition to the mature IIS, newer and under-populated IIS may be candidates for IIS-based denominators since census data will significantly underestimate coverage. A major positive for using the IIS is the consistency between the data sources for numerator and denominator. However, many factors can contribute to an overestimate or underestimate of the true coverage rates. The sections below describe the pros and cons for using IIS-derived data as a denominator source.

IIS Method 1: Individual Has Record in IIS With or Without Immunizations

You may decide to include all individual patient records within your given cohort in the denominator whether or not any immunizations are recorded in the IIS (excluding deceased and verified inactive records).

Conditions where best to use this method:

- When assessing very young children who may not have more than one immunization on their record and who have had less opportunity time-wise to move out of the jurisdiction.
- In areas with known high exemption rates.
- When examining smaller units that census data cannot provide.

Pros:

- Same data source as numerator – numerator is contained within the denominator.
- More likely to include non-vaccinators (i.e., exemptors) than if you require immunizations on the record (as in Method 2 below).

Cons:

- Might overestimate denominator, resulting in underestimate of coverage, because those who moved out of area still contribute to the denominator but their unknown out-of-state vaccines do not contribute to the numerator.
- Unidentified and unresolved duplicate records may contribute to an overestimate of the denominator and a resulting underestimate of coverage.

IIS Method 2: Individual Has Record in IIS with Immunizations

The difference between this method and the one described above is that this method includes in the denominator only those individuals with immunizations on their IIS record. It excludes individuals with no immunizations recorded in the IIS. Over the past two decades, many IIS have measured their progress by making denominator adjustments to approximate the true number of "active" persons in the IIS, and to compensate for duplicate records and lack of current address information. Such adjustments have often been based on the number of immunizations on a patient record. Under this approach, IIS have sometimes defined an "active" record as a record with two or more immunizations. This concept assumes that one dose is likely the Hepatitis B birth dose received through vital statistics, and that a second immunization makes it more likely the child has a provider and is "active." While this method provides a measure of IIS progress, it is not a proven method for producing population-based coverage assessments, has a number of pitfalls, and is not recommended at this time.

Conditions where best to use this method:

- When examining smaller geographic units that census data cannot provide.
- When IIS is mature, with total record numbers exceeding the census estimates.

Pros:

- More likely to exclude patients who have moved out of catchment area, especially younger children, since it takes those with few or no immunizations out of denominator (and usually out of the numerator as well).

Cons:

- Likely to underestimate denominator (e.g., in IIS that are new, have low provider reporting, or have high exemption rates), producing falsely high coverage rates – and may exclude patients who are true residents of the jurisdiction and who truly have one or no immunizations.
- May overestimate denominator, producing falsely low rates even with the "two or more Immunization" caveat – because may not catch all patient who should be marked as inactive at geographic level.
- Not backed by research as a reliable method.

IIS Method 3: Other Adjustments to IIS Data

Use of statistical adjustments to IIS data is in the early stages of development and use. It has been studied primarily with teen populations as a group whose numbers may be significantly inflated by the cumulative effects of out-migration not captured in the IIS. Less frequent reporting from providers for adolescents also hampers the IIS ability to track movement out of the jurisdiction.

Looking for more accurate IIS-derived denominator data, the Oregon Immunization Program has explored and developed mathematical approaches that an IIS may wish to emulate or use as a starting point for further research. These approaches, described by Robison in *Public Health Reports*, inactivate records based on length of time since last report to the IIS — or no report at expected immunization ages (*Robison 2015*). The Oregon team examined two existing approaches and created a third hybrid approach. The three described approaches were:

1. **Administrative Cut-Off:**
   Exclusion of records from rate calculation based on either length of time since last report, or no reports at fixed ages of expected vaccinations such as school entry.
2. **Uniform Time Record:**
   Individual weight assigned as probability of still being in IIS area or active, based on time since last report.

3. **Ogive Hybrid:**
   Use of Ogive function to include both individual weights based on time, and the strong effects of no reporting after 5 to 7 years.

The study concluded that the Ogive Hybrid method was the most reliable.

Conditions where best to use this measure:

- When measuring rates for older children, teens, adults, and other groups for whom IIS denominators are inflated.
- When conducting smaller area analysis than census data provides.

Pros:

- May provide denominators comparable to census data, especially for certain populations. (Robison 2015)
- Takes into account or infers those who have moved away.
- Modifiable formula that takes into account low or no immunization populations. (Steve Robison, email to Sherry Riddick, 4/15/2015)

Cons:

- Limited testing / confirmation of the reliability of this method in the IIS community
- More complicated in terms of analysis
- Time-consuming and has to be re-done every time you want to calculate coverage

Non-IIS-based Denominators

In general, using an external denominator with an IIS numerator may cause unintended bias – quite simply, there is no guarantee that the numbers in your denominator have a correlation with your numerator. That said, there are times when an external denominator provides more accuracy than an internal IIS-based denominator. Below is a description of situations where you may find that an external denominator is your best option.

Non-IIS Method 1: Census & Census-derived Data

The United States Census Bureau is the most commonly used source for non-IIS denominator data. Many national immunization-related surveys rely on census data. For example, CDC's IIS Annual Report (IISAR) calculates coverage rates using a denominator based on the most recent US Census estimates for the age group and geographic area being examined. Thus, in the IISAR, coverage for the 4:3:1:3:3:1:4 vaccination series among 19 through 35 months olds in the IIS is calculated by taking the number of children in the IIS meeting certain population and vaccination criteria and dividing by the most recent census figure for that population. (See Appendix F – Example 2).

Each year, the Census Bureau produces and publishes estimates of the population for the nation, states, counties, state/county equivalents, and Puerto Rico. The Census Bureau estimates the resident population for each year since the most recent decennial census by adding births, subtracting deaths, and adding net migration (both international and domestic). Key data sources for the annual adjustments are vital statistics as well as Internal Revenue Service and Medicare data to calculate net migration. Another population resource is the American Community Survey (ACS). Part of the Census Bureau, ACS is a user-friendly resource that has more detailed demographic statistics than the census and thus may be helpful in performing an assessment. ACS is an ongoing statistical survey that samples a small percentage of the population every year–"giving communities the information they need to plan investments and services." (*http://www.census.gov/acs*)

The Census Bureau releases county-level data updated annually only in five-year age increments. If you are conducting assessments at the county level and need single year of age data, you may want to explore CDC's National Center for Health Statistics (NCHS) and its National Vital Statistics System (*http://www.cdc.gov/nchs/nvss/bridged_race.htm*). The Census Bureau provides data to NCHS which then produces

single year population updates in the form of county-level bridged race population estimates. In addition, state or local agencies may be able to provide census-based data that have been adapted to reflect local circumstances. The name of the responsible office varies from state to state. For example, in California, the Department of Finance maintains and updates census-based demographic data available to researchers. In Washington State, you find this data at the Office of Financial Management.

TIP: For state-based census estimates, check with other public health programs in your area to see what sources they use when doing analyses that require population data.

Whatever your source, you may find yourself in a situation where you need to prorate the available data in order to come up with the appropriate age cohort. That situation arises when the study cohort crosses the available age groupings. For example, with a 19-35 months cohort you will need to pull data from both the 12-23 month age group and the 24-35 month age group (when you have single year data available). When you have 5-year age cohorts (e.g. 0-4, 5-9, 10-14, etc.) available for denominator data, and you want to study the 6-year through 11-year age group, you must prorate data from both the 5-9 year group and the 10-14 year group. (See Appendix E-4 for more details on prorating data.)

Conditions where best to use this method:

- For state-level assessments.
- When doing comparisons among/between IIS (for consistency of denominator methodology).
- When recommended age of vaccination being assessed is close to the age of assessment (census may be more accurate than IIS denominator especially for older children/teens).
- For IIS whose population counts greatly exceed census data (usually due to duplicate records and/or unaccounted for out-migration).

Pros:

- Provides uniform methodology for calculating population estimates across the US.
- Can compare results across and between IIS with assurance that denominator was developed by same methodology for each area.
- May be more realistic population number than IIS number, especially for older children and adults (combined effect of IIS including in-migration but unable to adequately track out-migration).

Cons:

- May not be a match to the IIS population from which the numerator is pulled.
- Potential undercounts of population, e.g., in areas with high immigration, undocumented or migrant workers.
- Limitations and delays in current data availability leading to less accurate extrapolations from older census estimates.
- If the IIS is newer and less populated, may underestimate coverage rates.
- If there is a large time gap between recommended age of vaccination and age at time of assessment, may overestimate coverage due to difficulty tracking those who have moved away (and who will be in numerator but not in denominator).
- At the local level (e.g., county, zip code), may have significant variation in accuracy of census estimates, compounded by different rates of local area reporting to the IIS, resulting in potentially significant error in coverage results.

Non-IIS Method 2: School Census Data

School census data as a denominator may be most appropriate if you are evaluating a specific school or school district population. In addition, if you are analyzing a school-age population and do not have reliable census data for the target geographic area, school census data is a reasonable source for a denominator. This may be especially true if you are analyzing coverage for a specific area or neighborhood at a level of granularity not readily obtained from the census.

An excellent source of school population data is the Common Core of Data (CCD). According to its website (*https://nces.ed.gov/ccd/*), CCD is a program of the US Department of Education's National Center for Education Statistics (NCES). It annually collects fiscal and non-fiscal data about all public schools, public school districts and state education agencies in the United States. The data are supplied by state education agency officials and include information describing schools and school districts, as well as demographics for students and staff. The NCES also collects data from private schools through an annually administered survey. Home-schooled children are not included.

The CCD may be comparable in quality to the census. However, for denominator completeness, data from CCD would need to be combined with the Private School Survey data and adjusted for home-schooled children. In addition, CCD for high school age students may have a downward bias, due to teens that have dropped out of the system and are not captured elsewhere. Student demographic data may also be available from each state's education department and/or from individual school districts.

Conditions where best to use this method:

- When the purpose of assessment is to look at school-age populations and census data is not available or is determined to be less reliable for the specific cohort, and IIS data is incomplete for the age group.
- When assessment at school or district level is desired.

Pros:

- Potential ability to measure at the more granular levels of school district or even school building.
- May have more accurate data than IIS as school-age population is harder for IIS to track (i.e., keeping addresses up-to-date).

Cons:

- May be variable in quality depending on nature of population within specific district or geographic area (e.g., areas of frequent in- and out-migration, high dropout rates).
- May have more issues with data fluidity as students move from school to school, district to district, state to state.
- May overestimate the student population due to difficulty tracking dropouts.
- Might not include private schools and home schooled children depending on the state and data collection procedures.

Non-IIS Method 3: Vital Statistics – Birth Data

Live birth records may be a sound denominator when assessing records of very young children. Birth records are less likely to be inflated than IIS numbers since they do not include fragmented records or duplicates. In addition, there is a direct correlation between birth records and IIS records since IIS are usually populated by births to residents of the state (*Clark et al. 2014*). Comparing vital statistics data with IIS data may provide a good reality check for other age groups as well – even older children – by giving an idea of how close or far off your IIS data may be. However, it is likely that birth records will never be a perfect match even for early immunization records because of the effects of adoption, name changes, and address changes.

Conditions where best to use this method:

- Coverage of very young children, especially for Hepatitis B birth dose coverage, and especially when IIS does not have good processes in place to resolve duplicates and handle in- and out-migration.
- Newer IIS that are performing coverage assessment of younger children.

Pros:

- May be more accurate than census estimates for youngest age groups.
- Less likely to be inflated than IIS data.
- Good match with IIS-derived numerator for youngest populations.

Cons:

- Does not include children who moved into the jurisdiction after birth but prior to the date range being measured.
- May inaccurately represent coverage due to in and out-migration:
  - Irrelevant if net movement of children in and out of the state is zero.
  - If net movement is positive, will overestimate coverage.
  - If net movement is negative, will underestimate coverage.

Other Denominator Options - Testing Out New Approaches

Researchers may wish to experiment with other approaches to enhance accuracy of the denominators used. Research projects that delve into alternative methods to arrive at more accurate denominators will be helpful to the IIS community. Approaches could include adding parameters and developing mathematical formulas based on IIS data or IIS data in combination with other data sources. The Oregon adolescent project is one example of this type of approach (*Robison 2015*).

Another example of such research appears in a Public Health Reports article that explored four methods of determining denominators for adolescents (*Gowda et al. 2013*). Key features of the four methods were:

- Method 1 included all adolescents with an IIS record (but not those marked deceased, without a valid Michigan county of residence, opt-out, or duplicate records);
- Method 2 excluded adolescents flagged at the user level as moved or gone elsewhere, those who only received vaccination from out of state providers, and migrants;
- Method 3 further excluded those without IIS activity for 10 years or more as a surrogate for those who likely moved out of state but were not flagged as such; and
- Method 4 was based solely on US Census data.

In comparing the four methods, the authors found a 20% difference in estimated vaccination coverage between the most inclusive and most restrictive denominator groups. They also found much more substantial differences by method at county-levels than at state-level, resulting in a recommendation to take special care in denominator selection at the more fragmented level (e.g. county). Interestingly, at the state level, the census denominator seemed as good as other methods. However, they did not reach any overarching conclusions, except to say that more research is needed.

In Washington State, Katelin Bugler, a fellow of the Council of State and Territorial Epidemiologists (CSTE), undertook research comparing National Immunization Survey (NIS) results to IIS-based results for 19-35 month olds (*Bugler 2010*). Bugler experimented with a variety of denominators. One approach limited the IIS dataset to "active records" which she specifically defined as records that had either a provider owner or ≥2 doses in the absence of a provider owner. She compared assessment results using five different denominators: the "active record" profile just described, all IIS patients, patients with 2 or more immunizations only, the U.S. Census, and live births. She identified pros and cons for

each method, and found that the "active record" method produced a denominator and results very similar to census data (Katelin Bugler, email to Sherry Riddick, 7/7/2010). Still, no conclusions were drawn.

Testing out new approaches to denominator selection is highly recommended. If you undertake research on denominator methodologies, we recommend you follow the models set by Oregon, Michigan and Washington in testing and analyzing the effects. We encourage you to share any such efforts with AIRA and CDC and to publish results whenever possible.

4.1. Data Quality

There are three primary data quality challenges that impact data in the IIS: accuracy, completeness and timeliness. If not addressed, these challenges can significantly affect the quality of IIS-based coverage assessments. Definitions of the three primary areas of data quality follow:

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
The information submitted to the IIS must contain the minimum/mandatory set of data items in order to be accepted by an IIS. Additionally, the data recorded in the IIS should reflect a complete history of all vaccinations ever administered to an individual.

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

Data quality issues affect all IIS to some degree and have been the focus of many expert discussions. Poor data quality leads to assessment results that may not reflect what is actually happening in the jurisdiction. Many jurisdictions have developed and implemented formal data quality improvement strategies supported by sophisticated IIS reporting tools and dedicated staff. Much work has been done in this area by AIRA, CDC and other groups – see sidebar for resources and Appendix C for other related links.

4.2. Deduplication Processes

Deduplication is a sub-category of data quality, and a big enough challenge that it deserves a separate description. Good deduplication processes are essential for good data quality. This applies to both patient record deduplication and vaccination level deduplication. Resources for improving deduplication processes are listed in the sidebar. Before starting a new assessment, be sure to ask the following questions:

- Is your automated patient deduplication process up-to-date for the age group selected for analysis?
- Do you have records that cannot be resolved through automated processes languishing in limbo as they wait for human intervention?
- Is your vaccination deduplication process up-to-date?

At a minimum, you should look at the number of records awaiting manual resolution for your target age group(s) to see the potential impact on your results. If you can devote resources to resolving records prior to your data pull or query, your results will be more accurate.

Helpful Resources for Guidance on Improving IIS Data Quality

MIROW Best Practice Guidelines:

- Chapter 2: Vaccination Level Deduplication in IIS – 2006
- Chapter 3: Data Quality Assurance in IIS: Incoming Data – 2008
- Chapter 7: Data Quality Assurance in Immunization Information Systems: Selected Aspects – 2013

The above MIROW resources can be found at *http://www.immregistries.org/resources/aira-mirow*.

From CDC EHR-IIS Interoperability Expert Panel Project:

- Patient Deduplication Best Practices and Test Cases – 2013, found at *http://www.cdc.gov/vaccines/programs/iis/interop-proj/ehr.html*.

4.3. Evaluation/Forecasting/Clinical Decision Support for Immunization (CDSi)

Having a high quality evaluation/forecasting (CDSi) tool will enable you to easily generate coverage assessment outputs that reflect the immunization status of individuals in your jurisdiction. Just as it's important for a provider to have access to a CDSi engine to determine if and when a patient needs immunizations, such access is equally important for IIS staff, researchers, and others to generate accurate population-level assessments. Prior to running a coverage assessment, you should check if your IIS is up-to-date with the latest ACIP recommendations for the age group and method – e.g., for children per the recommended schedule or per the catch-up schedule, or for adolescents or adults. You will also want to know if invalid doses are appropriately marked.

"The CDSi Logic Specification provides a single, authoritative, implementation-neutral foundation for development and maintenance of CDS engines. It captures ACIP recommendations in an unambiguous manner and improves both the uniform representation of vaccine decision guidelines, as well as the ability to automate vaccine evaluation and forecasting." http://www.cdc.gov/vaccines/programs/iis/interop-proj/cds.html

As described in the introduction to this guide, the CDSi Logic Specification is an effort to standardize how the ACIP recommendations are interpreted by IIS. Without a standard forecasting tool, different coverage rates among IIS could reflect differences in IIS-specific implementation of the vaccine schedule.

Some steps to take before pulling data for your assessment:

- Ensure your Clinical Decision Support (forecasting) algorithm is up to date with the latest ACIP recommendations — if possible use the CDSi Logic Specifications and Supporting Data tools. (See purple box for CDSi website and Appendix C-5 for instructions on accessing components of the CDSi.)
- Know how well your CDSi tool works — has it been adequately tested, are the evaluations and forecasts accurate?
- Make sure the CDSi algorithm has been recently applied to the population you are measuring. The size of some IIS makes it difficult to continually update the database of all patient vaccination records against the most current ACIP schedule. Applying the CDSi to the specific age range in the assessment can take significantly less processing time/power and is therefore often a much more manageable task.

Impact of changes in the ACIP recommended schedule:

What if the schedule has changed since a child was immunized AND your algorithm has been updated to reflect the new schedule? Doses that were previously invalid may now be considered valid, or vice versa, by your IIS. How do you deal with this in your data pull and assessment? First, review any schedule changes that have occurred and evaluate their significance. Chances are any changes will have a minimal impact on your results. If you determine that a change will have an impact, construct your query carefully to account for this.

4.4. Fluidity of IIS Data and Analysis Implications

IIS data is fluid, changing from day to day, even moment to moment. Do not expect the data to be static and provide the same results from one day to another. If you pull data for a specific query on March 1, and then discover you need more fields to complete your analysis, you may think, "okay, I'll just pull all the data again and include the fields I missed the first time." On April 1, when you do a fresh pull of the data, the results

will be different. With most IIS, you will not be able to replicate the results due to the fluidity of the data, and the difficulty of pulling the data field by field exactly as it was on a previous date. This fluidity is caused by a number of factors including:

- Continual updates of the database coming from multiple sources (health plans, historical records from new providers – or old providers). New, often better data may override the data you had available the first time around.
- Record deduplication processes – merging or separation of records – will add or subtract records to your count.
- Corrections made to birthdates, addresses, and active-inactive status since the first data pull will also affect the results.

4.5. IIS Maturity and Completeness

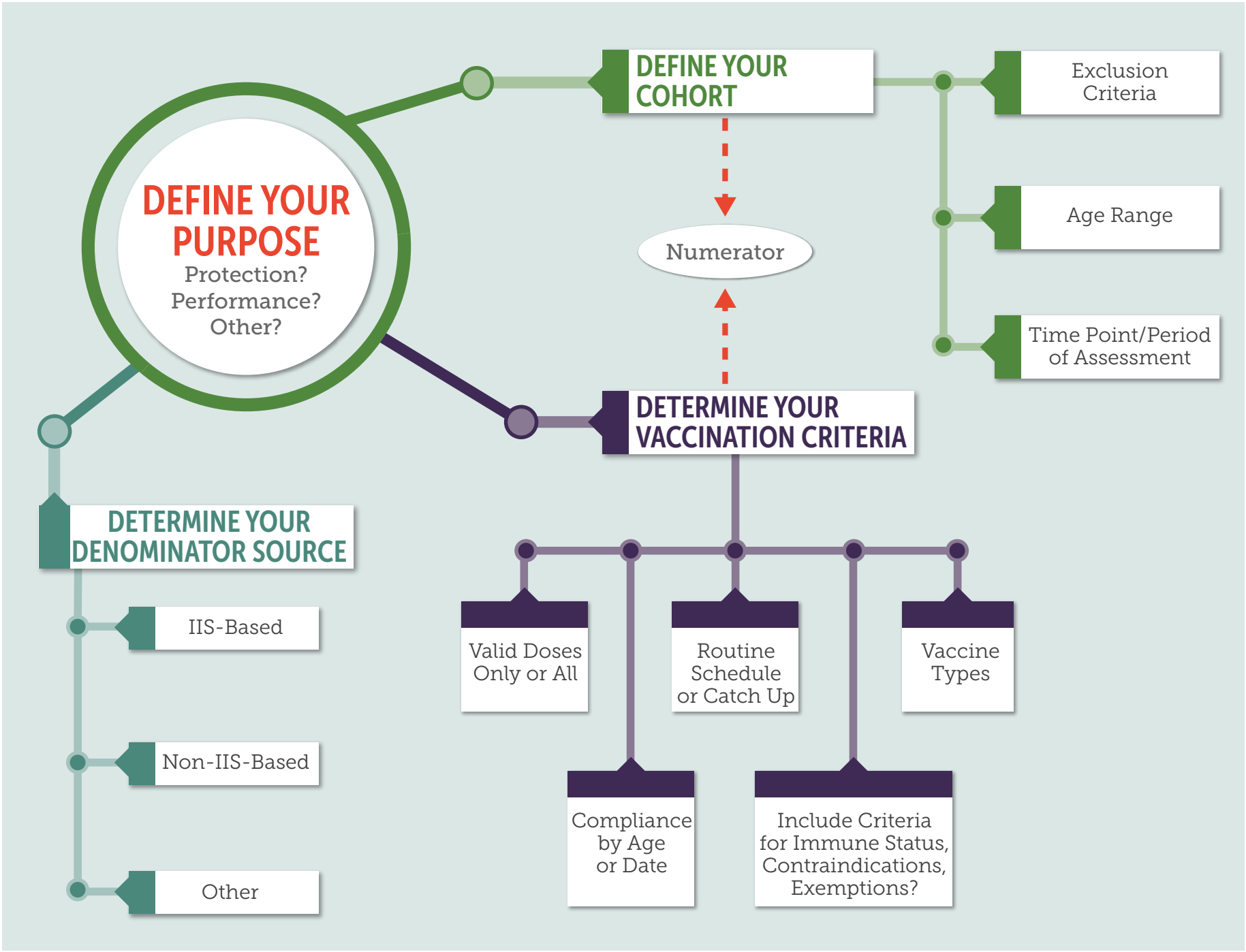
IDEA: Creating/maintaining a historical dated log of patient active-inactive status changes in your IIS can help when doing retrospective analyses.

The maturity and completeness of your IIS has an obvious impact on the results of your coverage assessments. Yet you do not have to wait until your data is complete to start using it and running assessments. IIS data has proven very useful in a variety of situations. Two examples are provided here:

1) Pabst reported that during a period of Hib shortage, several IIS compared Hib coverage to DTaP and PCV coverage rates for the same period, as these vaccines usually have similar coverage. Even for less mature IIS, where coverage for all vaccinations assessed was expected to be biased downward, a meaningful decline in Hib coverage rates during the shortage, as compared to the lack of a decline in DTaP and PCV, was obvious and useful despite incomplete data in the IIS. (Laura Pabst, telephone conference call with Sherry Riddick, 5/11/2015.)
2) DeBolt reported that Washington State experienced a pertussis epidemic and upped its promotion of Tdap vaccination. Interested to see the impact of the outbreak and promotion efforts on vaccination coverage, epidemiologists used the IIS to compare Tdap uptake to the previous year. An increase of 50% was deemed very significant even though the IIS did not have complete data on all Tdap vaccinations administered. (Chas DeBolt, telephone conference call with Sherry Riddick, 5/11/2015.)

Finally, by doing regular coverage assessments, you will be able to track the growth of your IIS. Though results may be low in the beginning, you will see improvement over time. Simply by running reports and analyzing the coverage levels, you will discover gaps in coverage – by geographic area, age group, antigen, and other variables. The results will help you ferret out areas of low reporting and potentially areas of true low coverage.

Key Decision Points



Conclusion

Over the past two decades, a number of IIS have developed measurement processes and tools for conducting population assessments with IIS data. CDC has used IIS data for special purpose coverage assessments and to measure IIS progress. State and local immunization programs have pulled data from the IIS to examine specific coverage rates. A great deal of knowledge exists in the immunization and IIS community on how to use IIS data for assessment purposes. However, such knowledge has been fragmented and lacking standardized methodology. Development of this guide allowed AIRA to bring together a group of SMEs, who shared, reviewed, and assessed current knowledge. The experience of the SMEs, together with related information from existing publications, resulted in the creation of this guide.

The guide describes practical considerations and decision points for designing a population-based immunization assessment using an IIS. Key decision points are described in detail and include determination of the assessment purpose, selection of the cohort, use of vaccination-related criteria, and selection of the denominator source. In addition, the guide discusses the importance of understanding how the IIS works in order to producing a meaningful assessment, with special attention to data quality, deduplication processes, forecasting/evaluation algorithms, data fluidity, and IIS maturity.

Your IIS is a valuable source of information. We recommend you use this guide to develop your own assessments, comparing the results of different methods for numerator and denominator selection. We also encourage you to write up your methodologies, present findings at conferences such as the AIRA National Meeting, and publish whenever possible. AIRA welcomes feedback on the utility of this guide and suggestions for improvement. The guide represents a big first step toward standardization of practices in IIS-based coverage assessments.

Appendix A. PAIS Rules at Geographic Level

Rules and procedures for inactivating individuals at the jurisdiction level are imperative. Your best resource for setting up inactivation rules and processes in your IIS is the MIROW chapter "Management of Patient Active/Inactive Status in IIS," or PAIS for short. The PAIS chapter enumerates a different set of rules for providers versus geographic-level status determination. For geographic-level assessments, the PAIS recommends that patients with both "active" and "unknown" statuses be included, and patients with "inactive" and "deceased status" be excluded. See definitions of these statuses in the table below, copied from PAIS. (*Reference:* AIRA Modeling of Immunization Registry Operations Work Group (Eds). ***Management of Patient Active/Inactive Status in Immunization Information Systems: Replacement of 2005 Guidelines***. Atlanta, GA: American Immunization Registry Association. March, 2015. (See AIRA website: *http://www.immregistries.org/resources/aira-mirow*.)

It may take time for IIS to implement the capabilities of PAIS as an automated process. MIROW PAIS Chapter 7 describes how data submitted using the Health Level Seven (HL7) specification might be used to determine patient status. Some states have developed electronic means to update address information using sources such as US Postal Service, schools, payers, and public health programs. Meanwhile, to compensate for IIS limitations in inactivating patients, you can place constraints on a data pull that mimic the PAIS rules. For example, you can limit patients in the numerator (and denominator if using the IIS) by zip code or state of residence and exclude patients with addresses outside your jurisdiction and those known to be deceased.

Individual statuses and examples of how status is determined at the geographic jurisdiction level are:	
ACTIVE	If an individual's residence within the geographic jurisdiction has been confirmed, or if an individual received an immunization from a provider organization within the geographic jurisdiction and the individual's address is not known, **BR412** is applied and the status at the geographic level is set to "Active."
INACTIVE	If an individual does not reside in the geographic jurisdiction, **BR413** is applied and the individual status at the geographic jurisdiction level is set to "Inactive" with the reason code "Outside jurisdiction."
UNKNOWN with the following reason codes	**No address - no vaccination.** If the IIS has never received an address or vaccination information about an individual, **BR414** is applied and the status at the geographic jurisdiction level is set to "Unknown" with the reason code "No address – no vaccination."
	No activity for extended period of time. If the IIS has not received demographic and/or immunization information for an individual for an extended period of time, **BR415** is applied and the individual's status at the geographic jurisdiction level is set to "Unknown" with the reason code "No activity for extended period of time."
DECEASED	If a patient's death is confirmed, then **BR421** is applied and the status is set to "Deceased" at the geographic jurisdiction level.

Note: "BR" refers to Business Rules contained within the PAIS document.

Appendix B. Definitions and Acronyms

Definitions

4:3:1:3:3:1:4
Primary vaccination series for children, typically completed by 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, up-to-date (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.

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 or the assessment process 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.

Assessment Age Range (also referred to as Age Range herein)
This term directly defines the cohort to be included in the assessment (e.g. 24-35 months, or 8-18 years). The Assessment Age Range will be used to calculate the birthdate range when combined with the As of Date or Period of Assessment.

Assessment Date
This reflects the date the coverage assessment is run.

Birthdate Range
Based on the criteria defined for Assessment Age Range and As of Date or Period of Time for assessment.

Clinical Decision Support for Immunization (CDSi)
The logic, based on Advisory Committee on Immunization Practices (ACIP) guidelines, applied for evaluating a single vaccine dose administered against a defined target dose to determine if the vaccine dose administered is **valid** or **not valid** for that specific target dose. Also includes the logic applied for determining past due status for vaccine doses and forecasting of dates for the next vaccine dose(s) to be administered. Forecast is based on a patient's immunization history, age, gender, and contraindications/precautions.

Cohort
Part of the population (individuals) within given parameters.

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.

CVX Code
CVX codes are codes that indicate the product used in a vaccination. These codes are maintained by the Centers for Disease Control and Prevention, Immunization Information System Support Branch (IISSB) for use in HL7 data transmissions and sometimes in flat files.

Exemption
Non-medical reasons applied that exclude a patient from vaccinations.

Forecasting Algorithm
See definition for Clinical Decision Support for Immunizations.

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.

UTD – Up-to-date
Patient is current on vaccinations, meeting ACIP recommendation for age, intervals and other requirements.

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.

ACRONYMS	
ACIP	Advisory Committee on Immunization Practices
ACS	American Community Survey
AFIX	Assessment, Feedback, Incentives, and eXchange
AIRA	American Immunization Registry Association
CDC	Centers for Disease Control and Prevention
CDSi	Clinical Decision Support for Immunization
CVX	CVX Code (see definition)
IIS	Immunization Information System
IISSB	IIS Support Branch
MIROW	Modeling of Immunization Registry Operations Workgroup
NCHS	National Center for Health Statistics
NCIRD	National Center of Immunization and Respiratory Diseases
NIS	National Immunization Survey
NVSS	National Vital Statistics System (NVSS)
PAIS	Patient Active Inactive Status
SME	Subject Matter Expert
UTD	Up to Date

Appendix C. Resources

The following list of resources was used in the development of this guide and contains additional, valuable information for the reader.

1. **AFIX-IIS Integration: Operational and Technical Guidance for Implementing IIS-Based Coverage Assessment - Phase 1**,American Immunization Registry Association, March 2015: *http://www.immregistries.org/resources/supporting-immunization-programs/AIRA_AFIX-IIS_Integration_Guide-_Final_-August_2015-.pdf*
2. **American Community Survey**: *http://www.census.gov/acs/www/*
3. **CDC IIS Website**: *http://www.cdc.gov/vaccines/programs/iis/index.html*
4. **Census data**: *https://www.census.gov/popest/data/index.html*
    a. For information on the methodology used by the Census Bureau to derive population estimates at any given point in time, refer to: *https://www.census.gov/popest/methodology/2014-natstcopr-meth.pdf*
    b. For population by year of age, the U.S. Census Populations with Bridged Race Categories, refer to: *http://www.cdc.gov/nchs/nvss/bridged_race.htm*
5. **Clinical Decision Support for Immunization (CDSi)–Logic Specification for ACIP Recommendations**; Version 2.0: June 2015 (or latest version available on website): Go to *http://www.cdc.gov/vaccines/programs/iis/interop-proj/cds.html* then scroll to CDSi Logic Specification and Supporting Data, click on "Supporting Data", save and unzip the file, and go to: "**Support Data**" then "**Excel files**"
    a. For immunity definitions, see "ScheduleSupportingDataImmunity."
    b. For true medical contraindications and precaution definitions, see "ScheduleSupportingDataContraindications"
    c. For CVX to antigen mapping, see Schedule "SupportingCVXtoAntigenMap"
    d. For specific information on ACIP recommendations by antigen and definitions of contraindications and precautions, see "AntigenSupportingData-name of disease."
6. **Common Core Data**, U.S. Department of Education, Institute of Education Sciences National Center for Education Statistics: *https://nces.ed.gov/ccd/*
7. **Modeling of Immunization Registry Operations Workgroup (MIROW): Best Practice Guidelines**: *http://www.immregistries.org/resources/aira-mirow*
    a. **Chapter 1: Management of Patient Active/Inactive Status in Immunization Information Systems - 2015**
    b. **Chapter 2: Vaccination Level Deduplication in IIS – 2006**
    c. **Chapter 3: Data Quality Assurance in IIS: Incoming Data – 2008**
    d. **Chapter 4: Reminder/Recall in Immunization Information Systems - 2009**
    e. **Chapter 7: Data Quality Assurance in Immunization Information Systems: Selected Aspects – 2013**
8. **Patient Deduplication Best Practices and Test Cases - EHR-IIS Interoperability Expert Panel Project; June/July 2013.** Deduplication section: *http://www.cdc.gov/vaccines/programs/iis/interop-proj/ehr.html*
9. **Private School Survey**, U.S. Department of Education,Institute of Education Sciences, National Center for Education Statistics: *http://nces.ed.gov/surveys/pss/*

10. **Vaccine-Related Code Sets (in addition to CDSi websites above)**:
    a. **Main CDC site for Vaccine Codes**: *http://www.cdc.gov/vaccines/programs/iis/code-sets.html*
    b. **CPT Codes Mapped to CVX Codes**: *http://www2a.cdc.gov/vaccines/iis/iisstandards/vaccines.asp?rpt=cpt*
    c. **IIS: HL7 Standard Code Set Mapping CVX to Vaccine Groups**: *http://www2a.cdc.gov/vaccines/iis/iisstandards/vaccines.asp?rpt=vg*
    d. **IIS: HL7 Standard Code Set CVX – Vaccines Administered; May 2014**: *http://www2a.cdc.gov/vaccines/iis/iisstandards/vaccines.asp?rpt=cvx*
11. **Zip Code Tabulation Areas (ZCTA)** - Zip Code Tabulation Area (ZCTA) as an option. See *https://www.census.gov/geo/reference/zctas.html* for more information on ZCTAs .

Appendix D. References

1. Bugler, Katelin. 2010. "Evaluating Washington State's Immunization Registry for Data Completeness and Utility in Assessing Immunization Coverage Levels." Poster session presented at the annual meeting of the Council of State & Territorial Epidemiologists, Portland, Oregon, June 2010.

2. Clark, Sarah, Cowan, Anne, and Dombkowski, Kevin. 2014. "Awardee Experiences in Using Immunization Information Systems (IIS) for Immunization Coverage Assessments." Published by American Immunization Registry Association, May 2014. Retrieved from http://www.immregistries.org/resources/other-aira-resources as "AIRA Survey Report on Awardee Experiences Using IIS for immunization Coverage Assessments."

3. Gowda, Charitha, Shiming Dong, Rachel C. Potter, Kevin J. Dombkowski, Shannon Stokley, and Amanda F. Dempsey. 2013. "A Systematic Evaluation of Different Methods for Calculating Adolescent Vaccination Levels Using IIS Data." *Public Health Rep.* 2013 Nov-Dec; 128(6): 489–497.

4. Pabst, Laura J. "Trends in hepatitis A vaccination among children 12-23 months of age, IIS sentinel site data, 2006-2009." Document received by email attachment from Laura Pabst, Evaluation Team Lead, CDC Immunization Information System Support Branch to Sherry Riddick, AIRA Consultant, 11/21/2014. Available from AIRA.

5. Pabst, Laura J. "Seasonal influenza vaccine use among US children – Immunization Information System (IIS), August 2011 – May 2012 (flu protocol for sentinel sites)". Document received by email attachment from Laura Pabst, Evaluation Team Lead, CDC Immunization Information System Support Branch to Sherry Riddick, AIRA Consultant, 11/21/2014. Available from AIRA.

6. Pabst, Laura J. "Methods for IIS-Based Vaccination Coverage Assessment: Learnings from IISB/CDC," November 2012. Unpublished presentation received by email attachment from Laura Pabst, Evaluation Team Lead, CDC Immunization Information System Support Branch to Sherry Riddick, AIRA Consultant, 11/21/2014. Available from AIRA.

7. Pabst, Laura J. Methods to Select Birth Cohorts for Coverage, November 2012. Document received by email attachment Laura Pabst, Evaluation Team Lead, CDC Immunization Information System Support Branch to Sherry Riddick, AIRA Consultant, 11/21/2014. Available from AIRA.

8. Robison, S. G. 2015. "Addressing immunization registry population inflation in adolescent immunization rates." *Public Health Rep.* 2015 Mar-Apr;130(2):161-6

9. White, Karen E., Laura J. Pabst, and Karen A. Cullen. 2011. Up-to-Date Haemophilus influenzae Type b Vaccination Coverage during a Vaccine Shortage. Pediatrics 2011;127:e707-712. Retrieved from http://pediatrics.aappublications.org/content/127/3/e707.full.pdf.

Appendix E. Calculation of Birth Date Ranges and Denominator Cohorts

E-1. Defining birth cohorts when you have an "as-of-date" query

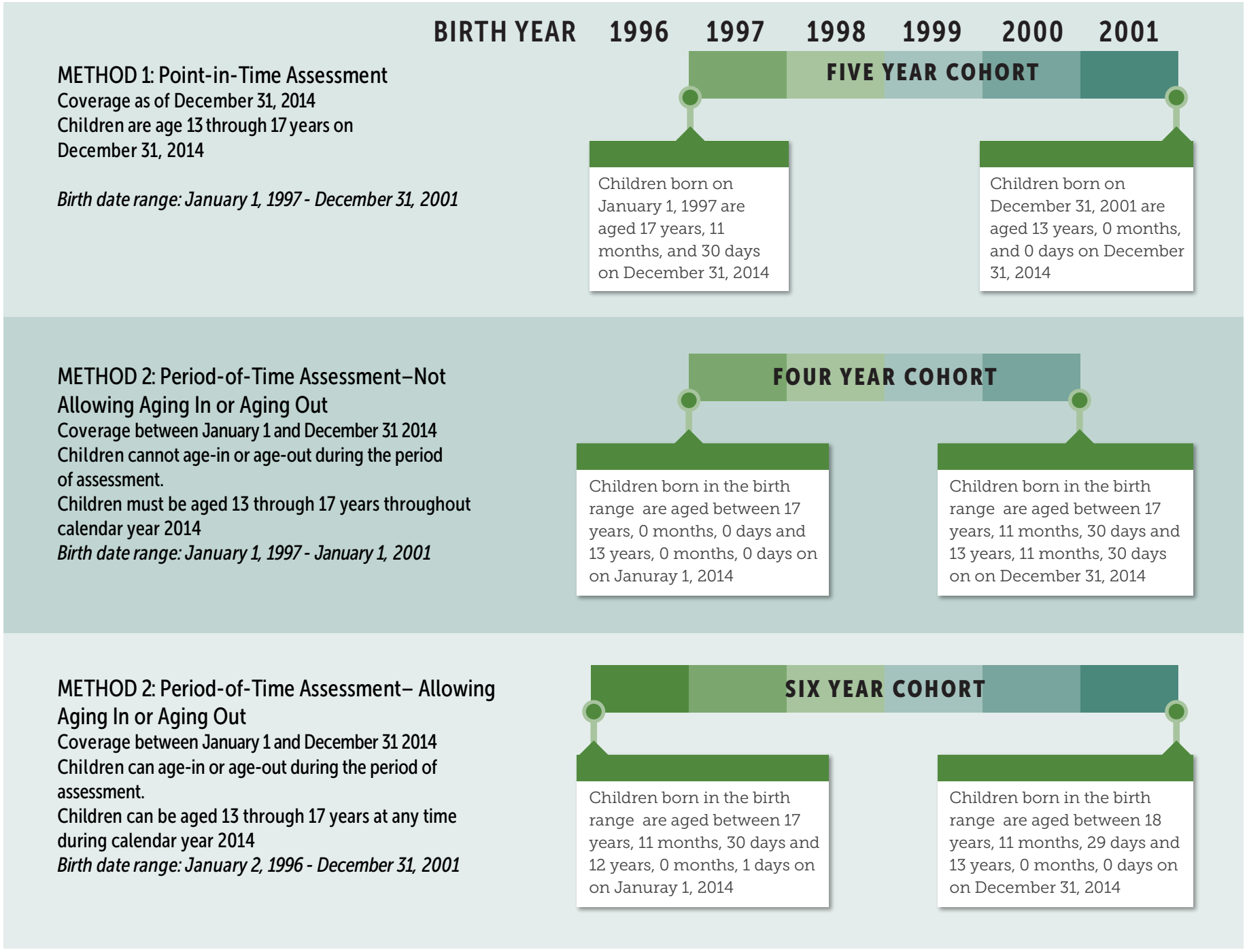
The table below provides examples of how to calculate birth data ranges based on age ranges with an as of date. This table is pulled directly from *AFIX IIS Integration, Operational & Technical Guidance for Implementing IIS-Based Coverage Assessment Phase 1*, American Immunization Registry Association, April 2015, p 32 - *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. 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."

E-2. A limitation of period of time assessment – not allowing aging in or out:

A limitation of using Method 2 occurs when the number of months/years in the period of assessment is approximately equal to the number of months/years in the birth cohort. The cohort can end up being only one day wide. This is best demonstrated through an example: If you want to assess coverage among children who were aged 1 through 2 years (a 2 year-wide birth cohort) from 01/01/2010 - 12/31/2011 (a 2 year-wide period of assessment), using this method the birth cohort would only include children born on 01/01/2009. Children born on 1/02/2009 (or later) would not qualify because they would not turn 1 until one day into the assessment period. Children born on 12/31/2008 (or earlier) would turn 3 on 12/31/2011, and thus would age out before end of the assessment period. Hence, you are left only with a one-day cohort – those born on 1/1/2009.

E-3. Birthdate range selection for three different methods of assessment



E-4. Calculation of denominator when using non-IIS based data

When the study age group crosses the available age cohorts in your denominator data source (e.g. census data), you will need to prorate data. Good practice is to search for a data source that has ages as close to the level of granularity as needed. For example, with a 19-35 months cohort, you could use the 5-year cohort of 0-4 years of age, but it would be better to take single-year age cohorts (if available) for 0 through 11 months and 12 through 23 months, and prorate the data as shown in Example 1 below. Example 2 shows how to prorate for 19-35 month olds when you only have 5-year age groups available. Example 3 shows how to prorate when you are assessing a multi-year age range and it crosses two different population cohorts.

Assessing coverage in the 19-35 month population:

Example 1
You are able to find census-related data for **single year cohorts**. 1) Find the **population estimates** from your denominator source for the **12 through 23-month** group and for the **24 through 35-month group**. 2) Determine that 19 through 23 months = **5 months**. 3) Take the population estimate for 12 through 23-month group, divide by **12 months** to get the population for each month of age in the younger group. 4) Multiply the results of step 3 by **5 months** to get the population for the 19 through 23 month olds. 5) Determine that 24 through 35 months (the rest of your age cohort) = **12 months** and is the same as one of the single year data cohorts available. 6) Use the single year cohort from your denominator data for 23 through 35-month years and add the results of step 4 to get your total population for the 19 through 35-month age group.

Example 2

You are only able to find **5-year age cohort** census data for 0 through 4 year olds. No single year data is available. 1) Find the **population estimate** from your denominator source for the 0 through 4 year (**60 months**) age group. 2) Determine that your 19 through 35 month cohort = total of **17 months**. 3) Divide the population estimate by **60 months** to get the population for each month of age. 4) Multiply the results of step 3 by 17 months to get your total 19-35 month population.

Assessing coverage in the 6 year through 11-year population:

Example 3
You are only able to find census-related data for **5-year cohorts**. 1) Find the **population estimates** from your denominator source for the **5-9 year** age group and for the **10-14 year** age group. 2) Determine that 6 through 9 years = **4 years**. 3) Take the population estimate for the 5-9 year age group, divide by 5 years to get the population estimate for each year of age in the younger group. 4) Multiply the results of step 3 by **4 years** to get the population for the 6 through 9-year population. 5) Determine that 10 through 11 years = **2 years**. 6) Take the population estimate for the 10 through 14-year age group, divide by 5 years to get the population estimate for each year of age in the older portion of your age group. 7) Multiply the results of Step 6 by **2 years** to get the population for the 10 through 11-year population 8) Add the results of step 4 with the results of step 7 to get your total population for the 6 through 11-year population.

Appendix F. Examples of Real-Life Coverage Assessments

Example 1.

Trends in hepatitis A vaccination among US children 12-23 months of age, Immunization Information System (IIS) sentinel site data, 2006-2009. See Appendix D-4 for reference. (Note original document has been modified by guide editor.)

Methods

Definitions:

Sentinel site group: Population of children residing specifically within the sentinel site geographic area; excludes children in the IIS who reside outside this defined geographic region, children who are permanently inactive, and children who are MOGE at the ***jurisdictional level***.

Eligible children: Includes children from the sentinel site group 12-23 months of age (i.e. ≥12 months and <24 months) on the last day of each quarter from 1st quarter 2006 through 4thquarter 2009. Birth ranges for 12-23 month olds by year and quarter are provided in Appendix A. (*Ed note: Appendix A not included here.*)

Hepatitis A vaccine: Any hepatitis A vaccine should be included, regardless of pediatric or adult formulation:

Vaccine Name/Description	CPT Code	CVX Code
Hepatitis A pediatric/adolescent 2-dose schedule (Vaqta, Havarix)	90633	83
Hepatitis A pediatric/adolescent 3-dose schedule	90634	84
Hepatitis A pediatric, NOS	NA	31
Hepatitis A adult dose	90632	52
Hepatitis A/hepatitis B adult dose (Twinrix)	90636	104
Hepatitis A, NOS	90730	85

ACIP 2006 hepatitis A vaccination recommendations for children:

- "All children should receive hepatitis A vaccine at age 1 year (i.e. 12-23 months). Vaccination should be completed according to the licensed schedules and integrated into the routine childhood vaccination schedule. Children who are not vaccinated by age 2 years can be vaccinated at subsequent visits.

Question:

- What is the hepatitis A vaccination coverage with ≥1 dose among **12-23 month olds** by quarter and year (**2006-2009**) in each of the IIS sentinel sites?

Logic code:

a. In cell D5 of the "12-23 mo. olds ≥1 dose" tab, report the number of children enrolled in the sentinel site group who were born in the date of birth range reported in B5 (i.e. 04/01/2004 - 3/31/2005). Repeat this process for cells D6-D20 using date of birth ranges in B6-B20.

b. In cell E5, report the number of children from D5 who:

   i. Received **≥1 dose** of hepatitis A vaccine (CPT codes: 90633, 90634, 90632, 90636, 90730 or CVX codes: 83, 84, 31 ,52, 104, 85),

   ii. Had that vaccine dose **administered** from the time the child was **12 months + 0 days of age to 23 months + 30/31 days of age**, and

   iii. Had that dose administered **on or before** the date in C5 (i.e. 03/31/2006).

c. Repeat this process for cells E6-E20 using the dates in C6-C20.

d. Divide cell E5 by D5 to get the % of 12-23 month olds with 1 or more doses = cell F5.

e. Repeat operation described in "d" for all remaining rows.

	Age of clients: 12-23 months			COVERAGE ≥1 DOSE		
	A	B	C	D	E	F
	Quarter, Year	Date of birth range	Hepatitis A vaccination on or before:	# of kids enrolled in the IIS who were born in the birth range in column B	# of kids in D5-D20 with ≥1 dose of hepatitis A vaccine administered 12 months + 0 days of age to 23 months + 30/31 days of age on or before the dates listed in column C	% of 12-23 month olds with ≥1 dose
5	Qtr 1 (Jan-Mar), 2006	04/01/2004 - 03/31/2005	3/31/2006			
6	Qtr 2 (Apr-Jun), 2006	07/01/2004 - 06/30/2005	6/30/2006			
7	Qtr 3 (Jul-Sep), 2006	10/01/2004 - 09/30/2005	9/30/2006			
8	Qtr 4 (Oct-Dec), 2006	01/01/2005 - 12/31/2005	12/31/2006			
9	Qtr 1 (Jan-Mar), 2007	04/01/2005 - 03/31/2006	3/31/2007			
30	Qtr 4 (Oct-Dec), 2009	01/01/2008 - 12/31/2008	12/31/2009			

Example 2

2014 Immunization Information Systems Annual Report (IISAR)
Logic Guidance for Questions 40-41
4:3:1:3:3:1:4 Series Coverage (for children aged 19 through 35 months)

Logic Guidance:

Coverage is defined as:

- The number of individuals in a certain age group who received an immunization(s) divided by the census-based estimate of persons in that age group in your geopolitical area.
- For children born from Jan 1, 2012 through May 31, 2013.
- Doses administered before 1/1/2015, including those recorded after 12/31/2014.
- The 4:3:1:3:3:1:4 series includes 4 or more DTaP/DTP/DT, 3 or more Polio, 1 or more MMR, 3 or more Hepatitis B, ≥3 or ≥4 of Hib*, 1 or more Varicella†, and 4 or more pneumococcal containing vaccine).

*When calculating Hib doses, include children who received 4+ Hib-containing vaccine doses (includes any type of Hib vaccine, including Hib, unspecified formulation) or 2 Hib-OMP doses (manufactured by Merck; includes PedVaxHib and Comvax) followed by ≥1 Hib dose of any type.

Valid Doses:

- Include:
  - Doses that were administered according to ACIP routine recommendations that meet criteria to satisfy requirements for series completion.

† When counting Varicella, INCLUDE those with history of disease.

- Exclude:
  - Exclude doses administered that are considered valid according to ACIP recommendations BUT that do not contribute to series completion (e.g. doses administered for increased/high risk conditions).

Example: A valid MMR dose administered to a 6-month-old prior to international travel does not contribute to the childhood standard measles, mumps, rubella series – another MMR dose would still be needed at 12 months. The 6-month dose would not be included when calculating the 4:3:1:3:3:1:4 series.

All Doses:

- Include:
  - Both valid and invalid doses.

† When counting Varicella, EXCLUDE those with history of disease.

For Both Columns (Valid and All Doses):

- Exclude:
  - Children with addresses outside of your state or geopolitical area. Geopolitical Area is defined as the area that contains the population of children residing in the geopolitical location covered by the IIS.
  - INACTIVE children in IIS. Children are considered inactive for this report if they are (1) inactive permanently, or (2) have moved or gone elsewhere from the geopolitical area covered by the IIS.

More information on IISAR at: *http://www.cdc.gov/vaccines/programs/iis/annual-report-IISAR/index.html*

Example 3

Seasonal influenza vaccine use among US children – Immunization Information System (IIS), August 2011 – May 2012 (Abridged for this document – see Appendix D-5)

Background (edited for this document)

Summary: The background section describes changes in ACIP recommendations for full influenza vaccination coverage from 2007 – 2012, issues with the changes, the impact of H1N1 recommendations on regular flu schedule, the uptake of LAIV, and the possibility in June 2012 of an ACIP preferential recommendation for LAIV. Further states: "IIS Sentinel Sites have been monitoring LAIV uptake since the 2007-08 season, and continue to monitor uptake to share with the Influenza Division at CDC and ACIP. Limited investigations of two-dose compliance have been conducted in the United States. In the 2010-11 season, IIS Sentinel Sites assessed trends in two-dose compliance since the 2007-08 season and assessed the impact of vaccination provider type on two-dose compliance. No studies have examined two-dose compliance by vaccine type (LAIV vs. TIV). "

Primary Objectives

For each IIS sentinel site:

1. Determine seasonal flu coverage (≥1 dose and fully vaccinated) for the 2011-2012 season among children aged 6 through 23 months, 24 through 59 months, 5 through 12 years, and 13-18 years.
2. Determine seasonal flu vaccine uptake in the 2011-12 season by vaccine type (LAIV vs. TIV) among children aged 24 through 59 months, 5 through 12 years and 13 through 18 years.
3. Assess two-dose compliance in the 2011-12 season based vaccination history among children aged 6-23 months, 24 through 59 months, and 5 through 8 years.
4. Assess two-dose compliance in the 2011-12 season based vaccination type (LAIV vs. TIV) among children aged 24 through 59 months and 5 through 8 years

Definitions

Sentinel site area enrollment: Population of children residing specifically within the sentinel site geographic area; excludes children in the IIS who reside outside this defined geographic region, and children who are MOGE or permanently inactive at the jurisdictional level.

Valid/invalid doses: Consider valid influenza doses only; this can be assessed by your IIS's validity algorithms. As an FYI, the following rules apply when assessing the validity of seasonal influenza doses:

- Minimum age for TIV: 6 months minus 4 days for the ACIP grace period
- Minimum age for LAIV: 24 months minus 4 days for the ACIP grace period
- Minimum interval between doses: 4 weeks minus 4 days for the ACIP grace period (i.e. 24 days)
- Live vaccines: LAIV and any other live vaccine that are not administered on the same day should be administered at least 4 weeks apart.

Birth cohorts: Includes children 6 months through 18 years of age during the flu season who were enrolled in the IIS. Members of the cohorts were within the given age range throughout the entire influenza season except children who were 8 years of age at the beginning of the seasonal influenza season and who turned 9 years during the flu season(*). These children needed only 1 dose to be up to date.

Age Group	Seasonal Flu Birth Cohort
6 through 23 month olds	6/1/2010 through 2/1/2011
24 through 59 month olds	6/1/2007 through 8/1/2009
5 through 8 year olds	6/1/2003 through 8/1/2006
9 through 12 year olds*	6/1/1999 through 5/31/2003
13 through 18 year olds	6/1/1993 through 8/1/1998

Seasonal influenza vaccine CPT/CVX codes:

TIV: CPT = 90654, 90655, 90656, 90657, 90658 or
CVX = 15, 140, 141, 144

LAIV: CPT = 90660 or CVX = 111

Other/ Unknown type
Influenza virus vaccine, NOS: CVX = 88
Whole cell influenza virus vaccine: CPT = 90659 or CVX = 16
Split virus, high-dose: CPT = 90662 or CVX = 135

Full Vaccination Coverage: For the 2011-2012 season we will be using the ACIP recommendations for full vaccination coverage. After consulting with NCIRD Influenza staff, the more simplified ACIP definition was adopted. Children aged 6 months through 8 years who received at least one dose of season influenza during the 2010-2011 season will be considered fully vaccinated if they receive at least one dose of influenza during the current season. For those who did not receive at least one dose during the 2010-2011 season, children will only be considered fully vaccinated if they receive two doses of seasonal influenza during the current season.

Logic to Complete Excel Spreadsheet "Flu Response Spreadsheet 2011-12 (*edited to show one age cohort for each question*):

1. What is the seasonal influenza vaccination coverage in the 2011-12 season among children aged 6 through 23 months, 24 through 59 months, 5 through 12 years, and 13 through 18 years in each of the IIS sentinel sites?

a. Coverage with at least 1 dose of vaccine (C5-C10 & E5-E10)

   i. Logic code for **6 through 23 month olds**: In cell C7 of the "Vaccine coverage 2011-12" tab, report the number of children enrolled in the sentinel site area (not MOGE or permanently inactive at the jurisdictional level) who were born from 6/1/2010 through 2/1/2011.

   ii. In cell E7, report the number of children from C7 who received 1 or more doses of seasonal influenza vaccine from 8/1/2011 through 5/31/2012.

b. Fully vaccinated children (G7-H7, G8-H8, & G9-H9)
NOTE: G-H should be mutually exclusive in the excel spreadsheet.

   i. Logic code for **6 through 23 month olds**: In cell G7, report the number of children born from 6/1/2010 through 2/1/2011 who meet all criteria below:

      1. Received no valid doses of seasonal influenza vaccine between 8/1/2010 and 5/31/2011 AND

      2. Received ≥2 valid seasonal doses from 8/1/2011 through 5/31/2012

   ii. In cell H7, report the number of children born from 6/1/2010 through 2/1/2011 who meet all criteria below:

      1. Received ≥1 valid dose of seasonal influenza vaccine between 8/1/2010 and 5/31/2011 AND

      2. Received ≥1 valid seasonal doses from 8/1/2011 through 5/31/2012

2. What percentage of children aged 24 months through 18 years who received flu vaccine in the 2011-12 season were administered TIV only, LAIV only, or a combination of both vaccines?

NOTE: The birth cohorts and the definition of the influenza season for this component of the query are different from those used in the vaccination coverage component of the query. This is done to allow for trends in LAIV uptake to be assessed from previous seasons using consistent methodology. Please adjust your analysis accordingly.

NOTE: If a child receives 3 or more influenza doses in the 2010-11 season that include: 1) TIV, 2) LAIV, and 3) NOS / whole cell / high-dose, count the child in the TIV & LAIV column.

i. Logic code for **24 through 59 month olds**: In cell C7 of the "LAIV vs. TIV 2011-12" tab, list the number of children born from 4/1/2007 through 8/1/2009 who received 1 or more doses of influenza from 8/1/2011 through 3/31/2012.

ii. In cell D7 list the number of children born from 4/1/2007 through 8/1/2009 that received 1 or more doses of TIV but received no doses of LAIV, whole cell influenza virus vaccine, high-dose influenza virus vaccine, and flu vaccine of unknown type from 8/1/2011 through 3/31/2012.

iii. In cell F7, list the number of children born from 4/1/2007 through 8/1/2009 who received 1 or more doses of LAIV but received no doses of TIV, whole cell influenza virus vaccine, high-dose influenza virus vaccine, and flu vaccine of unknown type from 8/1/2011 through 3/31/2012.

iv. In cell H7, list the number of children born from 4/1/2007 through 8/1/2009 who received 1 or more doses of TIV and 1 or more doses of LAIV, even if they also received doses of whole cell influenza virus vaccine, doses of high-dose influenza virus vaccine, or doses of flu vaccine of unknown type from 8/1/2011 through 3/31/2012.

v. In cell J7, list the number of children born from 4/1/2007 through 8/1/2009 who received at least 1 dose of TIV and at least 1 dose of whole cell influenza virus vaccine, high-dose influenza virus vaccine, or flu vaccine of unknown type, but no doses of LAIV from 8/1/2011 through 3/31/2012.

vi. In cell L7, list the number of children born from 4/1/2007 through 8/1/2009 who received at least 1 dose of LAIV and at least 1 dose of whole cell influenza virus vaccine, high-dose influenza virus vaccine, or flu vaccine of unknown type, but no doses of TIV from 8/1/2011 through 3/31/2012.

vii. In cell N7, list the number of children born from 4/1/2007 through 8/1/2009 who received at least 1 dose of whole cell influenza virus vaccine, high-dose influenza virus vaccine, or flu vaccine of unknown type, but no doses of TIV or LAIV from 8/1/2011 through 3/31/2012.

3. What percentage of children aged 6 months through 8 years were 2-dose compliant in the 2011-2012 season?

NOTE: The birth cohorts and the definition of the influenza season for this component of the query are different from those used in the vaccination coverage component of the query. This is done to allow for trends in LAIV uptake to be assessed from previous seasons using consistent methodology. Please adjust your analysis accordingly.

i. Logic code for **6 through 23 month olds**: In cell C7 of the "2 dose compliance" tab, report the number of children enrolled in the sentinel site area (not MOGE or permanently inactive at the jurisdictional level) who were born from 4/1/2010 through 2/1/2011.

ii. In cell D7, report the number of children from cell C7 who received zero valid doses of influenza vaccine from 8/1/2010 through 3/31/2011

iii. In cell E7, report the number of children from cell D7 who received at least 1 valid dose of influenza vaccine from 8/1/2011 through 3/31/2012

iv. In cell F7, report the number of children from cell E7 who received a second valid dose of influenza vaccine from 8/1/2011 through 3/31/2012.

NOTE: The Excel spreadsheet page is not included here. Also, the original document has been truncated.

4. What percentage of children aged 24 months through 59 months and 5 through 8 years were 2-dose compliant by vaccination type (LAIV vs. TIV) in the 2011-2012 season?

   i. Logic code for **24 through 59 month olds**: In cell E7, report the number of children from D7 who received their first valid flu dose from 8/1/2011 through 3/31/2012 as TIV.

   ii. In cell F7, report the number of children from E7 who received as their second valid dose of seasonal influenza vaccine from 8/1/2011 through 3/31/2012 as TIV.

   iii. In cell G7, report the number of children from E7 who received as their second valid dose of seasonal influenza vaccine from 8/1/2011 through 3/31/2012 as LAIV.

   iv. In cell H7, report the number of children from E7 who received as their second valid dose of seasonal influenza vaccine from 8/1/2011 through 3/31/2012 as whole cell influenza vaccine, high-dose influenza vaccine, or influenza vaccine, NOS.

   v. In J7, report the number of children in D7 who received their first valid flu dose from 8/1/2011 through 3/31/2012 as LAIV.

   vi. In K7, report the number of children in J7 who received their second valid flu dose from 8/1/2011 through 3/31/2012 as TIV.