



CLINICAL DECISION SUPPORT FOR IMMUNIZATION (CDSi): LOGIC SPECIFICATION FOR ACIP RECOMMENDATIONS

National Center for Immunization and Respiratory Disease (NCIRD)
Immunization Information Systems Support Branch (IISB)

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1 EXECUTIVE SUMMARY

1.1 BACKGROUND AND GOALS

In 2010, approximately 82% (18.8 million) of U.S. children under the age of six participated¹ in an Immunization Information System (IIS), an increase from 78% (18.0 million) in 2009. Further, a total of 11,536 public and 36,512 private provider sites also participated² in an IIS.³ Given this widespread IIS participation, it is important that each patient's immunization record is consistent and up-to-date within an IIS.

Currently, Health Information Systems (HIS) – which can include Health Information Exchanges (HIEs), IIS and Electronic Health Records (EHRs) – provide healthcare providers with immunization evaluation and forecasting tools designed to automatically determine the recommended childhood immunizations needed when a patient presents for vaccination. These recommendations are developed by the Advisory Committee on Immunization Practices (ACIP). ACIP is a federal advisory committee responsible for providing expert external advice and guidance to the Director of the Centers for Disease Control and Prevention (CDC) and the Secretary of the U.S. Department of Health and Human Services (DHHS) on use of vaccines and related agents for control of vaccine-preventable disease in the United States. Recommendations include age for vaccine administration, number of doses, dosing interval, and precautions and contraindications.

After ACIP recommendations are published, technical and clinical subject matter experts (SMEs) work to interpret and integrate them into their evaluation and forecasting engines. An example of an evaluation and forecasting engine is a tool an IIS might use to alert a physician that a presenting child is overdue for a Measles, Mumps, and Rubella (MMR) vaccination. New ACIP schedule changes are currently communicated only through clinical language, in publications like the Morbidity and Mortality Weekly Report (MMWR) and the Epidemiology and Prevention of Vaccine-Preventable Diseases ("The Pink Book"). The translation of that clinical language into technical logic that is processed within evaluation and forecasting engines is a time-consuming and complex process that happens mostly independently within the different HIS. Due to the challenge of interpreting clinically-written ACIP recommendations, clinical decision support (CDS) engine outputs often vary and do not always match the expectations of clinical SMEs.

In an effort to harmonize the outcomes of existing HIS CDS tools, the Immunization Information System Support Branch (IIS SB) at the CDC funded the Clinical Decision Support for Immunization (CDSi) Project to develop new clinical decision aids⁴ for each vaccine on the children's immunization schedule to:

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

The outcome of enabling the above results is to ensure that patients receive proper immunizations, i.e., "the right immunization at the right time."

¹ Participation was defined as having at least two recorded vaccinations in an Immunization Information System (IIS).

² Participation was defined as having submitted data to the IIS in their state or city in the previous six months (i.e. from July 1 through December 31, 2010), indicating recent submissions.

³ All data derived from the 2010 Immunization Information Systems Annual Report (IISAR). 54 of 56 Centers for Disease Control and Prevention (CDC) Immunization Program grantees/IIS reported. For further information, see: [2010 Immunization Information Systems Annual Report \(IISAR\)](#).

⁴ Aids refer to manual support mechanisms and in no way imply that an automated system is being developed or provided. These aids can, however, be used to refine existing or develop new automated systems.

1.2 APPROACH

As part of this project, an expert panel was formed in April 2011, consisting of SMEs and expert reviewers from:

- CDC Public Health Informatics and Technology Program Office (PHITPO)
- American Immunization Registry Association (AIRA)
- Indian Health Service (IHS)
- EHR vendors
- IIS programs and vendors
- Academic institutions

This panel was divided into three workgroups which met regularly to develop resources in support of the project's goals:

- **Logic Specification Panel (LSP)** – Developed the **Logic Specification for ACIP Recommendations** (Logic Specification) which 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
- **Validation and Testing Panel (VTP)** – Created the **Testing Methodology** to extensively test the compliance of CDS logic representation within CDS engines with ACIP recommendations
- **Process, Communication and Sustainability Panel (PCSP)** – Produced a **Sustainability Plan** to ensure the long-term viability of the clinical decision support for immunization (CDSi) resources

Please refer to Appendix C for more information regarding the expert panelists.

1.3 SCOPE

The vaccine groups in scope for the current phase of the project are those routinely recommended by ACIP for healthy children from birth through 18 years, including:

TABLE 1 - 1 VACCINE GROUPS IN SCOPE

Vaccine Groups			
• Diphtheria, Tetanus, and Pertussis/Tetanus-diphtheria (DTaP, Tdap, Td)	• Haemophilus influenzae type B (Hib)	• Meningococcal conjugate vaccine (MCV)	• Poliomyelitis
• Hepatitis A	• Human papillomavirus (HPV)	• Measles, Mumps, Rubella (MMR)	• Rotavirus
• Hepatitis B	• Influenza (Flu)	• Pneumococcal conjugate vaccine (PCV)	• Varicella

Additional items in scope include:

- Current ACIP recommendations with clarifications
- Compromised/sub-potent/expired doses
- Vaccine recalls
- Wrong vaccine formulations
- Underlying conditions related to contraindications listed in the General Recommendations
- The 4-day grace period
- Catch-up schedule

While not addressed specifically, the Logic Specification was developed to accommodate non-ACIP published rules (i.e., state law variations, local school schedules, rules published by other organizations, rules published in other countries). Supporting data in the specification can be adjusted by implementers to cover these variations from the ACIP recommendations.

Items currently out of scope but candidates for future project phases include the following:

- Adult vaccines
- Underlying conditions related to precautions and special indications
- High/increased/special risk series (e.g. Hib past 5 years, MCV HIV series)
- Outbreak recommendations
- Immune Globulin (IG)
- Route and body site of administration
- Travel vaccines
- Non-FDA approved vaccines (i.e., those used in clinical trials)

1.4 PRODUCTS

Logic Specification

The panel developed the Logic Specification which 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 Logic Specification provides a single, authoritative, implementation-neutral foundation for development and maintenance of clinical decision support engines. It increases the accuracy and consistency of forecasting and evaluation across the HIS community and improves the timeliness of HIS accommodation of new and changed rules.

The objectives of the Logic Specification are to:

- Create a standardized CDS logic representation for ACIP recommendations that allows for broad implementation and effective usage across IIS and other HIS
- Document the logic for applying ACIP business rules in CDS engines in order to improve the clarity, consistency, and computability of on-going childhood and adolescent immunization evaluation and forecasting

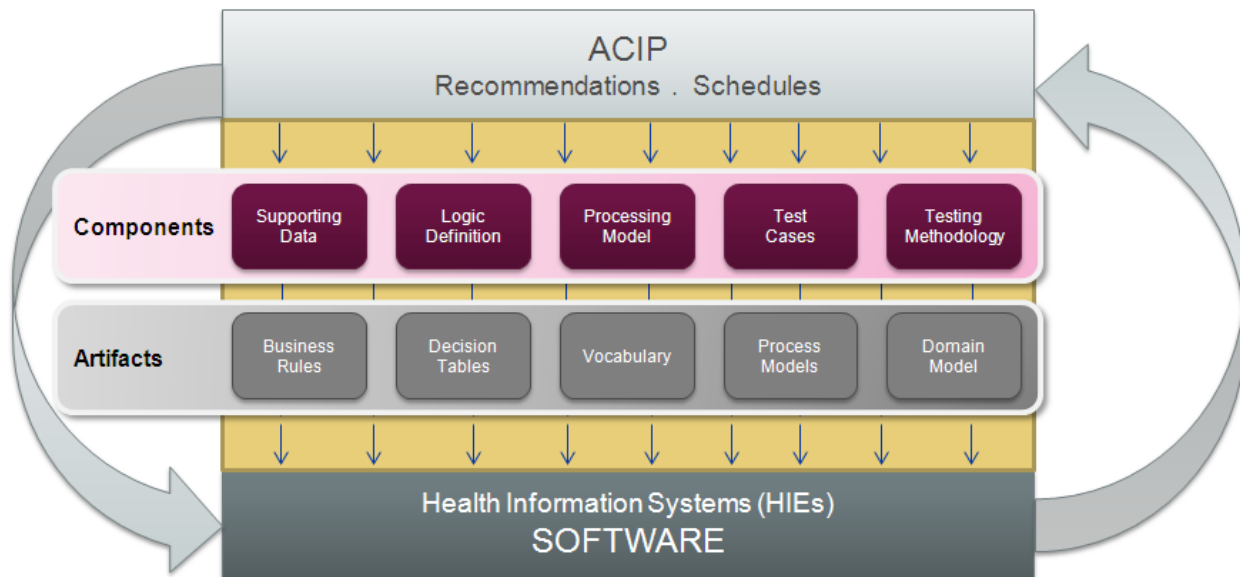


FIGURE 1 - 1 MECHANISMS USED IN LOGIC SPECIFICATION

As illustrated above, a variety of mechanisms (e.g., business rules, models, and logic diagrams) are used as part of the specification.

The table below describes the three major components of the Logic Specification.

TABLE 1 - 2 COMPONENTS OF LOGIC SPECIFICATION

Logic Specification	Supporting Data	Describes, by antigen, various factors and their accompanying sets of values to be considered when implementing ACIP recommendations
	Logic Definition	Describes the functionality required to evaluate and forecast based on a patient's immunization history and the supporting data
	Processing Model	Describes the technical structure necessary to pull the details of the logic definition and supporting data together

The intended audience of the Logic Specification includes business and technical implementers of immunization CDS engines. These implementers may support any system with an immunization evaluation and forecasting engine, including but not limited to an IIS.

The Logic Specification was developed to be as implementation-neutral as possible to support those currently with or without complete evaluation and forecasting engines as they:

- Refine, extend, or develop their implementation
- Clarify their understanding of immunization rules
- Troubleshoot and verify correct implementation of immunization rules

Testing Methodology

The panel developed a Testing Methodology to extensively test the compliance of CDS logic representation within CDS engines with the ACIP recommendations. The panel created test cases and expected results which can be processed against an immunization evaluation and forecasting engine to validate or test its algorithm against the Logic Specification.

The table below describes the two components of the Testing Methodology.

TABLE 1 - 3 COMPONENTS OF TESTING METHODOLOGY

Testing Methodology	Test Cases	Provide a representative set of scenarios and their expected outcomes as dictated by the Logic Specification
	Testing Document	Details the process used to develop the test cases and how to maintain them

The intended audience of the Testing Methodology is implementers of immunization evaluation and forecasting products and services with a sound understanding of immunization evaluation and forecasting testing. Both business analysts and software developers will find value in the testing components.

Sustainability Plan

The panel produced a Sustainability Plan to ensure the long-term viability of the CDSi resources. It provides recommendations and tools for both publicizing the project outputs to potential users and ensuring the long-term viability of the resources through training and support materials, recommended maintenance and support processes, and communications.

The table below describes the four components of the Sustainability Plan.

TABLE 1 - 4 COMPONENTS OF SUSTAINABILITY PLAN

Sustainability Plan	Training Plan	Details the CDSi intended short-term and long-term training and learning support activities
	Process Recommendations	Provide recommended processes for maintaining the CDSi resources as ACIP recommendations change, communicating these changes, and supporting users of the CDSi resources
	Communication Plan	Details the CDSi intended short-term and long-term communication activities and provides a structure for managing them
	Supplemental Recommendations	Provide additional recommendations towards the successful longevity of the CDSi resources

The intended audiences of the Sustainability Plan include members of the CDC IISSB who will be responsible for the sustainability and continued usability of the CDSi resources, namely the Logic Specification and Testing Methodology.

2 LOGIC SPECIFICATION OVERVIEW

2.1 CHAPTER OVERVIEW

The Logic Specification provides the rules to determine if the immunizations received meet the requirements stated by the ACIP. A description of each chapter is presented below:

TABLE 2 - 1 LIST OF CHAPTERS

Chapter	Title	Description	Emphasized Audience		
			Program Managers	Business Analysts	Technical Developers
Chapter 1	Executive Summary	Introduces the context, goals, and primary deliverable of the CDSi project.	✓	✓	✓
Chapter 2	Logic Specification Overview	Provides a high-level overview of the key components of the Logic Specification. The purpose and function are described for each component. In addition, the instruments used to document each component are also introduced.	✓	✓	✓
Chapter 3	Logic Specification Concepts	Provides an explanation of target dose, the meanings of statuses used in evaluation and forecasting, an introduction to supporting data, the business rules for calculating dates, and an explanation of the use of decision tables within the document.	✓	✓	✓
Chapter 4	Logic Definition – Evaluation	Provides the rules for evaluating a vaccine dose administered. The approach is documented using a process model, decision tables, and business rules.		✓	✓
Chapter 5	Logic Definition – Forecasting	Provides the rules for determining forecast dates. The approach is documented using a process model, decision tables, and business rules.		✓	✓
Chapter 6	Logic Definition – Select Best Patient Series	Provides the rules for selecting the patient series which best fits based on various important factors. The approach is documented using a process model, decision tables, and business rules.		✓	✓
Chapter 7	Logic Definition – Identify & Evaluate Vaccine Group	Provides the rules for combining selected patient series from an antigen-based forecast into a vaccine group-based forecast. The approach is documented using a		✓	✓

Chapter	Title	Description	Emphasized Audience		
			Program Managers	Business Analysts	Technical Developers
		process model, decision tables, and business rules.			
Chapter 8	Processing Model	Provides the major logical steps involved in the immunization evaluation and forecasting engine of the CDS process.			✓
Appendix A	Domain Model and Glossary	Provides a domain model that includes diagrams and vocabulary that is pertinent to the Logic Specification.		✓	✓
Appendix B	Acronyms and Abbreviations	Provides the meanings of acronyms and abbreviations used in the document.	✓	✓	✓
Appendix C	Acknowledgements	Provides biographies of subject matter experts who served as volunteer panelists for the CDSi project.	✓		
Appendix D	References	Provides citations of various reference materials that were used to document the business rules and supporting data tables.	✓	✓	✓
Appendix E	Supplemental Material	Provides supplemental material to aid with concepts found in the Logic Specification	✓	✓	✓
Appendix F	Document Management	Provides a table to track key changes and versions of the document.	✓	✓	✓

2.2 LOGIC SPECIFICATION DESIGN PRINCIPLES

The following guiding principles (GP) were central to the development and the design of the Logic Specification. Ultimately, the Logic Specification should:

- GP1. Reduce complexity of understanding and implementing ACIP recommendations
- GP2. Ensure consistency in interpretation of ACIP recommendations
- GP3. Enhance maintainability in response to newly published ACIP recommendations
 - Improved timeliness (i.e., turnaround time)
 - Reduction in rework
 - Minimal impact of changes
- GP4. Inform a variety of implementations

2.3 DESIGN AND DOCUMENTATION STRATEGY

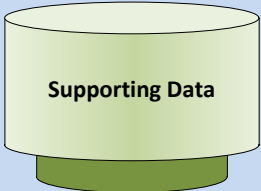
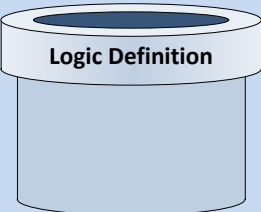
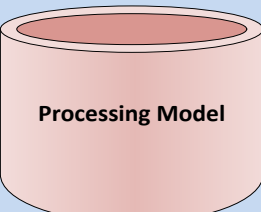
Giving the complexity of implementing ACIP recommendations and considering the guiding principles, the design strategy included two key elements:

- Focusing on three components by setting apart the configuration data, the business rules, and the processing model that pulls the business rules together

- Emphasizing “universal” functionality applicable across HIS instead of implementation-specific engineering requirements

In addition, a variety of mechanisms were chosen to document the specification in order to provide a concise, unambiguous, and computable description of the functionality required. Thus, the design of the Logic Specification is divided into three components. The graphic below lists each component, the description, and the documentation method.

TABLE 2 - 2 DESCRIPTIONS OF COMPONENTS

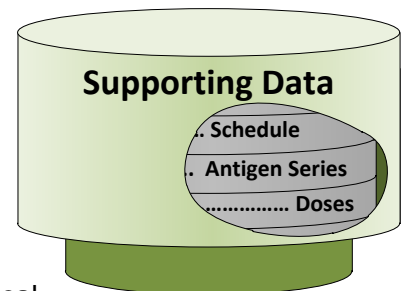
Component	Description	Documentation Method
	<p>Describes, by antigen, various factors and their accompanying sets of values to be considered when implementing ACIP recommendations</p>	<p>Chapter 3:</p> <ul style="list-style-type: none"> • Introduction to supporting data • Link to view supporting data spreadsheets
	<p>Describes the functionality required to evaluate and forecast based on a patient’s immunization history and the supporting data.</p> <p>Logic definitions include:</p> <ul style="list-style-type: none"> • Evaluation Logic • Forecasting Logic • Select Best Patient Series Logic • Identify and Evaluate Vaccine Group Logic 	<p>Chapters 4, 5, 6 & 7:</p> <ul style="list-style-type: none"> • Thin process models • Decision tables • Business rules
	<p>Describes the technical structure necessary to pull the details of the Logic Definition, Supporting Data, and Patient Related Data together</p>	<p>Chapter 8:</p> <ul style="list-style-type: none"> • Activity diagrams

Together these components describe the functionality to evaluate and forecast based on ACIP recommendations using a patient’s immunization history.

2.4 SUPPORTING DATA

Purpose

The **supporting data** component describes the attributes (e.g., minimum age, earliest recommended age, and preferable vaccine type) necessary and specific values (e.g., schedule-specific, antigen series-specific, and dose-specific) required to support evaluation and forecasting as described by the logic definition.



To reduce complexity, the supporting data elements are divided into logical components. Each focuses on one aspect of the more complex processes of evaluation and forecasting.

Simply put, supporting data is akin to configuration data which feeds the system. It is representative of the ACIP recommendations and completed either at dose level (one per dose per series) or schedule level (one for entire ACIP schedule - e.g., live virus supporting data and contraindications supporting data). The supporting data is able to be modified separately from the logic.

What problem does it help solve

The supporting data was separated from the logic definition in order to reduce and ease the maintenance of the logic as new and updated ACIP recommendations are released. The supporting data values are expected to change on a regular basis in conjunction with new and updated ACIP recommendations. It is not expected that the logic definition will change as rapidly. If supporting data are ultimately implemented as some form of a data store (e.g., database), new and updated recommendations can be reflected through simple supporting data changes. In essence, supporting data can be thought of as configuration parameters and values.

Although out of scope for the Logic Specification, separating the supporting data makes it easier to support local differences (e.g., state laws) with minimal impact on the implemented logic (i.e., code).

TABLE 2 - 3 SUPPORTING DATA SUGGESTED AUDIENCE

Role	Perspective
Business Analyst	Understanding and documenting the specific values that describe the relevant information about antigens, series, doses, etc.
Technical Developer	Implementing the data structures to support storage and access of the supporting data. Understanding the integration of the supporting data, logic definition, and processing model.

How and where it is documented

The vocabulary in Appendix A provides definitions of the data elements used within the logical components of the Logic Specification. Additional understanding can be obtained by reviewing the actual supporting data. Chapter 3 provides the link to access all supporting data spreadsheets.

For instance, a dose for a series is divided into the logical components of **age, interval, preferable vaccine type, allowable vaccine type, skip dose, recurring dose, conditional need, seasonal recommendation, substitute dose, and gender**. The appropriateness of each logical component and the appropriate value for each data element could (and in most cases, will) vary based on the specific antigen, series, or dose being described. The example below reflects different values for data elements associated with the logical component age.

TABLE 2 - 4 SUPPORTING DATA EXAMPLE

Series	Target Dose	Absolute Minimum Age	Minimum Age	Earliest Recommended Age	Latest Recommended Age (less than)	Maximum Age (less than)
HepA Standard 2 Dose Series	1	12m – 4d	12m	12m	24m +4w	n/a
Varicella 2 Dose Child Series	2	12m + 4w	15m	4y	7y + 4w	n/a
Rotavirus Standard Series	2	10w – 4d	10w	4m	5m + 4w	8m + 1d

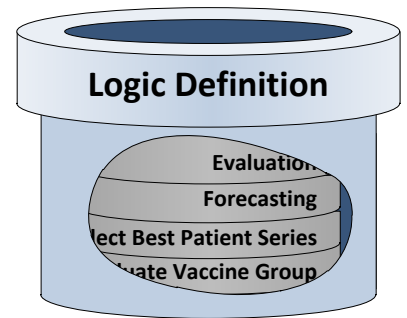
The current standard set of supporting data definitions with appropriate values, based on the ACIP recommendations without modification for any local differences can be found at <http://www.cdc.gov/vaccines/programs/iis/interop-proj/cds.html> .

2.5 LOGIC DEFINITION - PURPOSE

The logic definition describes, in a technology-neutral fashion, the functional steps necessary to process the patient’s medical history using the supporting data.

The logic definition is composed of four separate, but related functions:

- Evaluation
- Forecasting
- Select Best Patient Series
- Identify and Evaluate Vaccine Group



To further reduce complexity, the four logic definitions are divided into logical sub-steps, each of which focuses on one aspect of the more complex processes of evaluation and forecasting. In addition, the vaccine-specific values have been abstracted out of the logic and reside in the supporting data.

2.6 LOGIC DEFINITION – EVALUATION

Purpose

The logic definition **evaluation** describes the process of 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.

What problem it helps solve

Focusing only on evaluation of a patient’s immunization history greatly simplifies the complexity of interpreting ACIP recommendations. It also reduces the breadth of the impact on the logic of future ACIP recommendation changes.

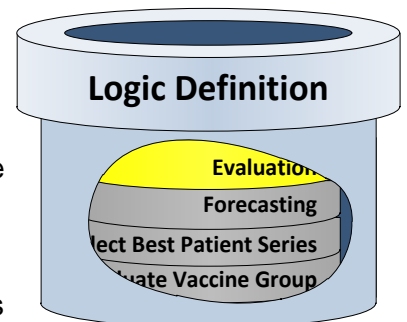


TABLE 2 - 5 EVALUATION SUGGESTED AUDIENCE

Role	Perspective
Business Analyst	Understanding and documenting the logical steps of evaluation and the impact of supporting data elements.
Technical Developer	Coding the system to implement the functional processes described in the logic definition. Understanding the integration of the supporting data, logic definition and processing model.

How and where it is documented

Chapter 4 of the Logic Specification describes the process of evaluation. It is documented using the following:

- A thin process model that represents the high-level steps to evaluate each of the logical sub-components which ultimately affect the validity of a vaccine dose administered.
- Timelines that graphically represent dates and/or time intervals used in evaluation.
- Attribute tables that provide the attribute type, name, and assumed value if empty.
- Decision tables that state the conditions and rules which must be assessed for a specific logical sub-component and the resulting outcomes.

2.7 LOGIC DEFINITION – FORECASTING

Purpose

The logic definition **forecasting** describes the process of using a patient’s medical and immunization history to determine immunization due dates.

What problem it helps solve

Focusing only on forecasting immunization due dates, separate from determining which possible paths to immunity a patient is on, greatly simplifies the complexity of interpreting ACIP recommendations. It also reduces the breadth of the impact on the logic of future ACIP recommendation changes. Even though the logic for evaluation and forecasting is separate, sound evaluation simplifies the work of forecasting; i.e., understanding which target dose has been satisfied simplifies forecasting the next target dose in the patient series.

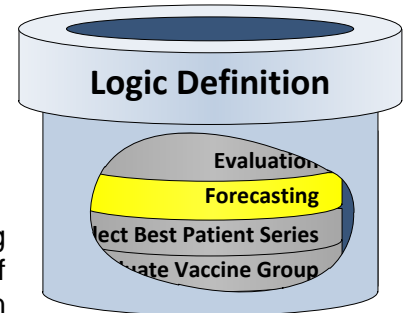


TABLE 2 - 6 FORECASTING SUGGESTED AUDIENCE

Role	Perspective
Business Analyst	Understanding and documenting the logical steps of forecasting and the impact of supporting data elements.
Technical Developer	Coding the system to implement the functional processes described in the logic definition. Understanding the integration of the supporting data, logic definition and processing model.

How and where it is documented

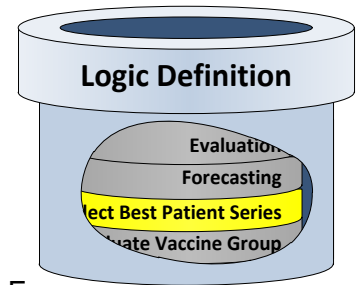
Chapter 5 of the Logic Specification describes the process of forecasting. It is documented using the following:

- A thin process model that represents the high-level steps to forecast immunization due dates.
- Attribute tables that provide the attribute type, name, and assumed value if empty.
- Timelines that graphically represent dates and/or time intervals used to generate or result from the generated forecasted dates.
- Decision tables that represent the combination of conditions and the resulting impact on the need to generate forecasted dates.

2.8 LOGIC DEFINITION – SELECT BEST PATIENT SERIES

Purpose

The logic definition **select best patient series** describes the process of selecting the patient series, out of the possible series, which puts the patient on the best path to immunity based on various important factors.



What problem it helps solve

There is more than one path which can lead a patient to immunity. See Appendix E for representations of multiple patient series (paths to immunity) for an antigen. Select best patient series helps to put a specific patient on the best path for them through the application of ACIP recommendations given the outcomes of evaluation and forecasting.

TABLE 2 - 7 SELECT BEST PATIENT SERIES SUGGESTED AUDIENCE

Role	Perspective
Business Analyst	Understanding and documenting the logical steps of Select Best Patient Series and the factors used when scoring Candidate Patient Series.
Technical Developer	Coding the system to implement the functional processes described in the logic definition. Understanding the integration of the supporting data, logic definition, and processing model.

How and where it is documented

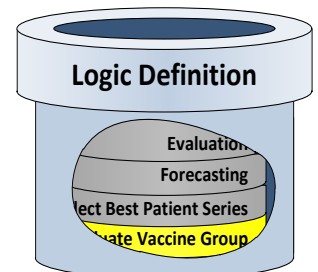
Chapter 6 of the Logic Specification describes the process of selecting best patient series. It is documented using the following:

- A thin process model that represents the high-level steps to select best patient series.
- A vocabulary table that provides meanings to terms used strictly in the select best patient series logic definition.
- Decision tables that represent the combination of conditions and the resulting impact on classifying and scoring patient series.
- Business rules used to concisely, unambiguously describe what and how various factors affect the score given to competing patient series.

2.9 LOGIC DEFINITION – IDENTIFY AND EVALUATE VACCINE GROUP

Purpose

The logic definition **identify and evaluate vaccine group** describes the process of combining patient series, described in terms of antigens, into vaccine group-based forecasts.



What problem it helps solve

Performing evaluation and forecasting at the antigen-level provides for an extremely effective and comprehensive approach. However, clinicians and physicians look at vaccines in a broader grouping known as vaccine groups. Identify and evaluate vaccine group pulls this notion together to provide a clinical-centric forecast based on vaccine groups.

TABLE 2 - 8 IDENTIFY AND EVALUATE VACCINE GROUP SUGGESTED AUDIENCE

Role	Perspective
Business Analyst	Understanding and documenting the logical steps of identifying and evaluating vaccine groups .
Technical Developer	Coding the system to implement the functional processes described in the logic definition. Understanding the integration of the supporting data, logic definition, and processing model.

How and where it is documented

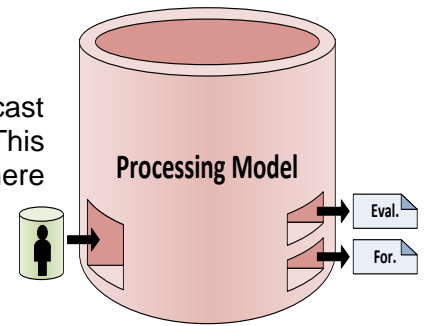
Chapter 7 of the Logic Specification describes the process of identifying and evaluating vaccine groups. It is documented using the following:

- A thin process model that represents the high-level steps to identify and evaluate vaccine groups.
- Decision tables that represent the combination of conditions which dictate which set of vaccine group forecasting rules apply.
- Business rules used to concisely, unambiguously describe how to apply the proper vaccine group forecasting rules to determine the appropriate vaccine group-based forecast.

2.10 PROCESSING MODEL

Purpose

The logic definitions focus on the functionality necessary to evaluate and forecast based on one specific target dose and one specific vaccine dose administered. This simplifies the entire process by only focusing on one item at a time. However, there are many possible paths to immunity which result in many potential target doses. In addition, a patient’s history often contains multiple vaccine doses administered. Thus, the **processing model** describes, in a technology-neutral fashion, the algorithms necessary to merge multiple executions and results of the logic definitions for evaluation and forecasting.



What problem it helps solve

Separating the functionality of evaluation from forecasting and the algorithmic details of handling multiple iterations of evaluation and forecasting greatly simplifies the complexity of implementing ACIP recommendations. It also reduces the breadth of the impact on the logic of future ACIP recommendation changes.

TABLE 2 - 9 PROCESSING MODEL SUGGESTED AUDIENCE

Role	Perspective
Technical Developer	Coding the system to implement the functional processes described in the logic definition. Understanding the integration of the patient related data, supporting data, and logic definition.

How and where it is documented

Chapter 8 of the Logic Specification describes the more detailed algorithms represented in the Logic Specification Processing Model. These algorithms are documented using activity diagrams, which represent the detailed looping necessary to evaluate a patient’s full immunization history against multiple potential

vaccination series resulting in multiple candidate forecasted immunization due dates. Since this chapter provides illustrations of the major logical steps involved in the immunization evaluation and forecasting engine, a technical developer may benefit by reading Chapter 8 prior to other chapters.

3 LOGIC SPECIFICATION CONCEPTS

The information contained in this chapter will be useful in understanding the business rules, decision tables, and process models that are used in the Logic Specification. The first section provides a basic understanding of target dose and how it is used throughout the document. Next, relevant meanings of statuses used during evaluation and forecasting are provided for clarity. Then, the link to review actual supporting data spreadsheets is provided as an easy way to view the data. Business rules used when calculating dates for evaluation and forecasting are provided next. The final section provides an example of how decision tables are used in the document to interpret the business rules used in evaluation and forecasting processes.

3.1 TARGET DOSE

Target dose is a term used often in the Logic Specification document. A target dose is a patient-specific dose required to satisfy the recommendations of ACIP. Until a target dose is satisfied, the patient is not allowed to move to the next target dose in the patient series. The patient remains on the “unsatisfied” target dose until the patient has a “valid” vaccine dose administered that satisfies the target dose. A target dose is also allowed to be skipped or substituted but those situations aren’t the common path and not immediately discussed here. Details on skipping and substituting target doses can be found in chapters 4 and 5.

This concept can be seen graphically below in figure 3-1. For simplicity in this hypothetical patient series, the target doses are defined only by the minimum age. The target doses have minimum ages of 0 days, 2 months, and 6 months. These are the minimum ages allowed by this patient series. The patient must have vaccine doses administered on or after these minimum ages to be considered valid. A valid vaccine dose administered will satisfy a target dose and allow movement to the next target dose. A vaccine dose administered which is anything but valid does not satisfy a target dose and does not allow movement to the next target dose.

This can be seen in figure 3-1 by looking at *target dose 2* and vaccine doses administered *dose 2* and *dose 3*. Dose 2 was administered too early and resulted in the evaluation status “not valid.” A not valid vaccine dose administered means the target dose was not satisfied and must be repeated. Dose 3 was given at an appropriate age which resulted in the evaluation status “valid” and satisfied the goals of target dose 2. This allows movement to target dose 3 which is subsequently satisfied by vaccine dose administered *dose 4*.

While not shown on this graphic, there is also a status which tracks the patient’s progress towards completion of a patient series. In this example, the patient series status is “not complete” for the first three vaccine doses administered. The patient series status is changed to “complete” once the fourth vaccine dose administered satisfies the third target dose which completes the patient series.

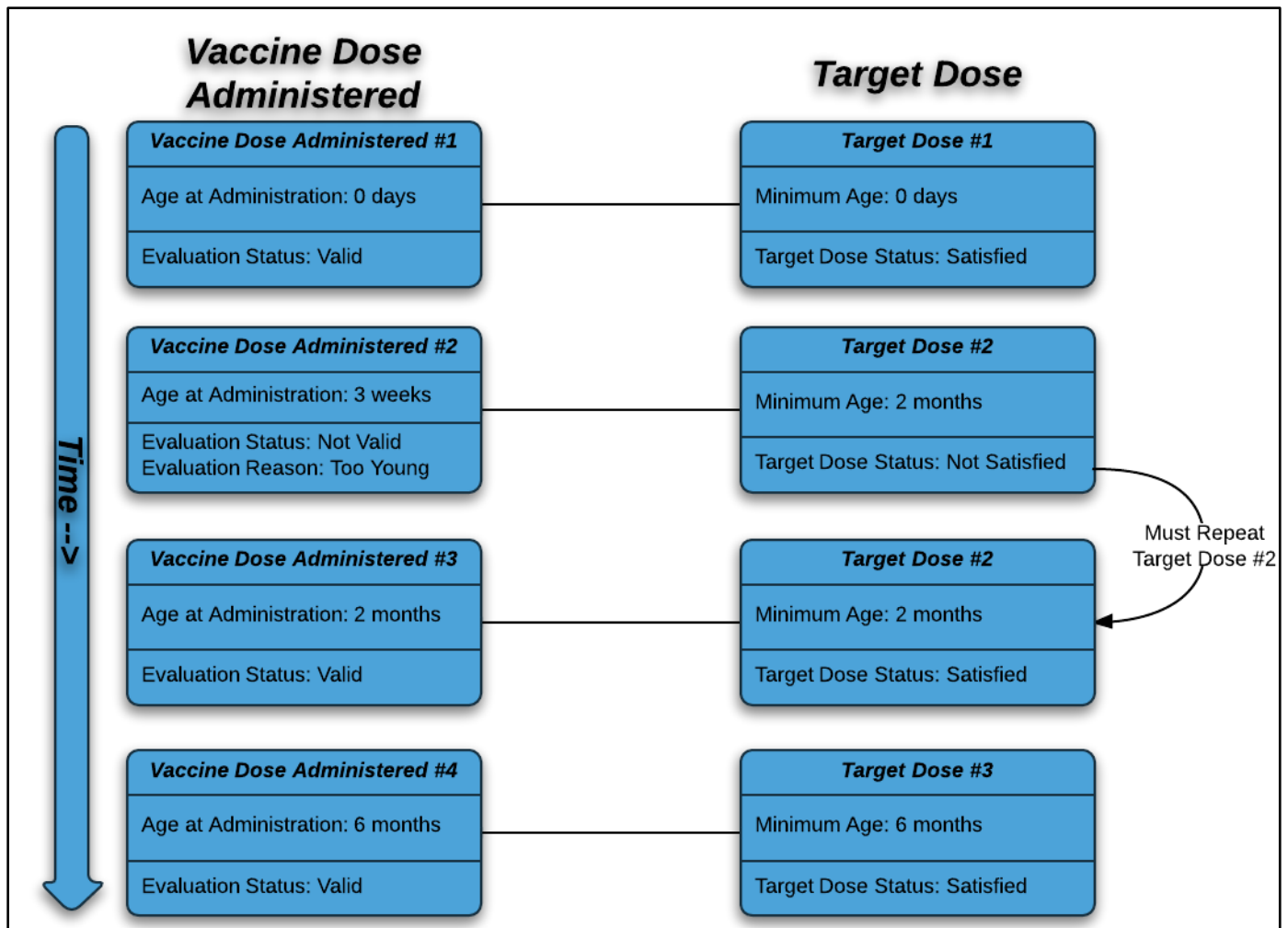


FIGURE 3 - 1 HOW A VACCINE DOSE ADMINISTERED SATISFIES A TARGET DOSE

3.2 STATUSES

The Logic Specification uses different statuses to denote the state of evaluation, target dose, and patient series. The following tables provide the meanings of statuses used in Logic Specification business rules and decision tables.

TABLE 3 - 1 EVALUATION STATUSES

Evaluation Status	Relevant Meaning
Extraneous	An <i>extraneous</i> evaluation status means the vaccine dose administered was not administered according to ACIP recommendations, but the dose does not need to be repeated (including maximum age and extra doses.)
Not Valid	A <i>not valid</i> evaluation status means the vaccine dose administered was not administered according to ACIP recommendations and must be repeated at an appropriate time in the future.
Valid	A <i>valid</i> evaluation status means the vaccine dose administered was administered according to ACIP recommendations.
Sub-standard	A <i>sub-standard</i> evaluation status means the vaccine dose administered has a known dose condition (e.g., expired, sub-potent, and recall) which requires the dose to be repeated at an appropriate time in the future.

TABLE 3 - 2 TARGET DOSE STATUSES

Target Dose Status	Relevant Meaning
Not Satisfied	A <i>not satisfied</i> target dose status means no vaccine dose administered has met the goals of the target dose.
Satisfied	A <i>satisfied</i> target dose status means a vaccine dose administered has met the goals of the target dose.
Skipped	A <i>skipped</i> target dose status means no vaccine dose administered has met the goals of the target dose. Due to the patient's age and/or interval from a previous dose, the target dose does not need to be satisfied.
Substituted	A <i>substituted</i> target dose status means a vaccine dose administered earlier in the patient series was used for the target dose.
Unnecessary	An <i>unnecessary</i> target dose status means the target dose is not needed and the target dose does not need to be satisfied.

TABLE 3 - 3 PATIENT SERIES STATUSES

Patient Series Status	Relevant Meaning
Complete	A <i>complete</i> patient series status means the patient has met all of the ACIP recommendations for the patient series.
Contraindicated	A <i>contraindicated</i> patient series status means the patient's medical history indicates no further immunizations should be administered for the patient series.
Immune	An <i>immune</i> patient series status means the patient has evidence of immunity indicating no further immunizations are needed for the patient series.
Not Complete	A <i>not complete</i> patient series status means the patient has not yet met all of the ACIP recommendations for the patient series.
Aged Out	An <i>Aged Out</i> patient series status means the patient exceeded the maximum age prior to completing the patient series.

3.3 SUPPORTING DATA

The purpose of supporting data is to provide the implementer with the necessary information needed for evaluation and forecasting. The Logic Specification defines supporting data by logical components. The logical components are: (1) Age, (2) Interval, (3) Preferable Vaccine, (4) Allowable Vaccine, (5) Skip Dose, (6) Recurring Dose, (7) Conditional Need, (8) Seasonal Recommendation, (9) Substitute Dose, and (10) Gender.

Click here to view all supporting data spreadsheets:

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

3.4 DATE CALCULATIONS

Business rules that are specific to calculating dates are provided in this section. A **calculated date** is a date that is mathematically derived from one or more terms. The first table provides rules for calculating dates in general. The second table provides rules for calculating dates by logical component.

TABLE 3 - 4 GENERAL DATE RULES

Business Rule ID	Business Rule	Example
CALCDT-1	The computed date of adding any number of years to an existing date must be calculated by incrementing the date-year while holding the date-month and date-day constant.	<ul style="list-style-type: none"> 01/01/2000 + 3 years = 01/01/2003
CALCDT-2	The computed date of adding any number of months to an existing date must be calculated by incrementing the date-month (and date-year, if necessary) while holding the date-day constant.	<ul style="list-style-type: none"> 01/01/2000 + 3 months = 04/01/2000 11/01/2000 + 3 months = 02/01/2001
CALCDT-3	The computed date of adding any number of weeks or days to an existing date must be calculated by adding the total days to the existing date.	<ul style="list-style-type: none"> 01/01/2000 + 3 weeks = 01/22/2000 01/01/2000 + 3 days = 01/04/2000 02/01/2000 + 5 weeks = 03/07/2000 (leap year) 02/01/2001 + 5 weeks = 03/08/2001 (not a leap year)
CALCDT-4	The computed date of subtracting any number of days from an existing date must be calculated by subtracting the total days from the existing date.	<ul style="list-style-type: none"> 01/15/2000 – 4 days = 01/11/2000
CALCDT-5	A computed date which is not a real date must be moved forward to first day of the next month.	<ul style="list-style-type: none"> 07/31/2000 + 2 months = 10/01/2000 01/31/2001 + 1 month = 03/01/2001
CALCDT-6	A computed date must be calculated by first adjusting the years, followed by the months, and finally the weeks and/or days.	<ul style="list-style-type: none"> 01/31/2000 + 1 month – 4 days = 02/25/2000

TABLE 3 - 5 LOGICAL COMPONENT DATE RULES

Business Rule ID	Business Rule	Logical Component
CALCDTSKIP-1	The patient's trigger age date must be calculated as the patient's date of birth plus the skip dose trigger age.	Skip Target Dose
CALCDTSKIP-2	The patient's trigger interval date must be calculated as the vaccine date administered which satisfied the previous target dose plus the skip dose trigger interval.	Skip Target Dose
CALCDTSUB-1	The patient's first dose begin age date must be calculated as the patient's date of birth plus substitute dose first dose begin age.	Substitute Target Dose
CALCDTSUB-2	The patient's first dose end age date must be calculated as the patient's date of birth plus substitute dose first dose end age.	Substitute Target Dose
CALCDTAGE-1	The patient's maximum age date must be calculated as the patient's date of birth plus the maximum age.	Age
CALCDTAGE-2	The patient's latest recommended age date must be calculated as the patient's date of birth plus the latest recommended age.	Age
CALCDTAGE-3	The patient's earliest recommended age date must be calculated as the patient's date of birth plus the earliest recommended age.	Age
CALCDTAGE-4	The patient's minimum age date must be calculated as the patient's date of birth plus the minimum age.	Age
CALCDTAGE-5	The patient's absolute minimum age date must be calculated as the patient's date of birth plus the absolute minimum age.	Age
CALCDTINT-1	The patient's reference dose date must be calculated as the date administered of the most immediate previous vaccine dose administered which has evaluation status "Valid" or "Not Valid" if from immediate previous dose administered is "Y".	Interval, Allowable Interval

Business Rule ID	Business Rule	Logical Component
CALCDTINT-2	The patient's reference dose date must be calculated as the date administered of the vaccine dose administered which satisfies the target dose defined in the interval from target dose number in series if from immediate previous dose administered is "N".	Interval, Allowable Interval
CALCDTINT-3	The patient's absolute minimum interval date must be calculated as the patient's reference dose date plus the absolute minimum interval.	Interval, Allowable Interval
CALCDTINT-4	The patient's minimum interval date must be calculated as the patient's reference dose date plus the minimum interval.	Interval
CALCDTINT-5	The patient's earliest recommended interval date must be calculated as the patient's reference dose date plus the earliest recommended interval.	Interval
CALCDTINT-6	The patient's latest recommended interval date must be calculated as the patient's reference dose date plus the latest recommended interval.	Interval
CALCDTINT-7	The patient's latest minimum interval date must be the latest date of all calculated minimum interval dates for a given target dose.	Interval
CALCDTLIVE-1	The patient's conflict begin interval date must be calculated as the date administered of the <i>conflicting</i> vaccine dose administered plus the live virus conflict begin interval.	Live Virus Conflict
CALCDTLIVE-2	The patient's conflict end interval date must be calculated as the date administered of the conflicting vaccine dose administered plus the live virus minimum conflict end interval when the conflicting vaccine dose administered has evaluation status "valid."	Live Virus Conflict
CALCDTLIVE-3	The patient's conflict end interval date must be calculated as the date administered of the conflicting vaccine dose administered plus the live virus conflict end interval when the conflicting vaccine dose administered does not have evaluation status "valid."	Live Virus Conflict
CALCDTLIVE-4	The patient's latest conflict end interval date must be the latest date of all calculated conflict end interval dates for a given target dose.	Live Virus Conflict
CALCDTPREF-1	The patient's preferable vaccine type begin age date must be calculated as the patient's date of birth plus the preferable vaccine type begin age.	Preferable Vaccine
CALCDTPREF-2	The patient's preferable vaccine type end age date must be calculated as the patient's date of birth plus the preferable vaccine type end age.	Preferable Vaccine
CALCDTALLOW-1	The patient's allowable vaccine type begin age date must be calculated as the patient's date of birth plus the allowable vaccine type begin age.	Allowable Vaccine
CALCDTALLOW-2	The patient's allowable vaccine type end age date must be calculated as the patient's date of birth plus the allowable vaccine type end Age.	Allowable Vaccine

3.5 DECISION TABLE OVERVIEW

A decision table documents the way that a system responds to various combinations of input conditions. It describes business rules where the required response depends on a number of factors that must all be considered at the same time. Decision tables are useful when trying to clearly define a set of conditions, how they work in combination, and what actions should be taken on encountering a given set of conditions.

There are various ways of documenting decision tables. The Logic Specification uses a simple business question as the title or subject of the decision table. The top half of the decision table lists conditions based on the business question. The bottom half of the decision table states the outcome after the rules have been applied to the condition.

In order to familiarize the reader with the use of decision tables in the Logic Specification, an example is provided below using a real-world scenario that is unrelated to immunizations.

TABLE 3 - 6 SHOULD I GET MY CAR WASHED?

CONDITIONS	RULES			
Is the car wash open?	No	-	-	Yes
Is my car dirty?	-	No	-	Yes
Do I have enough money?	-	-	No	Yes
OUTCOMES	No. The car wash is closed.	No. My car is not dirty.	No. I cannot afford it.	Yes. I should get my car washed.

The following table provides explanations of how the various outcomes were determined.

TABLE 3 - 7 EXPLANATIONS OF OUTCOMES

Outcome	Explanations
No. The car wash is closed.	The answer “No” to the first condition means the car wash was not open. The other conditions (Is my car dirty? or Do I have enough money?) do not matter.
No. My car is not dirty.	The answer “No” to the second condition means my car is not dirty. The other conditions (Is the car wash open? Or Do I have enough money?) do not matter.
No. I cannot afford it.	The answer “No” to the third condition means I do not have enough money. The other conditions (Is the car wash open? Or Is my car dirty?) do not matter.
Yes. I should get my car washed.	The answer “Yes” to all of the conditions means the car wash is open, my car is dirty, and I have enough money. The outcome (Yes. I should get my car wash.) is based on answers to all conditions.

A decision table is helpful when decision-based rules have to be applied in combination. As illustrated above, the Logic Specification refers to key components of a decision table as (1) Conditions, (2) Rules, and (3) Outcomes. These components function together in the following manner: Conditions + Answers = Rules; Rules determine Outcomes.

Logical reasoning used to determine the outcome in the example decision table above is similar to the decision tables used in the Logic Specification. The goal of a decision table is to answer a business question while providing the correct technical outcome.

4 EVALUATE VACCINE DOSE ADMINISTERED

The core of a CDS engine is the process of evaluating a single vaccine dose administered against a defined target dose to determine if the vaccine dose administered is “valid” or “not valid.” The results will ultimately determine if all conditions of the target dose are satisfied and the dose does not need to be repeated. This can be accomplished by breaking the evaluation process into simple and logical components. After processing each logical component, the results of those logical components are used to determine if the vaccine dose administered satisfies the goals of the target dose.

Each logical component has its own set of business rules that are used to determine if a target dose is “satisfied.” These business rules are documented using the decision table format. (See section 3.5 to review an example of a decision table using a real-world scenario.) The decision table describes the way that the CDS engine responds to various combinations of conditions. The implementer is able to clearly see the set of conditions, how they work in combination, and what actions should be taken on a given set of conditions.

Specific attributes and decision tables are provided for each step of the evaluation process.

TABLE 4 - 1 EVALUATION PROCESS STEPS

Section	Activity	Goal
4.1	Evaluate Dose Administered Condition	The goal of this step is to determine if a vaccine dose administered can be evaluated.
4.2	Evaluate Skip Target Dose	The goal of this step is to determine if the target dose can be skipped due to a patient’s age.
4.3	Evaluate Substitute Target Dose	The goal of this step is to determine if target doses can be substituted based on doses administered earlier in the series.
4.4	Evaluate Age	The goal of this step is to determine if the vaccine dose administered was given at an appropriate age.
4.5	Evaluate Interval	The goal of this step is to determine if the vaccine dose administered was given at an appropriate interval.
4.6	Evaluate Allowable Interval	The goal of this step is to determine if the vaccine dose administered was given at an allowable interval.
4.7	Evaluate Live Virus Conflict	The goal of this step is to determine if the vaccine dose administered was in conflict with any live virus vaccines.
4.8	Evaluate Preferable Vaccine Administered	The goal of this step is to determine if the vaccine dose administered was one of the preferable vaccines.
4.9	Evaluate Allowable Vaccine Administered	The goal of this step is to determine if the vaccine dose administered was one of the allowable vaccines.
4.10	Evaluate Gender	The goal of this step is to determine if the vaccine dose administered was given to an appropriate gender.
4.11	Satisfy Target Dose	The goal of this step is to determine if the target dose is satisfied.

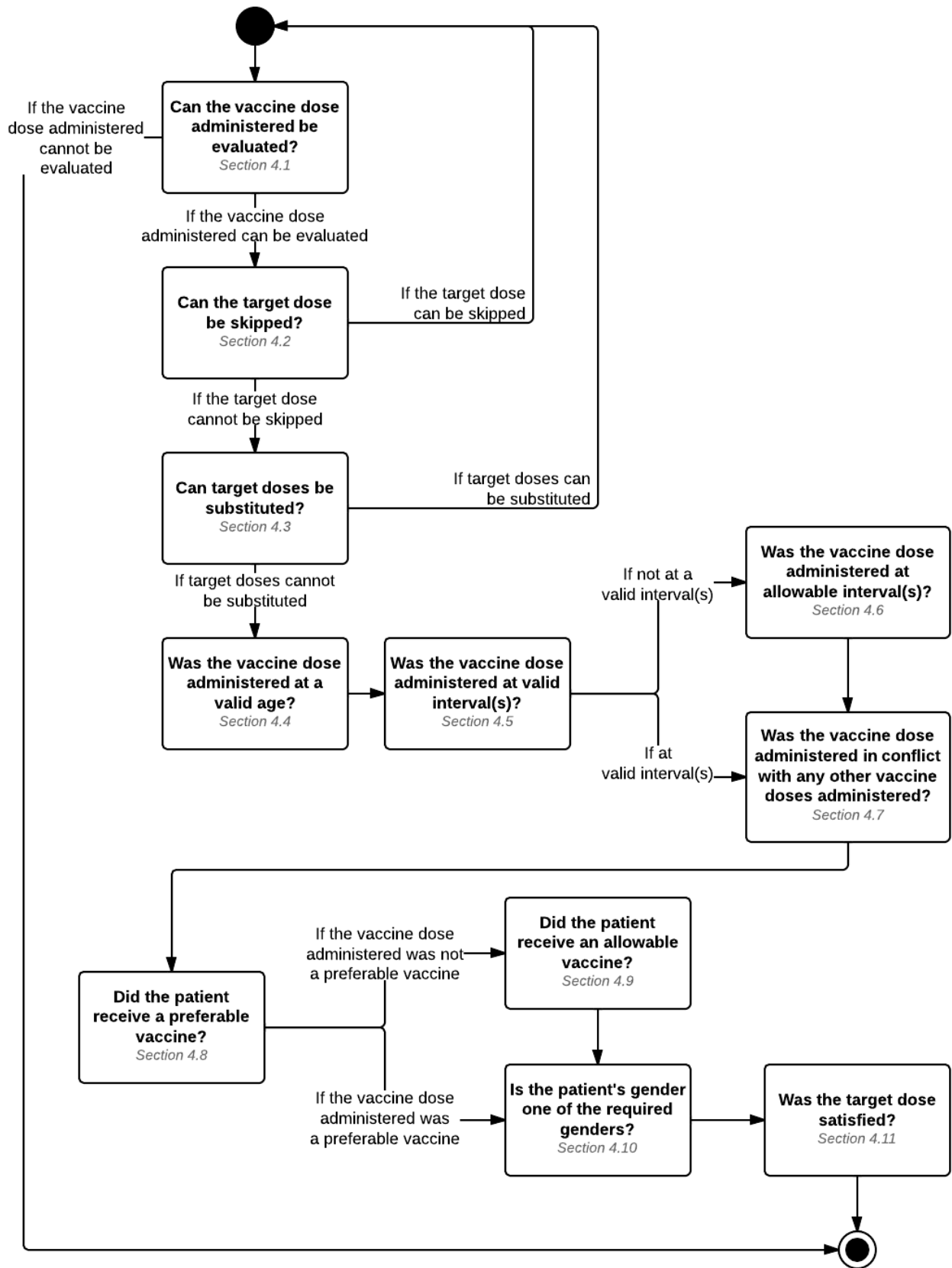


FIGURE 4 - 1 EVALUATION PROCESS MODEL

4.1 VACCINE DOSE ADMINISTERED CONDITION

Vaccine dose administered condition checks the dose administered to see if the target dose must be repeated regardless of the other evaluation rules.

Relationship to ACIP recommendations:

- Doses which were administered after the lot expiration date or which contain a condition do not need to be evaluated.
- Examples of conditions which would prevent evaluation of a vaccine dose administered range from misadministration to recalls to cold chain breaks.

The following processing model, attribute table and decision table are used to determine if dose administered can be evaluated.

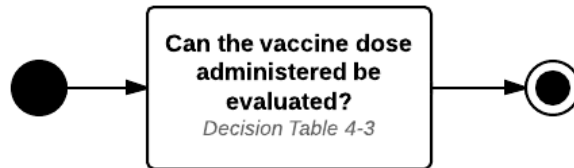


FIGURE 4 - 2 VACCINE DOSE ADMINISTERED CONDITION PROCESS MODEL

TABLE 4 - 2 DOSE ADMINISTERED CONDITION ATTRIBUTES

Attribute Type	Attribute Name	Assumed Value if empty
Vaccine dose administered	Date Administered	-
Vaccine dose administered	Lot Expiration Date	12/31/2999
Vaccine dose administered	Dose Condition	-

TABLE 4 - 3 CAN THE VACCINE DOSE ADMINISTERED BE EVALUATED?

CONDITIONS	RULES		
	Date administered > lot expiration date?	Yes	No
Dose condition indicated?	-	Yes	No
OUTCOMES	No. The vaccine dose administered cannot be evaluated. Target dose status is "not satisfied." Evaluation status is "sub-standard."	No. The vaccine dose administered cannot be evaluated. Target dose status is "not satisfied." Evaluation status is "sub-standard."	Yes. The vaccine dose administered can be evaluated.

4.2 SKIP TARGET DOSE

Skip target dose addresses times when a target dose can be skipped. In most settings, this occurs when a patient is behind schedule and the total number of doses needed to satisfy patient series can be reduced. In cases where a target dose does not specify skip target dose attributes, the target dose cannot be skipped.

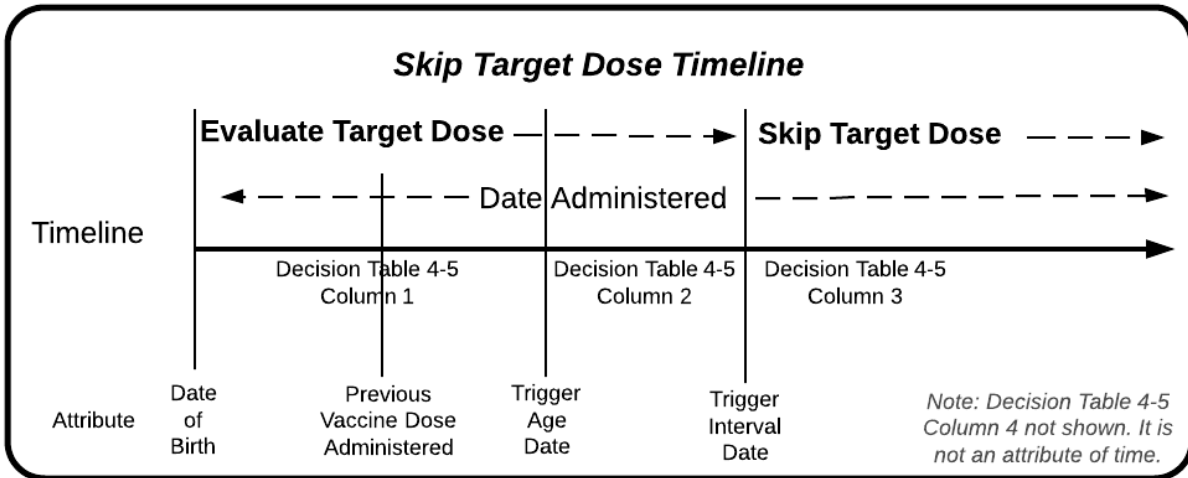


FIGURE 4 - 3 SKIP TARGET DOSE TIMELINE

The following process model, attribute table, and decision table are used to determine if the target dose can be skipped.

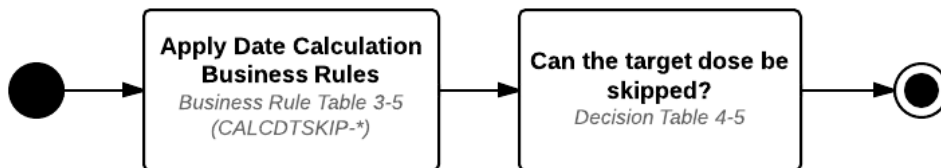


FIGURE 4 - 4 SKIP TARGET DOSE PROCESS MODEL

TABLE 4 - 4 SKIP TARGET DOSE ATTRIBUTES

Attribute Type	Attribute Name	Assumed Value if empty
Vaccine dose administered	Date Administered	-
Calculated date (CALCDTSKIP-1)	Trigger Age Date	12/31/2999
Calculated date (CALCDTSKIP-2)	Trigger Interval Date	01/01/1900
Supporting Data (Skip Dose)	Trigger Target Dose	-

TABLE 4 - 5 CAN THE TARGET DOSE BE SKIPPED?

CONDITIONS	RULES
------------	-------

CONDITIONS	RULES			
date administered < trigger age date?	Yes	No	No	-
date administered < trigger interval date?	-	Yes	No	-
Is the trigger target dose status "satisfied"?	No	No	-	Yes
OUTCOMES	No. The target dose cannot be skipped.	No. The target dose cannot be skipped.	Yes. The target dose can be skipped. The target dose status is "skipped."	Yes. The target dose can be skipped. The target dose status is "skipped."

4.3 SUBSTITUTE TARGET DOSE

Substitute target dose is similar to skip target dose as a means to adjust where the patient is in the patient series. The goal of substitute target dose is to look at previously satisfied target doses within the patient series to determine how many future target doses – if any – can be substituted and not recommended.

When a target dose does specify substitute target *dose* attributes, it will contain a set of substitution possibilities. If a substitution is found, the remaining substitute target dose sets can be ignored. If all of the sets are examined and no substitution is found, then the current target dose should be used for evaluation. This can be seen with the process model shown in figure 4-5.

In cases where a target dose does not specify substitute target dose attributes, the target dose cannot be substituted.

Relationship to ACIP recommendations:

- At present, substitute target dose is only used for children who have partially completed their DTaP series and have turned seven years old. Once the child is seven years old, the number of Tdap/Td doses recommended is based on the number of DTaP vaccine doses administered the child received prior to age seven. See MMWR 2006; 55 (No. RR-3); Appendix D.

The following process model, attribute table, decision table, and business rule table are used to determine if target dose (s) can be substituted.

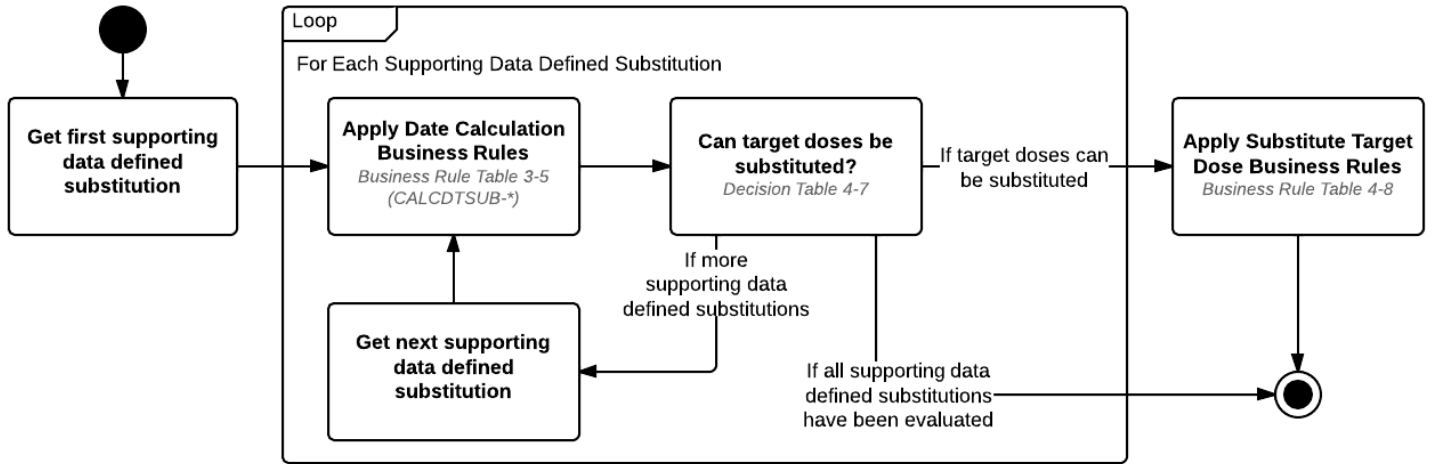


FIGURE 4 - 5 SUBSTITUTE TARGET DOSE PROCESS MODEL

TABLE 4 - 6 SUBSTITUTE TARGET DOSE ATTRIBUTES

Attribute Type	Attribute Name	Assumed Value if empty
Patient Series	Target Doses with a Target Dose Status “Satisfied”	-
Vaccine dose administered	Date Administered of the first satisfied target dose	-
Calculated date (CALCDTSUB-1)	First Dose Begin Age Date	-
Calculated date (CALCDTSUB-2)	First Dose End Age Date	-
Supporting data (Substitute Dose)	Total Count of Valid Doses	-
Supporting data (Substitute Dose)	Number of Target Doses to substitute	-

TABLE 4 - 7 CAN TARGET DOSES BE SUBSTITUTED?

CONDITIONS	RULES		
	Yes	-	No
First dose begin age date ≤ date administered of first satisfied target dose in patient series < first dose end age date?	Yes	-	No
Total count of satisfied target doses in patient series = substitute dose total count of valid doses?	Yes	No	-
OUTCOMES	Yes. Target doses can be substituted.	No. Target doses cannot be substituted.	No. Target doses cannot be substituted.

TABLE 4 - 8 SUBSTITUTE TARGET DOSE BUSINESS RULES

Business Rule ID	Rule
SUBDOSE-1	The new target dose must be calculated as the current target dose plus the number of target doses to substitute.
SUBDOSE-2	Each target dose which is substituted must have the target dose status “substituted”.

4.4 EVALUATE AGE

Evaluate age validates the age at administration of a vaccine dose administered against a defined age range of a target dose. In cases where a target dose does not specify age attributes, the age at administration is considered “valid.”

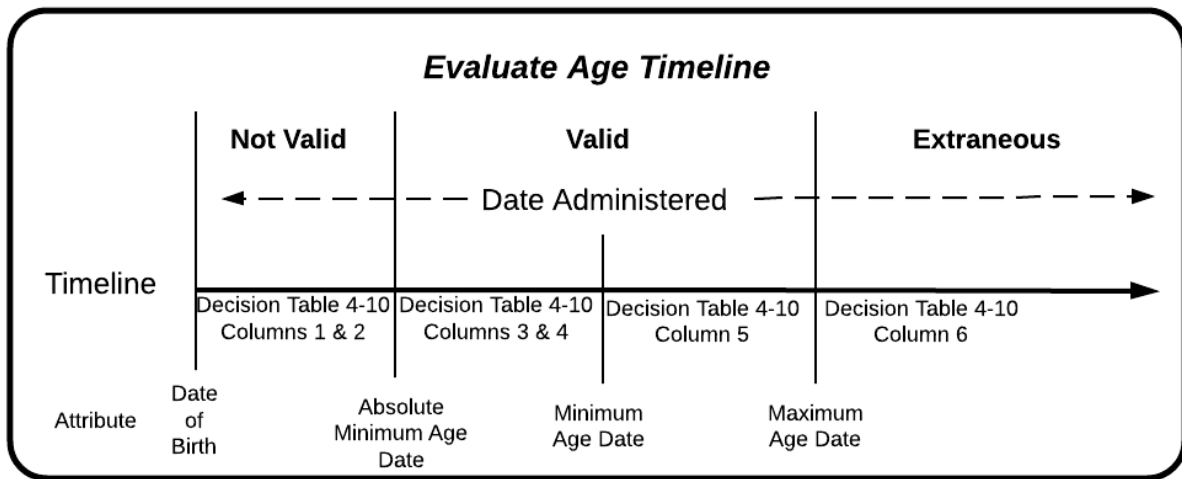


FIGURE 4 - 6 EVALUATE AGE TIMELINE

The following process model, attribute table and decision table are used to evaluate age at administration.

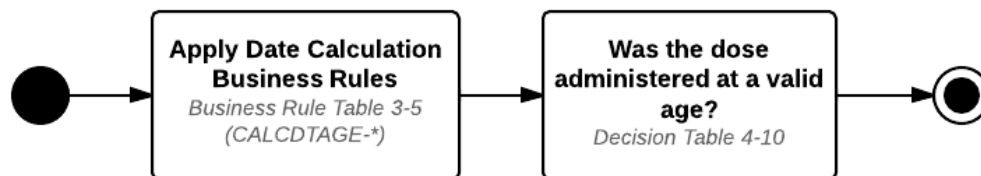


FIGURE 4 - 7 EVALUATE AGE PROCESS MODEL

TABLE 4 - 9 AGE ATTRIBUTES

Attribute Type	Attribute Name	Assumed Value if empty
Vaccine dose administered	Date Administered	-
Calculated date (CALCDTAGE-1)	Maximum Age Date	12/31/2999
Calculated date (CALCDTAGE-4)	Minimum Age Date	01/01/1900
Calculated date (CALCDTAGE-5)	Absolute Minimum Age Date	01/01/1900

TABLE 4 - 10 WAS THE VACCINE DOSE ADMINISTERED AT A VALID AGE?

CONDITIONS	RULES
------------	-------

Date administered < absolute minimum age date?	Yes	No	No	No	No	No
Absolute minimum age date ≤ date administered < minimum age date?	No	Yes	Yes	Yes	No	No
Minimum age date ≤ date administered < maximum age date?	No	No	No	No	Yes	No
Date administered ≥ maximum age date?	No	No	No	No	No	Yes
Is this the first target dose?	-	No	No	Yes	-	-
Is the previous vaccine dose administered “not valid” due to age or interval requirements?	-	Yes	No	-	-	-
OUTCOMES	No. The vaccine dose was not administered at a valid age. Evaluation reason is “too young.”	No. The vaccine dose was not administered at a valid age. Evaluation reason is “too young.”	Yes. The vaccine dose was administered at a valid age. Evaluation reason is “grace period.”	Yes. The vaccine dose was administered at a valid age. Evaluation reason is “grace period.”	Yes. The vaccine dose was administered at a valid age.	No. The vaccine dose was administered after the maximum age and is extraneous. Evaluation reason is “too old.”

4.5 EVALUATE INTERVAL

Evaluate interval validates the date administered of a vaccine dose administered against defined interval(s) from previous vaccine dose(s) administered. In cases where a target dose does not specify interval attributes, the interval is considered “valid.”

Relationship to ACIP Recommendations:

- The majority of cases will require the interval to be evaluated from the immediate previous vaccine dose administered.
- At present, dose 3 of HepB and dose 3 of HPV have two intervals. The first interval is from the immediate previous vaccine dose administered. The second interval is from satisfied target dose 1 in each respective series.

Figure 4-8 provides the evaluation interval timeline used to define all adjacent intervals by using *from immediate previous dose administered* as the reference point.

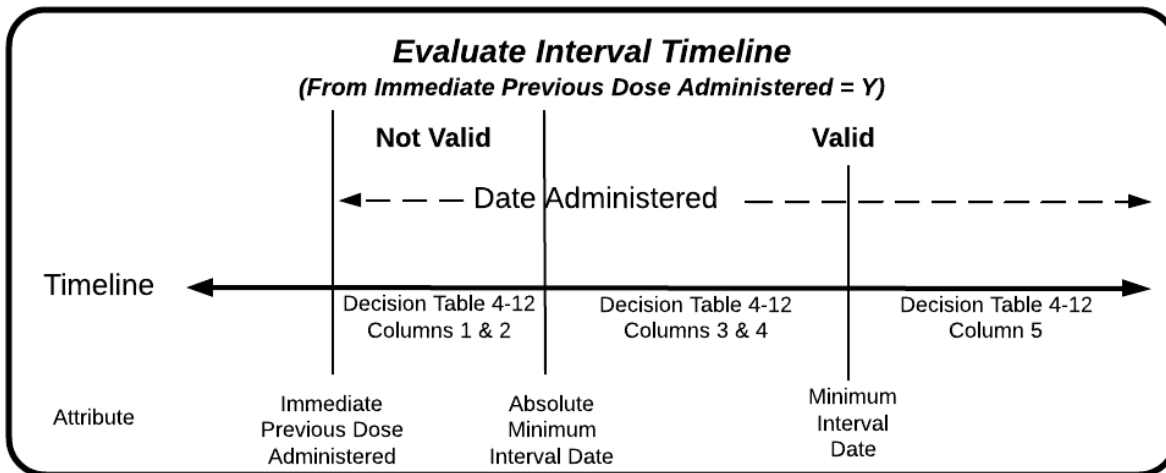


FIGURE 4 - 8 EVALUATE INTERVAL 'FROM IMMEDIATE PREVIOUS DOSE' TIMELINE

Figure 4-9 illustrates the evaluation interval timeline used to define all non-adjacent intervals by using *from target dose number in series* as the reference point. This timeline is used only when from immediate previous dose administered is “N.”

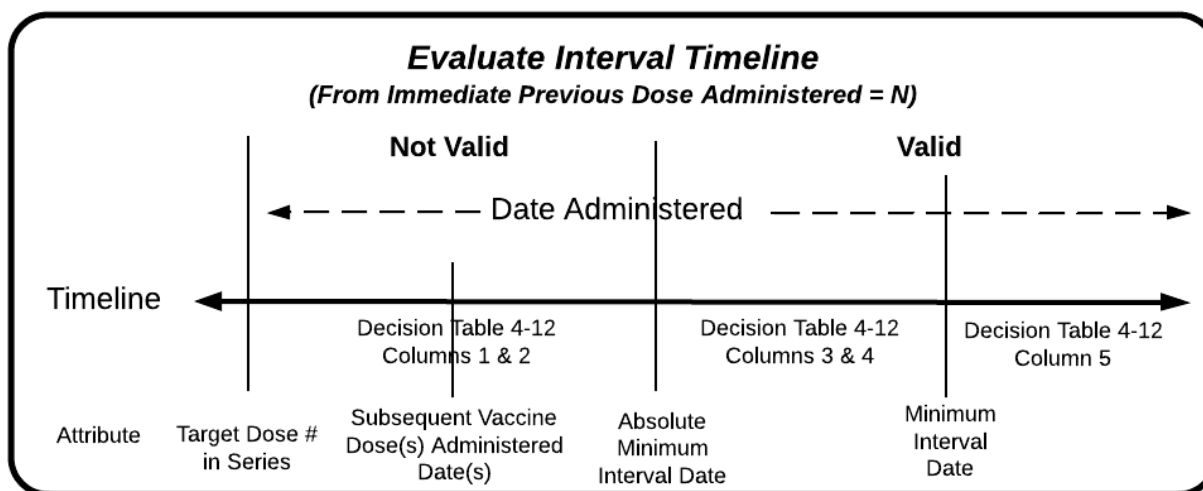


FIGURE 4 - 9 EVALUATE INTERVAL 'FROM TARGET DOSE NUMBER IN SERIES' TIMELINE

The following process model, attribute table, decision table, and business rule table are used to evaluate interval of a vaccine dose administered.

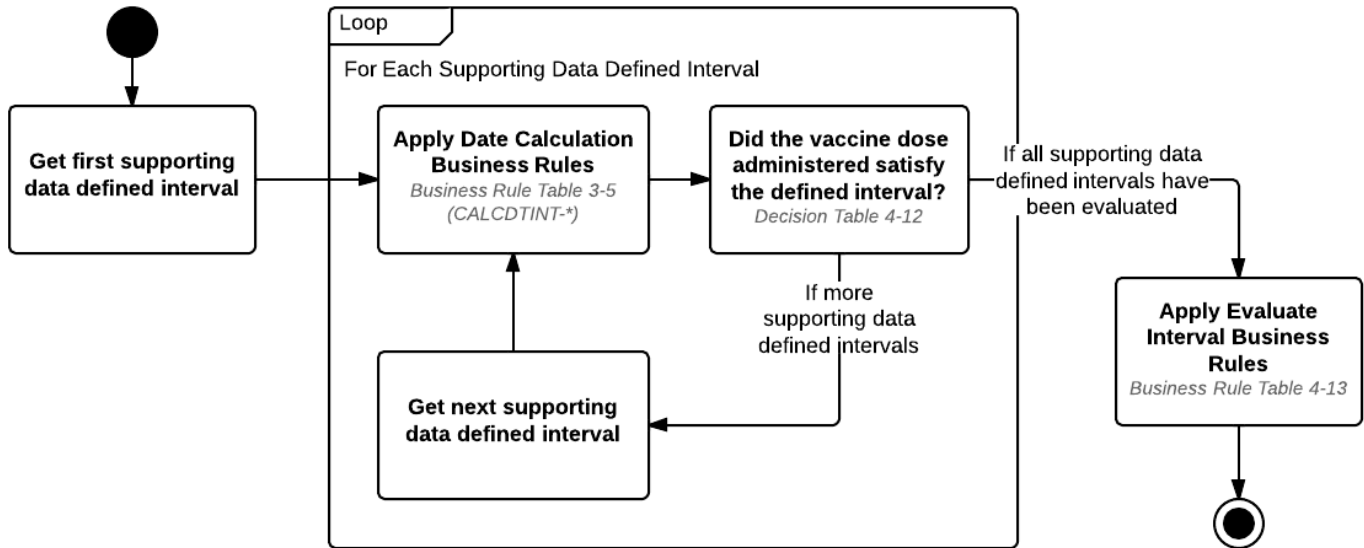


FIGURE 4 - 10 EVALUATE INTERVAL PROCESS MODEL

TABLE 4 - 11 INTERVAL ATTRIBUTES

Attribute Type	Attribute Name	Assumed Value if empty
Vaccine dose administered	Date Administered	-
Supporting data (Interval)	From Immediate Previous Dose Administered	-
Supporting data (Interval)	From Target Dose Number In Series	-
Calculated date (CALCDTINT-3)	Absolute Minimum Interval Date	01/01/1900
Calculated date (CALCDTINT-4)	Minimum Interval Date	01/01/1900

TABLE 4 - 12 DID THE VACCINE DOSE ADMINISTERED SATISFY THE DEFINED INTERVAL?

CONDITIONS	RULES				
	Yes	No	No	No	No
date administered < absolute minimum interval date?	Yes	No	No	No	No
Absolute minimum interval date ≤ date administered < minimum interval date?	No	Yes	Yes	Yes	No
Minimum interval date ≤ date administered?	No	No	No	No	Yes
Is this the first target dose?	-	No	No	Yes	-
Is the previous vaccine dose administered "not valid" due to age or interval requirements?	-	Yes	No	-	-
OUTCOMES	No. The vaccine dose did not satisfy	No. The vaccine dose did not satisfy	Yes. The vaccine dose administered	Yes. The vaccine dose administered	Yes. The vaccine dose

TABLE 4 - 15 DID THE VACCINE DOSE ADMINISTERED SATISFY THE DEFINED INTERVAL?

CONDITIONS	RULES	
	Yes	No
date administered < absolute minimum interval date?		
OUTCOMES	No. The vaccine dose did not satisfy the defined interval. Reason is "too soon."	Yes. The vaccine dose administered did satisfy the defined interval.

TABLE 4 - 16 EVALUATE INTERVAL BUSINESS RULES

Business Rule ID	Rule
EVALINT-1	The vaccine dose administered was administered at a valid interval if all defined intervals were satisfied.
EVALINT-2	The vaccine dose administered was not administered at a valid interval if any of the defined intervals were not satisfied.

4.7 EVALUATE FOR LIVE VIRUS CONFLICT

Evaluate live virus conflict validates the date administered of a live virus vaccine dose administered against previous live virus administered vaccines to ensure proper spacing between administrations. For some live virus vaccines and for inactivated vaccines, this condition does not exist. Therefore, if no live virus supporting data exists for the vaccine dose administered being evaluated, the vaccine dose administered is not in conflict with any other vaccine dose administered.

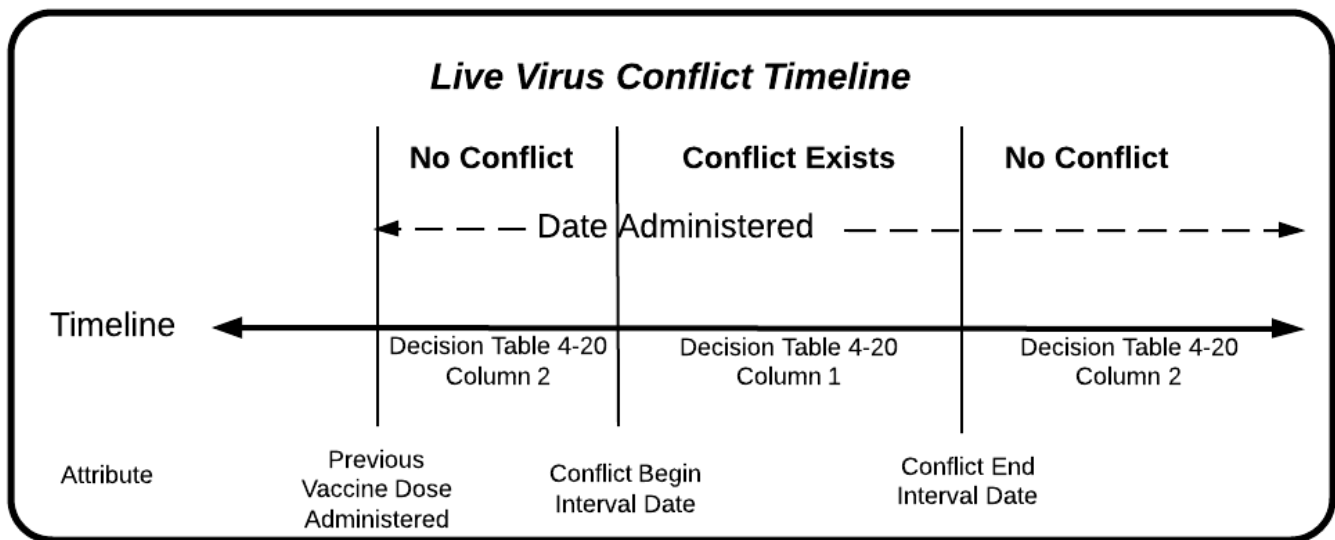


FIGURE 4 - 14 EVALUATE LIVE VIRUS CONFLICT TIMELINE

The following process model, attribute table, decision tables, and business rule table are used to evaluate for a live virus conflict.

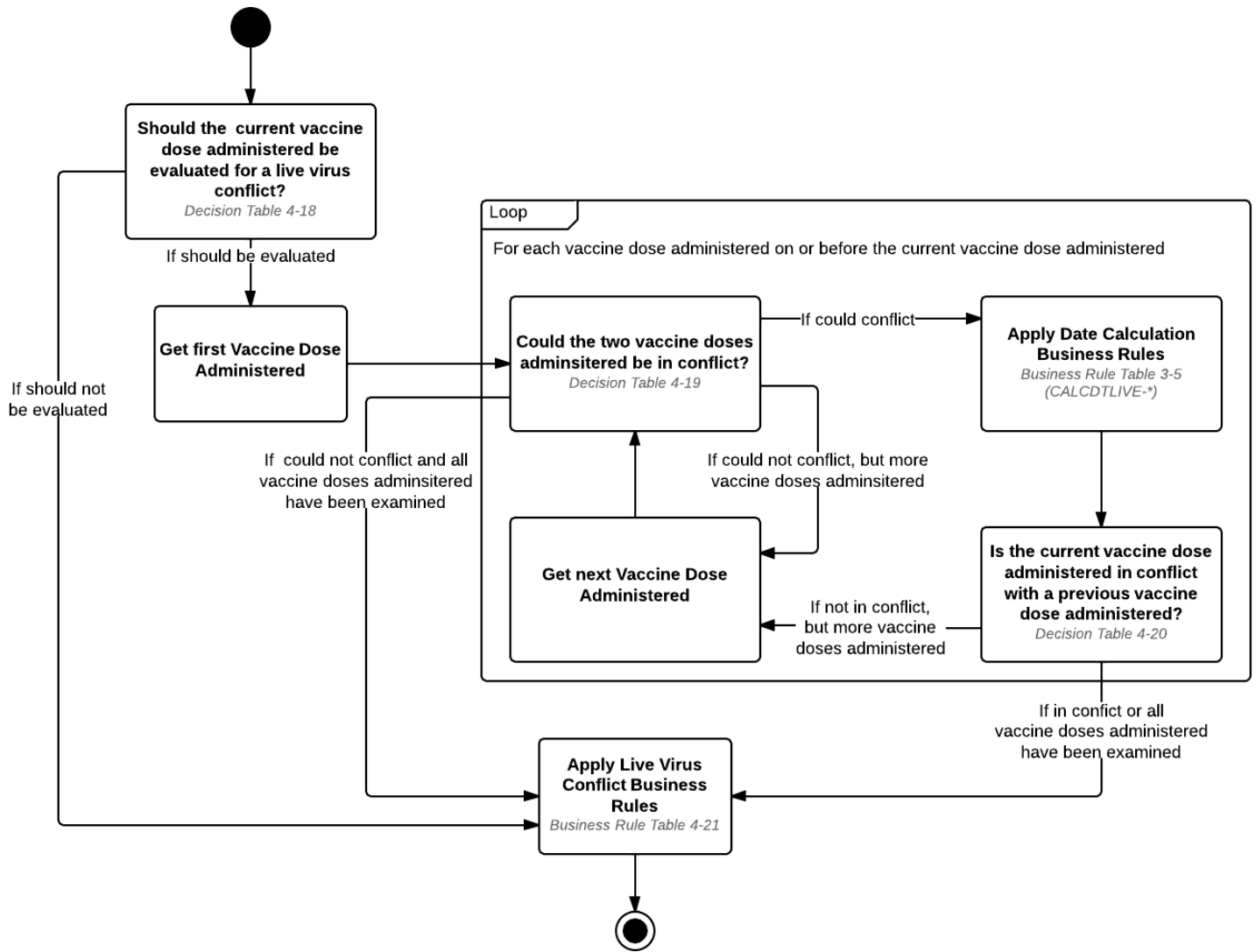


FIGURE 4 - 15 EVALUATE LIVE VIRUS CONFLICT PROCESS MODEL

TABLE 4 - 17 LIVE VIRUS CONFLICT ATTRIBUTES

Attribute Type	Attribute Name	Assumed Value if empty
Vaccine dose administered	Date Administered	-
Calculated date (CALCDTLIVE-1)	Conflict Begin Interval Date	-
Calculated date (CALCDTLIVE-2 & CALCDTLIVE-3)	Conflict End Interval Date	-
Supporting Data (Live Virus Conflict)	Current Vaccine Type	-
Supporting Data (Live Virus Conflict)	Previous Vaccine Type	-

TABLE 4 - 18 SHOULD THE CURRENT VACCINE DOSE ADMINISTERED BE EVALUATED FOR A LIVE VIRUS CONFLICT?

CONDITIONS	RULES
------------	-------

Is the current vaccine dose administered type one of the supporting data defined current vaccine types?	Yes	No	-
Is there at least one vaccine dose administered on or before the current vaccine dose administered?	Yes	-	No
OUTCOMES	Yes. The vaccine dose administered should be evaluated for a Live Virus Conflict	No. The vaccine dose administered should not be evaluated for a conflict.	No. The vaccine dose administered should not be evaluated for a conflict.

TABLE 4 - 19 COULD THE TWO VACCINE DOSES ADMINISTERED BE IN CONFLICT?

CONDITIONS	RULES	
Is the previous vaccine dose administered type the same as one of the live virus conflict previous vaccine types when the current vaccine dose administered type is same as the live virus conflict current vaccine type?	Yes	No
OUTCOMES	Yes. The two doses must be checked for a live virus conflict	No. The two doses need not be checked for a live virus conflict

TABLE 4 - 20 IS THE CURRENT VACCINE DOSE ADMINISTERED IN CONFLICT WITH A PREVIOUS VACCINE DOSE ADMINISTERED?

CONDITIONS	RULES	
Conflict begin interval date \leq current date administered < conflict end interval date?	Yes	No
OUTCOMES	Yes. The vaccine dose administered is in conflict with a previous vaccine dose administered.	No. The vaccine dose administered is not in conflict with a previous vaccine dose administered.

TABLE 4 - 21 LIVE VIRUS CONFLICT BUSINESS RULES

Business Rule ID	Rule
CONFLICT-1	The current vaccine dose administered has a conflict if it is in conflict with any previous vaccine doses administered.
CONFLICT-2	The current vaccine dose administered does not have a conflict if it is not in conflict with any previous vaccine dose administered.

4.8 EVALUATE FOR PREFERABLE VACCINE

Evaluate for preferable vaccine validates the vaccine of a vaccine dose administered against the list of preferable vaccines.

Figures 4-16 depicts a patient who received a preferable vaccine while figure 4-17 depicts a patient who did not receive a preferable vaccine.

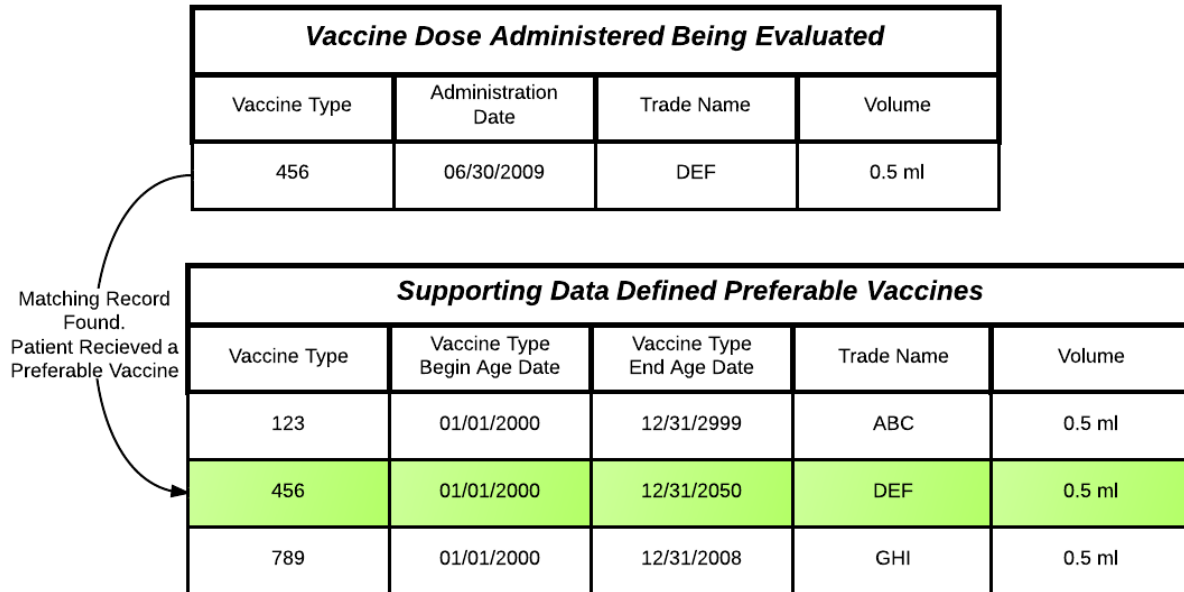


FIGURE 4 - 16 PATIENT RECEIVED A PREFERABLE VACCINE

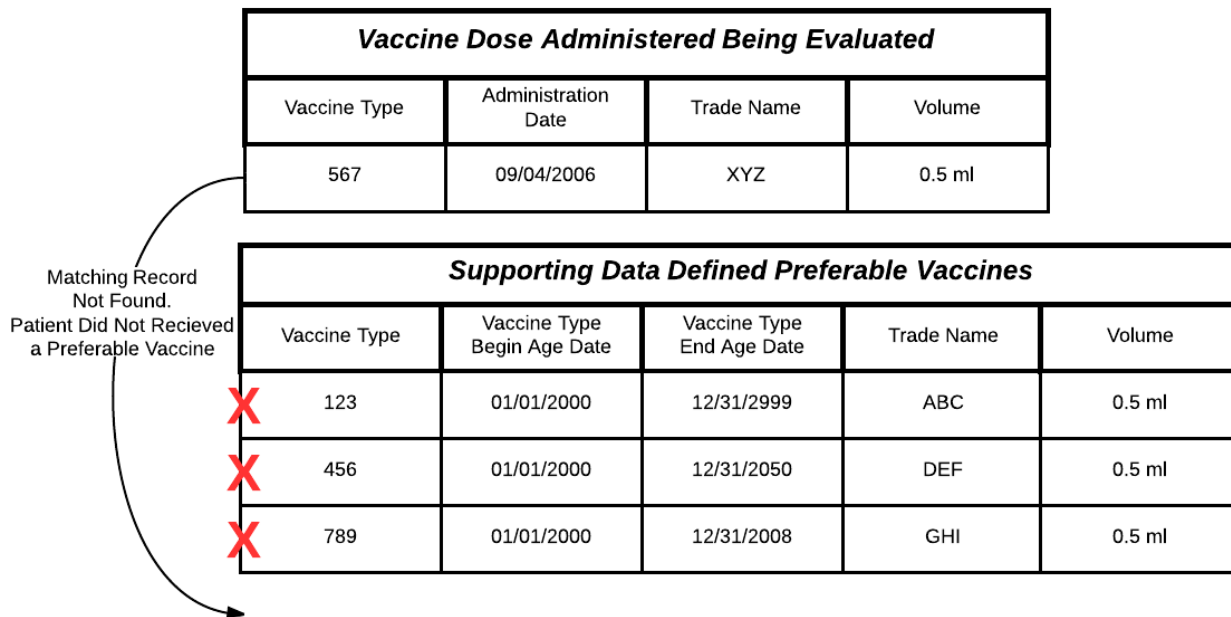


FIGURE 4 - 17 PATIENT DID NOT RECEIVE A PREFERABLE VACCINE

It should be noted that volume is sparsely populated and tracked differently in most systems. Therefore, volume will not be used to evaluate the validity of a vaccine dose administered. However, it will be provided as an evaluation reason that less than sufficient volume was administered.

The following process model, attribute table, decision table, and business rule table are used to evaluate for a preferable vaccine.

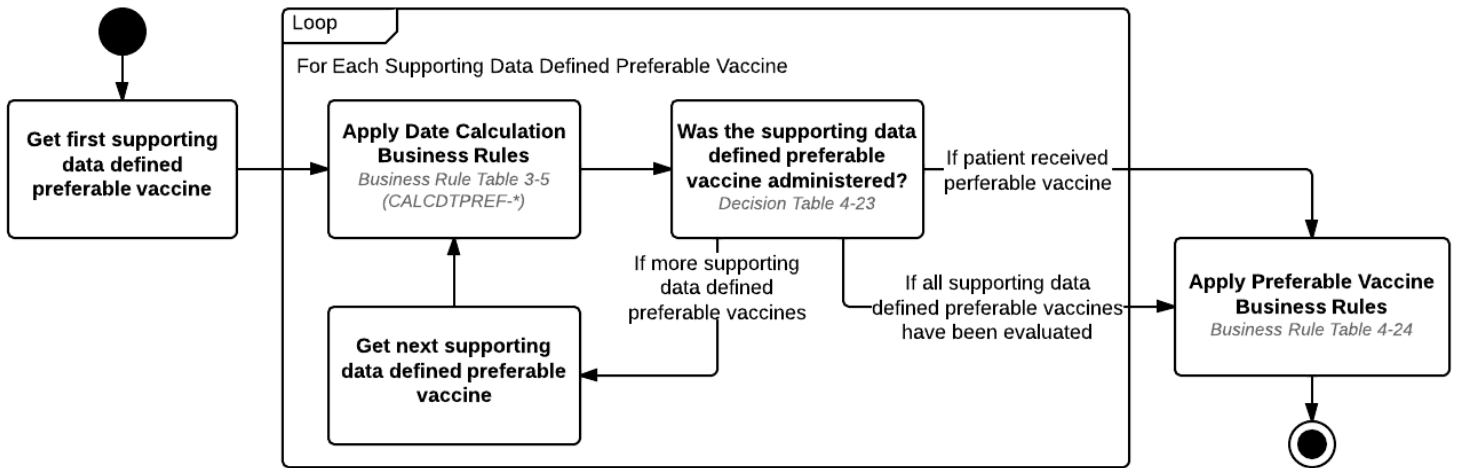


FIGURE 4 - 18 EVALUATE FOR A PREFERABLE VACCINE PROCESS MODEL

TABLE 4 - 22 PREFERABLE VACCINE ADMINISTERED ATTRIBUTES

Attribute Type	Attribute Name	Assumed Value if empty
Vaccine dose administered	Date Administered	-
Vaccine dose administered	Trade Name	-
Calculated date (CALCDTPREF-1)	Vaccine Type Begin Age Date	01/01/1900
Calculated date (CALCDTPREF-2)	Vaccine Type End Age Date	12/31/2999
Supporting data (Preferable Vaccine)	Preferable Vaccine Trade Name	Equal to the vaccine dose administered trade name.
Supporting data (Preferable Vaccine)	Preferable Vaccine Volume	Equal to the vaccine dose administered trade name.

TABLE 4 - 23 WAS THE SUPPORTING DATA DEFINED PREFERABLE VACCINE ADMINISTERED?

CONDITIONS	RULES				
	Yes	Yes	No	Yes	Yes
Is the vaccine dose administered type the same as the preferable vaccine type?	Yes	Yes	No	Yes	Yes
Preferable vaccine type begin age date ≤ date administered < preferable vaccine type end age date?	Yes	Yes	-	No	Yes

Is the vaccine dose administered trade name the same as the preferable vaccine trade name?	Yes	Yes	-	-	No
Vaccine dose administered volume >= preferable vaccine volume?	Yes	No	-	-	-
OUTCOMES	Yes. A preferable vaccine was administered.	Yes. A preferable vaccine was administered. Reason is volume administered is "less than recommended volume."	No. This supporting data defined preferable vaccine was not administered.	No. This supporting data defined preferable vaccine was administered out of the preferred age range.	No. This supporting data defined preferable vaccine was of the wrong trade name.

TABLE 4 - 24 PREFERABLE VACCINE BUSINESS RULES

Business Rule ID	Rule
PREFERABLE-1	The patient has received a preferable vaccine if one of the supporting data defined preferable vaccines were administered.
PREFERABLE-2	The patient has not received a preferable vaccine if none of the supporting data defined preferable vaccines were administered.

4.9 EVALUATE FOR ALLOWABLE VACCINE

Evaluate for allowable vaccine validates the vaccine of a vaccine dose administered against the list of allowable vaccines.

Figures 4-19 depicts a patient who received an allowable vaccine while figure 4-20 depicts a patient who did not receive an allowable vaccine.

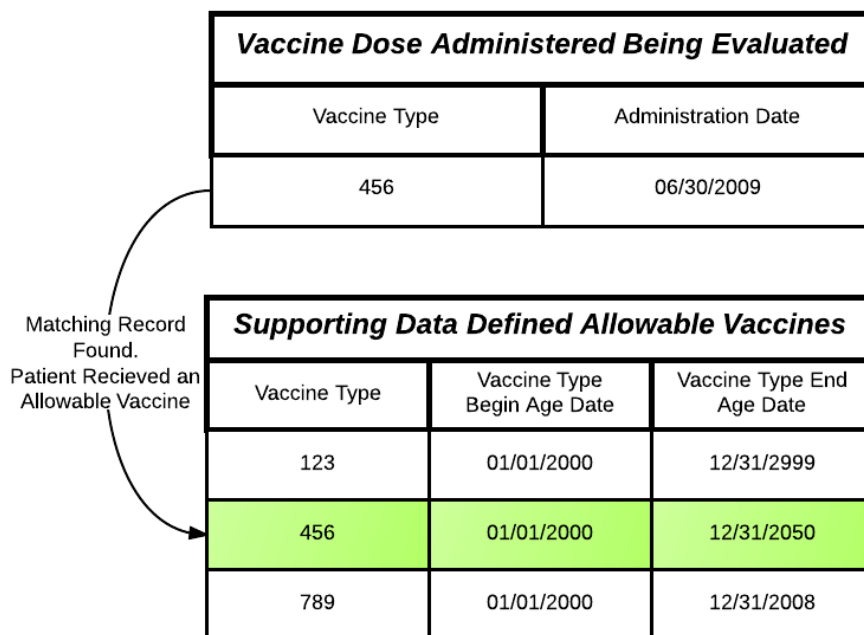


FIGURE 4 - 19 PATIENT RECEIVED AN ALLOWABLE VACCINE

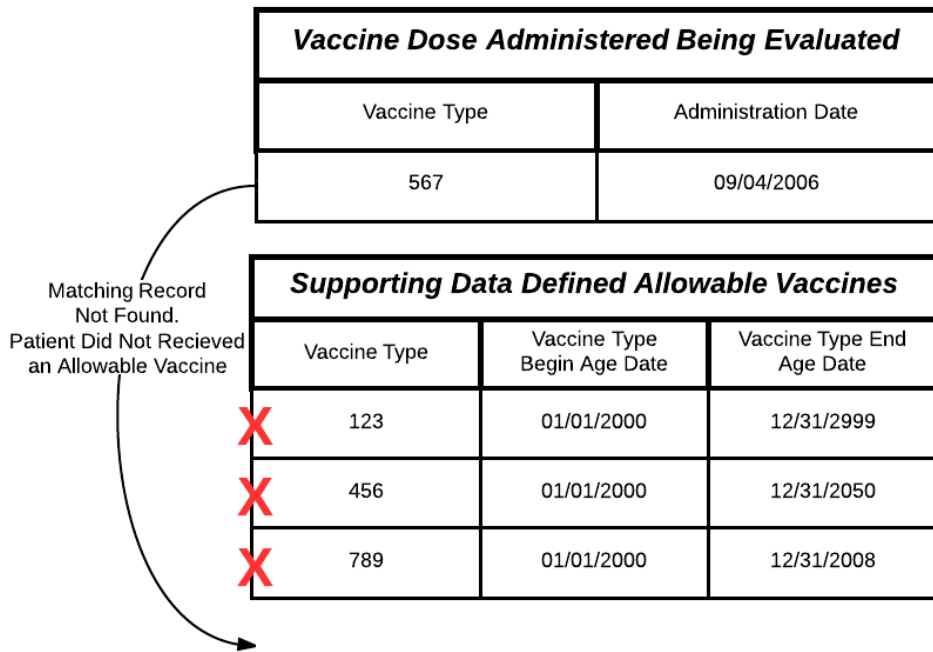


FIGURE 4 - 20 PATIENT DID NOT RECEIVE AN ALLOWABLE VACCINE

The following process model, attribute table, decision table, and business rule table are used to evaluate for an allowable vaccine.

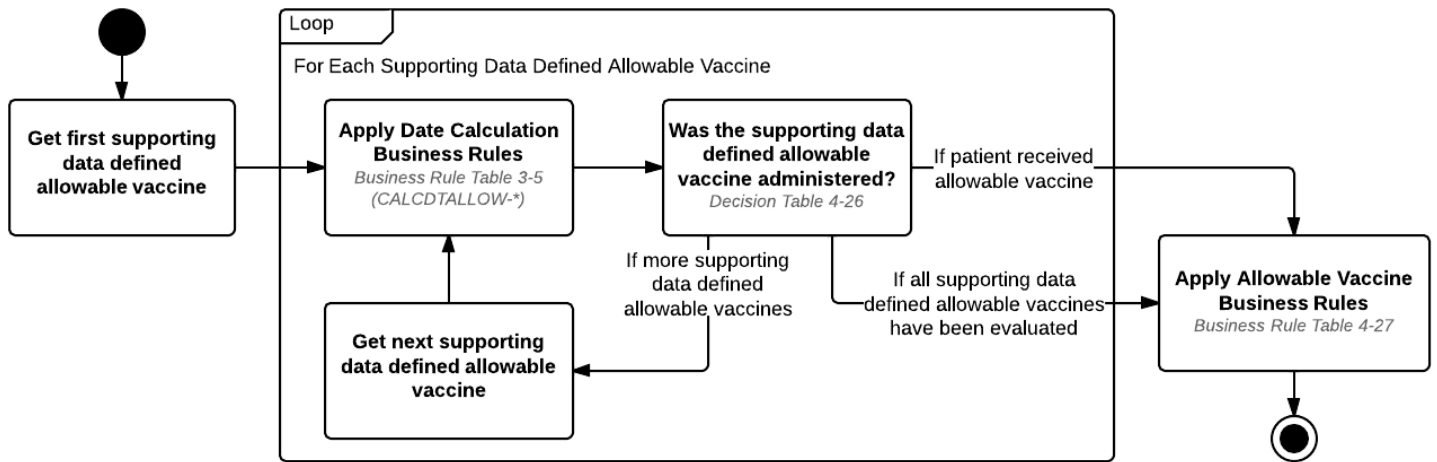


FIGURE 4 - 21 EVALUATE FOR AN ALLOWABLE VACCINE PROCESS MODEL

TABLE 4 - 25 ALLOWABLE VACCINE ATTRIBUTES

Attribute Type	Attribute Name	Assumed Value if empty
Vaccine dose administered	Date Administered	-

Attribute Type	Attribute Name	Assumed Value if empty
Vaccine dose administered	Vaccine Type	-
Supporting data (Allowable Vaccine)	Allowable Vaccine Type	-
Calculated date (CALCDTALLOW-1)	Allowable Vaccine Type Begin Age Date	01/01/1900
Calculated date (CALCDTALLOW-2)	Allowable Vaccine Type End Age Date	12/31/2999

TABLE 4 - 26 WAS THE SUPPORTING DATA DEFINED ALLOWABLE VACCINE ADMINISTERED?

CONDITIONS	RULES		
	Is the vaccine type of the vaccine dose administered type the same as the allowable vaccine type?	Yes	No
Allowable vaccine type begin age date ≤ date administered < allowable vaccine type end age date?	Yes	-	No
OUTCOMES	Yes. An allowable vaccine was administered.	No. This supporting data defined allowable vaccine was not administered.	No. This supporting data defined allowable vaccine was administered out of the allowable age range.

TABLE 4 - 27 ALLOWABLE VACCINE BUSINESS RULES

Business Rule ID	Rule
ALLOWABLE-1	The patient has received an allowable vaccine if one of the supporting data defined allowable vaccines were administered.
ALLOWABLE-2	The patient has not received an allowable vaccine if none of the supporting data defined allowable vaccines were administered.

4.10 EVALUATE GENDER

Evaluate gender validates the *patient* gender against the *required* gender. In cases where a target dose does not specify gender attributes, the gender is valid.

The following process model, attribute table, and decision table are used to evaluate the gender.

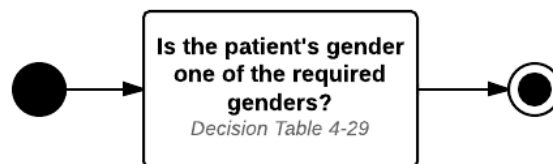


FIGURE 4 - 22 GENDER PROCESS MODEL

TABLE 4 - 28 GENDER ATTRIBUTES

Attribute Type	Attribute Name	Assumed Value if empty
Patient	Gender	Unknown
Supporting data (Gender)	Required Gender	-

TABLE 4 - 29 IS THE PATIENT'S GENDER ONE OF THE REQUIRED GENDERS?

CONDITIONS	RULES	
Is patient's gender the same as one of the required genders?	Yes	No
OUTCOMES	Yes. Patient's gender is one of the required genders.	No. Patient's gender is not one of the required genders. Reason is "incorrect gender."

4.11 SATISFY TARGET DOSE

Satisfy target dose uses the results from the previous evaluation sections as conditions to determine if the target dose is satisfied.

The following processing model and decision table are used to determine if the target dose was satisfied.

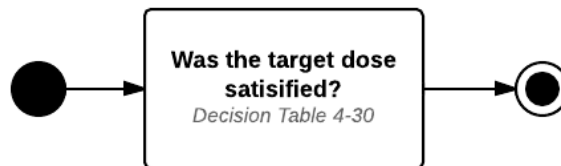


FIGURE 4 - 23 SATISFY TARGET DOSE PROCESS MODEL

TABLE 4 - 30 WAS THE TARGET DOSE SATISFIED?

CONDITIONS	RULES						
Was the vaccine dose administered at a valid age?	Yes	Extraneous	No	-	-	-	-
Was the vaccine dose administered at a valid or allowable interval?	Yes	-	-	No	-	-	-
Was the live virus vaccine dose administered in	No	-	-	-	Yes	-	-

conflict with any previous live virus vaccine doses administered?							
Did the patient receive a preferable or allowable vaccine?	Yes	-	-	-	-	No	-
Is the patient's gender one of the required genders?	Yes	-	-	-	-	-	No
OUTCOMES	Yes. The target dose status is "satisfied." Evaluation status is "valid" with possible evaluation reason(s).	No. The target dose status is "not satisfied." Evaluation status is "extraneous" with possible evaluation reason(s).	No. The target dose status is "not satisfied." Evaluation status is "not valid" with evaluation reason(s).	No. The target dose status is "not satisfied." Evaluation status is "not valid" with evaluation reason(s).	No. The target dose status is "not satisfied." Evaluation status is "not satisfied." Evaluation status is "not valid" with evaluation reason(s).	No. The target dose status is "not satisfied." Evaluation status is "not valid" with evaluation reason(s).	No. The target dose status is "not satisfied." Evaluation status is "not valid" with evaluation reason(s).

5 FORECAST DATES AND REASONS

A CDS engine uses a patient's medical and vaccine history to forecast immunization due dates. This chapter identifies specific business rules that are used by a CDS engine to forecast the next target dose. The major steps involved in this process are listed in the table below.

TABLE 5 - 1 FORECAST DATES AND REASONS PROCESS STEPS

Section	Activity	Goal
5.1	Skip Target Dose	The goal of this step is to determine if the target dose can be skipped.
5.2	Substitute Target Dose	The goal of this step is to determine if target doses can be substituted.
5.3	Conditionally Needed Target Dose	The goal of this step is to determine if the target dose is conditionally needed.
5.4	Determine Forecast Need	The goal of this step is to determine if the patient should receive another dose.
5.5	Generate Forecast Dates	The goal of this step is to generate forecast dates for the next target dose.

The figure below provides an illustration of the *forecast dates and reasons* process.

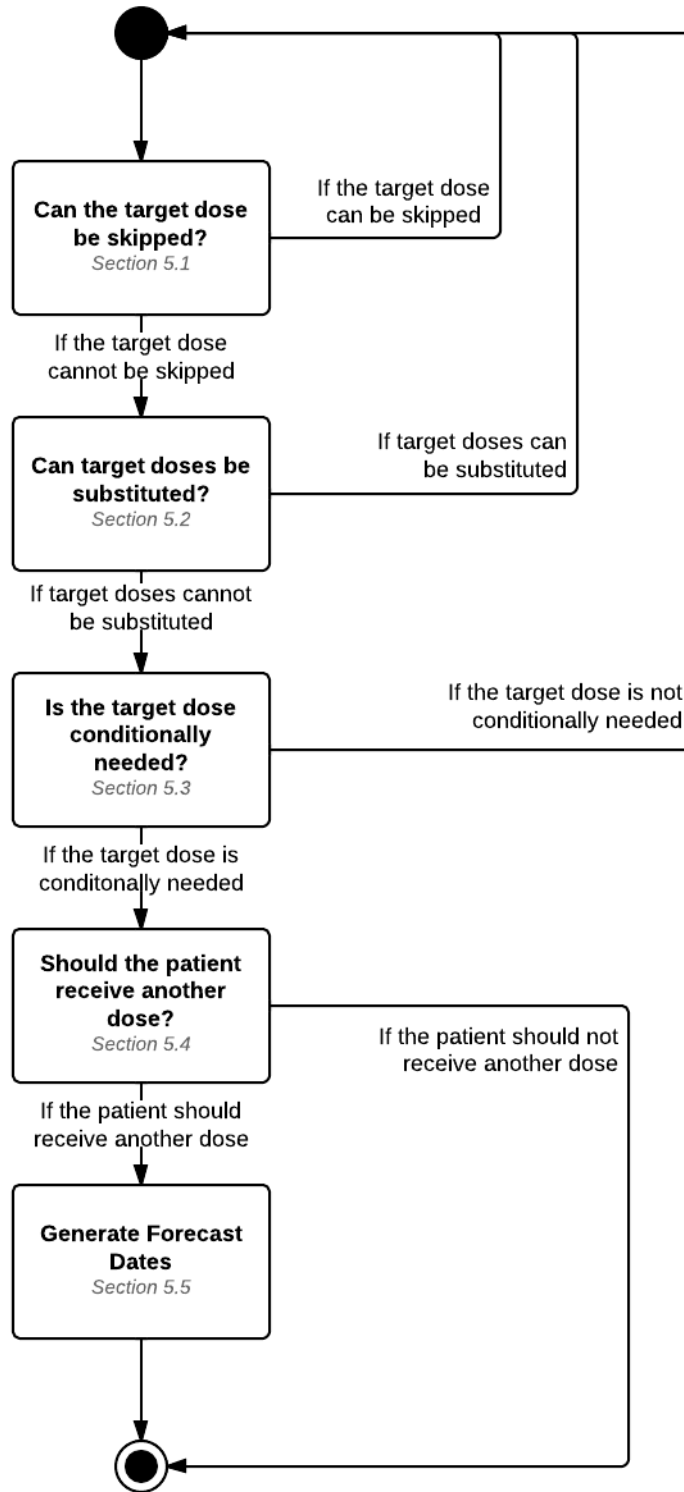


FIGURE 5 - 1 FORECAST DATES AND REASON PROCESS MODEL

5.1 SKIP TARGET DOSE

Skip target dose addresses the certain times when a target dose can be skipped. In most settings this occurs when a patient is behind schedule and the total number of doses needed to reach presumed immunity can be reduced. In cases where a target dose does not specify skip target dose attributes, the target dose cannot be skipped. Figure 5-2 provides an illustration of the skip target dose timeline used during forecasting.

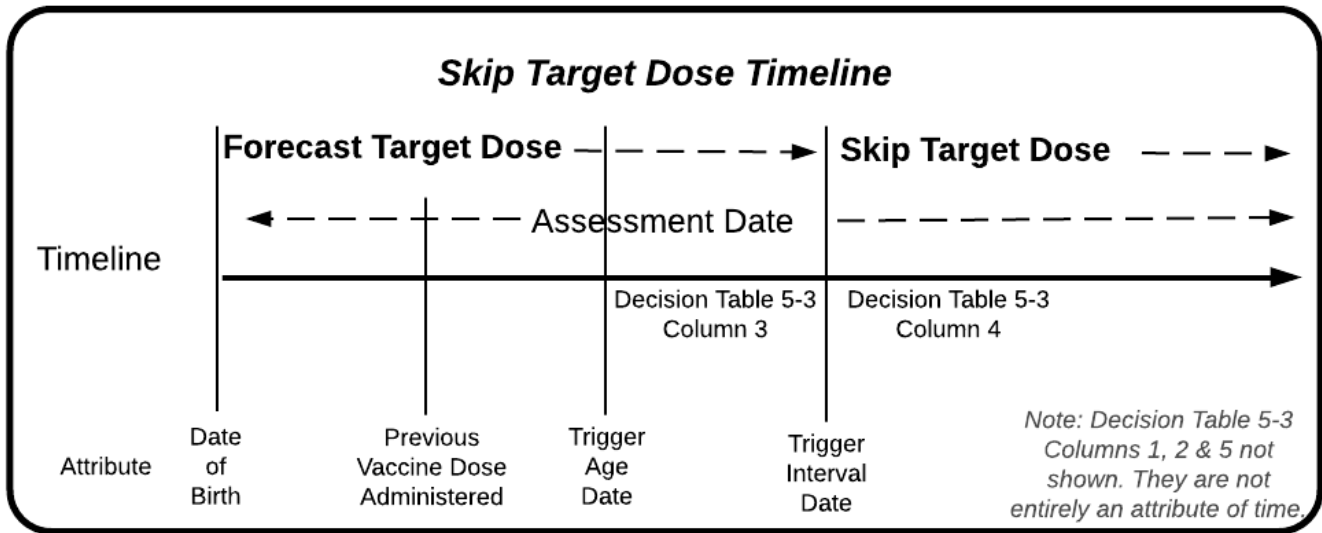


FIGURE 5 - 2 FORECAST SKIP TARGET DOSE TIMELINE

The following process model, attribute table, and decision table are used to determine if the target dose can be skipped.

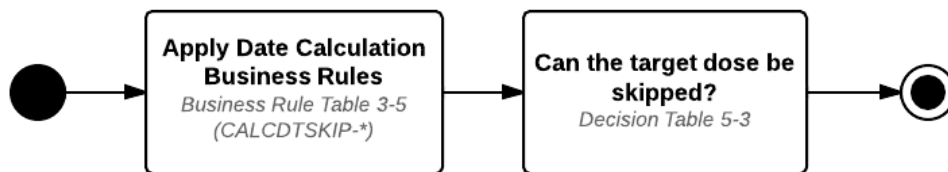


FIGURE 5 - 3 SKIP TARGET DOSE PROCESS MODEL

TABLE 5 - 2 SKIP TARGET DOSE ATTRIBUTES

Attribute Type	Attribute Name	Assumed Value if empty
Patient	Date of Birth	-
Processing data	Assessment Date	current date
Calculated date (CALCDTSKIP-1)	Trigger Age Date	12/31/2999
Calculated date (CALCDTSKIP-2)	Trigger Interval Date	01/01/1900
Supporting Data (Skip Dose)	Trigger Target Dose	-
Supporting Data (Skip Dose)	Trigger Doses Administered	999

TABLE 5 - 3 CAN THE TARGET DOSE BE SKIPPED?

CONDITIONS	RULES				
Assessment date < trigger age date?	Yes	Yes	No	No	-

Assessment date < trigger interval date?	-	-	Yes	No	-
Is the trigger target dose status "satisfied"?	No	-	No	-	Yes
Vaccine Doses Administered >= trigger doses administered	No	Yes	-	-	-
OUTCOMES	No. The target dose cannot be skipped.	Yes. The target dose can be skipped. The target dose status is "skipped".	No. The target dose cannot be skipped.	Yes. The target dose can be skipped. The target dose status is "skipped."	Yes. This target dose can be skipped. The target dose status is "skipped."

5.2 SUBSTITUTE TARGET DOSE

Substitute target dose is similar to skip target dose as a means to adjust where the patient is in the patient series. The goal of substitute target dose is to look at previously satisfied target doses within the patient series to determine how many future target doses – if any – can be substituted and not recommended.

When a target dose does specify substitute target dose attributes, it will contain a set of substitution possibilities. If a substitution is found, the remaining substitute target dose sets can be ignored. If all of the sets are examined and no substitution is found, then the current target dose should be used for forecasting. This can be seen with the process model shown in figure 5-4.

In cases where a target dose does not specify substitute target dose attributes, the target dose cannot be substituted.

Relationship to ACIP Recommendations:

- At present, substitute target dose is only used for children who have partially completed their DTaP series and have turned seven years old. Once the child is seven years old, the number of Tdap/Td doses recommended is based on the number of DTaP vaccine doses administered the child received prior to age seven. See MMWR 2006; 55 (No. RR-3); Appendix D.

The following process model, attribute table, decision table, and business rule table are used to determine if target dose (s) can be substituted.

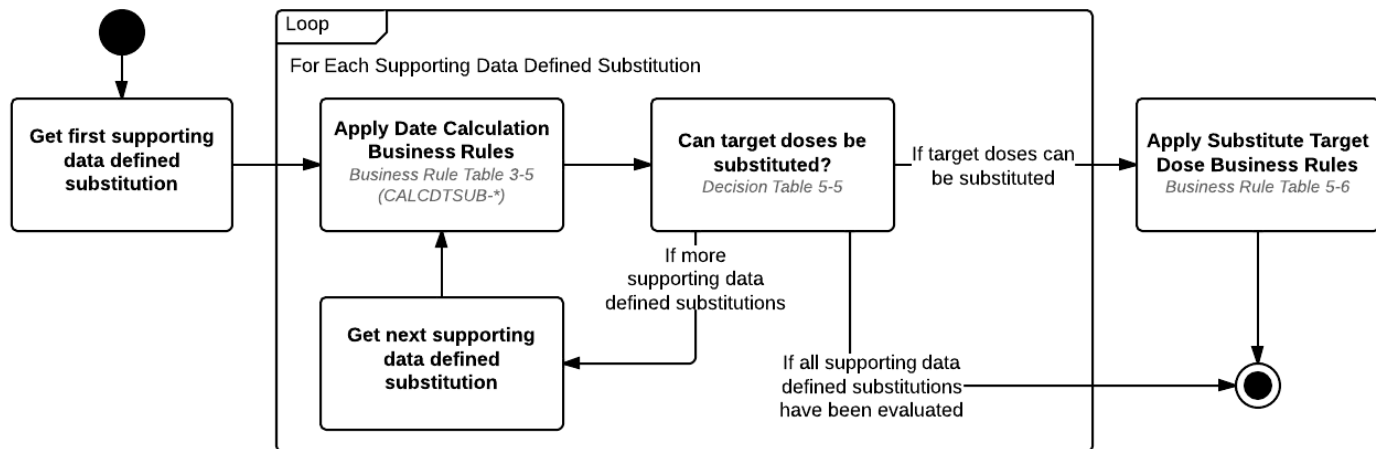


FIGURE 5 - 4 SUBSTITUTE TARGET DOSE PROCESS MODEL

TABLE 5 - 4 SUBSTITUTE TARGET DOSE ATTRIBUTES

Attribute Type	Attribute Name	Assumed Value if empty
Vaccine dose administered	Date Administered	-
Patient series	Target Doses with a Target Dose Status "Satisfied"	-
Calculated date (CALCDTSUB-1)	First Dose Begin Age Date	-
Calculated date (CALCDTSUB-2)	First Dose End Age Date	-
Supporting data (Substitute Dose)	Total Count of Valid Doses	-
Supporting data (Substitute Dose)	Number of Target Doses to Substitute	-

TABLE 5 - 5 CAN TARGET DOSES BE SUBSTITUTED?

CONDITIONS	RULES		
First dose begin age date ≤ date administered of first satisfied target dose in patient series < first dose end age date?	Yes	Yes	No
Total count of satisfied target dose in patient series = substitute dose total count of valid doses?	Yes	No	-
OUTCOMES	Yes. Target doses can be substituted.	No. Target doses cannot be substituted.	No. Target doses cannot be substituted.

TABLE 5 - 6 SUBSTITUTE TARGET DOSE BUSINESS RULES

Business Rule ID	Rule
SUBDOSE-1	The new target dose must be calculated as the current target dose plus the number of target doses to substitute.
SUBDOSE-2	Each target dose which is substituted must have the target dose status "substituted".

5.3 CONDITIONALLY NEEDED TARGET DOSE

The goal of Conditionally Needed Target Dose is to assess the patient's previous vaccine dose administrations to determine if a patient is in need of an additional dose. In cases where a target dose does not specify conditional need attributes, the target dose is needed.

Relationship to ACIP Recommendations:

- At present, ACIP has two places where doses are conditionally needed based on previous vaccine dose administrations. Seasonal flu recommendations in children conditionally require a second dose if the child has not received adequate vaccine dose administrations of flu in previous seasons. The second place ACIP has a conditional recommendation is in PCV where a patient did not receive a dose of PCV13.

The following process model, attribute table, decision tables, and business rule table are used to determine if the target dose is conditionally needed.

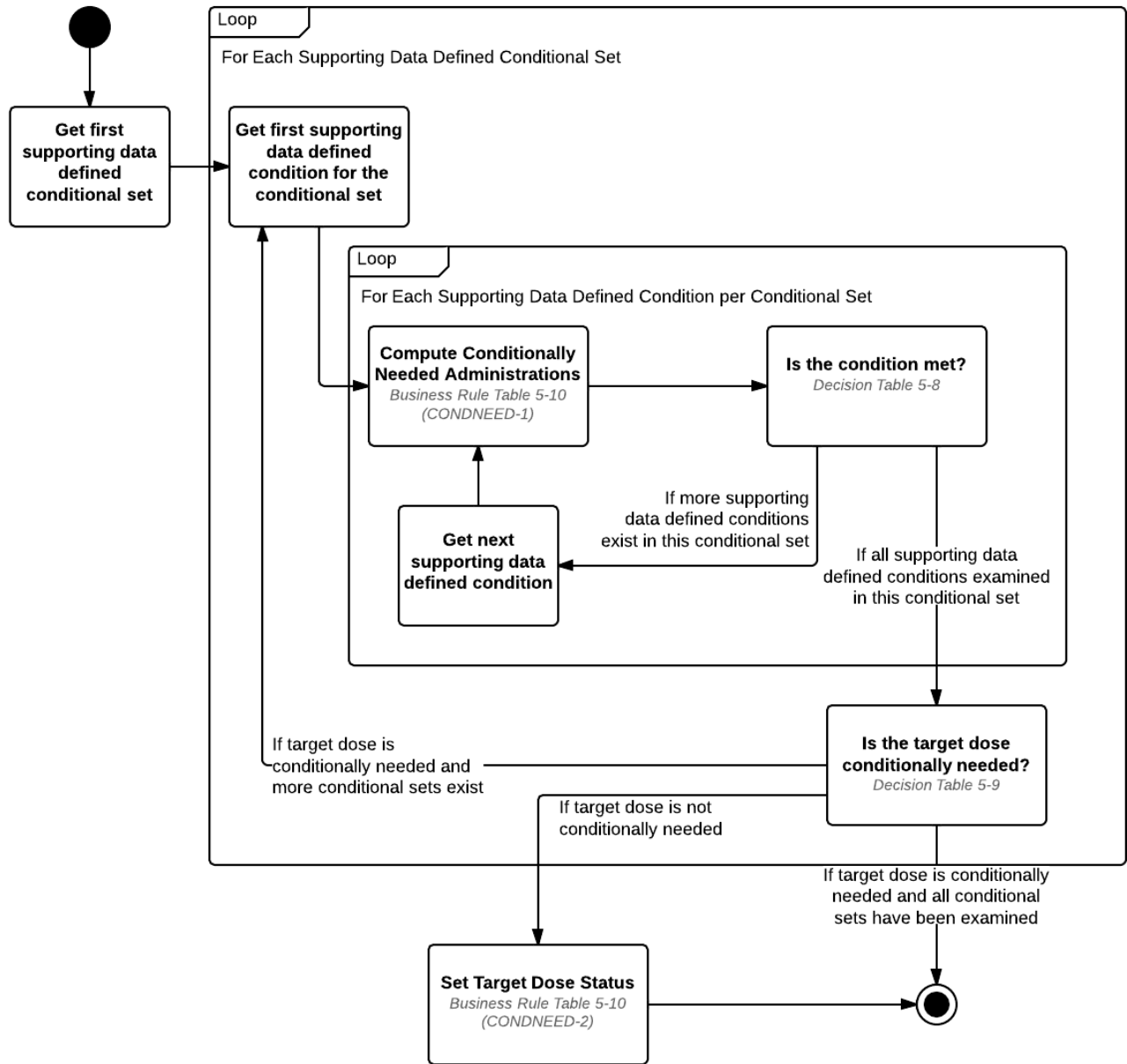


FIGURE 5 - 5 CONDITIONALLY NEEDED TARGET DOSE PROCESS MODEL

TABLE 5 - 7 CONDITIONALLY NEEDED ATTRIBUTES

Attribute Type	Attribute Name	Assumed Value if empty
Immunization history	Vaccine Dose(s) Administered	-
Patient series	Target Dose	-
Supporting data (Conditional Need)	Start Date	-
Supporting data (Conditional Need)	End Date	-
Supporting data (Conditional Need)	Dose Count	-
Supporting data (Conditional Need)	CVX List	-

TABLE 5 - 8 IS THE CONDITION MET?

CONDITIONS	RULES	
Conditionally needed administrations < dose count?	Yes	No
OUTCOMES	Yes. The defined condition is met.	No. The defined condition is not met.

TABLE 5 - 9 IS THE TARGET DOSE CONDITIONALLY NEEDED?

CONDITIONS	RULES	
Are all supporting data defined conditions for the conditional set met?	Yes	No
OUTCOMES	Yes. The target dose is conditionally needed.	No. The target dose is not conditionally needed.

TABLE 5 - 10 CONDITIONALLY NEEDED BUSINESS RULES

Business Rule ID	Term	Business Rule
CONDNEED-1	Conditionally Needed Administrations	Conditionally Needed Administrations must be computed as the count of vaccine doses administered of conditional need vaccine type which were administered on or after the conditional need start date and before the conditional need end date.
CONDNEED-2	-	The target dose status must be “unnecessary” if the target dose is not conditionally needed.

5.4 DETERMINE FORECAST NEED

Before a CDS engine can produce forecast dates and reasons, the CDS engine must determine if there is a need to forecast dates. This involves reviewing patient data, antigen administered records, and patient series.

The following process model, attribute table, and decision table are used to determine the need to generate forecast dates.

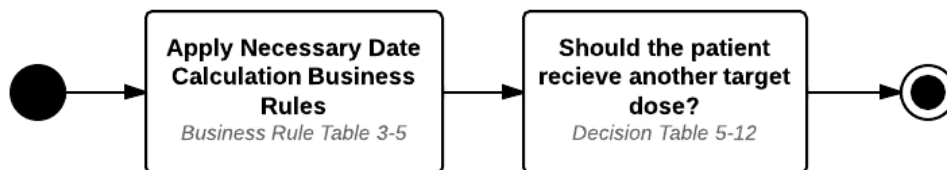


FIGURE 5 - 6 DETERMINE FORECAST NEED PROCESS MODEL

TABLE 5 - 11 DETERMINE FORECAST NEED ATTRIBUTES

Attribute Type	Attribute Name	Assumed Value if empty
Immunization history	Vaccine Dose(s) Administered	-
Immunization history	Adverse Events	-
Medical history	Relevant Medical Observation	-
Patient series	Target Dose (s)	-
Calculated date (CALCDTAGE-1)	Maximum Age Date	12/31/2999
Supporting data (Seasonal Recommendation)	End Date	12/31/2999
Data entry	Assessment Date	current date
Supporting Data	Contraindication	-
Supporting Data	Immunity	-

TABLE 5 - 12 SHOULD THE PATIENT RECEIVE ANOTHER TARGET DOSE?

CONDITIONS	RULES					
	Yes	No	-	-	-	-
Does the patient have at least one target dose with target dose status "not satisfied"?	Yes	No	-	-	-	-
Is patient without a contraindication for this patient series?	Yes	-	No	-	-	-
Is patient without immunity to this patient series?	Yes	-	-	No	-	-
Assessment date < the maximum age date?	Yes	-	-	-	No	-
Assessment date < seasonal recommendation end date?	Yes	-	-	-	-	No
OUTCOMES	Yes. The patient should receive another dose. Patient Series Status is "Not Complete"	No. The patient should not receive another dose. Patient Series Status is "Complete" Forecast reason is "patient series is complete."	No. The patient should not receive another dose. Patient Series Status is "Contraindicated" Forecast reason is "patient has a contraindication."	No. The patient should not receive another dose. Patient Series Status is "Immune" Forecast reason is "patient has evidence of immunity."	No. The patient should not receive another dose. Patient Series Status is "Aged Out" Forecast reason is "patient has exceeded the maximum age."	No. The patient should not receive another dose. Patient Series Status is "Not Complete" Forecast reason is "past seasonal recommendation end date."

5.5 GENERATE FORECAST DATES

Generate forecast dates determines the forecast dates for the next target dose. The forecast dates are generated based on the patient’s immunization history. If the patient has not adhered to the preferred

schedule, then the forecast dates are adjusted to provide the best dates for the series. Figure 5-7 below provides an illustration of how forecast dates appear on the timeline.

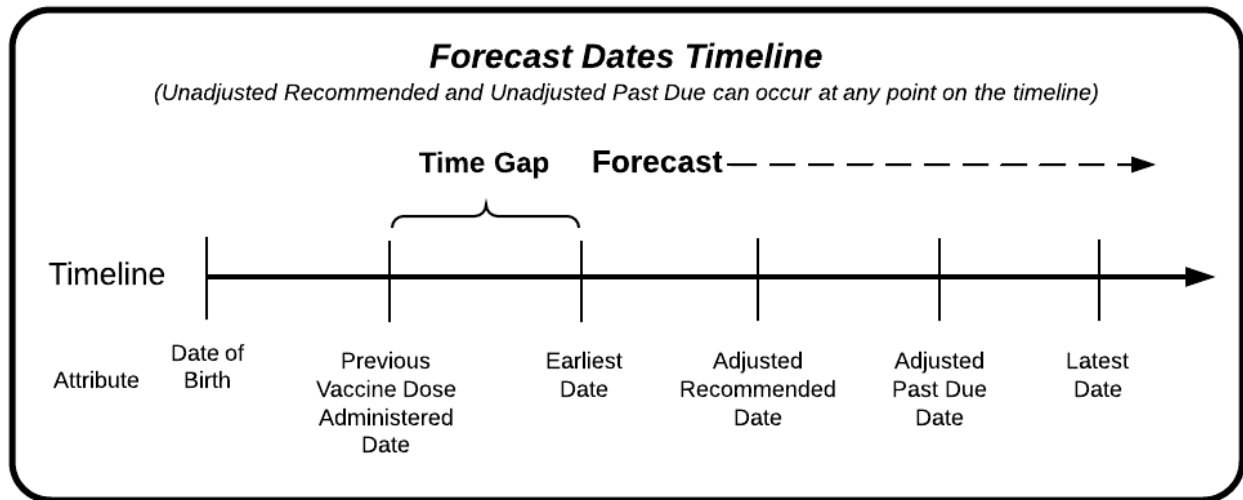


FIGURE 5 - 7 FORECAST DATES TIMELINE

The following process model, attribute table, and business rule table are used to generate forecast dates. If an attribute value is empty, then the date calculations will remain empty. No assumptions will be made for the attribute.

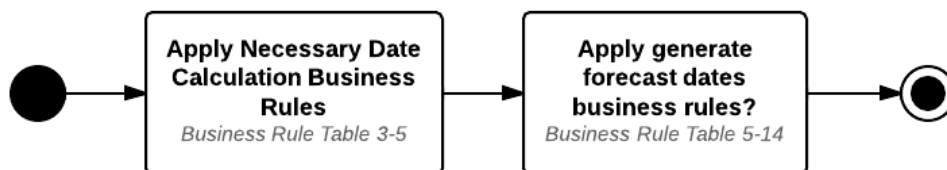


FIGURE 5 - 8 GENERATE FORECAST DATES PROCESS MODEL

TABLE 5 - 13 GENERATE FORECAST DATES ATTRIBUTES

Attribute Type	Attribute Name	Assumed Value if empty
Calculated date (CALCDTAGE-4)	Minimum Age Date	-
Calculated date (CALCDTAGE-3)	Earliest Recommended Age Date	-
Calculated date (CALCDTAGE-2)	Latest Recommended Age Date	-
Calculated date (CALCDTAGE-1)	Maximum Age Date	-
Calculated date (CALCDTINT-4)	Minimum Interval Date(s)	-
Calculated date (CALCDTINT-5)	Earliest Recommended Interval Date(s)	-
Calculated date (CALCDTINT-6)	Latest Recommended Interval Date(s)	-
Calculated date (CALCDTLIVE-4)	Latest Conflict End Interval Date	-
Supporting data (Seasonal Recommendation)	Start Date	01/01/1900

TABLE 5 - 14 GENERATE FORECAST DATE BUSINESS RULES

Business Rule ID	Term	Business Rule
FORECASTDT-1	Earliest Date	Earliest date must be the latest of the following dates: a. Minimum age date b. Latest minimum interval date c. Latest conflict end interval date d. Seasonal recommendation start date
FORECASTDT-2	Unadjusted Recommended Date	Unadjusted recommended date must be the earliest recommended age date. a. The earliest of all earliest recommended interval dates must be used if earliest recommended age date is not present. b. Earliest date must be used if earliest recommended age date and earliest recommended interval date are not present.
FORECASTDT-3	Unadjusted Past Due Date	Unadjusted past due date must be the latest recommended age date – 1 day. a. The latest of all latest recommended interval dates – 1 day must be used if latest recommended age date is not present. b. Unadjusted past due date must remain empty if latest recommended age date and latest recommended interval date are not present.
FORECASTDT-4	Latest Date	The latest date must be the maximum age date – 1 day if present.
FORECASTDT-5	Adjusted Recommended Date	Adjusted recommended date must be the later of the earliest date and unadjusted recommended date.
FORECASTDT-6	Adjusted Past Due Date	Adjusted past due date must be the later of the earliest date and the unadjusted past due date. a. Adjusted past due date must remain empty if the unadjusted past due date is not present.

6 SELECT BEST PATIENT SERIES

Select best patient series involves reviewing all potential patient series which might satisfy the goals of an antigen and determining the one series which best fits the patient based on several important factors. The four steps of this process are listed in table 6-1.

TABLE 6 - 1 SELECT BEST PATIENT SERIES PROCESS STEPS

Section	Activity	Goal
6.2	Identify Superior Patient Series	The goal of this step is to determine if one patient series is superior to the other entire patient series.
6.3	Classify Patient Series	The goal of this step is to classify where the patient is in the overall path to immunity and pass those candidate patient series on to the next step. Only those patient series with the most likely chance to be considered the best are retained for further consideration.
6.4-6.6	Scoring Patient Series	The goal of this step is to apply the proper scoring business rules based on results of the second step. The scoring business rules will determine the best patient series. Scoring business rules are specific to where the patient is in the overall path to immunity. The complete patient series scoring business rules look at factors important when candidate patient series are complete. Similarly in-process patient series scoring business rules and no valid doses scoring business rules look at factors important to their respective situation. For any given antigen, only one set of these scoring business rules will be applied to each candidate patient series.
6.7	Select Best Patient Series	The goal of this step is to evaluate the scored candidate patient series and determine which of the candidate patient series is the one and only <i>best patient series</i> .

The process model below illustrates the major steps involved in selecting the best patient series.

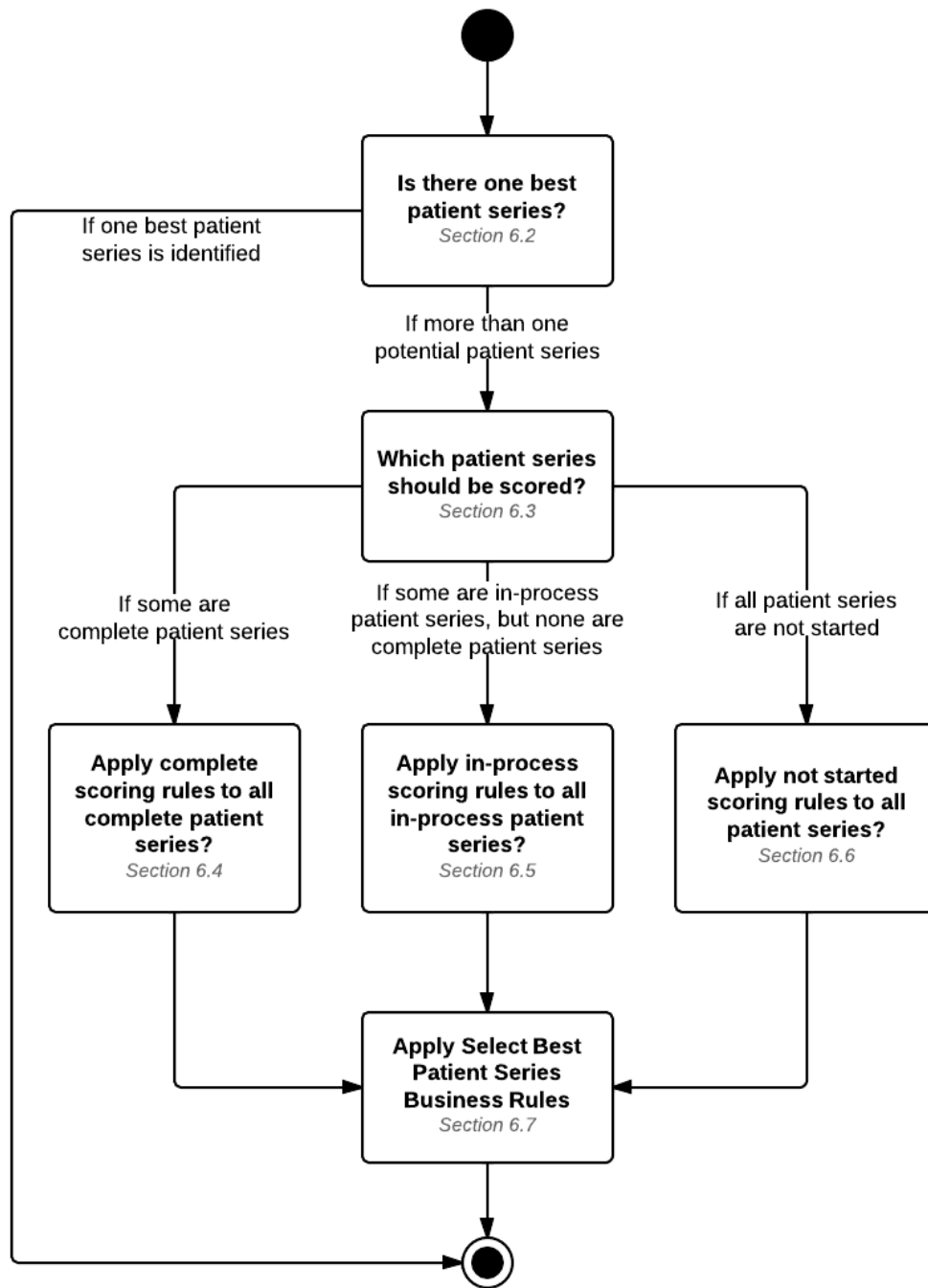


FIGURE 6 - 1 SELECT BEST PATIENT SERIES PROCESS MODEL

6.1 SELECT BEST PATIENT SERIES VOCABULARY

The following table provides the vocabulary used during the process of selecting the best patient series.

TABLE 6 - 2 SELECT BEST PATIENT SERIES VOCABULARY

Term	Definition or Definitional Rule
Actual Finish Date	The <i>actual finish date</i> of a complete patient series must be the latest date administered of a vaccine dose administered with an evaluation status “valid.”

Term	Definition or Definitional Rule
All Valid Doses	A patient series has <i>all valid doses</i> if all doses administered have an evaluation status "valid."
Completable	A patient series must be considered <i>completable</i> if the forecast finish date is less than the maximum age date of the last target dose.
Candidate Patient Series	A <i>candidate patient series</i> is a patient series considered for scoring.
Closest to Completion	A patient series must be the <i>closest to completion</i> if the number of target doses with target dose status 'Not Satisfied' is less than the number of target doses with target dose status 'Not Satisfied' in all other candidate patient series.
Complete Patient Series	A patient series must be considered a <i>complete patient series</i> if the patient series status is "complete."
Default Patient Series	A patient series must be the default patient series if the supporting data "default series" attribute is specified as "Yes."
Earliest Completing	A complete patient series must be considered to be the <i>earliest completing</i> if the actual finish date is before the actual finish date for all other candidate patient series.
Exceeded Maximum Age	A patient series must be considered to have <i>exceeded maximum age</i> if the patient series status is "Aged Out."
Exceeded Maximum Age to Start	A patient series must be considered to have <i>exceeded maximum age to start</i> if the date administered of the first valid vaccine dose administered is on or after the maximum age to start date.
Finish Earliest	A patient series can <i>finish earliest</i> if the patient series is completable and the forecast finish date is earlier than the forecast finish date in all other completable candidate patient series.
Forecast Finish Date	The <i>forecast finish date</i> for a patient series must be the forecast earliest date plus the latest minimum interval from the remaining target dose(s).
Gender-Specific Patient Series	A patient series must be a <i>gender-specific patient series</i> if a required gender for dose 1 of the supporting data is given.
In-Process Patient Series	An <i>in-process patient series</i> must be a patient series with at least one target dose status "satisfied" and the patient series status "not complete."
Maximum Age to Start Date	The <i>maximum age to start date</i> must be calculated as the patient's date of birth plus the Select Best Patient Series Maximum Age To Start.
Most Valid Doses	A patient series has the <i>most valid doses</i> if the number of valid doses is greater than the number of valid doses in all other candidate patient series.
Number of Doses Remaining	The <i>number of doses remaining</i> must be the count of target doses with the status "unsatisfied."
Number of Valid Doses	The <i>number of valid doses</i> must be the count of Target Doses with the status "satisfied."
Preferred Candidate Patient Series	The <i>preferred candidate patient series</i> is identified in the supporting data table by a number value, with "1" being the most preferred, "2" being the next in line and so on.
Product Patient Series	A <i>product patient series</i> must have the supporting data "patient path" attribute specified as "Yes."
Start Date	The <i>start date</i> for a patient series with 0 valid doses must be the forecast earliest date.
Start Earliest	A patient series can <i>start earliest</i> if the start date is before the start date for all other candidate patient series with a start date.

6.2 ONE BEST PATIENT SERIES

One best patient series examines all of the patient series for a given antigen to determine if one of the patient series is superior to all other patient series and can be considered the best patient series.

TABLE 6 - 3 IS THERE ONE BEST PATIENT SERIES?

CONDITIONS	RULES
------------	-------

Antigen contains only 1 patient series?	Yes	No	No	No	No
Patient has only 1 complete patient series?	-	Yes	No	No	No
Patient has only 1 in-process patient series and no complete patient series?	-	-	Yes	No	No
Patient has all Patient Series with 0 valid doses and 1 patient series is identified as the default patient series?	-	-	-	Yes	No
OUTCOMES	Yes. The lone patient series is the best patient series.	Yes. The lone complete patient series is the best patient series.	Yes. The lone in-process patient series is the best patient series.	Yes. The default patient series is the best patient series.	No. More than one patient series has potential. All patient series are examined to see which should be scored and selected as the best patient series.

6.3 CLASSIFY PATIENT SERIES

Classify patient series is an attempt to reduce the total number of patient series to only those which have a chance to be selected as the best patient series.

TABLE 6 - 4 WHICH PATIENT SERIES SHOULD BE SCORED?

CONDITIONS	RULES		
2 or more are complete patient series?	Yes	No	No
2 or more are in-process patient series and 0 are complete patient series?	-	Yes	No
All Patient Series have 0 valid doses?	-	No	Yes
OUTCOMES	Apply complete patient series scoring business rules to all complete patient series. In-process patient series and patient series with 0 valid doses are not scored and dropped from consideration.	Apply in-process patient series scoring business rules to all in-process patient series. Patient Series with 0 valid doses are not scored and dropped from consideration.	Apply no valid doses scoring business rules to all patient series.

6.4 COMPLETE PATIENT SERIES

Complete patient series provides the decision table for determining the number of points to assign to a complete patient series based on a specified condition.

TABLE 6 - 5 HOW MANY POINTS ARE AWARDED TO A COMPLETE PATIENT SERIES WHEN 2 OR MORE CANDIDATE PATIENT SERIES ARE COMPLETE?

Conditions	If this condition is true for the candidate patient series	If this condition is true for two or more candidate patient series	If this condition is not true for the candidate patient series
A candidate patient series has the most valid doses.	+1	0	-1
A candidate patient series is a product patient series and has all valid doses.	+1	n/a	-1
A candidate patient series is the earliest completing.	+2	+1	-1

6.5 IN-PROCESS PATIENT SERIES

In-process patient series provides the decision table for determining the number of points to assign to an in-process patient series based on a specified condition.

TABLE 6 - 6 HOW MANY POINTS ARE AWARDED TO AN IN-PROCESS PATIENT SERIES WHEN 2 OR MORE CANDIDATE PATIENT SERIES ARE IN-PROCESS AND NO CANDIDATE PATIENT SERIES ARE COMPLETE?

Conditions	If this condition is true for the candidate patient series	If this condition is true for two or more candidate patient series	If this condition is not true for the candidate patient series
A candidate patient series is a product patient series and has all valid doses.	+2	n/a	-2
A candidate patient series is completable.	+3	n/a	-3
A candidate patient series has the most valid doses.	+2	0	-2
A candidate patient series is closest to completion.	+2	0	-2
A candidate patient series can finish earliest.	+1	0	-1
A candidate patient series exceeded maximum age to start.	-10	n/a	0

6.6 NO VALID DOSES

This section provides the decision table for determining the number of points to assign to a candidate patient series when there are no valid doses.

TABLE 6 - 7 HOW MANY POINTS ARE AWARDED TO A CANDIDATE PATIENT SERIES WHEN ALL PATIENT SERIES HAVE 0 VALID DOSES AND NO DEFAULT PATIENT SERIES IS SPECIFIED?

Conditions	If this condition is true for the candidate patient series	If this condition is true for two or more candidate patient series	If this condition is not true for the candidate patient series
A candidate patient series can start earliest.	+1	0	-1
A candidate patient series is completable.	+1	n/a	-1
A candidate patient series is a gender patient series and the patient's gender matches a required gender specified on the first target dose.	+1	n/a	0
A candidate patient series is a product patient series.	-1	n/a	+1
A candidate patient series has exceeded maximum age.	-1	n/a	+1

6.7 SELECT BEST CANDIDATE PATIENT SERIES

Select best candidate patient series provides the business rules to be applied to the scored candidate patient series which will result in the best patient series for the patient.

TABLE 6 - 8 SELECT BEST PATIENT SERIES BUSINESS RULES

Business Rule ID	Rule
SELECTBEST-1	Candidate patient series score must be the sum of all points awarded to the candidate patient series.
SELECTBEST-2	The best patient series must be the candidate patient series with the highest candidate patient series score.
SELECTBEST-3	The best patient series must be the preferred candidate patient series if the candidate patient series score is tied.

7 IDENTIFY AND EVALUATE VACCINE GROUP

Identify and evaluate vaccine group combines patient series into a vaccine group-based forecast to provide a common and consistent view for a forecast. In the evaluation, forecasting, and select best patient series chapters, all logic was specified for antigens. At this point it is important to define how those antigen-based evaluation and forecasting results can be merged into vaccine group forecasts.

Relationship to ACIP Recommendations

At present, MMR and DTaP/Tdap/Td vaccine groups are comprised of multiple antigens. MMR contains the antigens Measles, Mumps, and Rubella. DTaP/Tdap/Td contains the antigens Diphtheria, Tetanus, and Pertussis.

TABLE 7 - 1 IDENTIFY AND EVALUATE VACCINE GROUP PROCESS STEPS

Section	Activity	Goal
7.1	Classify vaccine group	The goal of this activity is to classify the type of vaccine group and the patient's current path towards immunity. This step will determine which set of vaccine group forecasting rules to apply.
7.2	Single antigen vaccine group	The goal of this activity is to apply the business rules necessary to generate a vaccine group based forecast in situations where only a single antigen is associated with a vaccine group
7.3	Multiple antigen vaccine group	The goal of this activity is to apply the decision logic and business rules necessary to generate a vaccine group based forecast in situations where more than one antigen is associated with a vaccine group.

The following figure provides an illustration of the identifying and evaluating vaccine group process.

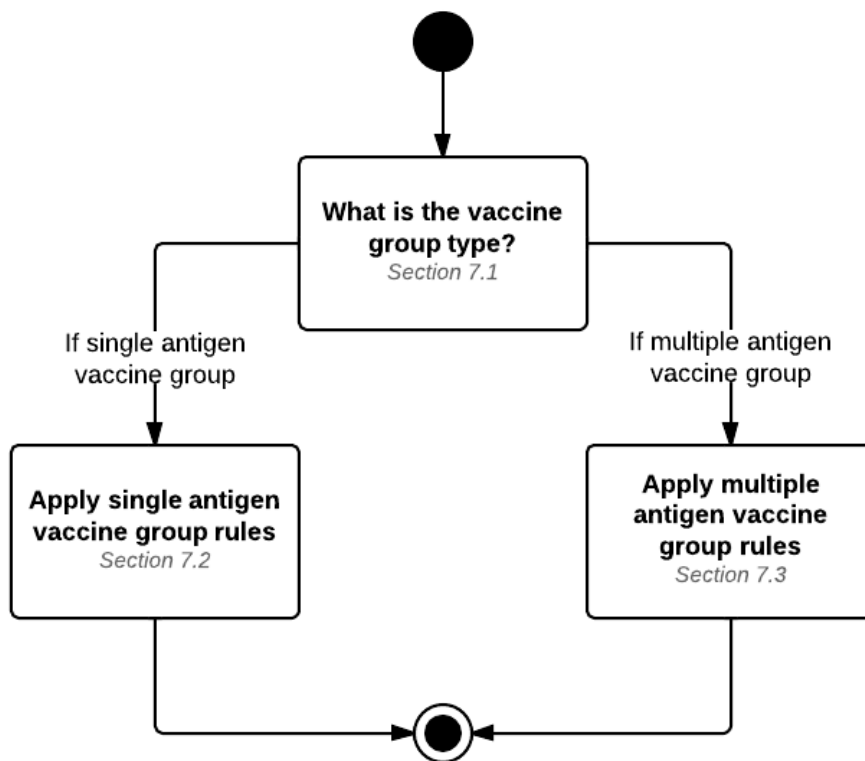


FIGURE 7 - 1 IDENTIFY AND EVALUATE VACCINE GROUP PROCESS MODEL

7.1 CLASSIFY VACCINE GROUP

Classify vaccine group provides initial questioning to determine which vaccine group forecast rules to apply.

TABLE 7 - 2 WHAT IS THE VACCINE GROUP TYPE?

CONDITION	RULES	
	Yes	No
Does the vaccine group contain exactly 1 antigen?		
OUTCOME	Vaccine group is a single antigen vaccine group.	Vaccine group is a multiple antigen vaccine group.

7.2 SINGLE ANTIGEN VACCINE GROUP

The forecasting rules which need to be applied to a single antigen vaccine group are listed in the table below.

TABLE 7 - 3 SINGLE ANTIGEN VACCINE GROUP RULES

Business Rule ID	Rule
------------------	------

Business Rule ID	Rule
SINGLEANTVG-1	The vaccine group status must be the best patient series status.
SINGLEANTVG-2	The vaccine group forecast earliest date must be the best patient series forecast earliest date.
SINGLEANTVG-3	The vaccine group forecast adjusted recommended date must be the best patient series forecast adjusted recommended date.
SINGLEANTVG-4	The vaccine group forecast adjusted past due date must be the best patient series forecast adjusted past due date.
SINGLEANTVG-5	The vaccine group forecast latest date must be the best patient series forecast latest date.
SINGLEANTVG-6	The vaccine group forecast unadjusted recommended date must be the best patient series forecast unadjusted recommended date.
SINGLEANTVG-7	The vaccine group forecast unadjusted past due date must be the best patient series forecast unadjusted past due date.
SINGLEANTVG-8	The vaccine group forecast reason must be set the best patient series forecast reason.
SINGLEANTVG-9	The vaccine group forecast antigens needed must be the best patient series target disease.

7.3 MULTIPLE ANTIGEN VACCINE GROUP

The forecasting decisions and rules which need to be applied to a multiple antigen vaccine group are listed below.

TABLE 7 - 4 WHAT IS THE VACCINE GROUP STATUS?

CONDITION	RULES					
	1	2	3	4	5	6
Is at least 1 best patient series status "Not Completed"?	No	No	-	Yes	Yes	-
Are all best patient series status "Immune"?	No	No	No	No	No	Yes
Is at least 1 best patient series status "Contraindicated"?	No	Yes	Yes	No	-	-
Is the recommendation for the vaccine group to administer full vaccine group?	-	No	Yes	Yes	No	-
OUTCOME	Complete	Contraindicated	Contraindicated	Not Complete	Not Complete	Immune

TABLE 7 - 5 MULTIPLE ANTIGEN VACCINE GROUP RULES

Business Rule ID	Rule
MULTIANTVG-1	The vaccine group forecast earliest date must be the latest of all best patient series forecast earliest dates.
MULTIANTVG-2	The vaccine group forecast adjusted recommended date must be the latest of the following dates: <ul style="list-style-type: none">• the earliest of all best patient series forecast adjusted recommended dates• the vaccine group forecast earliest date
MULTIANTVG-3	The vaccine group forecast adjusted past due date must be the latest of the following dates: <ul style="list-style-type: none">• the earliest of all best patient series forecast adjusted past due dates• the vaccine group forecast earliest date
MULTIANTVG-4	The vaccine group forecast latest date must be the earliest of all best patient series forecast latest dates.
MULTIANTVG-5	The vaccine group forecast unadjusted recommended date must be the earliest of all best patient series forecast unadjusted recommended dates.
MULTIANTVG-6	The vaccine group forecast unadjusted past due date must be the earliest of all best patient series forecast unadjusted past due dates.
MULTIANTVG-7	The vaccine group forecast reason must be the collection of best patient series forecast reasons.
MULTIANTVG-8	The vaccine group forecast antigens needed must be the collection of best patient series target disease with patient series status "not complete."

8 PROCESSING MODEL

At a very simple level, the major logical steps involved in the immunization evaluation and forecasting engine can be described in two parts. The first part, illustrated by the top row in figure 8-1, is very mechanical in nature and focuses on gathering and prepping all of the required data. The second part illustrated by the bottom row in Figure 8-1 uses the data gathered in the top row to generate the evaluation and forecast via three major steps.

The following table lists the major steps of the processing model.

TABLE 8 - 1 LOGIC SPECIFICATION PROCESSING STEPS

Section	Activity	Goal
8.1	Gather Necessary Data	The goal of this step is to gather all pertinent information which will be used in subsequent steps in the process.
8.2	Create All Patient Series	The goal of this step is to instantiate all antigen series defined through supporting data into patient series for this patient.
8.3	Prepare Immunization History	The goal of this step is to break apart vaccine doses administered into their antigen parts.
8.4	For Each Patient Series, Perform Evaluation and Forecast	The goal of this step is to evaluate (chapter 4) each antigen administered and create a forecast for each patient series (chapter 5).
8.5	For Each Antigen, Select the Best Patient Series	The goal of this step is to select the best patient series (chapter 6) for the patient based on their evaluated history and forecast.
8.6	For Each Vaccine Group, Identify and Evaluate the Vaccine Group	The goal of this step is to merge together antigen-based forecasts into a vaccine group forecast (chapter 7).

Figure 8-1 provides the high-level process of the major steps.

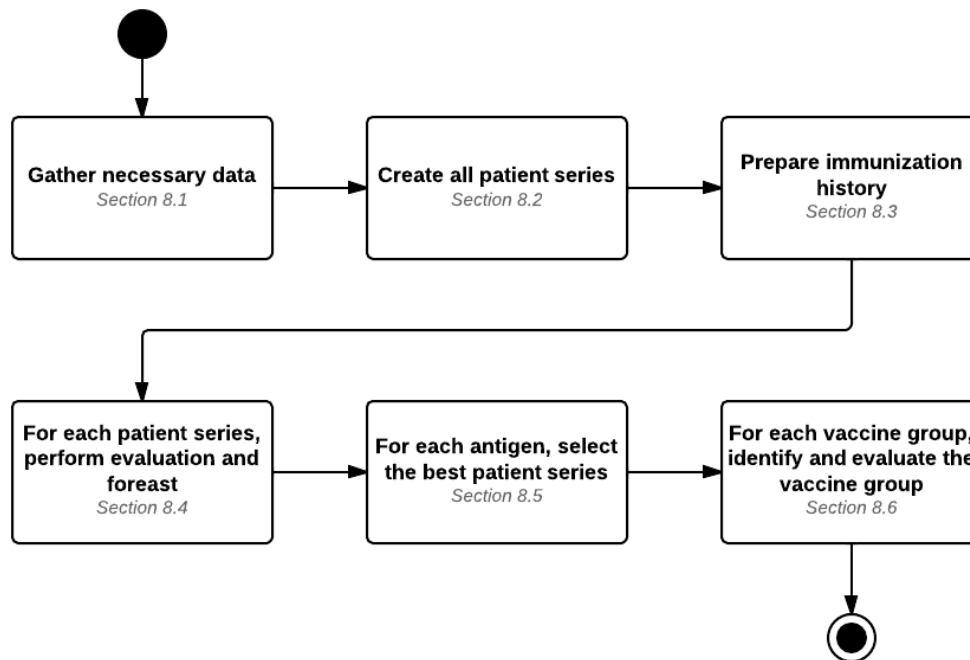


FIGURE 8 - 1 LOGIC SPECIFICATION PROCESSING MODEL

8.1 GATHER NECESSARY DATA

Gathering all of the necessary data is a generic step which could technically be performed in several different ways. While this step is important, it is outside of the purview of this document and is only noted as a generic step in the process.

The required data fall into two categories (1) Patient-related data and (2) Evaluation and forecasting data. The lists below provide class level data needed. Further details on these classes can be found in Appendix A.

Patient-related data needed:

- Patient
- Vaccine Dose Administered
- Vaccine
- Immunization History
- Adverse Event
- Relevant Medical History

Evaluation and forecasting data needed:

- Schedule
- Antigen Series
- Series Dose
- Vaccine Group
- Antigen
- Vaccine

Finally, the term “gather” is not meant to imply a fetch, get, or retrieve operation to accumulate this data. Depending upon the implementation, some of this data may be passed by an external entity; other data may already be known; and still other data may arrive at different points in the process on an as needed basis. It is an acknowledgement of the minimal data needed in the evaluation and forecasting processes.

8.2 CREATE PATIENT SERIES

An antigen series is one way to reach perceived immunity against a disease. An antigen series can be thought of as a “path to immunity” and is described in relative terms. In many cases, a single antigen may have more than one successful path to immunity and as such may have more than one antigen series. Antigen series are defined through supporting data spreadsheets defined in chapter 3.

Similar to gathering necessary data (section 8.1), *create patient series* will likely vary from system to system based on design details and technologies used. The important aspect of this step is to instantiate each antigen series as a patient series. Patient series and target dose are discussed in detail in chapter 3.

At the end of this step, each antigen series for the patient is turned into a patient series for the patient.

8.3 ORGANIZE IMMUNIZATION HISTORY

The third step in the process is to look at the patient's immunization history and prepare those records for evaluation and forecasting by breaking them into their antigen parts. This allows the evaluation and forecasting engine to be as granular and specific as possible for both evaluation and forecasting purposes. Later in the process (section 8.6), these antigens are assembled into commonly known vaccine groups (vaccine families) for vaccine group forecasts.

To provide some immunization specifics to this step, the following tables are provided as a high-level example of the work *organize immunization history* performs.

TABLE 8 - 2 PRIOR TO ORGANIZE IMMUNIZATION HISTORY EXAMPLE

Product (CVX/MVX) – Description	Date
Engerix B-Peds (08/SKB) – HepB	01/01/2011
Pediarix (110/SKB) – DTaP-HepB-IPV	03/01/2011
Hibtiter (47/WAL) – Hib	03/01/2011
Prevnar 13 (133/WAL) – PCV13	03/01/2011
Pediarix (110/SKB) – DTaP-HepB-IPV	06/01/2011
Hibtiter (47/WAL) – Hib	06/01/2011
Prevnar 13 (133/WAL) – PCV13	06/01/2011
ProQuad (94/MSD) – MMRV	01/01/2012

TABLE 8 - 3 AFTER ORGANIZE IMMUNIZATION HISTORY EXAMPLE

*Sorted by antigen and then by date

Product (CVX/MVX) – Description	Date	Antigen*
Pediarix (110/SKB) – DTaP-HepB-IPV	03/01/2011	Diphtheria
Pediarix (110/SKB) – DTaP-HepB-IPV	06/01/2011	Diphtheria
Engerix B-Peds (08/SKB) – HepB	01/01/2011	HepB
Pediarix (110/SKB) – DTaP-HepB-IPV	03/01/2011	HepB
Pediarix (110/SKB) – DTaP-HepB-IPV	06/01/2011	HepB
Comvax (51/MSD) – Hib	03/01/2011	Hib
Comvax (51/MSD) – Hib	06/01/2011	Hib
ProQuad (94/MSD) – MMRV	01/01/2012	Measles
ProQuad (94/MSD) – MMRV	01/01/2012	Mumps
Prevnar 13 (133/Wal) – PCV13	03/01/2011	PCV
Prevnar 13 (133/Wal) – PCV13	06/01/2011	PCV
Pediarix (110/SKB) – DTaP-HepB-IPV	03/01/2011	Pertussis
Pediarix (110/SKB) – DTaP-HepB-IPV	06/01/2011	Pertussis
Pediarix (110/SKB) – DTaP-HepB-IPV	03/01/2011	Polio
Pediarix (110/SKB) – DTaP-HepB-IPV	06/01/2011	Polio
ProQuad (94/MSD) – MMRV	01/01/2012	Rubella
Pediarix (110/SKB) – DTaP-HepB-IPV	03/01/2011	Tetanus
Pediarix (110/SKB) – DTaP-HepB-IPV	06/01/2011	Tetanus
ProQuad (94/MSD) – MMRV	01/01/2012	Varicella

The figure below illustrates how an immunization history of vaccine doses administered can be converted into antigen administered records.

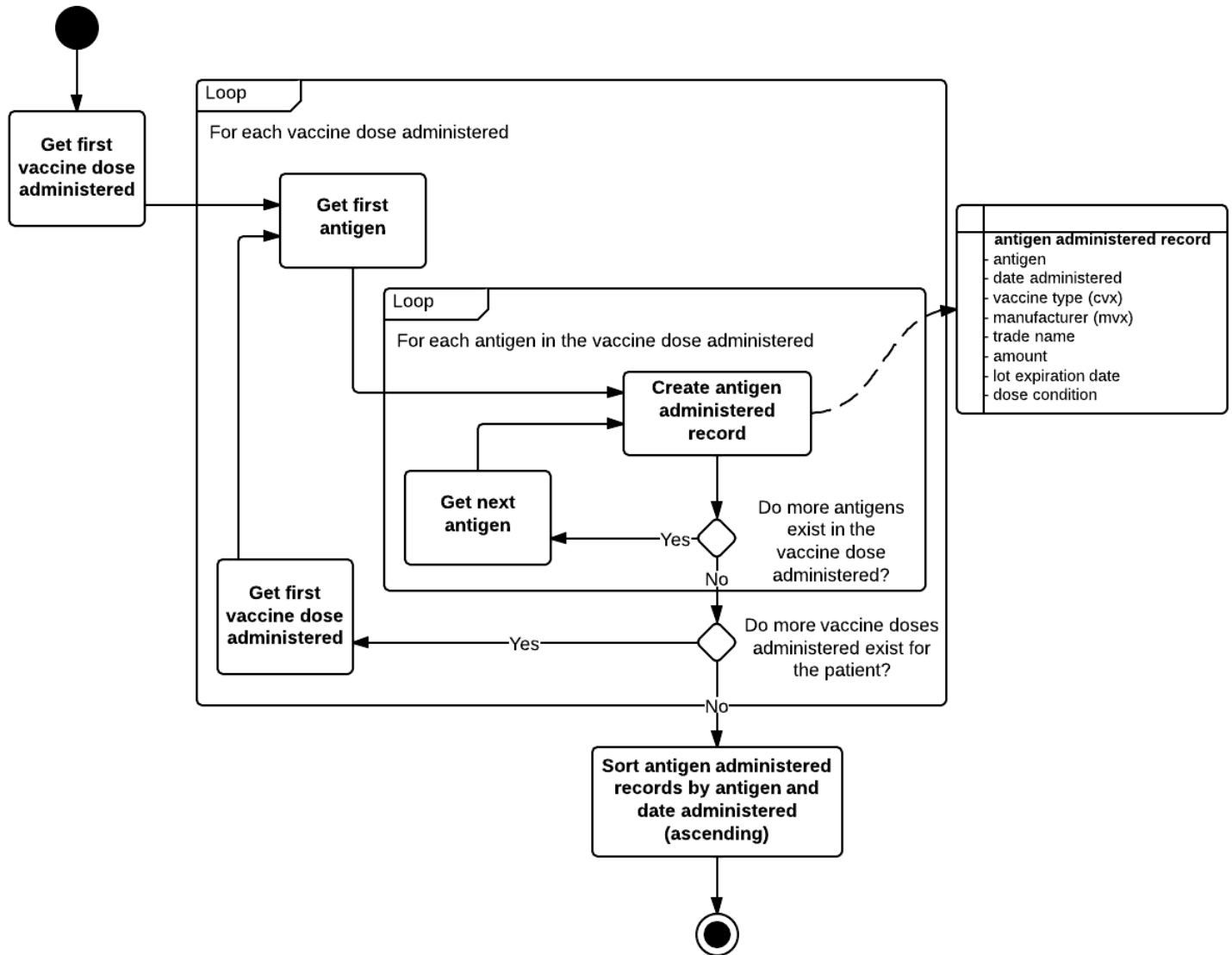


FIGURE 8 - 2 ORGANIZE IMMUNIZATION HISTORY PROCESS MODEL

The process of breaking apart vaccine doses administered into their antigen parts is a fairly simple iterative process.

1. For each vaccine dose administered in the patient's immunization history, the vaccine dose administered is interrogated for the antigens contained within.
2. For each antigen within a vaccine dose administered, an antigen administered record is created. The activity diagram above provides the basic data elements used in evaluation and forecasting. It is entirely possible different implementations may use more or less attributes from this list.
3. After all vaccine doses administered have been turned into antigen administered records, the final step in the activity diagram is to sort the antigen administered records by antigen and then by ascending date order within each antigen. Sorting these now will allow for consistent and accurate results in remainder of the steps.

A supporting data table mapping CVX codes to antigens to aid in this process can be found at the following location: <http://www.cdc.gov/vaccines/programs/iis/interop-proj/cds.html>.

8.4 EVALUATE AND FORECAST ALL PATIENT SERIES

This step is the core of the business logic and decision points many people think of when describing evaluation and forecasting. In the Logic Specification, this step contains all of the clinical business rules and decision logic in the form of business rules and decision tables.

At the end of this step, each patient series will have an evaluated history and a forecast.

The iterative nature of this step is best described with two activity diagrams. First, figure 8-3 shows the high-level iterative process of looping through all patient series. Next, figure 8-4 specifically deals with the details of evaluation. A description of the activity diagram follows each figure.

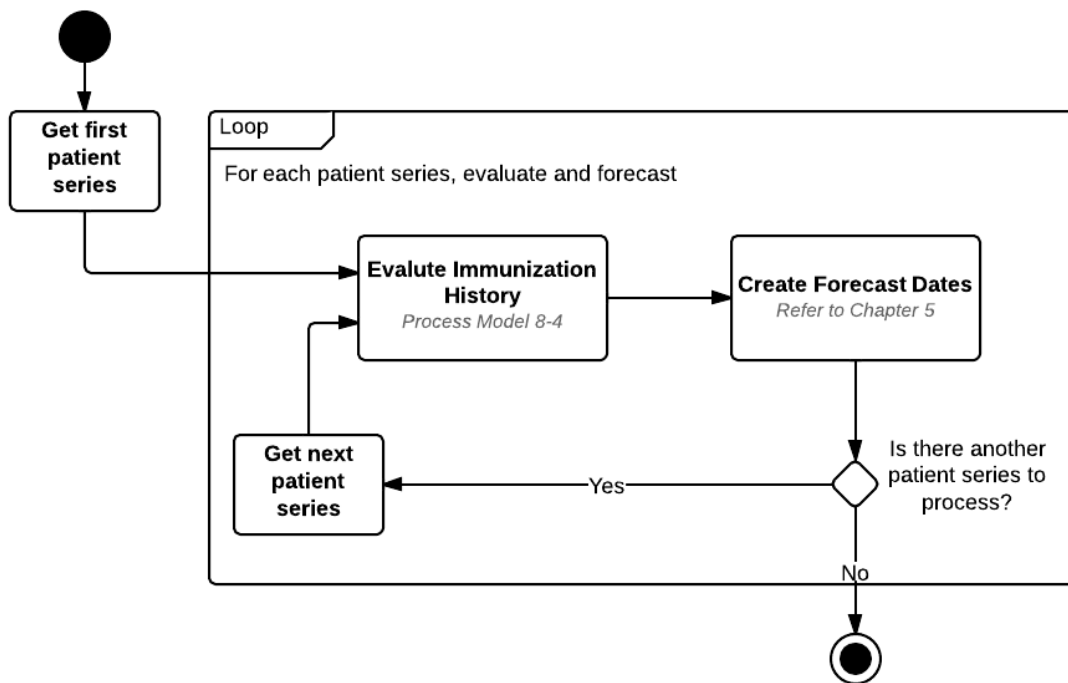


FIGURE 8 - 3 EVALUATE AND FORECAST PROCESS MODEL

At the highest level of this step, as illustrated in figure 8-3, a simple iterative process is used to walk through each patient series and apply the logic defined in the evaluation and forecasting chapters.

For each patient series created in the *create patient series* step (see section 8.2), the following steps are performed:

1. Evaluate the immunization history. See the *evaluate immunization history* activity diagram below for further details.
2. Create forecast dates and/or reasons for the next target dose to be administered. Process models and detailed decision logic on forecasting are located in chapter 5.

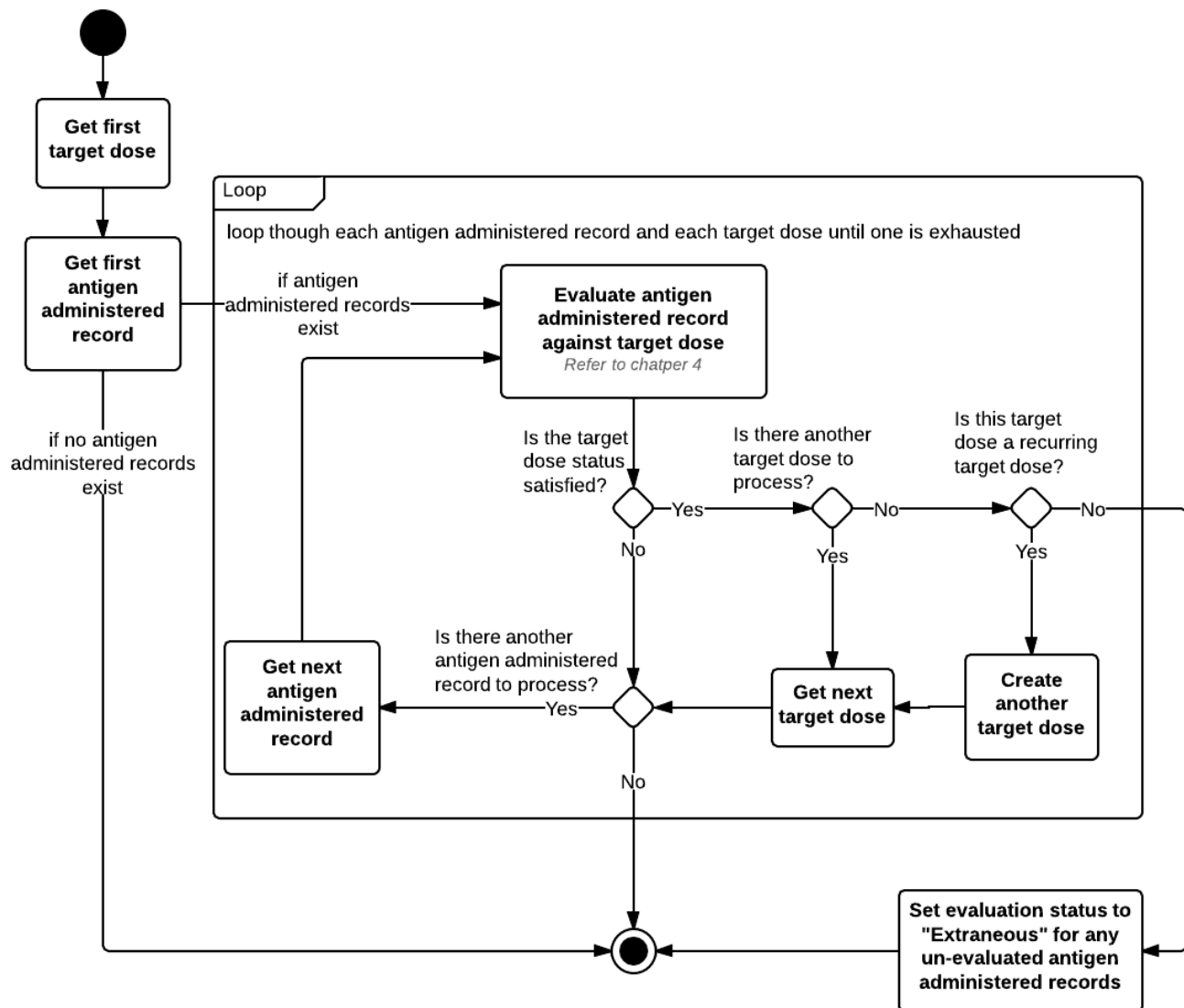


FIGURE 8 - 4 EVALUATE IMMUNIZATION HISTORY PROCESS MODEL

Figure 8-4 illustrates the iterative nature of *evaluate immunization history* in greater detail. There are two collections (arrays, lists, etc.) which must be traversed. The first collection is the patient series consisting of one or more target doses. The second collection is the antigen administered records. At any point in the iterative process either collection could be the trigger to end our evaluation process. Specifically, whichever collection is exhausted first will be the trigger for ending the evaluation process.

It is important to note the contents of antigen administered records at this point in the process. Antigen administered records are only those which could potentially satisfy the goals of the patient series. For example, if the patient series is a path to immunity for HepB, then the antigen administered records will only contain HepB records in ascending date order.

The *evaluate immunization history* process is as follows:

1. The process begins by getting the first target dose from the patient series collection. The current target dose is an important concept as the process moves from evaluation into forecasting. The evaluation process will inform the forecasting process which target dose needs to be forecasted.

2. If the antigen administered collection has elements in it, the process gets the first antigen administered and continues to step 3.
 - a. If the antigen administered collection is empty, the evaluation process for this patient series ends.
3. The step described as “evaluate the antigen administered record against the target dose ” is a reference to chapter 4 which contains process models and detailed decision logic that must be followed prior to moving on to step 4.
4. After the antigen administered record was evaluated against the target dose, the next step is to determine which collections to iterate based on the results of the evaluation.
 - a. If the target dose status is satisfied, proceed to step 5.
 - i. The antigen administered was valid. The target dose is satisfied. The evaluation process can push forward to the next target dose if one exists.
 - b. If the target dose status is not satisfied, proceed to step 7.
 - i. The antigen administered did not meet the goals of the target dose. The evaluation process cannot move onto the next target dose.
5. This step determines if there are more target doses in the patient series collection.
 - a. If the patient series collection has been exhausted, proceed to step 6.
 - b. If the patient series collection contains another target dose, get the next target dose and proceed to step 7.
6. This step determines if the current target dose (now the last target dose in the patient series) is a recurring dose. (This is a rare condition for Td and Flu.)
 - a. If the target dose is defined to be a recurring dose, initialize a new target dose identical to the current target dose. The newly created target dose must now be the last element in the collection. Finally, iterate the collection to get this target dose and proceed to step 7.
 - b. If the target dose is not defined to be a recurring dose, the evaluation process for this patient series ends. Any remaining antigen administered records should have their evaluation statuses set to “extraneous.”
7. This step determines if there are any more antigen administered records to evaluate.
 - a. If the antigen administered collection has been exhausted, the evaluation process for this patient series ends.
 - b. If the antigen administered collection contains another record, get the next antigen administered record and return back to step 3.
 - i. Repeat steps 3 – 7 until the evaluation process for this patient series ends. At this point the process can end in one of two ways: (1) No more target doses (step 6.b) or (2) No more antigen administered records (step 7a).

8.5 SELECT BEST PATIENT SERIES

Select Best Patient Series determines the best path to immunity (patient series) for the patient based on the evaluated immunization history and forecast. Each antigen evaluated and forecasted may contain more than one patient series and the goal of *select best patient series* is to select one of those patient series as being superior to the others based on several factors. The factors and associated business rules are defined in chapter 6.

The process of selecting the best patient series at the highest level is a simple iterative process which loops through each antigen and applies the business rules found in chapter 6 to each antigen. A sample iterative process model is shown below to detail the looping structure.

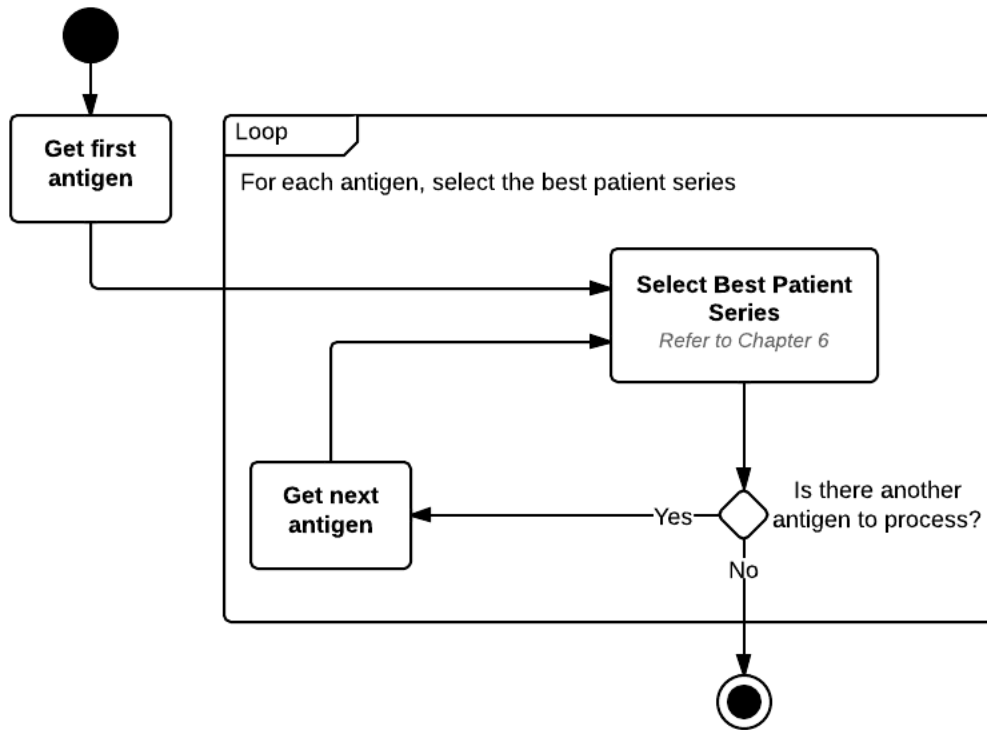


FIGURE 8 - 5 SELECT BEST SERIES PROCESS MODEL

8.6 IDENTIFY AND EVALUATE VACCINE GROUP

The goal of *identify and evaluate vaccine group* is to merge together antigen-based forecasts into vaccine group forecasts. This is especially important in MMR and DTaP/Tdap/Td vaccine groups which each contain more than one antigen in their respective vaccine groups. In these cases, it is important to provide a forecast consistent with the vaccine group rather than the individual antigen. The business rules to create vaccine group forecasts are defined in chapter 7.

The process of identifying and evaluating a vaccine group at the highest level is a simple iterative process which loops through each vaccine group and applies the business rules defined in chapter 7 to each vaccine group. The figure on the next page is a sample iterative process model that shows the looping structure.

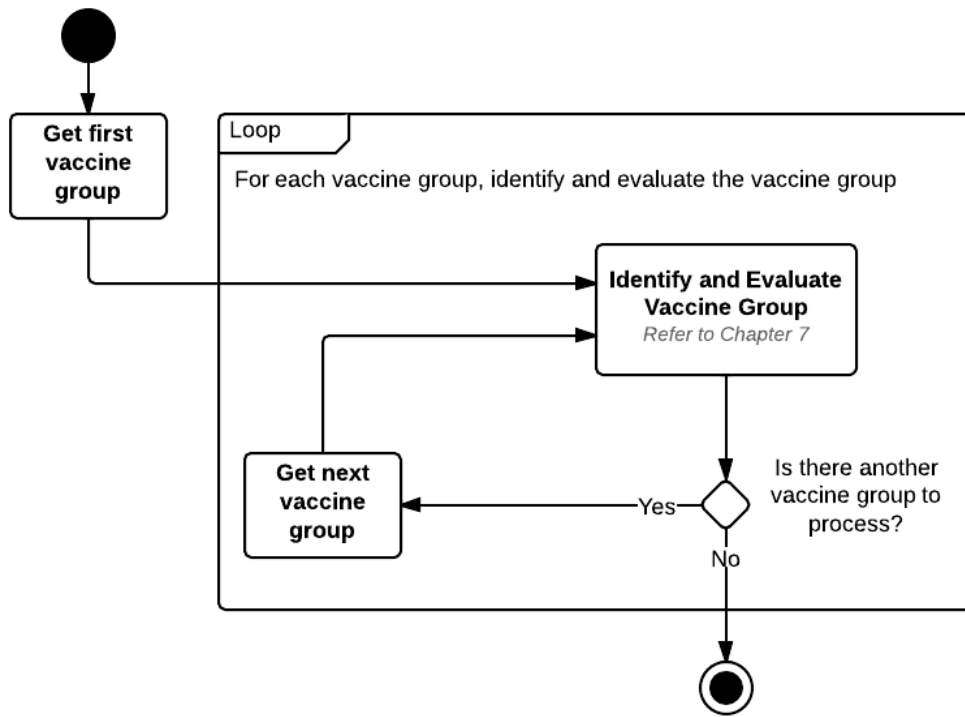


FIGURE 8 - 6 IDENTIFY AND EVALUATE VACCINE GROUP PROCESS MODEL

APPENDIX A: DOMAIN MODEL AND GLOSSARY

Domain Model (Fact Model, Vocabulary) Overview

Purpose

The purpose of employing a domain model (i.e. fact model) is to:

- Document agreed-upon terms and definitions for the project
- Facilitate discussions of the terms and definitions among project participants and provide tools to capture outcomes of these discussions
- Establish a foundation and a reference source (common vocabulary) for other project materials

About Domain Model

A domain is an area of knowledge or activity characterized by a set of concepts and terminology understood by the practitioners in the area. A domain model captures vocabulary—terms and definitions. It ensures that all terminology and concepts that will appear in the project materials (e.g., business rules, specifications, and process descriptions) are known and understood by the domain practitioners (agreed-upon definitions and meaning).

A domain model includes:

- Domain diagram(s) that shows major business entities, their characteristics (attributes), and their relationships (Figure A-1, Figure A-2, and Figure A-3)
- A glossary that provides the definitions of vocabulary terms represented on the diagrams
- A description of the domain diagram(s) (presented below)

Unlike a data model diagram that depicts storage of information or a workflow/process diagram that depicts the sequence of steps in a process, a domain diagram is a high-level static representation of the main “things” (entities) involved in the immunization process, including a description of how these “things” (entities) are related. It is important to note that the domain diagram is not a technical specification. Instead, the domain diagram provides the foundation for other modeling diagrams and materials.

Description of the Domain Diagrams

The domain diagram for the CDSi project is broken into three neighborhoods for enhanced readability and ease of printing. Each neighborhood encapsulates a logical grouping of entities.

Patient Neighborhood

The *patient neighborhood* (Figure A-1) focuses on the patient and the patient’s medical history. The patient’s medical history is composed of two distinct items of importance. The first is the relevant medical observation which may not be directly related to a previous immunization event. The second is the immunization history which is composed of vaccine doses administered and adverse events.

Schedule Neighborhood

The *schedule neighborhood* (Figure A-2) focuses on what a vaccine is, how it is related to an Antigen and a Vaccine Group, and how those three entities relate to a schedule.

A vaccine has several attributes which uniquely identify it and are important during evaluation and forecasting. Each vaccine contains antigen and also belongs to a vaccine group. While not critically important at this stage, it should be noted that a vaccine can contain more than one antigen and can belong to more than one vaccine group. Combination vaccines – such as Hib-HepB – contain more than one antigen and belong to more than one vaccine group.

A schedule is the highest level entity which encompasses a collection of recommendations. Within the CDSi project, this is the routinely recommended vaccines by the ACIP for children from birth through 18 years of age. A schedule is composed of antigen series. Each antigen series defines a path to immunity for an antigen. That is to say, an antigen series focuses on a specific antigen and not a specific vaccine or a vaccine group. Each antigen series is composed of series dose(s). A series dose defines the recommendations of the ACIP through dose specific entities.

Evaluation and Forecasting Neighborhood

The *evaluation and forecasting neighborhood* (Figure A-3) is the result of merging the *patient neighborhood* with the *vaccine and schedule neighborhood* and applying the recommendations of ACIP. That is, it is the result of the evaluating vaccine doses administered against the ACIP recommendations and creating the forecast for when the next vaccine should be administered according to the ACIP recommendations.

While the schedule, antigen series, and series doses from the *vaccine and schedule neighborhood* encompass the recommendations of the ACIP, they do not go beyond that. They are the recommendations of the ACIP. When the process of evaluation and forecasting occurs, it is important to track the progress of the patient against the goals of the ACIP to know how close to series completion the patient is. This concept is depicted as the patient series and target dose. They are the measuring stick tracking the progress of the patient (and his/her history) against the recommendations of the ACIP. The target dose is the “virtual dose” according to the ACIP. The vaccine dose administered is what patient actually received.

Each vaccine dose administered is evaluated against the target dose and assigned an evaluation status and possible evaluation reason. The target dose is also used to create a forecast for the next time an immunization is due.

Domain Diagrams

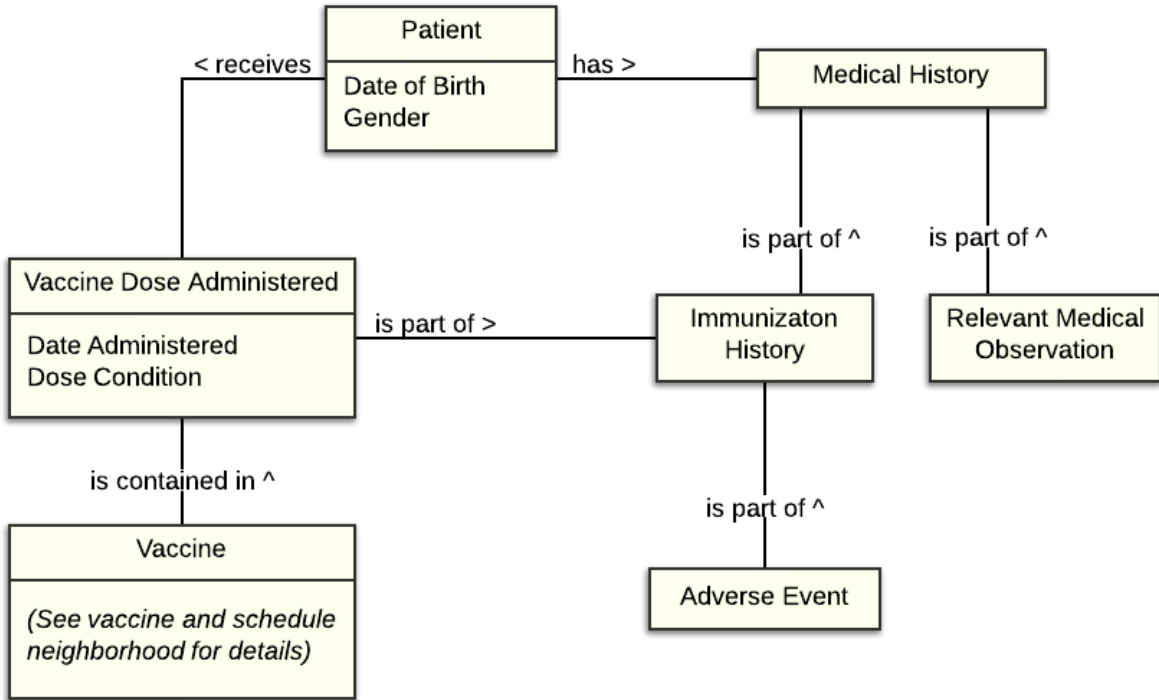


FIGURE A - 1 CDSI DOMAIN DIAGRAM: PATIENT NEIGHBORHOOD

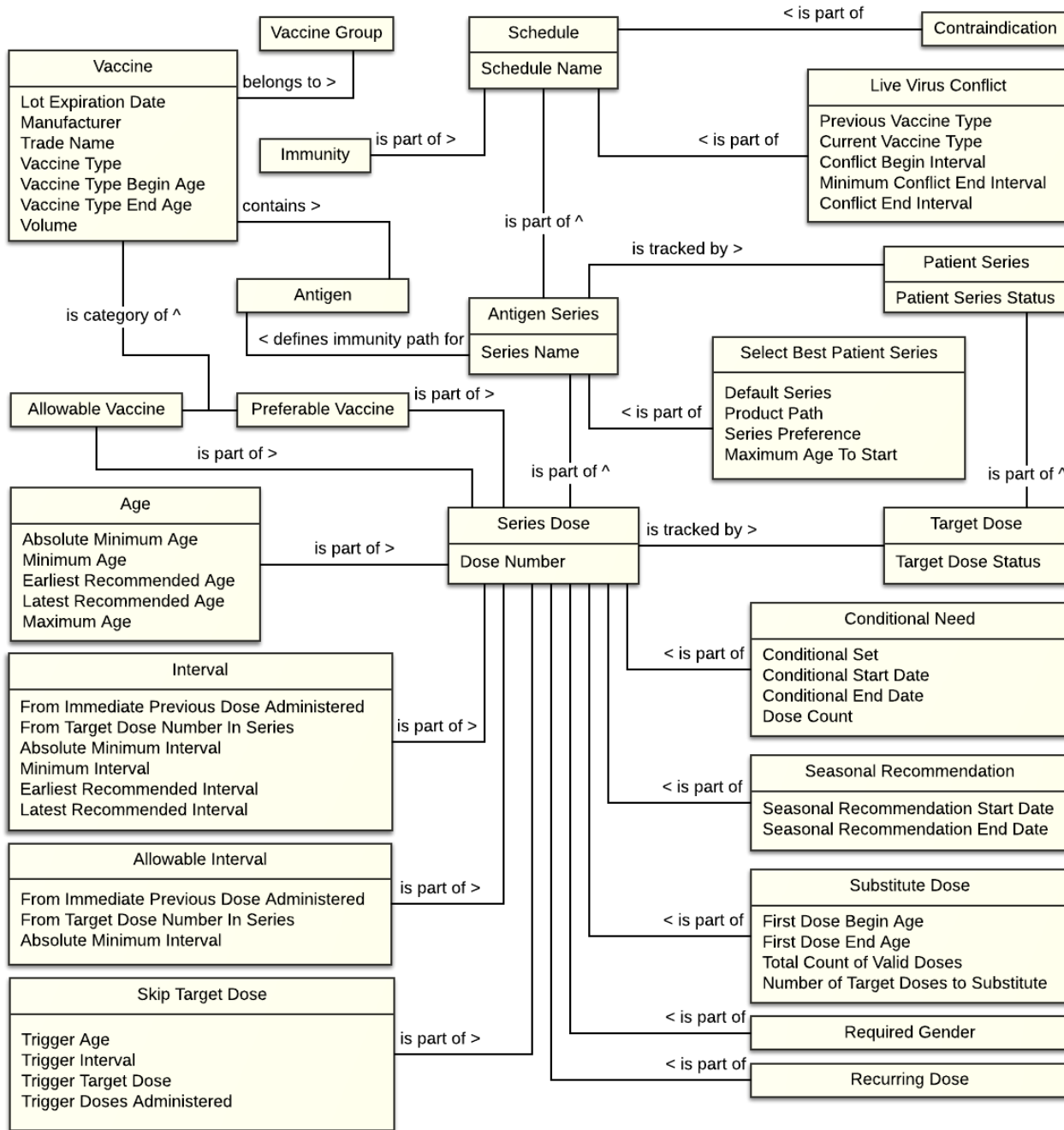


FIGURE A - 2 CDSI DOMAIN DIAGRAM: SCHEDULE NEIGHBORHOOD

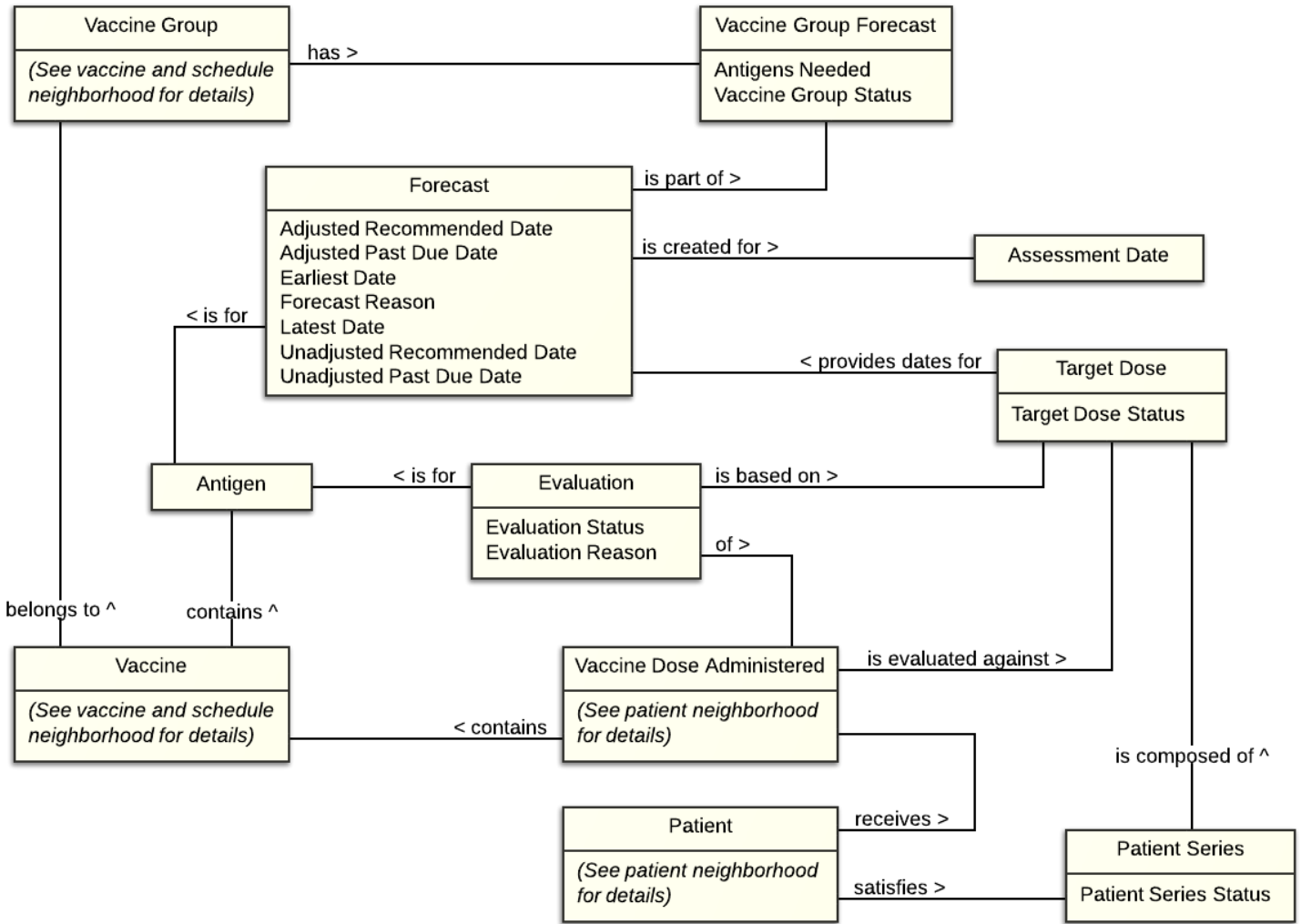


FIGURE A - 3 CDSI DOMAIN DIAGRAM: EVALUATION AND FORECASTING NEIGHBORHOOD

The glossary provides the definitions of terms identified by the domain model.

TABLE A - 1 GLOSSARY

Term	Definition
Absolute Minimum Age	Absolute minimum age is an age which may be earlier than the minimum age and allows for abnormally early vaccine administration (e.g. grace period).
Absolute Minimum Interval	Absolute minimum interval is an interval which maybe shorter than the minimum interval and allows for abnormally early vaccine administration (e.g. grace period).
Adjusted Past Due Date	Adjusted past due date is the date at which the next target dose for the patient is considered overdue.
Adjusted Recommended Date	Adjusted recommended date is the date at which the next target dose should be given.
Adverse Event	An adverse event is a negative health consequence experienced by the patient related in time to administration of vaccine(s). "In time" means that it happens in some reasonable time after the immunization event. It might not be related to a specific vaccine dose administered, especially in cases when the patient receives several shots in one visit.
Age	Age is the length of time from birth to a specified time.
Allowable Interval	Allowable Interval is a space of time between vaccine doses administered outside of the base interval recommendations, but still count towards immunity.
Allowable Vaccine	An allowable vaccine is a vaccine which is administered outside of the recommendations of vaccine administration, but still count towards immunity.
Antigen	A foreign (non-self) substance which can cause an immune response.
Antigen Series	An antigen series is one possible path to achieve presumed immunity against a disease.
Antigens Needed	Antigens needed are the antigens from a vaccine group which the patient is in need of receiving.
Assessment Date	Assessment date is the date for which the forecast is created.
Conditional End Date	Conditional end date is the last day which bounds a conditional need.
Conditional Need	A conditional need is a situation where based on a patient's immunization history, the patient may or may not need an additional dose of a vaccine.
Conditional Set	A conditional set is one or more facts about a patient's immunization history which indicate a patient needs another vaccine dose administered.
Conditional Start Date	Conditional start date is the first day which bounds a conditional need.
Conflict Begin Interval	Conflict begin interval is an interval which identifies the start of a live virus conflict.
Conflict End Interval	Conflict end interval is an interval which identifies the end of a live virus conflict.
Contraindication	A contraindication is a condition in a patient that greatly increases the chance of a serious adverse event.
Current Vaccine Type	Current vaccine type is the vaccine type of the vaccine dose administered currently undergoing evaluation.
Date Administered	Date of the vaccination event.
Date of Birth	The patient's date of birth either stated or reported on the patient's birth certificate.
Default Series	Default series is an antigen series which best describes the standard recommendations of the ACIP.

Term	Definition
Dose Condition	Dose condition is an indication a vaccine dose administered should not be considered when evaluating the immunization history due to a negative external effect on the vaccine dose administered.
Dose Count	Dose count is the number of vaccine doses administered between the conditional need start date and conditional need end date.
Dose Number	Dose number is the ordinal dose position in the antigen series.
Earliest Date	Earliest date is the earliest point in time at which the next target dose could be given.
Earliest Recommended Age	Earliest recommended age is the preferred age a vaccine should be administered.
Earliest Recommended Interval	Earliest recommended interval is the shortest, preferred time period between vaccine doses administered.
Evaluation	Evaluation is the result of the process of applying recommendations for a given series dose. It is the outcome of the evaluation process that determines whether a vaccine dose administered is valid.
Evaluation Reason	Evaluation reason provides reasons a vaccine dose administered is or is not valid.
Evaluation Status	Evaluation status indicates validity of a vaccine dose administered in relation to a specific target dose.
First Dose Begin Age	First dose begin age is the begin age of the first valid dose administered.
First Dose End Age	First dose end age is the end age of the first valid dose administered.
Forecast	Forecast is the result of the process of applying rules for the next series dose. The outcome of the forecasting process would be dates for the next target dose.
Forecast Reason	Forecast reason provides reasons a target dose is or is not recommended to be administered.
From Immediate Previous Dose Administered	From immediate previous dose administered indicates the interval an IS applied from the previous vaccine dose administered within the antigen series.
From Target Dose Number in Series	From target dose number in series is the target dose from which the interval is applied.
Gender	Gender is the observed or reported patient's sex.
Immunity	Immunity is a condition of being able to resist a particular disease ⁵
Immunization History	Immunization history is a collection of vaccine doses administered and any associated adverse events for a patient.
Interval	Interval is a space of time between vaccine doses administered.
Latest Date	Latest date is the latest point in time at which the next target dose could be given.
Latest Recommended Age	Latest recommended age is the age a vaccine must be administered before the patient is considered overdue.
Latest Recommended Interval	Latest recommended interval is the time period from a previous vaccine dose administered before the patient is considered overdue.
Live Virus Conflict	A live virus conflict is a condition when two live virus vaccines are administered at too close of an interval.
Lot Expiration Date	Lot expiration date is the date at which point the lot of vaccine is no longer considered potent.
Manufacturer	Manufacturer is the company that develops and distributes a vaccine.
Maximum Age	Maximum age is the latest age a vaccine may be administered.

⁵ Immunity. (n.d.). Merriam-Webster.com. Retrieved December 26, 2013, from <http://www.merriam-webster.com/dictionary/immunity>

Term	Definition
Maximum Age To Start	Maximum age to start is the latest age an antigen series may be started.
Medical History	Medical history is “a narrative or record of past (or current) events and circumstances that are or may be relevant to a patient's current state of health. Informally, an account of past diseases, injuries, treatments, and other strictly medical facts. More formally, a comprehensive statement of facts pertaining to past and present health gathered, ideally from the patient, by directed questioning and organized under the following heads.” http://www.medilexicon.com/medicaldictionary.php?t=41172
Minimum Age	Minimum age is the earliest age a vaccine may be administered.
Minimum Conflict End Interval	Minimum conflict end interval is an interval which identifies the absolute earliest end of a live virus conflict.
Minimum Interval	Minimum interval is the shortest interval between two vaccine doses administered.
Number of Target Doses to Substitute	Number of target doses to substitute is the number of doses of adolescent Tdap which can be substituted due to previous DTaP vaccine doses administered.
Patient	Patient is the actual or potential recipient of a vaccine dose administered.
Patient Series	Patient series tracks the patient's progress towards the completion of an antigen series.
Patient Series Status	Patient series status indicates whether the patient has met the goals for the Patient series.
Preferable Vaccine	A preferable vaccine is a vaccine which follows the recommendations of vaccine administration.
Previous Vaccine Type	Previous vaccine type is the vaccine type of the vaccine dose administered during a previous vaccination event.
Product Path	Product path is an antigen series which specifically targets a product, vaccine type, and or trade name.
Recurring Dose	A recurring dose indicates a target dose is to be repeated endlessly.
Relevant Medical Observation	A relevant medical observation is a factor (e.g., condition) that is related to a Patient that may have an impact on the forecasting of future doses. It could be a contraindication, precaution or some special indication.
Required Gender	Required gender is the gender the patient must be for the dose to be considered valid.
Schedule	A schedule is a collection of antigen series that specify various paths to achieve presumed immunity against respective diseases.
Schedule Name	Schedule name is a meaningful identifier for the schedule.
Seasonal Recommendation	A seasonal recommendation is a recommendation which is indicated by a seasonal start date and a seasonal end date in conjunction with the patient's age.
Seasonal Recommendation End Date	Seasonal end date is the last day a seasonal vaccine should be recommended.
Seasonal Recommendation Start Date	Seasonal start date is the first day a seasonal vaccine should be recommended.
Select Best Patient Series	Select best patient series is the process of reviewing all potential patient series which might satisfy the goals of an antigen and determining which patient series is best for the patient.
Series Dose	Series dose is an individually defined dose within an antigen series.
Series Name	Series name is a meaningful identifier for an antigen series.
Series Preference	Series preference is a ranking given to antigen series within an antigen.

Term	Definition
Skip Target Dose	Skip target dose is a target dose which remains unsatisfied while allowing a patient to move forward towards completion of a patient series.
Target Dose	Target dose is a patient-specific dose required to satisfy a recommendation of the ACIP.
Target Dose Status	Dose status indicates whether or not a vaccine dose administered has met the goals of the target dose.
Total Count of Valid Doses	Total count of valid doses is the total number of valid doses regardless of age.
Trade Name	Trade name is the manufacturer's proprietary name and in some cases its intended use (e.g. adults, pediatrics).
Trigger Age	Trigger age is the age at which the target dose is no longer recommended and can be skipped.
Trigger Doses Administered	Trigger Doses Administered is the point at which enough doses have been administered regardless of validity to skip the target dose.
Trigger Interval	Trigger interval is the interval at which the target dose is no longer recommended and can be skipped.
Trigger Target Dose	Trigger target dose is a previously satisfied target dose which allows the current target dose to be skipped.
Unadjusted Past Due Date	Unadjusted past due date is the static past due date a patient should be considered overdue for the next target dose regardless of patient's current age and previous vaccine doses administered.
Unadjusted Recommended Date	Unadjusted recommended date is the static recommended date a patient should receive the next target dose regardless of patient's current age and previous vaccine doses administered.
Vaccine	Vaccine is a specific instance of the medicine (containing antigen(s)) given during a vaccination.
Vaccine Dose Administered	A vaccine dose administered is the record of the event where a vaccine was administered.
Vaccine Group	Vaccine group is a classification category. Vaccine group describes broad categories of diseases. In many cases this reflects individual diseases. In some cases, the group characterizes multiple diseases.
Vaccine Group Forecast	Vaccine group forecast is the forecast for a vaccine group.
Vaccine Group Status	Vaccine group status indicates whether the patient has met the goals for the Vaccine group.
Vaccine Type	Vaccine type is the specific type of vaccine dose administered.
Vaccine Type Begin Age	Vaccine type begin age is the earliest age the vaccine type can be administered.
Vaccine Type End Age	Vaccine type end age is the latest age the vaccine type can be administered. Vaccine type end age date is derived from vaccine type end age.
Volume	Volume is a measurement of the size of the vaccine.

APPENDIX B: ACRONYMS AND ABBREVIATIONS

The table below provides the meanings of acronyms and abbreviations stated within the document.

TABLE B - 1 ACRONYMS AND ABBREVIATIONS

Term	Meaning
ACIP	Advisory Committee on Immunization Practices
CDC	Centers for Disease Control and Prevention
CDS	Clinical Decision Support
CDSi	Clinical Decision Support for Immunization
DHHS	U.S. Department of Health and Human Services
DT	Diphtheria and tetanus toxoids adsorbed (children)
DTaP	Diphtheria and tetanus toxoids and acellular pertussis vaccine adsorbed
EHR	Electronic Health Record
EIPB	Education, Information and Partnership Branch
FDA	Federal Drug Administration
Flu	Influenza
HepA	Hepatitis A vaccine
HepB	Hepatitis B vaccine
Hib	Haemophilus influenza type b conjugate vaccine
HIE	Health Information Exchange
HIS	Health Information System
HIV	Human Immunodeficiency Virus
HPV	Human papillomavirus vaccine
IIS	Immunization Information System
IISSB	Immunization Information Systems Support Branch
MCV	Meningococcal conjugate vaccine
MMR	Measles, Mumps, and Rubella vaccine
MMRV	Measles, Mumps, Rubella, and Varicella vaccine

Term	Meaning
MMWR	Morbidity and Mortality Weekly Report
NCIRD	National Center for Infectious Diseases
PCV	Pneumococcal conjugate vaccine
Polio	Poliomyelitis vaccine
Rota	Rotavirus vaccine
SME	Subject Matter Expert
Td	Tetanus and diphtheria toxoids adsorbed (adult)
Tdap	Tetanus toxoid, reduced diphtheria toxoid and acellular pertussis vaccine, adsorbed
VZ	Varicella vaccine

APPENDIX C: ACKNOWLEDGEMENTS

Logic Specification Panel Members

Bill Adams, MD, Boston University School of Medicine

Dr. William Adams is an epidemiologist, medical informatician, and practicing pediatrician at Boston Medical Center (BMC). He is Director of BU-CTSI Clinical Research Informatics, Director of Child Health Informatics, and Professor of Pediatrics at Boston University School of Medicine. His research focuses on developing and evaluating information technology (IT)-based solutions for improving the quality of health and healthcare for children. His focuses include immunization registries, the child health EHR, patient-centered IT and clinical data warehousing for quality improvement and research. He is a member of the Massachusetts Immunization Information System (MIIS) technical and programmatic teams. He is a founding member of the American Academy of Pediatrics (AAP) Partnership for Policy Implementation (PPI), a group of child health informaticians committed to improving AAP guideline quality including computability. He also serves as advisor to the AAP Center for Child Health Informatics and is a member of the AAP Steering Committee for the Quality Innovation Network.

Gerry Bragg, MBA, Altarum Institute / Michigan Care Improvement Registry (MCIR)

Gerry Bragg has over 20 years of experience in systems analysis and programming and for the past 15 years, has supported the Michigan Care Improvement Registry (MCIR) as a Senior Systems Developer. He has supported the MCIR system in a variety of capacities, including the development of patient de-duplication/match-merge processes and clinical decision support/immunization forecasting algorithms. Mr. Bragg also specializes in database/SQL performance, scalability, tuning, refactoring, design, technical planning, and configuration management. The system currently supports more than 25,000 users. Mr. Bragg holds an MBA in Management Information Systems from the University of Minnesota in Minneapolis, Minnesota, and a BA in Accounting from Hillsdale College in Hillsdale, Michigan.

Nathan Bunker, Dandelion Software & Research, LLC

Nathan is a software developer and public health consultant for public and private agencies; focusing specifically on immunization software and data exchange. His work has given him experience with key immunization registry functions, including: immunization recommendation/forecast, HL7 interfacing, data quality analysis, vaccination matching, patient matching, and vaccine barcoding.

Daryl Chertcoff, BSE, HLN Consulting, LLC

Mr. Chertcoff has been providing information technology consulting services and delivering electronic healthcare systems to public health agencies and their partners for the past 12 years. He has worked with a wide range of technologies throughout his career, is an ongoing student of Health Information Technology standards, and believes strongly in participating in volunteer efforts to further the adoption of Health IT nationwide. Mr. Chertcoff offers each new business process analysis or development effort a combination of project management and technical leadership skills to get the job done. He enjoys collaborating with partners and considers each new challenge an opportunity to make sense of the problem in a practical manner, by drawing on experience from past projects as well as from involvement in standards groups and technology forums.

Shaun Grannis, MD, MS, FAAFP, Regenstrief Institute / Indiana University

Dr. Shaun Grannis is a Research Scientist at Regenstrief Institute, Inc. and Assistant Professor of Family Medicine at the Indiana University School of Medicine. He received an Aerospace Engineering degree from the Massachusetts Institute of Technology, and underwent post-doctoral training in Medical Informatics and Clinical Research at Regenstrief Institute. He joined Indiana University in 2001 and collaborates closely with national and international

public health stakeholders to advance the technical infrastructure and data-sharing capabilities. He is a member of World Health Organization (WHO) Collaborating Center for the Design, Application, and Research of Medical Information Systems, where he provides consultancy on issues related to health information system identity management and implementing automated patient record matching strategies.

Dr. Grannis completed an analysis of an automated regional electronic laboratory reporting system that revealed substantial increases in the capture rates for diseases of public health significance when compared to manual, paper-based procedures. He is project director for an initiative integrating data flows from over 120 hospitals across the state of Indiana for use in public health disease surveillance. For the last 5 years this system has received real-time data from hospitals amounting to more than 2 million transactions per year, and has detected public health outbreaks of gastrointestinal illness, carbon monoxide poisoning, and other events of interest to public health. Most recently this system was leveraged to monitor H1N1 influenza disease burden across the state of Indiana. As co-chair of the U.S. Health Information Technology Standards Panel (HITSP) Population Health technical work group, Dr. Grannis helped lead development of technical Interoperability Specifications for nationally recognized public health IT use cases.

Dr. Grannis also serves as the Director of the Indiana Center of Excellence in Public Health Informatics, which recognizes that public health practice is driven by a wide variety of data types, data sources, and data management techniques.

Janel Jorgenson, Utah Statewide Immunization Information System (USIIS)

Janel Jorgenson is a graduate of the University of Utah with a degree in Health Education & Promotion. She has an interest in children's health issues and has been with the Utah Department of Health Immunization Program since 2000. Janel is currently the Provider Relations Coordinator where she provides supervision, support, training, and education for both the Utah VFC Program and the Utah Statewide Immunization Information System (USIIS).

Pinar Keskinocak, PhD, Georgia Institute of Technology School of Industrial and Systems Engineering

Pinar Keskinocak is the Joseph C. Mello Professor in the School of Industrial and Systems Engineering and the co-founder and co-director of the Center for Humanitarian Logistics at the Georgia Institute of Technology. She also serves as the Associate Director for Research at the Health Systems Institute at Georgia Tech.

Her research focuses on applications of operations research and management science with societal impact (particularly health and humanitarian applications), supply chain management, pricing and revenue management, and logistics/transportation. She has worked on projects in several industries including automotive, semiconductor, paper manufacturing, printing, healthcare, hotels, and airlines. Her research has been published in journals such as Operations Research, Management Science, Manufacturing & Service Operations Management, Production and Operations Management, IIE Transactions, Naval Research Logistics, and Interfaces.

Tom Maerz, Wisconsin immunization Registry (WIR)

Tom Maerz is an Applications Developer, Computer Electronics Builder and Network Specialist by trade. He's worked with Health Care records and integration with Electronic Medical Record (EMR) systems since 1979 and Vital Records de-duplication of information since 1990. In addition, his experience includes working with Health Care providers, HMO's, Schools and EMR vendors regarding an Immunization Registry for the State of Wisconsin since 1995.

Judy Merritt, Scientific Technologies Corporation (STC)

Judy Merritt is the Clinical Decision Support Specialist and Senior Developer for Scientific Technologies Corporation focusing on interfaces between immunization forecasting services and health applications. She has over 17 years' experience with design, development, implementation and support of immunization systems in public health. She also served as the Immunization Registry Coordinator for one of the first state immunization registry systems in the nation implemented as an early CDC immunization registry pilot project.

Ninad Mishra, MD, MS, CDC Public Health Informatics and Technology Program Office (PHITPO)

Mark Sawyer, MD, American Immunization Registry Association (AIRA)

Dr. Sawyer is a Professor of Clinical Pediatrics and a Pediatric Infectious Disease specialist at the UCSD School of Medicine and Rady Children's Hospital San Diego. He is the medical director of the UCSD San Diego Immunization Partnership, a contract with the San Diego County Agency for Health and Human Services to improve immunization delivery in San Diego. He is also the Past-President of the California Immunization Coalition and a member of the CDC Advisory Committee on Immunization Practices (ACIP).

Eric Schuh, Hewlett Packard (HP) / Oregon Immunization Program (OIP)

Eric Schuh is a business analyst with Hewlett Packard and has been focused on statewide immunization information systems for 10 years. During this time Eric has provided support for the Georgia Registry of Immunization Transactions and Services (GRITS) and is currently working with the Oregon ALERT Immunization Information System. While working on the Georgia and Oregon projects, Eric played a key role in the design, testing, and implementation of multiple upgrades to the immunization evaluation and forecasting tool utilized by the states. Eric is an active member of AIRA, Immunization Evaluator Workgroup, and the WIR Consortium.

Rosalyn Singleton, MD, Alaska Native Tribal Health Consortium (ANTHC)

Rosalyn Singleton received her medical degree from Northwestern University Medical School, Chicago in 1982, and completed a Pediatric residency at Children's Memorial Hospital, Chicago, and a MPH from Loma Linda University. During 1984-88 Dr. Singleton worked in a small Navajo hospital in Chinle, Arizona as a pediatrician. Since 1988 Dr. Singleton has worked as a part-time pediatrician at Alaska Native Medical Center, an Immunization Consultant for Alaska Native Tribal Health Consortium and a visiting research associate with Arctic Investigations Program – Centers for Disease Control and Prevention (CDC). Her research grants and publications have been in the areas of RSV, Hib, and Pneumococcal disease and chronic respiratory disease.

Shane Speciale, Avanza Systems, Inc.

Shane Speciale is the President of Avanza Systems, Inc., an immunization registry product manufacturer. Shane has been personally involved in the planning, design, development, implementation, and/or support of more than 20 immunization registries at the local, state, and federal (DOD) levels over the past 19 years and has intimate knowledge of and experience with immunization-related recommendations and clinical decision support.

Amanda Timmons, Oregon Immunization Program (OIP) / ALERT Immunization Information System

Amanda Timmons has worked with computerized forecasting algorithms for the past twelve years; first in Oregon's home grown immunization registry, Oregon Immunization ALERT and more recently, with Oregon's new implementation of WIR. Amanda's other professional interests include providing technical support to immunization providers, conducting ongoing training and learning whatever new skills will be required in the ever-changing world of immunization.

Stuart Weinberg, MD, FAAP, Vanderbilt University School of Medicine

Stuart Weinberg's involvement with immunization registries began in 1992 with his participation as an informatics consultant in an "All Kids Count" Planning Grant. Dr. Weinberg also served as Co-Chair of the Pennsylvania Statewide Immunization Information System (SIIS) Task Force from 1994-1997. His recent activities at Vanderbilt have included developing two-way functionalities between Vanderbilt's electronic medical record and Tennessee's immunization registry, and piloting immunization assessment and forecasting through web services. In 2012, Dr. Weinberg was the recipient of Tennessee's first Childhood Immunization Champion Award from the Centers for Disease Control and Prevention (CDC).

Process, Communication and Sustainability Panel

Rebecca Coyle, MS Ed, American Immunization Registry Association (AIRA)

Amy Groom, MPH, Indian Health Service (IHS)

Chip Hart, Physicians Computer Company (PCC)

Chip Hart has worked among and for private primary care practices for over 20 years as part of the Physician's Computer Company, a pediatric-focused EHR and PM software developer. Chip's clients have tracked immunizations and printed school forms for nearly 30 years. He has hands-on experience working with more than two dozen state IIS organizations: the AAP, CDC, CCHIT, various state HIEs, and MGMA.

Priya Rajamani, MBBS, PhD, MPH, Minnesota Immunization Information Connection (MIIC)

Sripriya Rajamani is a physician with medical training from India. She holds a public health and doctoral degree in Health Informatics from the University of Minnesota. She is actively involved with the Minnesota e-Health Initiative and staffing its Standards and Interoperability workgroup for the last five years. She is currently with the Minnesota Immunization Registry (MIIC) program as part of the EHR-IIS Interoperability grant. One of the deliverables of the MN grant is the upgrade of vaccine forecasting. She got interested in clinical decision support and volunteered for the Process, Communications and Sustainability panel of CDC Clinical Decision Support (CDS) team.

Bobby Sanchez, New Mexico Statewide Immunization Information System (NMSIIS)

Rosemary Spence, RN, Colorado Immunization Information System (CIIS)

Rosemary Spence is a public health nurse consultant with the Colorado Immunization Section. She has been a nurse consultant in the Section for 14 years. Previous roles have included managing Colorado's Vaccines for Children Program. She currently serves as the nurse consultant for the Colorado Immunization Information System (CIIS) and provides clinical guidance for updating the registry's vaccine forecasting algorithm. Rosemary was the immunization coordinator and child health nursing manager at the Weld County Department of Public Health and Environment in Greeley, CO prior to working at the Colorado Department of Public Health and Environment.

Validation and Testing Panel

Greg Anderson, Connexin Software

Janis Betten, Oregon Immunization System (OIS)

Janis has worked in Oregon with the development of immunization forecasting logic and testing for use with clinical evaluation programs and school student information system immunization modules since the early 1990's. Her other professional interests include all activities involved with Oregon school immunization law—a passion for over 30 years.

Joan Christison-Lagay, Connecticut Immunization Registry and Tracking System (CIRTS)

Joan Christison-Lagay, a former Peace Corps volunteer, is a graduate of Smith College and holds master's degrees from both Brown University and the UNC. She began her public health career for the City of Hartford, CT in 1980 working on projects to reduce the incidence of low birth weight infants. In 1993 she was named the director of the first immunization registry in New England, now known as the CT Immunization Registry and Tracking System (CIRTS).

She currently contracts with CT DPH, MA DPH and Community Health Centers, CT on issues relating to immunization assessment and training.

Christine Marr Gray, MPH, CHES, Virginia Immunization Information System (VIIS)

Christine Gray has been working with the Virginia Immunization Information System (VIIS) since March 2009. Currently as the VIIS Business Plan and Data Quality Manager, Ms. Gray develops and evaluates data quality standards for registry data; coordinating and executing VIIS application testing, proposed changes and system enhancements, immunization scheduling. Prior to this position, Ms. Gray was the VIIS Consultant for the South Central region of Virginia. Primarily she trained interested providers and other health care workers to use the registry, and acted as a liaison to the rest of the VIIS staff. Ms. Gray received her Master in Public Health from The George Washington University in 2009 and is a Certified Health Education Specialist. She graduated from Virginia Tech in 2004 with a Bachelors of Science in Economics. Before her tenure at the Virginia Department of Health, Ms. Gray worked for five years with the National Turkey Federation (NTF) improving worker safety and decreasing food borne illness.

Nichole Lambrecht, Envision Technology Partners, Inc.

Nichole Lambrecht is a Senior Project Manager with Envision Technology Partners, Inc. and has been with the company for two years. Envision Technology Partners, Inc. has developed the immunization information system (IIS) called WebIZ in which several state and city governments utilize. In Nichole's current role, she works with state and city governments to develop and manage their WebIZ application, as well as provides training and system quality assurance. Nichole previously worked with the Kansas Immunization Registry where she served a total of five years in all aspects of the project, including user support and Project Manager. Nichole has participated in several national workgroups with the Centers of Disease Control (CDC) and American Immunization Registry (AIRA) and she has served as a subject matter expert regarding aspects of IIS functionality and best practices. During this project she helped test and develop the test case toolkit.

Vikki Papadouka, PhD, MPH, New York Citywide Immunization Registry (CIR)

Vikki Papadouka worked for the New York City Immunization Registry in NYC's Department of Health and Mental Hygiene since 1997, and has been the director of research and evaluation since 2003. Her work includes designing systems and protocols to ensure data quality for the IIS, working with internal and external agencies in collaborative research projects that use CIR data, working with clinical experts to translate immunization schedule rules into algorithms, and working with vendors to improve registry operations and data capture.

Narasimha Velagaleti, EPIC Systems Corporation

Kent Ware, Ohio Statewide Immunization Information System (SIIS)

Kent Ware was privileged to lead a great team in Ohio for 26 years through many program areas including VFC, outbreak management, Strategic National Stockpile, Pandemic Influenza and the IIS program. Managing and directing these programs have been simultaneously humbling and rewarding, for the tasks were often daunting. Mr. Ware is now VP of Health Integration at Esah Health Integration Services. Working with the CDS team continues to strengthen his perspective that there are many talented individuals applying their skills for the betterment of public health.

External Reviewers

Freddie Barber, RN, BA, MSHCA, Scientific Technology Company (STC)

Freddie Barber became a Registered Nurse in 1983. She started her nursing career as a critical care nurse spending 20 years at various levels in the acute care setting in monitored units. In 1997 she received her BA in Sociology and Anthropology and her MS in Health Care Administration in 2003. In 2011 Freddie completed a Certificate in Informatics in Public Health from Johns Hopkins Bloomberg School of Public Health. Freddie began working in Public Health as a Vaccines for Children Representative in Arkansas and then as the Vaccines for Children Coordinator. She is currently a Data Transfer Coordinator/Public Health Advisor for Scientific Technologies Corporation working with State IIS on interfacing with EHRs.

John Canning, Physicians Computer Company (PCC)

Mark Dente, MD, General Electric (GE) Healthcare

Dr. Dente's informatics career spans over 19 years, focusing on new approaches to increase patient safety and creating new methods to implement evidence-based medicine.

As Chief Medical Officer for GE Healthcare IT, his responsibilities include: Leading the organization's clinical and Informatics strategy; representing GE on government, health ministries, and advocacy committees; evaluating and executing on strategic corporate, industry and research objectives as well as supporting GE Healthcare IT's regulatory needs.

Ruth Gubernick, MPH, HLN Consulting, LLC

Ruth Gubernick is an independent consultant. For over 15 years, she has been part of a consulting team with HLN, LLC which has performed needs assessments regarding immunization registries in WA, UT, KY, NH and VT. She was a subject matter expert (SME) for registry planning in MN and LA and registry evaluation and enhanced development in CA, RI, OH, New York City and Philadelphia. Ruth has been a participant, as a SME, on the American Immunization Registry Association (AIRA)'s Modeling Immunization Registry Operations Workgroup (MIROW).

Ruth works with the Pediatric Council on Research and Education (PCORE), the Foundation of the American Academy of Pediatrics, NJ Chapter (AAPNJ), as a Program Specialist facilitating quality improvement efforts with pediatric medical home teams and practice-based systems change. She is also working with the National AAP's Quality Improvement Innovation Network (QuIIN) as a Quality Improvement Advisor.

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Saad Omer, MBBS, MPH, PhD, Emory University Schools of Public Health & Medicine & Emory Vaccine Center

Dr. Saad Omer is an Assistant Professor of Global Health, Epidemiology, and Pediatrics at Emory University, Schools of Public Health & Medicine and an affiliate faculty of the Emory Vaccine Center. He has worked on studies in the United States, Guatemala, Ethiopia, India, Pakistan, Uganda and South Africa. Dr. Omer has conducted several studies to evaluate the roles of schools, parents, health care providers, and state-level legislation in relation to immunization coverage and disease incidence. Dr. Omer's research portfolio includes clinical trials to estimate efficacy and/or immunogenicity of influenza, polio, measles and pneumococcal vaccines; studies on the impact of spatial clustering of vaccine refusers; and clinical trials to evaluate drug regimens to reduce mother-to-child transmission of HIV in Africa. Dr. Omer is the principal investigator for the Georgia site of the Vaccine Safety Datalink -based at Kaiser Permanente, Georgia. He is also the principal investigator of a cohort study in Georgia (United States) for evaluating the impact of influenza vaccine receipt in pregnancy and fetal/birth outcomes. He was awarded the Maurice Hilleman Early-stage Investigator award in vaccinology by the National Foundation of Infectious Diseases.

Kim Salisbury-Keith, MBA, KIDSNET, Rhode Island Department of Health

Kim Salisbury-Keith has worked in Public Health for over 25 years. She has an undergraduate degree from the University of North Carolina at Chapel Hill and an MBA from the University of Rhode Island. Kim has worked in a variety of public health programs including WIC, Lead poisoning prevention, and Newborn screening. She has served as Rhode Island's Immunization Program Manager and is currently the Development Manager for KIDSNET, RI's integrated childhood information system. Kim was a founding member of the American Immunization Registry Association (AIRA) and has served as an officer and board member for that organization. She has also served on a variety of CDC and AIRA work groups and panels including two MIROW initiatives.

Richard Shiffman, MD, MCIS, Yale University School of Medicine

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APPENDIX D: REFERENCES

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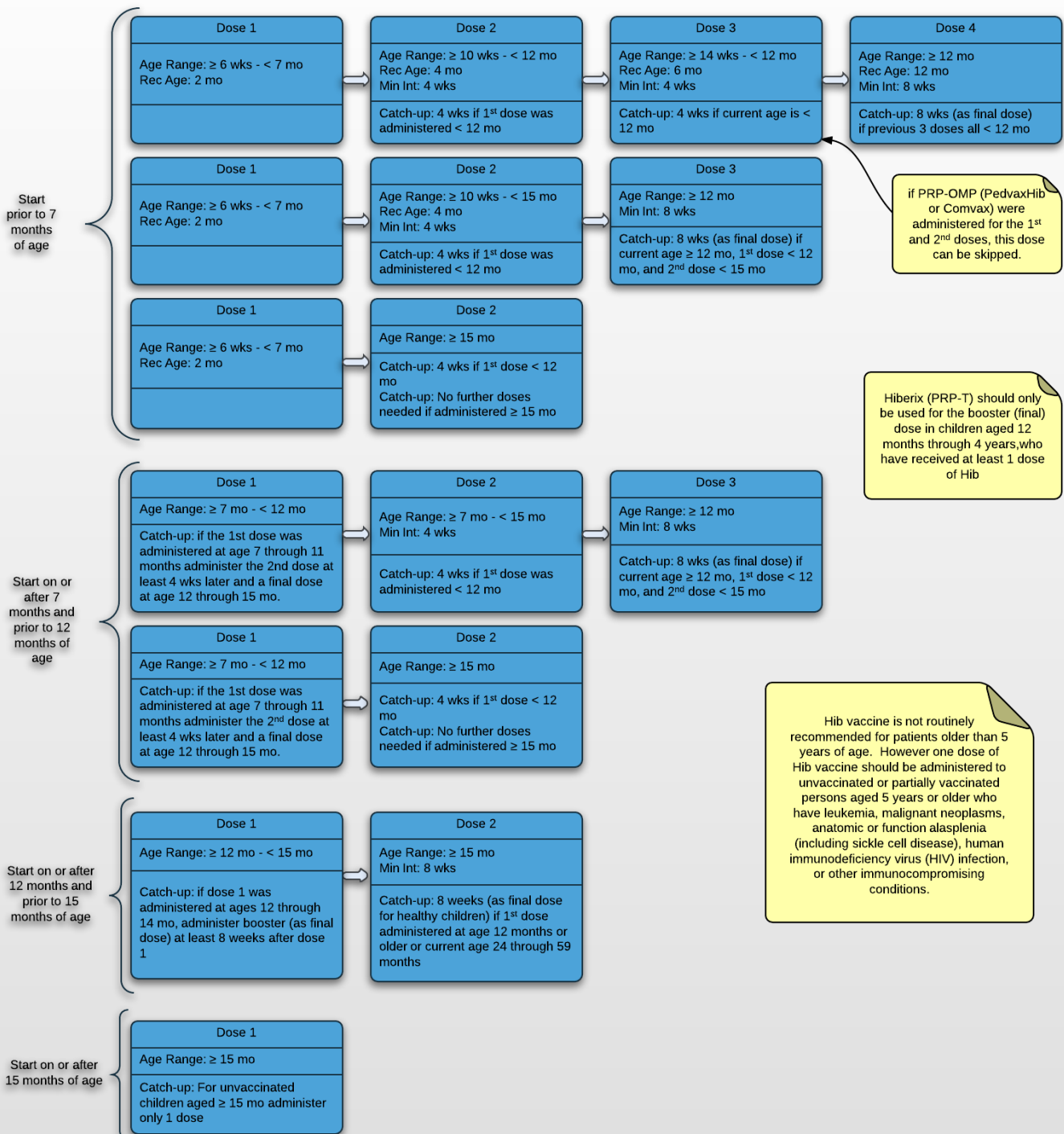
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APPENDIX E: SUPPLEMENTAL MATERIAL

Hib Paths to Immunity

ACIP Recommended Immunization Schedule for Persons Aged 0 Through 18 Years — United States, 2014 *



* <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6305a6.htm>

This diagram is for illustrative purposes only. Full CDSi Logic Specification, Supporting Data, and Test Cases can be found at: <http://www.cdc.gov/vaccines/programs/iis/interop-proj/cds.html>

APPENDIX F: DOCUMENT MANAGEMENT

Date	Changed By	Comments	Version #
8/31/12	L. McKenzie/E. Larson	Draft distributed to Expert Panel and Reviewers	0.1
10/05/12	L. McKenzie/E. Larson	Final Draft distributed to CDC leadership	0.2
10/29/12	L. McKenzie/E. Larson	Initial publication	1.0
11/14/12	L. McKenzie/J. Wain	Updated Executive Summary (1.3 and 1.4) Updated to meet section 508 requirements	1.1
01/09/13	J. Wain	Fixed minor errors in Acknowledgements Appendix	1.2
09/19/13	E. Larson	<ul style="list-style-type: none"> • Select Best Patient Series language clarifications <ul style="list-style-type: none"> ○ Sections 6.1, 6.2, 6.3, 6.5, and 6.6 • Select Best Patient Series Decision Table correction <ul style="list-style-type: none"> ○ Section 6.3 • Updated Date Calculation Intervals to define intervals to only be from Valid or Not Valid doses. Substandard doses do not need an interval. <ul style="list-style-type: none"> ○ Section 3.4 • Assessment date was added to the domain model and a typo was corrected in the definition of the term assessment date <ul style="list-style-type: none"> ○ Appendix A • Evaluation and Forecasting for Skipping Doses were updated to incorporate a Trigger Interval in addition to the existing Trigger Age to address issues found while testing polio, guidance from EIPB, and the harmonized schedule. <ul style="list-style-type: none"> ○ Sections 3.4, 4.2, 5.1, Appendix A • Updated business rule numbers to an improved identification scheme for referencing business rules and improved ability to insert newly needed business rules in the future. <ul style="list-style-type: none"> ○ Sections 3.4, 5.4, 6.7, 7.3, 7.4, 7.6 • Minor wording updates in various business rules to improve clarity and ability to implement <ul style="list-style-type: none"> ○ Section 3.4 	1.3
11/07/13	E. Larson	<ul style="list-style-type: none"> • Updates to properly select the catch-up schedule when children start late by age. A new concept (Maximum Age To Start) was defined in the appendix and added to the select best patient series logic. <ul style="list-style-type: none"> ○ Sections 6.1, 6.5, Appendix A • Added new appendix to address multiple paths to immunity concept as supplemental material and references to the new appendix in various sections. <ul style="list-style-type: none"> ○ Sections 2.1, 2.8, Appendix E • Updates to Forecast sections regarding Conditional Need. The logic remained the same as previously, but moved Conditional Need into its own section (New section 5.3) and added a specific target dose status for improved clarity on the use of conditional need. <ul style="list-style-type: none"> ○ Changes to Sections 3.2, 5, 5.3 (New), 5.4 (previously 5.3) • Document editorial consistency improvements 	1.4

Date	Changed By	Comments	Version #
		<ul style="list-style-type: none"> ○ Entire document 	
01/09/14	E. Larson	<ul style="list-style-type: none"> ● Evaluation and Forecasting for Skipping Doses were updated to incorporate a Trigger Target Dose to address issues found while testing Tdap/Td, guidance from EIPB, and the harmonized schedule. <ul style="list-style-type: none"> ○ Sections 4.2, 5.1, Appendix A ● Identify and Evaluate Vaccine Group (Chapter 7) was refactored to apply a cleaner process model, decision tree, and business rules based on Tdap/Td and MMR testing and research. <ul style="list-style-type: none"> ○ Chapter 7 	1.5
03/20/14	E. Larson	<ul style="list-style-type: none"> ● Updated inconsistencies found in Supplemental Material graphics. <ul style="list-style-type: none"> ○ Appendix E ● Added Business Rule to Calculate Dates to ensure consistent application of date calculations <ul style="list-style-type: none"> ○ Section 3.4 – See CALCDT-6 Business Rule 	1.6
08/14/2014	E. Larson	<ul style="list-style-type: none"> ● Updated definition of Maximum Age to Start <ul style="list-style-type: none"> ○ Section 6.1 ● Added/improved diagrams and process models <ul style="list-style-type: none"> ○ chapters 4, 5, 6, 7, 8 and appendices ● Updated attribute tables to cross-reference with date calculation business rules <ul style="list-style-type: none"> ○ chapters 4 and 5 ● Added a new Patient Series Status and associated usage of new “Aged Out” status. <ul style="list-style-type: none"> ○ Section 3.2 and chapters 5 and 6 ● Improved decision table and business rule language to fully utilize vocabulary. <ul style="list-style-type: none"> ○ Chapters 5 and 6 ● Assigned Patient Series Status to outcomes section of decision table. <ul style="list-style-type: none"> ○ Section 5.4 ● New Evaluation section was added to accommodate clarifications from EIPB on Hep A intervals after a not valid dose. <ul style="list-style-type: none"> ○ Section 4.6 was created (Allowable Interval). ○ Other updates due to this were in the chapter 4 process model, section 4.11, and Appendix A. 	1.7
12/16/2014	E. Larson	<ul style="list-style-type: none"> ● Added support for maximum doses by age (i.e.: 6 doses by 7 years in DTaP <ul style="list-style-type: none"> ○ Section 5.1 and Appendix A 	1.8