

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

National Center for Immunization and Respiratory Disease (NCIRD)

Immunization Information Systems Support Branch (IISSB)

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#### 1 EXECUTIVE SUMMARY

#### 1.1 BACKGROUND AND GOALS

In 2018, approximately 95% of U.S. children under the age of six participated<sup>1</sup> in an Immunization Information System (IIS), an increase from 82% in 2010.<sup>2</sup> Adolescent participation in 2018 was approximately 80%, up from 60% in 2010. Adult participation in 2018 increased to 56% up from 22% in 2010. Given this widespread IIS participation, it is important that each patient's immunization record is consistent and up to date within an IIS.

Health Information Systems (HIS) – which can include Health Information Exchanges (HIEs), IIS, Electronic Health Records (EHRs), and others – provide healthcare providers with immunization evaluation and forecasting tools designed to automatically determine the recommended 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 but are not limited to age for vaccine dose administered, number of doses, dosing interval, risk factors, 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.

To harmonize the outcomes of existing HIS CDS tools, the Immunization Information System Support Branch (IISSB) at the CDC funded the Clinical Decision Support for Immunization (CDSi) Project to develop clinical decision aids<sup>3</sup> for each vaccine preventable disease in accordance with ACIP recommendations 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 ultimate goal of the project is to ensure that patients receive proper immunizations, i.e., "the right immunization at the right time."

<sup>&</sup>lt;sup>1</sup> Participation was defined as having at least two recorded vaccinations in an Immunization Information System (IIS).

<sup>&</sup>lt;sup>2</sup> All data derived from the 2018 Immunization Information Systems Annual Report (IISAR). For further information, see: 2018 Immunization Information Systems Annual Report (IISAR).

<sup>&</sup>lt;sup>3</sup> 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

Please refer to Appendix D 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 individuals from birth through age 65+ years as well as those recommended because of underlying conditions.

**TABLE 1-1 VACCINE GROUPS IN SCOPE** 

Vaccine Groups			
Cholera	<ul> <li>Diphtheria, Tetanus, and Pertussis (DTaP, Tdap, Td)</li> </ul>	• Ebola	Hepatitis A
Hepatitis B	<ul> <li>Haemophilus influenzae type B (Hib)</li> </ul>	<ul> <li>Human         Papillomavirus         (HPV)     </li> </ul>	<ul> <li>Influenza</li> </ul>
Japanese Encephalitis	<ul> <li>Measles, Mumps, Rubella (MMR)</li> </ul>	<ul> <li>Meningococcal ACWY</li> </ul>	<ul><li>Meningococcal</li><li>B</li></ul>
<ul> <li>Pneumococcal</li> </ul>	<ul> <li>Polio</li> </ul>	<ul> <li>Rabies</li> </ul>	<ul> <li>Rotavirus</li> </ul>
<ul> <li>Typhoid</li> </ul>	<ul> <li>Varicella</li> </ul>	<ul> <li>Yellow Fever</li> </ul>	<ul> <li>Zoster</li> </ul>

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
- Immunities
- The 4-day grace period
- Catch-up schedule

While not addressed specifically, the CDSi resources were 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 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:

- Outbreak recommendations
- Immune Globulin (IG)
- Route and body site of administration
- Non-FDA approved vaccines (i.e., those used in clinical trials)
- Precautions
- Shared Clinical Decision Making

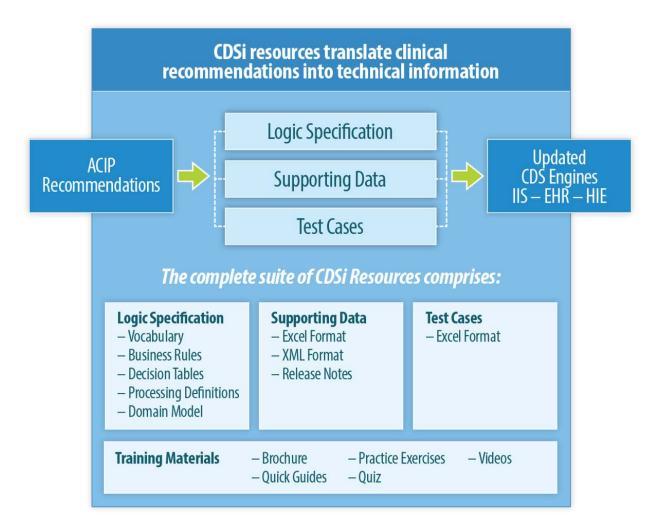
#### 1.4 Products

#### 1.4.1 Resources

The CDSi team has developed the resources 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 resources provide 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 CDSi resources 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, adolescent, and adult immunization evaluation and forecasting
- Provide testing scenarios to ensure the accurate implementation of the Supporting Data and Logic Specification by CDS engines
- Educate audiences regarding the content and use of the CDSi resources



**FIGURE 1-1 CDSI RESOURCES** 

The CDSi resources were developed to be as technology-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

#### 1.4.2 Logic Specification

The CDSi team developed a Logic Specification that describes the functionality required to evaluate and forecast based on the Supporting Data as applied to a patient's immunization history and patient observations. The Logic Specification uses defined vocabulary and domain models to build business rules, decision tables and a processing model which can be implemented by a CDS engine.

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.

#### 1.4.3 Supporting Data

The CDSi team developed Supporting Data to describe, by antigen, various factors and their accompanying sets of values to be considered when implementing ACIP recommendations. Supporting Data can be thought of as a set of configuration files used as input to a CDS engine. Supporting Data is published both as Excel spreadsheets and XML.

The intended audience of the Supporting Data 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.

#### 1.4.4 Test Cases

The CDSi team developed a representative set of test cases for use to compare and improve CDS engine actual results with ACIP recommendations and clarifications.

The intended audience of the Test Cases includes business implementers of immunization CDS engines who are responsible for ensuring the accuracy of the CDS engine. These implementers may support any system with an immunization evaluation and forecasting engine, including but not limited to an IIS.

#### 1.4.5 Training Materials

The CDSi team developed training materials to educate audiences interested in knowing more about the CDSi project and how to implement the accompanying CDSi resources. These materials are also intended to promote the use of CDSi by a variety of HIS.

The intended audience of the Training Materials includes anyone interested in knowing more about CDSi.

#### **2 RESOURCE 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	
Chapter 1	Executive Summary	Introduces the context, goals, and primary deliverable of the CDSi project.	
Chapter 2	Resource Overview	Provides a high-level overview of the key components of the CDSi resources. 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	Processing Model	Provides the major logical steps involved in the immunization evaluation and forecasting engine of the CDS process.	
Chapter 5	Create Relevant Patient Series	Provides the process for selecting series which are relevant for the patient.	
Chapter 6	Evaluate Vaccine Dose Administered	Provides the rules for evaluating a vaccine dose administered. The approach is documented using a process model, decision tables, and business rules.	
Chapter 7	Forecast Dates and Reasons	Provides the rules for determining forecast dates. The approach is documented using a process model, decision tables, and business rules.	
Chapter 8	Select 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 9	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 process model, decision tables, and business rules.	
Appendix A	Domain Model and Glossary	Provides a domain model that includes diagrams and vocabulary that is pertinent to the CDSi resources.	
Appendix B	Acronyms and Abbreviations	Provides the meanings of acronyms and abbreviations used in the document.	
Appendix C	Retired Items	Provides a list of concepts that have been previously included in the CDSi resources but are no longer used.	
Appendix D	Acknowledgements	Provides biographies of subject matter experts who served as volunteer panelists for the CDSi project.	
Appendix E	References	Provides citations of various reference materials that were used to document the business rules and Supporting Data tables.	
Appendix F	Supplemental Material	Provides supplemental material to aid with concepts found in CDSi resources.	
Appendix G	Document Management	Provides a table to track key changes and versions of the document.	

#### 2.2 RESOURCE DESIGN PRINCIPLES

The following guiding principles (GP) were central to the development and the design of the CDSi resources. Ultimately, the CDSi resources 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 CDSi resources 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	<b>Documentation Method</b>	
Supporting Data	Describes, by antigen, various factors and their accompanying sets of values to be considered when implementing ACIP recommendations	<ul> <li>Chapter 3:</li> <li>Introduction to Supporting Data</li> <li>Link to view Supporting Data spreadsheets</li> </ul>	
Logic Definition	Describes the functionality required to evaluate and forecast based on a patient's immunization history and the Supporting Data. Logic definitions include:  Select Relevant Series Logic Evaluation Logic Forecasting Logic Select Patient Series Logic Identify and Evaluate Vaccine Group Logic	<ul> <li>Chapters 3, 5, 6, 7, 8 &amp; 9:</li> <li>Thin process models</li> <li>Decision tables</li> <li>Business rules</li> </ul>	

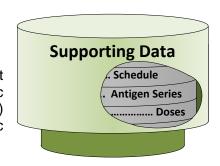
Component	Description	<b>Documentation Method</b>	
Processing Model	Describes the technical structure necessary to pull the details of the Logic Definition, Supporting Data, and patient related data together	<ul><li>Chapter 4:</li><li>Activity diagrams</li></ul>	

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

#### 2.4 SUPPORTING DATA

#### 2.4.1 Purpose

The **Supporting Data** 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 Specification.



Simply put, Supporting Data is akin to configuration data which feeds the system and is able to be modified separately from the logic. The Supporting Data supplied by the CDSi project represents the ACIP recommendations and clarifications from Subject Matter Experts at the Communication and Education Branch (CEB).

#### 2.4.2 What problem it helps solve

The Supporting Data was separated from the Logic Specification in order to reduce and ease the maintenance of the resources as clinical guidance evolves. The Supporting Data values change on a regular basis in conjunction with new and updated ACIP recommendations. The Logic Specification evolves much more slowly. When 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.

TABLE 2-3 SUPPORTING DATA SUGGESTED AUDIENCE

Role	Perspective	
	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 Specification, and processing model.	

#### 2.4.3 How and where it is documented

The format of the Supporting Data files is described below and the vocabulary in Appendix A provides definitions of the concepts and elements used within the CDSi resources. Additional understanding can be obtained by reviewing the actual Supporting Data. 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/cdsi.html.

The CDSi project provides two **Types** of Supporting Data:

- Antigen Supporting Data which holds the discrete data describing the ACIP recommendations for each antigen listed in the Scope section of Chapter 1.
- Schedule Supporting Data which documents information used across all antigens or between antigens.
   Flavors of schedule Supporting Data are:
  - A consolidated list of Coded Observations used to identify risk indications, underlying patient conditions and contraindications in the antigen Supporting Data files
  - A CVX to Antigen map which links individual CVX codes to antigen Supporting Data
  - A list of Vaccine Groups
  - A Vaccine Group to Antigen map to identify the antigens which make up a vaccine group
  - A Live Virus Conflict table to identify situations where the timing of administration of live virus vaccine may be impacted

Each Type of Supporting Data is available in both XML format as well as in spreadsheet form. The former is intended to be machine processable while the latter will be more helpful for humans reviewing the Supporting Data. Should the content of the two formats conflict, the Excel format should be considered the source of truth.

The antigen Supporting Data spreadsheets are split into a number of different **Sections** organized as different tabs of the spreadsheets:

- The Antigen Series Overview tab provides high level data for the antigen.
- The Change History tab documents the evolution of the Supporting Data across multiple releases of the CDSi resources.
- The FAQ tab is home to common questions about the antigen Supporting Data.
- The Immunity tab contains discrete data regarding when a patient may have sufficient evidence of immunity to the disease.
- The Contraindication tab identifies discrete patient scenarios which indicate when a dose should not be administered to a patient.
- One or more Series tabs which document different paths to immunity drawn from the ACIP recommendations.

Note that the Antigen Series Overview, Change History and FAQ tabs are largely intended for human consumption and the data in these Sections are not represented in the cognate XML file for the antigen.

Each Section is further sub-divided into multiple **Logical Components** which group sets of related data **Elements**. The figure below shows the Logical Components (which are always in Column A of the tab with a dark orange background) outlined in purple. The Elements of the Logical Component extend across the spreadsheet (with a light orange background) and are outlined in pink the figure. For a given Logical Component, there will be zero or more **Instances** of data (with a yellow background). For example, in the figure below, the Preferable Vaccine Logical Component contains three different Instances (Preferable Vaccines), each outlined in a different shade of green.

Furthermore, the Series tabs include a single set of series-level Logical Components which apply to the Series in general and are outlined in red in the figure below. As well, each Series includes one or more sets of dose-level Logical Components outlined in shades of blue in the figure. While the set of Logical Components is

identical in all doses, the Instance data may be different between doses within a series. For example, the Preferable Interval for the second dose in the Series may be different than the Preferable Interval for the third dose in the series.

A	В	С	D			G
Series Name	HepB 3-dose series	y	i i			
Target Disease	НерВ					
Vaccine Group	НерВ					
Administrative	Test					
Guidance	n/a					
Series Type	Type					
Selles Type	Standard					
Equivalent Series Groups	Series Groups					
Groups	2					
Gender	Required Gender					
EC-111(1957).	n/a					
Select Patient Series	Default Series	Product Path	Series Group Name	Series Group	Series Priority	Series Preference
	Yes	No	Standard	1	A	1
Indication	Observation (Code)	Text Description	Indication Begin Age	Indication End Age (less than)	Administrative Guidance	
participants.	n/a	n/a	n/a	n/a	n/a	
Tarana and a same and						
Series Dose	Dose 1					
Age	Absolute Minimum Age	Minimum Age	Earliest Recommended Age	Latest Recommended Age (less than)	Maximum Age (less than)	
	0 days	0 days	0 days	4 weeks	19 years	
Preferable Interval	From Immediate Previous Dose Administered? Y/N	From Target Dose # in Series	From Most Recent (CVX List)	From Relevant Observation (Code)	Absolute Minimum Interval	Minimum Interval
	n/a	n/a	n/a	n/a	n/a	n/a
Allowable Interval	From Immediate Previous Dose Administered? Y/N	From Target Dose # in Series	Absolute Minimum Interval			
	n/a	n/a	n/a			
Preferable Vaccine	Vaccine Type (CVX)	Vaccine Type Begin Age	Vaccine Type End Age (less than)	Trade Name (MVX)	Volume (in ml)	Forecast Vaccine Type (YM
	Hep B, Adol/peds (08)	0 days	20 years	n/a	0.5	N
	Hep B, Adult (43)	20 years	n/a	n/a	1.0	I N
	Hep B. Dialysis (44)	20 years	n/a	n/a	1.0	N
Allowable Vaccine	Vaccine Type (CVX)	Vaccine Type Begin Age	Vaccine Type End Age (less			- Harbita
	Hep B, Adol/peds (08)	0 days	than) 20 years			
	Hep B, Adult (43)	0 days	n/a			
	Hep B, Dialysis (44)	0 days	n/a			
	HepA-HepB (104)	0 days	n/a			
Inadvertent Vaccine	Vaccine Type (CVX)	0 days	iva			
induction vocality	n/a					
Conditional Skip	Set Logic	Set ID	Description	Condition Logic	Condition ID	Туре
	n/a	n/a	n/a	n/a	n/a	n/a
Recurring Dose	Recurring Dose (Yes/No)	100	100	11.0	100	10.0
Bedanto Waller and Calanti	No					
Seasonal Recommendation	Start Date	End Date				
- John Maria	n/a	n/a				
decreases on the same						
Series Dose	Dose 2					
Age	Absolute Minimum Age	Minimum Age	Earliest Recommended Age	Latest Recommended Age (less than)	Maximum Age (less than)	
	4 weeks - 4 days	4 weeks	1 month	3 months + 4 weeks	n/a	
Preferable Interval	From Immediate Previous Dose Administered? Y/N		From Most Recent (CVX List)	From Relevant Observation	Absolute Minimum Interval	Minimum Interval
	V	n/a	n/a	(Code) n/a	4 weeks - 4 days	4 weeks
Allowable Interval	From Immediate Previous Dose Administered? Y/N	From Target Dose # in Series	Absolute Minimum Interval	11/4	4 WCCNS - 4 Uays	4 WCCKS
and a second second	n/a	n/a	n/a			
	Vaccine Type (CVX)	Vaccine Type Begin Age	Vaccine Type End Age (less	Trade Name (MVX)	Volume (in ml)	Forecast Vaccine Type (YA
Preferable Vaccine			than)	trade reality ferried	A STATE OF THE STA	The state of the last
Preferable Vaccine	Hep B, Adol/peds (08)	0 days	20 years	n/a	0.5	N

FIGURE 2-1 SUPPORTING DATA

#### 2.5 LOGIC DEFINITION - PURPOSE

The logic definition describes, in a technology-neutral fashion, the functional steps necessary to process the patient's history using the Supporting Data.

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

- Evaluation
- Forecasting
- Select 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

#### 2.6.1 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.

# Evaluation Forecasting lect Best Patient Series late Vaccine Group

**Logic Definition** 

ect Best Patient Series

vate Vaccine Group

Evaluation Forecasting

#### 2.6.2 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 2-4 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 Specification and processing model.

#### 2.6.3 How and where it is documented

Chapter 6 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 subcomponent and the resulting outcomes.

#### 2.7 LOGIC DEFINITION - FORECASTING

#### 2.7.1 Purpose

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

#### 2.7.2 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.



Role	Perspective
	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 Specification and processing model.

#### 2.7.3 How and where it is documented

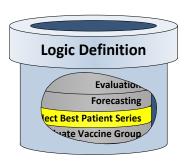
Chapter 7 describes the process of forecasting. It is documented using the following:

- 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 PATIENT SERIES

#### 2.8.1 Purpose

The logic definition **select 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.



**Logic Definition** 

ect Best Patient Series

vate Vaccine Group

**Evaluation** 

**Forecasting** 

#### 2.8.2 What problem it helps solve

There is more than one path which can lead a patient to immunity. See Appendix F for representations of multiple patient series (paths to immunity) for an antigen. Select 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 2-6 SELECT PATIENT SERIES SUGGESTED AUDIENCE**

Role	rspective					
<b>Business Analyst</b>	Understanding and documenting the logical steps of Select Patient Series and the factors used when scoring 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 Specification, and processing model.					

#### 2.8.3 How and where it is documented

Chapter 8 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 patient series.
- A vocabulary table that provides meanings to terms used strictly in the select 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

#### 2.9.1 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.



#### 2.9.2 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 2-7 IDENTIFY AND EVALUATE VACCINE GROUP SUGGESTED AUDIENCE

Role	Perspective
<b>Business Analyst</b>	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 Specification, and processing model.

#### 2.9.3 How and where it is documented

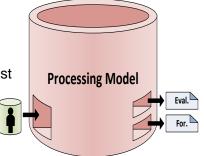
Chapter 9 describes the process of identifying and evaluating vaccine groups. It is documented using the following:

- 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

#### 2.10Processing Model

#### **2.10.1 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.

#### 2.10.2 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 2-8 PROCESSING MODEL SUGGESTED AUDIENCE

Role	Perspective
	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 Specification.

#### 2.10.3 How and where it is documented

Chapter 4 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.

#### 2.11 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 two different styles. Both start with a simple business question as the title or subject of the decision table.

The majority of decision tables in the Logic Specification use a condition/outcome style formatting. In this approach, the top half 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 2-9 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	No. My car is not	No. I cannot	Yes. I should get					
	wash is closed.	dirty.	afford it.	my car washed.					

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

**TABLE 2-10 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.						

In the second style, the outcome is the intersection of a row and column where the row and column heading are the conditions. The example below illustrates exercise based on the day of the week and the weather outside. For example, the exercise on Saturday when it is raining outside is a Yoga Class.

**TABLE 2-11 WHAT EXERCISE SHOULD I DO TODAY?** 

		Weather	
	Dry	Raining	Snowing
Monday	Trail Run	Treadmill	Cross Country Ski
Tuesday	No Exercise	No Exercise	No Exercise
Wednesday	Trail Run	Treadmill	Cross Country Ski
Thursday	Trail Run	Treadmill	Cross Country Ski
Friday	No Exercise	No Exercise	No Exercise

Weather					
Saturday	Golf	Yoga Class	Downhill Ski		
Sunday	Golf	Yoga Class	Downhill Ski		

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 tables 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.

#### 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 however this situation isn't the common path and not immediately discussed here. Details on skipping target doses can be found in Chapters 6 and 7.

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.

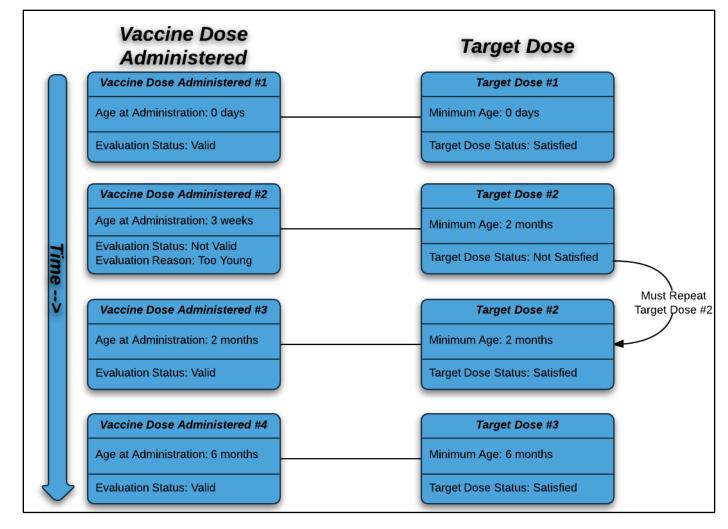


FIGURE 3-1 HOW A VACCINE DOSE ADMINISTERED SATISFIES A TARGET DOSE

#### 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** 

Status	Meaning					
Extraneous	An evaluation status that indicates 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	An evaluation status that indicates the vaccine dose administered was not administered according to ACIP recommendations and must be repeated at an appropriate time in the future					
Sub-standard	An evaluation status that indicates 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					
Valid	An evaluation status that indicates the vaccine dose administered was administered according to ACIP recommendations					

#### **TABLE 3-2 TARGET DOSE STATUSES**

Status	Meaning			
Not Satisfied	A target dose status that indicates no vaccine dose administered has met the goals of the target dose			
Satisfied A target dose status that indicates a vaccine dose administered has met the goals of the target do				
Skipped	A target dose status that indicates 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.			

#### TABLE 3-3 PATIENT SERIES STATUSES

Status	Meaning
Aged Out	A patient series status that indicates the patient exceeded the maximum age prior to completing the patient series
Complete	A patient series status that indicates the patient has met all of the ACIP recommendations for the patient series
Contraindicated	A patient series status that indicates no further vaccines should be administered at this time for the patient series
Immune	A patient series status that indicates the patient has evidence of immunity indicating no further vaccines are needed for the patient series
Not Complete	A patient series status that indicates the patient has not yet met all of the ACIP recommendations for the patient series
Not Recommended	A patient series status that indicates the patient's immunization history provides sufficient protection against a disease and there's no recommended action at this time

#### 3.3 SELECTING SUPPORTING DATA

When a clinical recommendation is changed, it is typically applied to patient evaluation and forecasting retroactively but, depending on the nature of the change, the evaluation status of administered doses may or may not change. For example, if a recommendation changed the minimum interval from 6 months to 4 months, previously administered doses that met the 6 month interval requirement are still considered valid when the new 4 month interval is applied. For this reason, many recommendations changes are instituted in new published versions of the Supporting Data simply as a new value with no indication of the previous value.

However, some recommendation changes are not applied retroactively and historical Supporting Data must be retained and selectively applied during the evaluation and forecasting processes. For example, prior to the ACIP HPV recommendation published 12/16/2016, the absolute minimum interval between Doses 1 and 3 was 16 weeks but the recommendation increased the absolute minimum interval to 5 months minus 4 days. However, the change was not applied retroactively. Therefore, a third dose administered prior to 12/16/2016 need only meet the 16 week interval while a third dose (for a different patient) administered on or after 12/16/2016 would need to meet the longer 5 month interval. In the figure below, these differential requirements are represented, highlighted in blue, in the Supporting Data using Effective and Cessation Dates which indicate a date range that the Supporting Data component was in effect.

Only a subset of the Supporting Data Logical Components use Effective and Cessation Dates elements (e.g. Age, Preferable Interval, Allowable Interval and Conditional Skip). When a Logical Component does not include Effective and Cessation Dates elements (e.g. Preferable Vaccine, Allowable Vaccine, Inadvertent Vaccine, Recurring Dose and Seasonal Recommendation), the Instances of supporting data in that Logical Component must be selected for evaluation and forecasting purposes.

In order to determine if a Supporting Data Logical Component Instance is relevant, the anchor date (the administration date in the case of an evaluation or the assessment date in the case of a forecast) must fall between the Effective and Cessation Dates (see decision table below) for the Supporting Data. This selection process must be applied any time either the Effective Date or Cessation Date is valued other than "n/a" in the Supporting Data as highlighted in red below. Data Instances where both valued "n/a" must be always be applied during the evaluation and forecasting process.

Preferable Interval	From Immediate Previous Dose Administered? Y/N	From Target Dose # in Series	From Most Recent (CVX List)	From Relevant Observation (Code)	Absolute Minimum Interval	Minimum Interval	Earliest Recommended Interval	Latest Recommended Interval (less than)	Interval Priority Flag	Effective Date	Cessation Date
	N	1	n/a	n/a	16 weeks	5 months	6 months	7 months + 4 weeks	n/a	n/a	12/15/2016
	N	1	n/a	n/a	5 months - 4 days	5 months	6 months	7 months + 4 weeks	n/a	12/16/2016	n/a
	Y	n/a	n/a	n/a	12 weeks - 4 days	12 weeks	n/a	n/a	n/a	n/a	n/a

FIGURE 3-2 SELECTING SUPPORTING DATA

#### **TABLE 3-4 RELEVANT SUPPORTING DATA ATTRIBUTES**

Attribute Type	Attribute Name	Assumed Value if Empty
Vaccine dose administered	Date Administered	-
Processing date	Assessment Date	current date
Supporting Data (Effective Date)	Effective Date	01/01/1900
Supporting Data (Cessation Date)	Cessation Date	12/31/2999

#### TABLE 3-5 SELECT RELEVANT SUPPORTING DATA LOGICAL COMPONENT ELEMENT

Business Rule ID	Business Rule
RELEVANT-1	A logical component instance must be used in evaluation if one of the following is true:  • neither an Effective Date nor a Cessation Date are defined for the logical component  • the Effective Date and Cessation Date are both populated "n/a"  • the Effective Date <= Date Administered <= Cessation Date
RELEVANT-2	A logical component instance must be used in forecasting or selecting the best patient series if one of the following is true:  • neither an Effective Date nor a Cessation Date are defined for the logical component  • the Effective Date and Cessation Date are both populated "n/a"  • the Effective Date <= Assessment Date <= Cessation Date

In addition to Supporting Data selection by Effective and Cessation Dates, relevant Conditional Skip Logic Component Instances must be selected on the basis of context. In some scenarios, the rationale for skipping a dose in a series differs depending on whether a retrospective evaluation or a prospective forecast is being performed. In the Supporting Data, 4 contexts are possible:

• Evaluation – applicable when a dose is being evaluated (see section 6.2)

- Forecast applicable when a dose is being forecasted (see section 7.1)
- Both applicable when a dose is being either evaluated or forecasted (see sections 6.2 and 7.1)
- n/a there are no conditions that can result in a dose being skipped during either evaluation or forecast

Conditional Skip	Skip Context	Set Logic	Set ID	Description
				Dose is not
	Evaluation	AND	4	required for those 4
	Evaluation	AND	'	years - 4 days or
				older.
				Interval greater
				than or equal to 6
				months - 4 days
				Dose is not
				required for those
	Forecast	n/a	2	who will be 4 years
	i orecast	II/a	2	or older at the
				earliest forecasted
				date for next dose.

FIGURE 3-3 CONDITIONAL SKIP CONTEXT

#### 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 3-6 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.	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 datemonth (and date-year, if necessary) while holding the dateday constant.	01/01/2000 + 6 months = 07/01/2000 11/01/2000 + 6 months = 05/01/2001
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.	01/01/2000 + 3 days = 01/04/2000 01/01/2000 + 3 weeks = 01/22/2000 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.	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.	03/31/2000 + 6 months = 10/01/2000 (September 31 does not exist) 08/31/20010 + 6 months = 03/01/2001 (February 31 does not exist)

Business Rule ID	Business Rule	Example
CALCDT-6	A computed date must be calculated by first adjusting the years, followed by the months, and finally the weeks and/or days.	01/31/2000 + 6 months - 4 days = 07/27/2000

#### **TABLE 3-7 LOGICAL COMPONENT DATE RULES**

Business Rule ID	Business Rule
CALCDTAGE-1	A patient's maximum age date must be calculated as the patient's date of birth plus the maximum age.
CALCDTAGE-2	A patient's latest recommended age date must be calculated as the patient's date of birth plus the latest recommended age.
CALCDTAGE-3	A patient's earliest recommended age date must be calculated as the patient's date of birth plus the earliest recommended age.
CALCDTAGE-4	A patient's minimum age date must be calculated as the patient's date of birth plus the minimum age.
CALCDTAGE-5	A patient's absolute minimum age date must be calculated as the patient's date of birth plus the absolute minimum age.
CALCDTALLOW-1	A patient's allowable vaccine type begin age date must be calculated as the patient's date of birth plus the vaccine type begin age of an allowable vaccine.
CALCDTALLOW-2	A patient's allowable vaccine type end age date must be calculated as the patient's date of birth plus the vaccine type end age of an allowable vaccine.
CALCDTCI-1	A patient's contraindication begin age date must be calculated as the patient's date of birth plus the contraindication begin age of either the antigen contraindication or vaccine contraindication.
CALCDTCI-2	A patient's contraindication end age date must be calculated as the patient's date of birth plus the contraindication end age of either the antigen contraindication or vaccine contraindication.
CALCDTIND-1	A patient's indication begin age date must be calculated as the patient's date of birth plus the indication begin age.
CALCDTIND-2	A patient's indication end age date must be calculated as the patient's date of birth plus the indication end age.
CALCDTINT-1	A patient's reference dose date for an interval must be calculated as the date administered of the most immediate previous vaccine dose administered if all the following are true for the interval:  • from immediate previous dose administered is "Y"  • the evaluation status is "Valid" or "Not Valid"  • the vaccine dose administered is not an inadvertent administration.
CALCDTINT-2	A patient's reference dose date for an interval must be calculated as the date administered of the vaccine dose administered that satisfies the target dose with the same dose number as the from target dose number in series if all the following are true for the interval:  • from immediate previous dose administered is "N"  • from target dose number in series is not "n/a".
CALCDTINT-3	A patient's absolute minimum interval date must be calculated as the patient's reference dose date plus the absolute minimum interval.
CALCDTINT-4	A patient's minimum interval date must be calculated as the patient's reference dose date plus the minimum interval.
CALCDTINT-5	A patient's earliest recommended interval date must be calculated as the patient's reference dose date plus the earliest recommended interval.

Business Rule ID	Business Rule
CALCDTINT-6	A patient's latest recommended interval date must be calculated as the patient's reference dose date plus the latest recommended interval.
CALCDTINT-7	A patient's latest minimum interval date must be the latest date of all calculated minimum interval dates for a given target dose.
CALCDTINT-8	A patient's reference dose date for an interval must be calculated as the date administered of the most recent vaccine dose administered that is the same vaccine type as the from most recent vaccine type if all the following are true for the interval:  • from immediate previous dose administered is "N"  • from most recent vaccine type is not "n/a"  • the vaccine dose administered is not an inadvertent administration.
CALCDTINT-9	A patient's reference dose date for an interval must be calculated as the observation date of the most recent active patient observation if all the following are true for the interval:  • from immediate previous dose administered is "N"  • from relevant observation code is not "n/a".
CALCDTLIVE-1	A patient's conflict begin interval date must be calculated as the date administered of the conflicting vaccine dose administered plus the live virus conflict begin interval.
CALCDTLIVE-2	A 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 if the conflicting vaccine dose administered has evaluation status "valid."
CALCDTLIVE-3	A 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 if the conflicting vaccine dose administered does not have evaluation status "valid."
CALCDTLIVE-4	A patient's latest conflict end interval date must be the latest date of all calculated conflict end interval dates for a given target dose.
CALCDTPREF-1	A patient's preferable vaccine type begin age date must be calculated as the patient's date of birth plus the vaccine type begin age of a preferable vaccine.
CALCDTPREF-2	A patient's preferable vaccine type end age date must be calculated as the patient's date of birth plus the vaccine type end age of a preferable vaccine.
CALCDTSKIP-3	A patient's conditional skip begin age date must be calculated as the patient's date of birth plus the Begin Age of the conditional skip condition.
CALCDTSKIP-4	A patient's conditional skip end age date must be calculated as the patient's date of birth plus the End Age of the conditional skip condition.
CALCDTSKIP-5	A patient's conditional skip interval date must be calculated as the vaccine date administered from the immediate previous vaccine dose administered plus the Interval of the conditional skip condition.

#### 4 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, is very mechanical in nature and focuses on gathering and prepping all of the required data. The second part uses the data gathered earlier to generate the evaluation and forecast.

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

**TABLE 4-1 LOGIC SPECIFICATION PROCESSING STEPS** 

Section	Activity	Goal
4.1	Gather Necessary Data	The goal of this step is to gather all pertinent information which will be used in subsequent steps in the process.
4.2	Organize Immunization History	The goal of this step is to break apart vaccine doses administered into their antigen parts.
4.3	Create Relevant Patient Series	The goal of this step is to instantiate (Chapter 5) all antigen series defined through supporting data into patient series for this patient.
4.4	Evaluate and Forecast All Patient Series	The goal of this step is to evaluate (Chapter 6) each antigen administered and create a forecast for each patient series (Chapter 7).
4.5	Select Patient Series	The goal of this step is to select the patient series (Chapter 8) for the patient based on their evaluated history and forecast.
4.6	Identify and Evaluate Vaccine Group	The goal of this step is to merge together antigen-based forecasts into a vaccine group forecast (Chapter 9).

FIGURE 4-1 PROVIDES THE HIGH-LEVEL PROCESS OF THE MAJOR STEPS OF THE PROCESSING MODEL.

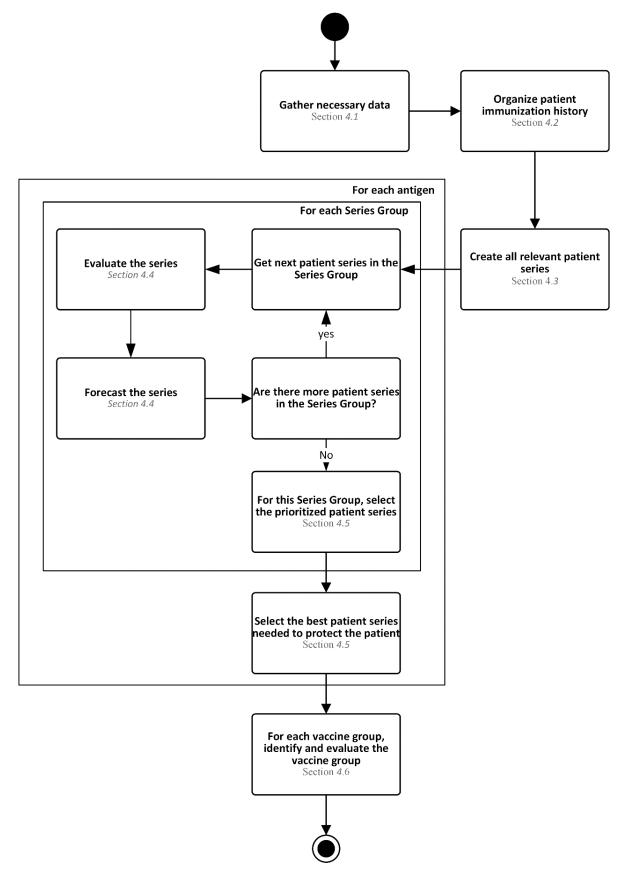


FIGURE 4-1 LOGIC SPECIFICATION PROCESSING MODEL

As illustrated in Figure 4-2, as the process model progresses, the set of patient series continually becomes more restricted as:

- Relevant Patient Series are selected from the total list of Antigen Series based on standard recommendations, patient gender and patient observations
- Scorable Patient Series are selected from the evaluated and forecasted Relevant Patient series
- A single Prioritized Patient Series is selected for Series Group based on score
- One or more non-redundant Best Patient Series are selected from the Prioritized Patient Series

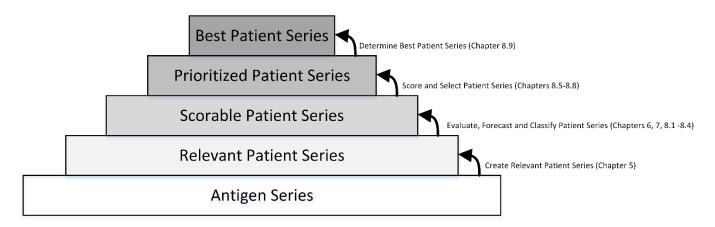


FIGURE 4-2 REFINEMENT OF PATIENT SERIES

#### 4.1 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 Reaction
- Patient Observations

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.

#### 4.2 Organize Immunization History

The second 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, these antigens are assembled into commonly known vaccine groups (vaccine families) for vaccine group forecasts.

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

TABLE 4-2 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
ActHIB (48/PMC) – Hib	03/01/2011
Prevnar 13 (133/WAL) – PCV13	03/01/2011
Pediarix (110/SKB) – DTaP-HepB-IPV	06/01/2011
ActHIB (48/PMC) – Hib	06/01/2011
Prevnar 13 (133/WAL) – PCV13	06/01/2011
ProQuad (94/MSD) – MMRV	01/01/2012

TABLE 4-3 AFTER ORGANIZE IMMUNIZATION HISTORY EXAMPLE

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	НерВ
Pediarix (110/SKB) – DTaP-HepB-IPV	03/01/2011	НерВ
Pediarix (110/SKB) – DTaP-HepB-IPV	06/01/2011	НерВ
ActHIB (48/PMC) – Hib	03/01/2011	Hib
ActHIB (48/PMC) - 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

Product (CVX/MVX) – Description	Date	Antigen*
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

<sup>\*</sup>Sorted by antigen and then by date

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

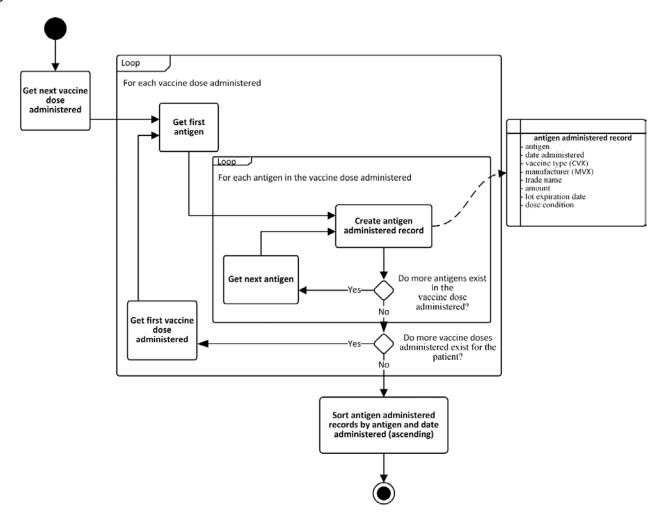


FIGURE 4-3 ORGANIZE IMMUNIZATION HISTORY PROCESS MODEL

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.
- 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. The following notes should be considered:
  - a. The CVX to Antigen Supporting Data includes Association Begin Age and Association End Age attributes to properly associate the administered vaccine with the proper antigen based on the age of patient at the time of administration (e.g., a Zoster vaccine administered below 50 years should be associated with Varicella).
  - b. 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.
- 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/cdsi.html

#### 4.3 CREATE RELEVANT 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. Some series, classified here as "Standard" series, are based on recommendations for all patients based on age. Other series, classified as "Risk" series, are based on recommendations for patients with specific characteristics or underlying conditions which put them at increased risk. Standard series should be created and evaluated for all patients. Risk series will only be relevant to a subset of patients and should be created selectively so as to avoid false positive recommendations.

Similar to gathering necessary data (section 4.1), *create relevant 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 are discussed in detail in Chapter 5.

The process model below shows the iterative steps to create relevant patient series. At the end of this step, each antigen series relevant for the patient is turned into a patient series.

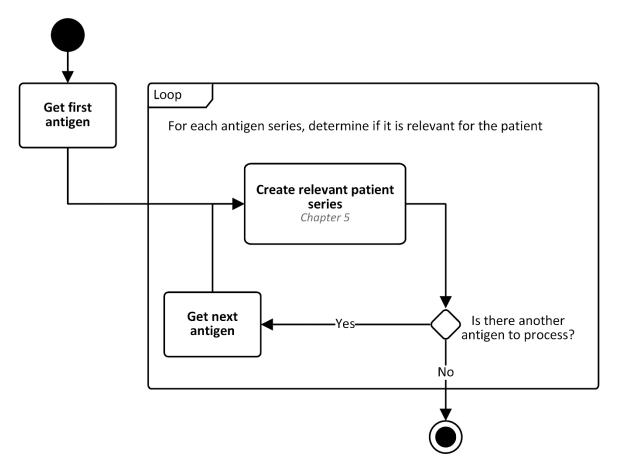


FIGURE 4-4 CREATE RELEVANT PATIENT SERIES PROCESS MODEL

## 4.4 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 4-5 shows the high-level iterative process of looping through all patient series. Next, Figure 4-6 specifically deals with the details of evaluation. A description of the activity diagram follows each figure.

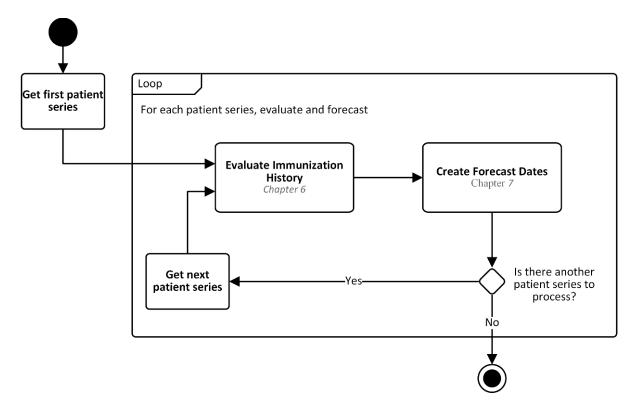


FIGURE 4-5 EVALUATE AND FORECAST PROCESS MODEL

At the highest level of this step, as illustrated in the figure above, 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 relevant patient series* step (Chapter 5), 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 7.

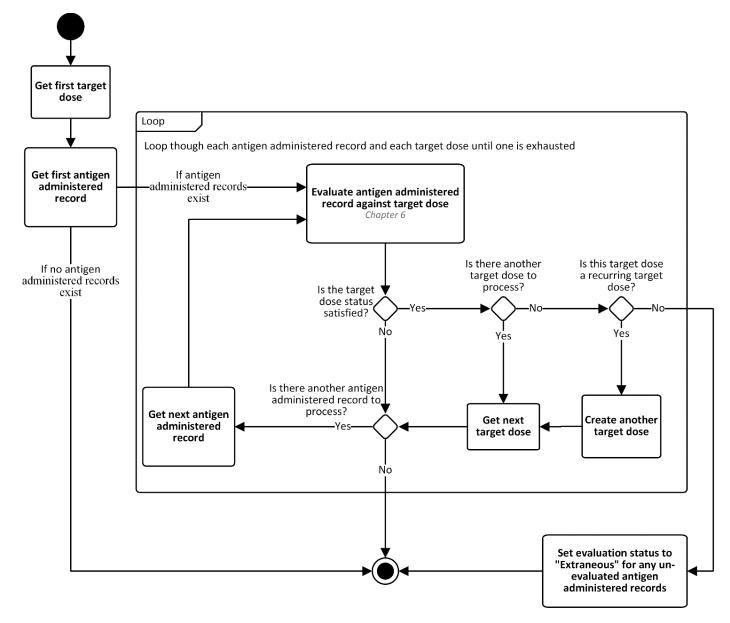


FIGURE 4-6 EVALUATE IMMUNIZATION HISTORY PROCESS MODEL

Figure 4-6 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.

It should also be noted that when multiple patient series have been created (Chapter 5), all antigen administered records for the patient should be evaluated against each series, and a status (valid, invalid, etc.) should be assigned per dose per series. An administered dose that is "valid" for one series may be "invalid" for a different series for the same patient.

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 6 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 as well as certain risk series.) A recurring dose may recur based on a time interval from the previous dose (i.e. a tetanus recurring dose every 10 years for adults) or based on a patient observation (i.e. a pertussis recurring dose with every pregnancy).
  - 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).

## 4.5 SELECT PATIENT SERIES

The goal of select patient series is to determine the best path(s) to immunity for the patient based on the evaluated immunization history, forecast, and any patient observations. Typically, a best series will be selected for each Series Group, however, some antigen define Equivalent Series Groups which allow a single best series to be selected from across multiple Series Groups. In most cases, it will be possible to select a single best patient

series, in other cases, multiple best patient series may be relevant to a patient. For example, a patient may need to complete a risk series in the short term to address an underlying risk condition but still need to complete a standard series later in life.

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 8 to each antigen. A sample iterative process model is shown below to detail the looping structure.

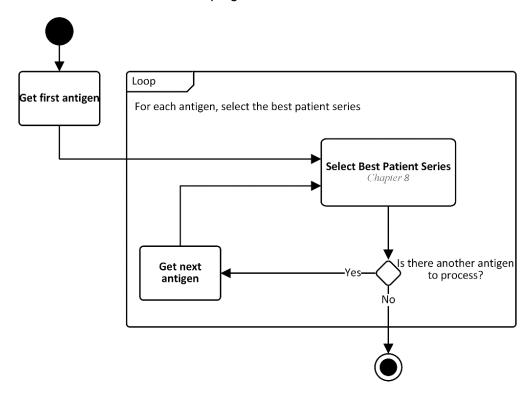


FIGURE 4-7 SELECT BEST SERIES PROCESS MODEL

#### 4.6 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 9. For vaccine groups which contain non-equivalent series groups, it is important to only blend patient series of the same series type (i.e. risk with risk and standard with standard).

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 9 to each vaccine group. Figure 4-8 is a sample iterative process model that shows the looping structure.

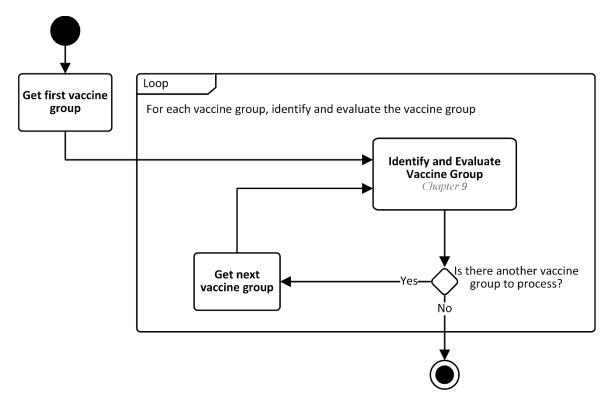


FIGURE 4-8 IDENTIFY AND EVALUATE VACCINE GROUP PROCESS MODEL

# 5 CREATE RELEVANT PATIENT SERIES

The antigen Supporting Data provided defines one or more series for each antigen. Before beginning the evaluation process for a given patient, a set of relevant patient series must first be selected and created for the patient. Not all series will be relevant for a given patient and only series appropriate for the patient should be evaluated. The appropriateness of a series is based on criteria such as patient gender, age and underlying conditions.

**TABLE 5-1 CREATE PATIENT SERIES PROCESS STEPS** 

Section	Activity	Goal
5.1	Select Relevant Patient Series	The goal of this step is to identify the series which are appropriate for the patient.

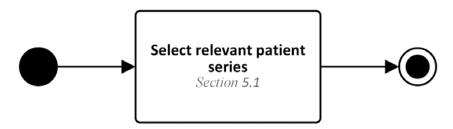


FIGURE 5-1 CREATE RELEVANT SERIES PROCESS MODEL

## 5.1 SELECT RELEVANT PATIENT SERIES

Select relevant patient series determines which series defined by the Supporting Data are appropriate to evaluate for the patient. Series with a Series Type of "Standard" are relevant for all patients of the appropriate gender. Not all series with a Series Type of "Risk" will be appropriate for a given patient.

Given the complex nature of indications, it may not always be possible to conclusively determine if an indication applies to a patient. To minimize false positive forecasts, in the case where a Risk Series cannot be definitively determined to be relevant for a patient (that is some or all indications are inconclusive and none unambiguously apply to the patient) the series will not be evaluated or forecast, but a notification should be available to a clinician alerting them to the presence of the indication(s) which could not be resolved.

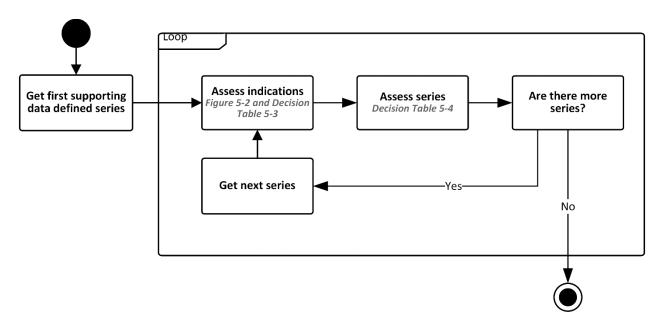


FIGURE 5-2 SELECT SERIES PROCESS MODEL

**TABLE 5-2 SELECT SERIES ATTRIBUTES** 

Attribute Type	Attribute Name	Assumed Value if Empty	
Patient	Gender	Unknown	
Supporting Data (Gender)	Required Gender	Gender of the patient	
Supporting Data (Series Type)	Series type	-	
Supporting Data (Observation Code)	Indication	-	
Processing data	Assessment Date	current date	
Calculated date (CALCDTIND-1)	Indication Begin Age Date	01/01/1900	
Calculated date (CALCDTIND-2)	Indication End Age Date	12/31/2999	

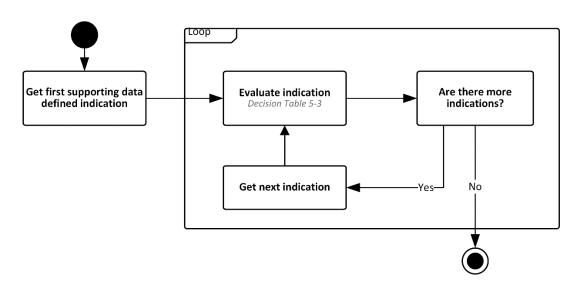


FIGURE 5-3 ASSESS INDICATIONS PROCESS MODEL

## TABLE 5-3 DOES THE INDICATION APPLY TO THE PATIENT?

CONDITIONS	RULES			
Does the indication describe any active patient observations?	Yes	No	-	Unknown
Is the indication begin age date ≤ assessment date < indication end age date?	Yes	-	No	Yes
OUTCOMES	Indication	No. The Indication does not apply to the patient.	No. The Indication does not apply to the patient.	No. The Indication does not apply to the patient; however, the Indication Text Description should be made available to the clinician for manual determination.

## TABLE 5-4 IS THE SERIES RELEVANT FOR THE PATIENT?

CONDITIONS	RULES				
Is the patient's gender one of the required genders?	Yes	No	Yes	Yes	
Is the series a Standard Series?	Yes	-	No	No	
Does at least one indication apply to the patient?	-	-	Yes	No	
OUTCOMES	Yes. The series is relevant for the patient.	No. The series is not relevant for the patient.	Yes. The series is relevant for the patient.	No. The series is not relevant for the patient.	

## 6 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 within a series to determine if the vaccine dose administered is "valid" or "not valid" for the series. The results will ultimately determine if all requirements of the target dose are satisfied. 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 6-1 EVALUATION PROCESS STEPS**

Section	Activity	Goal	
6.1	Evaluate Dose Administered Condition	The goal of this step is to determine if a vaccine dose administered can be evaluated.	
6.2	Evaluate Conditional Skip	The goal of this step is to determine if the target dose can be skipped due to a patient's age or immunization history.	
6.3	Evaluate For Inadvertent Vaccine	The goal of this step is to determine if the vaccine dose administered was an inadvertent administration due to the vaccine type that was administered.	
6.4	Evaluate Age	The goal of this step is to determine if the vaccine dose administered was giv at an appropriate age.	
6.5	Evaluate Preferable Interval	The goal of this step is to determine if the vaccine dose administered was give at an appropriate interval.	
6.6	Evaluate Allowable Interval	The goal of this step is to determine if the vaccine dose administered was given at an allowable interval.	
6.7	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.	
6.8	Evaluate For Preferable Vaccine	The goal of this step is to determine if the vaccine dose administered was one of the preferable vaccines.	
6.9	Evaluate For Allowable Vaccine	The goal of this step is to determine if the vaccine dose administered was one of the allowable vaccines.	
6.10	Satisfy Target Dose	The goal of this step is to determine if the target dose is satisfied.	

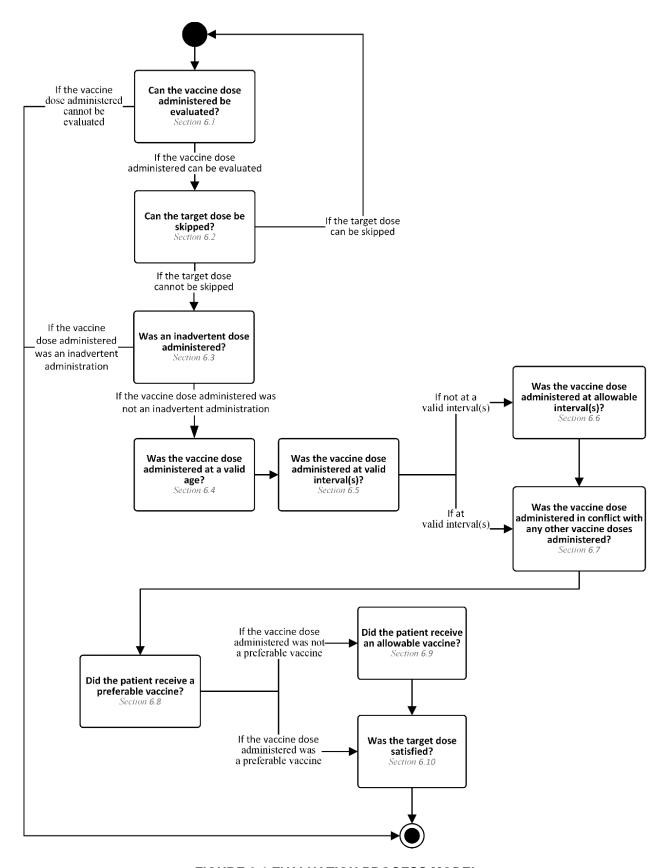


FIGURE 6-1 EVALUATION PROCESS MODEL

## 6.1 EVALUATE DOSE ADMINISTERED CONDITION

Evaluate 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.

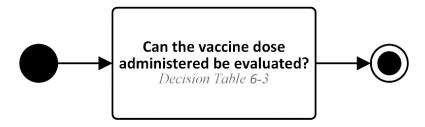


FIGURE 6-2 VACCINE DOSE ADMINISTERED CONDITION PROCESS MODEL

#### **TABLE 6-2 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 6-3 CAN THE VACCINE DOSE ADMINISTERED BE EVALUATED?

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

## 6.2 EVALUATE CONDITIONAL SKIP

Evaluate Conditional Skip addresses times when a target dose can be skipped. A dose should be considered necessary unless it is determined that it can be skipped. The most common scenarios for skipping a dose are:

- Catch-up doses where the patient is current with their administrations and does not need to catch-up
- The patient is behind schedule and the total number of doses needed to satisfy the patient series can be reduced
- The previously administered dose(s) negates the need for the current target dose

Only Conditional Skip Instances with a context of Evaluation or Both should be used. In cases where a target dose does not specify Conditional Skip attributes, the target dose cannot be skipped.

A dose may be skipped based on whether or not one or more conditions evaluates to true. Conditions are classified as one of a number of types, each with one or more parameters in the Supporting Data. Conditions are contained within sets. Each set contains one or more conditions to be evaluated. Within a set, one or more conditions must be met for the set to be met. In the case where a set contains multiple conditions, whether all conditions or just one condition must be met is specified by the Condition Logic (e.g., AND vs. OR). Similarly, a dose may contain multiple sets. In the case where a dose contains multiple sets, whether all sets or just one set must be met is specified by the Set Logic.

Finally, in an effort to reduce page size and eliminate duplicate logic which could result in typographical and consistency errors, this section of logic is defined here once, but used in both Evaluation and Forecasting. The forecasting chapter refers the reader back to this section for appropriate logic.

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

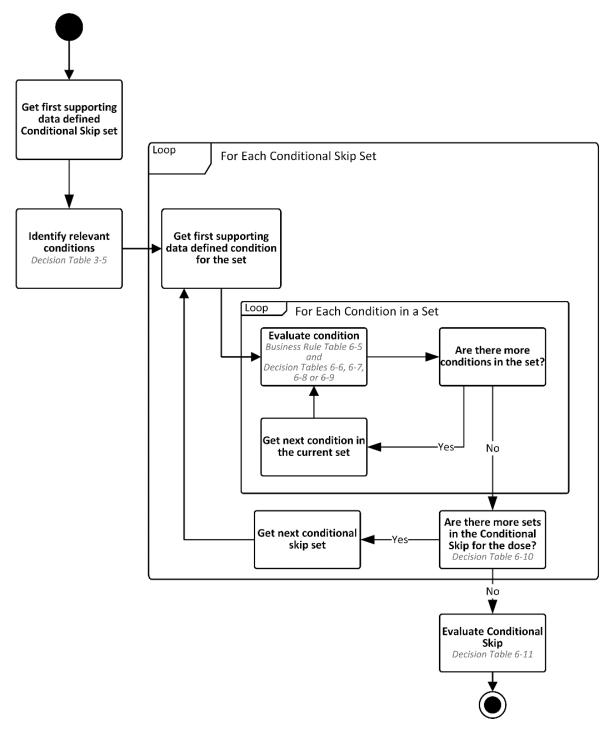


FIGURE 6-3 CONDITIONAL SKIP PROCESS MODEL

#### **TABLE 6-4 CONDITIONAL SKIP ATTRIBUTES**

Attribute Type	Attribute Name	Assumed Value if Empty	
Vaccine dose administered	Date Administered	-	
Processing data	Assessment Date	current date	
Processing data	Earliest Date	-	
Patient Immunization History	Administered Dose Count	-	

Attribute Type	Attribute Name	Assumed Value if Empty
Calculated date (CALCDTSKIP-3)	Conditional Skip Begin Age Date	-
Calculated date (CALCDTSKIP-4)	Conditional Skip End Age Date	-
Calculated date (CALCDTSKIP-5)	Conditional Skip Interval Date	-
Supporting Data (Conditional Skip)	Conditional Skip Start Date	-
Supporting Data (Conditional Skip)	Conditional Skip End Date	-
Supporting Data (Conditional Skip)	Conditional Skip Dose Type	-
Supporting Data (Conditional Skip)	Conditional Skip Dose Count Logic	-
Supporting Data (Conditional Skip)	Conditional Skip Dose Count	-
Supporting Date (Conditional Skip)	Conditional Skip Series Group	-

## **TABLE 6-5 CONDITIONAL SKIP BUSINESS RULES**

Business Rule ID	Business Rule	
CALCDTSKIP-3	A patient's conditional skip begin age date must be calculated as the patient's date of birth plus the Begin Age of the conditional skip condition.	
CALCDTSKIP-4	A patient's conditional skip end age date must be calculated as the patient's date of birth plus the End Age of the conditional skip condition.	
CALCDTSKIP-5	A patient's conditional skip interval date must be calculated as the vaccine date administered from the immediate previous vaccine dose administered plus the Interval of the conditional skip condition.	
CONDSKIP-1	The Number of Conditional Doses Administered must be computed as the count of vaccine doses administered where all of the following are true:  • Vaccine Type is one of the supporting data defined conditional skip vaccine types.  • Date Administered is:  • on or after the conditional skip begin age date and before the conditional skip end age date OR  • on or after the conditional skip start date and before conditional skip end date  • Evaluation Status is:  • "Valid" if the conditional skip dose type is "Valid" OR  • of any status if the conditional skip dose type is "Total".	
CONDSKIP-2	<ul> <li>The Conditional Skip Reference Date must be one of the following:</li> <li>The Date Administered of the vaccine dose administered when evaluating a vaccine dose administered</li> <li>The Assessment Date when determining a forecast.</li> <li>The Earliest Date when validating a forecast.</li> </ul>	

# TABLE 6-6 CONDITIONAL TYPE OF AGE – IS THE CONDITION MET?

CONDITIONS	RULES		
Is the Conditional Skip End Age Date > Conditional Skip Reference Date ≥ Conditional Skip Begin Age Date?	Yes	No	
OUTCOMES	Yes. The condition is met.	No. The condition is not met.	

## TABLE 6-7 CONDITIONAL TYPE OF COMPLETED SERIES – IS THE CONDITION MET?

CONDITIONS	RULES		
Does the Conditional Skip Series Group identify a Series Group with at least one series with a status of "Complete"?	Yes	No	
OUTCOMES	Yes. The condition is met.	No. The condition is not met.	

## TABLE 6-8 CONDITIONAL TYPE OF INTERVAL – IS THE CONDITION MET?

CONDITIONS	RULES			
Has at least one dose been administered to the patient?	Yes	Yes	No	
Is the Conditional Skip Reference Date ≥ Conditional Skip Interval Date?	Yes	No	-	
OUTCOMES	Yes. The condition is met.	No. The condition is not met.	No. The condition is not met.	

## TABLE 6-9 CONDITIONAL TYPE OF VACCINE COUNT BY AGE OR DATE - IS THE CONDITION MET?

Number of conditional doses administered (BR: CONDSKIP-1) / Dose Count Logic	Greater than Conditional Skip Dose Count	Equal to Conditional Skip Dose Count	Less than Conditional Skip Dose Count
Greater Than	Yes. The condition is met.	No. The condition is not met.	No. The condition is not met.
Equal	No. The condition is not met.	Yes. The condition is met.	No. The condition is not met.
Less Than	No. The condition is not met.	No. The condition is not met.	Yes. The condition is met.

## **TABLE 6-10 IS THE CONDITIONAL SKIP SET MET?**

How many conditions were met? / Condition Logic Type	All	At least one, but not all	None
AND	Yes. The set is met.	No. The set is not met.	No. The set is not met.
OR	Yes. The set is met.	Yes. The set is met.	No. The set is not met.

#### **TABLE 6-11 CAN THE TARGET DOSE BE SKIPPED?**

How many sets were met?/ Set Logic Type	AII	At least one, but not all	None
AND	Yes. The target dose can be skipped. The target dose status is "skipped".	No. The target dose cannot be skipped.	No. The target dose cannot be skipped.
OR	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".	No. The target dose cannot be skipped.

## 6.3 EVALUATE FOR INADVERTENT VACCINE

Evaluate for inadvertent vaccine determines if the vaccine type of a vaccine dose administered was an inadvertent administration due to the vaccine type that was administered.

The following process model, attribute table, Business Rule table and decision table, are used to evaluate for an unallowable vaccine.



FIGURE 6-4 EVALUATE FOR AN INADVERTENT VACCINE PROCESS MODEL

#### **TABLE 6-12 INADVERTENT VACCINE ATTRIBUTES**

Attribute Type	Attribute Name	Assumed Value if Empty
Vaccine dose administered	Vaccine Type	-
Supporting Data (inadvertent Vaccine)	Vaccine Type	-

#### TABLE 6-13 EVALUATE FOR INADVERTENT VACCINE BUSINESS RULES

Business Rule ID	Business Rule
	A vaccine dose administered must be considered an inadvertent administration if the vaccine type of the vaccine dose administered is one of the vaccine types of an inadvertent vaccine.

**TABLE 6-14 WAS AN INADVERTENT VACCINE ADMINISTERED?** 

CONDITIONS	RULES				
Is the vaccine type of the vaccine dose administered one of the vaccine types of an inadvertent vaccine?	Yes	No			
OUTCOMES	Yes. The vaccine dose administered must be considered an inadvertent administration. Target Dose Status is "Not Satisfied". Evaluation Status is "Not Valid". Evaluation Reason is "Inadvertent Administration"	No. The patient was not administered an unallowable vaccine.			

## 6.4 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."

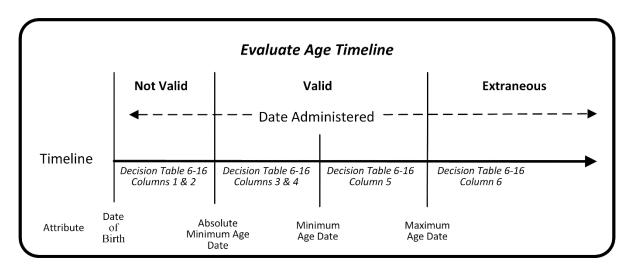


FIGURE 6-5 EVALUATE AGE TIMELINE

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

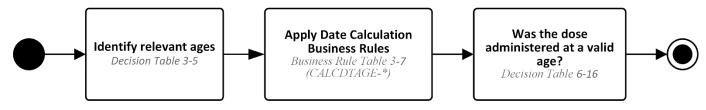


FIGURE 6-6 EVALUATE AGE PROCESS MODEL

## **TABLE 6-15 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 6-16 WAS THE VACCINE DOSE ADMINISTERED AT A VALID AGE?

CONDITIONS	RULES					
Is the date administered < absolute minimum age date?	Yes	No	No	No	No	No
Is the absolute minimum age date ≤ date administered < minimum age date?	No	Yes	Yes	Yes	No	No
Is the minimum age date ≤ date administered < maximum age date ?	No	No	No	No	Yes	No
Is the date administered ≥ maximum age date?	No	No	No	No	No	Yes
Is this the first target dose?	-	No	No	Yes	-	-
Is the evaluation status of the previous vaccine dose administered "not valid" due to age or interval recommendations and < 1 year from the vaccine dose administered being evaluated?	-	Yes	No	-	-	-

CONDITIONS	RULES					
OUTCOMES	No. The vaccine dose administered was not administered at a valid age. Evaluation reason is "too young."	No. The vaccine dose administered was not administered at a valid age. Evaluation reason is "too young."	Yes. The vaccine dose administered was administered at a valid age. Evaluation reason is "grace period."	Yes. The vaccine dose administered was administered at a valid age. Evaluation reason is "grace period."	Yes. The vaccine dose administered was administered at a valid age.	No. The vaccine dose administered was administered after the maximum age and is extraneous. Evaluation reason is "too old".

## 6.5 EVALUATE PREFERABLE INTERVAL

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

Preferable intervals can be measures in four different ways:

- "From Immediate Previous Dose Administered" requires the interval to be evaluated from the immediate previous vaccine dose administered and is used in the majority of cases.
- "From Target Dose # in Series" requires the interval to be evaluated from the date of the specified dose.
- "From Most Recent (CVX List)" requires the interval to be evaluated from the date of the most recently
  administered dose of any of the specific vaccine types listed (e.g., this is used in Pneumococcal to ensure
  proper spacing between the different intervals between PCV13 and PPSV23).
- "From Relevant Observation (Code)" requires the interval to be evaluated from the date of a particular
  patient observation (e.g. the interval for a dose of Pertussis vaccine is measured from the date of the
  onset of pregnancy).

It is possible for a given dose to use multiple preferable interval types. For example, dose 3 of HepB and dose 3 of HPV, each have two preferable 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. Note that if multiple intervals are specified, then all intervals must be satisfied in order for the dose to satisfy the interval requirements.

Figure 6-7 provides the evaluation interval timeline used to define adjacent intervals by using *from immediate previous dose administered* as the reference point.

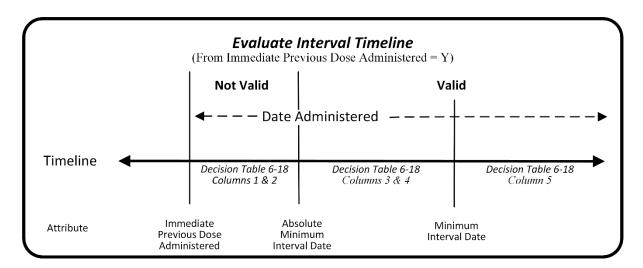


FIGURE 6-7 EVALUATE INTERVAL 'FROM IMMEDIATE PREVIOUS DOSE' TIMELINE

Figure 6-8 illustrates the evaluation interval timeline used to define 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."

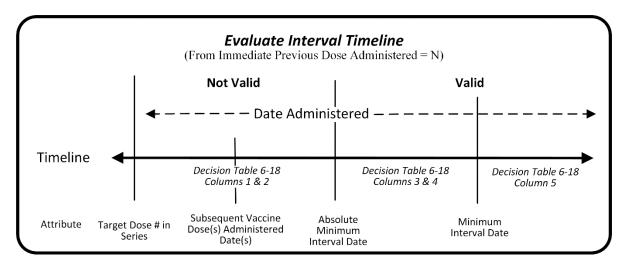


FIGURE 6-8 EVALUATE INTERVAL 'FROM TARGET DOSE NUMBER IN SERIES' TIMELINE

Figure 6-9 illustrates the evaluation interval timeline used to define most recent vaccine intervals by using *from most recent vaccine type* as the reference point.

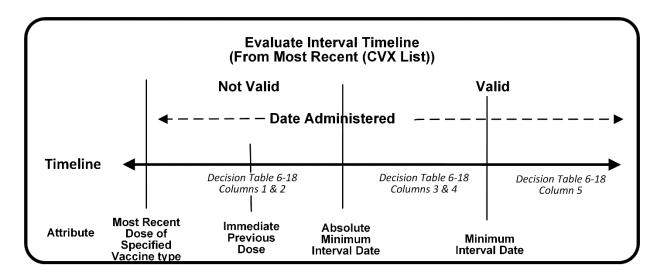


FIGURE 6-9 EVALUATE INTERVAL 'FROM MOST RECENT VACCINE TYPE' TIMELINE

Figure 6-10 illustrates the evaluation interval timeline used to define most recent vaccine intervals by using *from relevant observation* as the reference point.

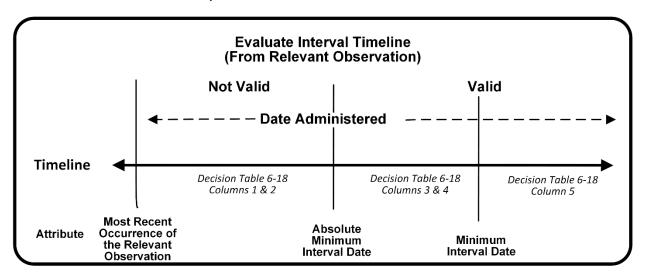


FIGURE 6-10 EVALUATE INTERVAL 'FROM RELEVANT OBSERVATION' TIMELINE

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

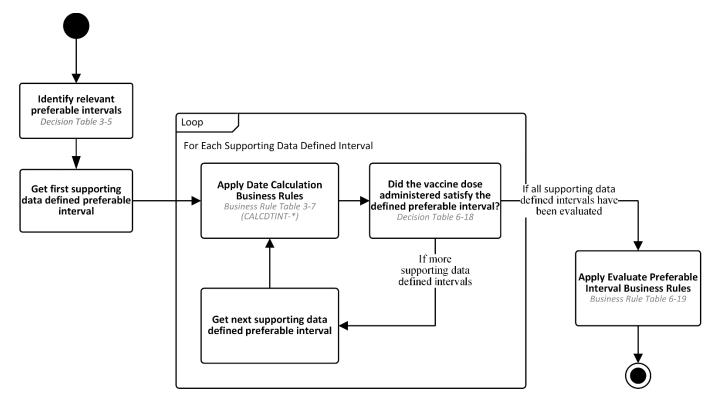


FIGURE 6-11 EVALUATE PREFERABLE INTERVAL PROCESS MODEL

#### **TABLE 6-17 PREFERABLE 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	-
Supporting Data (Interval)	From Most Recent (CVX List)	-
Supporting Data (Interval)	From Relevant Observation (Code)	-
Calculated date (CALCDTINT-3)	Absolute Minimum Interval Date	01/01/1900
Calculated date (CALCDTINT-4)	Minimum Interval Date	01/01/1900

#### TABLE 6-18 DID THE VACCINE DOSE ADMINISTERED SATISFY THE DEFINED PREFERABLE INTERVAL?

CONDITIONS	RULES				
Is the date administered < absolute minimum interval date?	Yes	No	No	No	No
Is the absolute minimum interval date ≤ date administered < minimum interval date?	No	Yes	Yes	Yes	No

CONDITIONS	RULES				
Is the minimum interval date ≤ date administered?	No	No	No	No	Yes
Is this the first target dose?	-	No	No	Yes	-
Is the evaluation status of the previous vaccine dose administered "not valid" due to age or interval recommendations and < 1 year from the vaccine dose administered being evaluated?	-	Yes	No	-	-
OUTCOMES	No. The vaccine dose administered did not satisfy the defined preferable interval. Evaluation reason is "too soon."	No. The vaccine dose administered did not satisfy the defined preferable interval. Evaluation reason is "too soon."	Yes. The vaccine dose administered satisfied the defined preferable interval. Evaluation reason is "grace period."	Yes. The vaccine dose administered satisfied the defined preferable interval. Evaluation reason is "grace period."	Yes. The vaccine dose administered satisfied the defined preferable interval.

## TABLE 6-19 EVALUATE PREFERABLE INTERVAL BUSINESS RULES

Business Rule ID	Business Rule
CALCDTINT-1	A patient's reference dose date for an interval must be calculated as the date administered of the most immediate previous vaccine dose administered if all the following are true for the interval:  • from immediate previous dose administered is "Y"  • the evaluation status is "Valid" or "Not Valid"  • the vaccine dose administered is not an inadvertent administration.
CALCDTINT-2	A patient's reference dose date for an interval must be calculated as the date administered of the vaccine dose administered that satisfies the target dose with the same dose number as the from target dose number in series if all the following are true for the interval:  • from immediate previous dose administered is "N"  • from target dose number in series is not "n/a".
CALCDTINT-3	A patient's absolute minimum interval date must be calculated as the patient's reference dose date plus the absolute minimum interval.
CALCDTINT-4	A patient's minimum interval date must be calculated as the patient's reference dose date plus the minimum interval.
CALCDTINT-8	A patient's reference dose date for an interval must be calculated as the date administered of the most recent vaccine dose administered that is the same vaccine type as the from most recent vaccine type if all the following are true for the interval:

Business Rule ID	Business Rule
	<ul> <li>from immediate previous dose administered is "N"</li> <li>from most recent vaccine type is not "n/a"</li> <li>the vaccine dose administered is not an inadvertent administration.</li> </ul>
CALCDTINT-9	A patient's reference dose date for an interval must be calculated as the observation date of the most recent active patient observation if all the following are true for the interval:  • from immediate previous dose administered is "N"  • from relevant observation code is not "n/a".
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.

## 6.6 EVALUATE ALLOWABLE INTERVAL

Evaluate allowable interval validates the date administered of a vaccine dose administered against defined allowable interval(s) from previous vaccine dose(s) administered. In rare cases, intervals can be applied which are either abnormally early – usually specified in ACIP footnotes or subsequent clarifications – or intervals which differ following a not valid administration.

In cases where a target dose does not specify allowable interval attributes, evaluate allowable interval cannot be used to validate a vaccine dose administered. To avoid a false validation, the allowable interval should be considered "not valid" in these cases.

The figure below provides evaluate allowable interval timeline used to define all adjacent intervals by using *from immediate previous dose administered* as the reference dose.

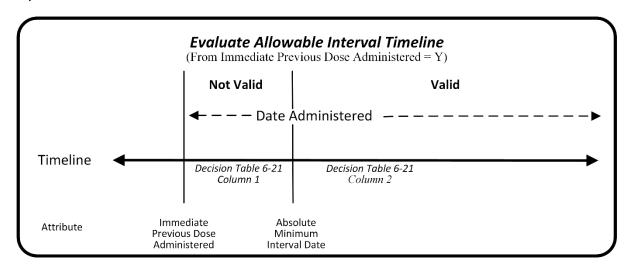


FIGURE 6-12 EVALUATE ALLOWABLE INTERVAL 'FROM IMMEDIATE PREVIOUS DOSE' TIMELINE

The figure below illustrates evaluate allowable interval timeline used to define all non-adjacent intervals by using from target dose number in series as the reference dose.

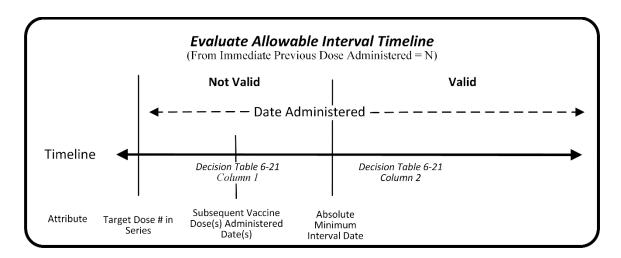


FIGURE 6-13 EVALUATE ALLOWABLE INTERVAL 'FROM TARGET DOSE NUMBER IN SERIES' TIMELINE

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

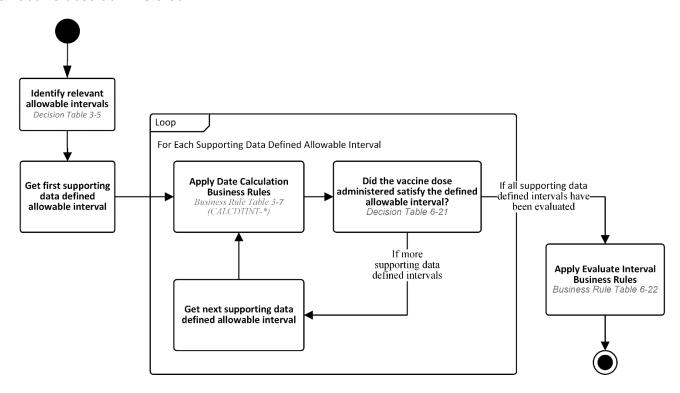


FIGURE 6-14 EVALUATE ALLOWABLE INTERVAL PROCESS MODEL

#### **TABLE 6-20 ALLOWABLE INTERVAL ATTRIBUTES**

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

#### TABLE 6-21 DID THE VACCINE DOSE ADMINISTERED SATISFY THE DEFINED ALLOWABLE INTERVAL?

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

#### **TABLE 6-22 EVALUATE ALLOWABLE INTERVAL BUSINESS RULES**

Business Rule ID	Business Rule
CALCDTINT-3	A patient's absolute minimum interval date must be calculated as the patient's reference dose date plus the absolute minimum interval.
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.

## 6.7 EVALUATE 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 virus or recombinant 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.

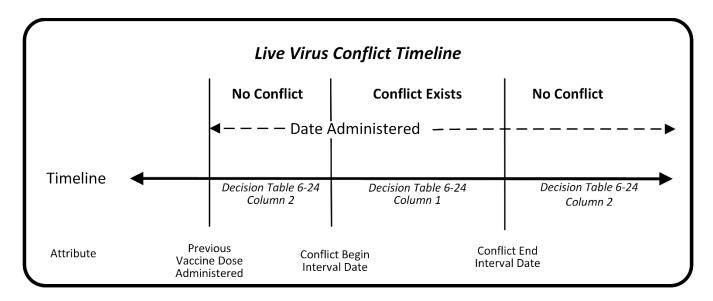
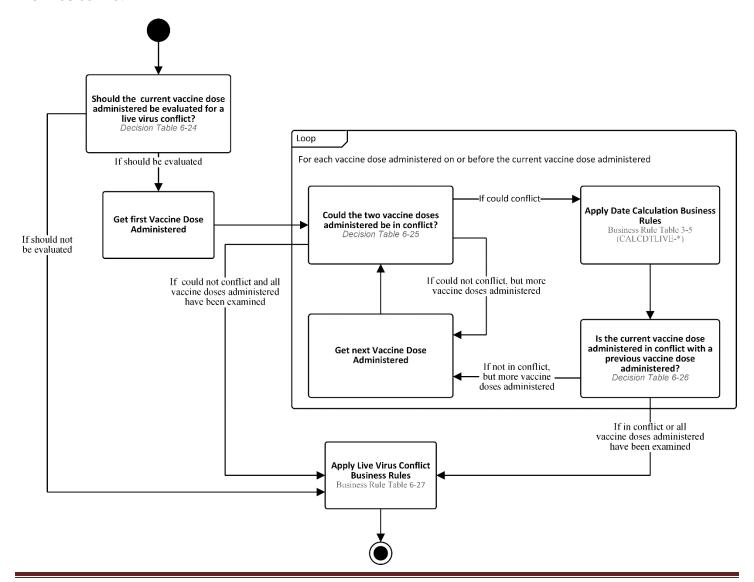


FIGURE 6-15 EVALUATE LIVE VIRUS CONFLICT TIMELINE

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



#### FIGURE 6-16 EVALUATE LIVE VIRUS CONFLICT PROCESS MODEL

#### **TABLE 6-23 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 6-24 SHOULD THE CURRENT VACCINE DOSE ADMINISTERED BE EVALUATED FOR A LIVE VIRUS CONFLICT?

CONDITIONS	RULES			
Is the current vaccine type of the vaccine dose administered one of the supporting data defined live virus conflict 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 live virus conflict.	No. The vaccine dose administered should not be evaluated for a live virus conflict.	

#### TABLE 6-25 COULD THE TWO VACCINE DOSES ADMINISTERED BE IN CONFLICT?

CONDITIONS	RULES	
Is the vaccine type of the previous vaccine dose administered the same as one of the supporting data defined 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 6-26 IS THE CURRENT VACCINE DOSE ADMINISTERED IN CONFLICT WITH A PREVIOUS VACCINE DOSE ADMINISTERED?

CONDITIONS	RULES		
Is the conflict begin interval date ≤ 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 6-27 LIVE VIRUS CONFLICT BUSINESS RULES**

Business Rule ID	Business Rule
CALCDTLIVE-1	A patient's conflict begin interval date must be calculated as the date administered of the conflicting vaccine dose administered plus the live virus conflict begin interval.
CALCDTLIVE-2	A 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 if the conflicting vaccine dose administered has evaluation status "valid."
CALCDTLIVE-3	A 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 if the conflicting vaccine dose administered does not have evaluation status "valid."
CONFLICT-1	A current vaccine dose administered must be considered to be a conflicting vaccine dose administered if it is in conflict with any previous vaccine doses administered.
CONFLICT-2	A current vaccine dose administered must not be considered to be a conflicting vaccine dose administered if it is not in conflict with any previous vaccine doses administered.

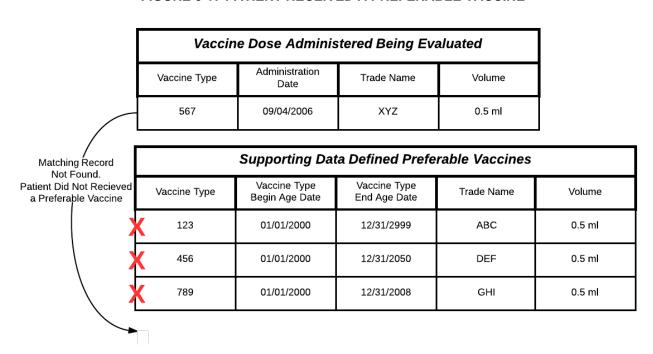
# 6.8 EVALUATE FOR PREFERABLE VACCINE

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

Figures 6-17 depicts a patient who received a preferable vaccine while Figure 6-18 depicts a patient who did not receive a preferable vaccine.

	Vaccine Dose Administered Being Evaluated				]
	Vaccine Type	Administration Date	Trade Name	Volume	
	456	06/30/2009	DEF	0.5 ml	
/ Matching Record Found.	Supporting Data Defined Preferable Vaccines				
Patient Recieved a Preferable Vaccine	Vaccine Type	Vaccine Type Begin Age Date	Vaccine Type End Age Date	Trade Name	Volume
	123	01/01/2000	12/31/2999	ABC	0.5 ml
	456	01/01/2000	12/31/2050	DEF	0.5 ml
	789	01/01/2000	12/31/2008	GHI	0.5 ml

#### FIGURE 6-17 PATIENT RECEIVED A PREFERABLE VACCINE



#### FIGURE 6-18 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.

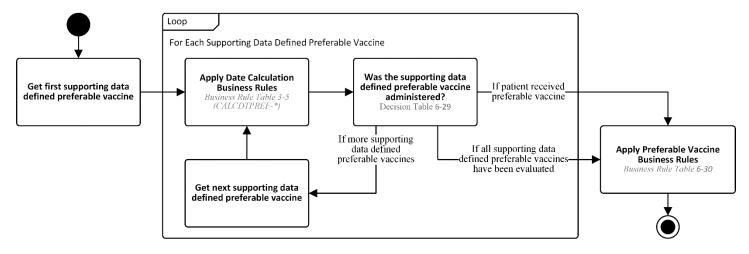


FIGURE 6-19 EVALUATE FOR A PREFERABLE VACCINE PROCESS MODEL

#### **TABLE 6-28 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)	Preferable Vaccine Type Begin Age Date	01/01/1900	
Calculated date (CALCDTPREF-2)	Preferable 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 volume.	

#### TABLE 6-29 WAS THE SUPPORTING DATA DEFINED PREFERABLE VACCINE ADMINISTERED?

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

CONDITIONS	RULES					
Is the volume of the vaccine dose administered ≥ the volume of the preferable vaccine?	Yes	No	-	-	-	
OUTCOMES	Yes. A preferable vaccine was administered.	Yes. A preferable vaccine was administered. Evaluation 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 6-30 PREFERABLE VACCINE BUSINESS RULES**

Business Rule ID	Business Rule
CALCDTPREF-1	A patient's preferable vaccine type begin age date must be calculated as the patient's date of birth plus the vaccine type begin age of a preferable vaccine.
CALCDTPREF-2	A patient's preferable vaccine type end age date must be calculated as the patient's date of birth plus the vaccine type end age of a preferable vaccine.
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.

# 6.9 EVALUATE FOR ALLOWABLE VACCINE

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

Figures 6-20 depicts a patient who received an allowable vaccine while Figure 6-21 depicts a patient who did not receive an allowable vaccine.

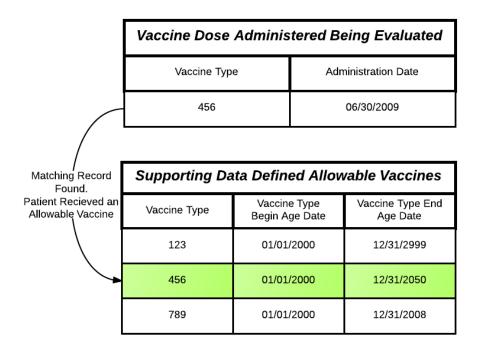


FIGURE 6-20 PATIENT RECEIVED AN ALLOWABLE VACCINE

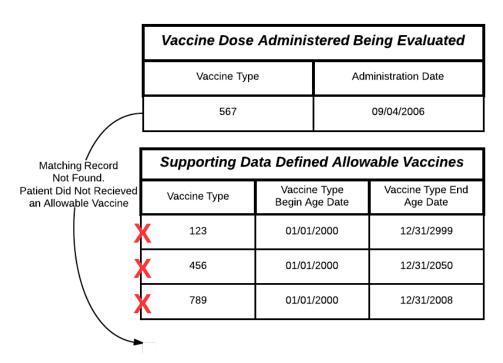


FIGURE 6-21 PATIENT DID NOT RECEIVE AN ALLOWABLE VACCINE

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

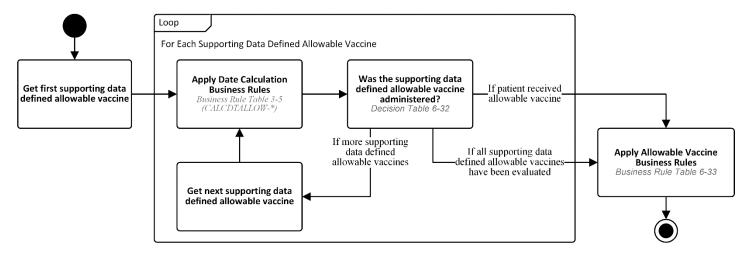


FIGURE 6-22 EVALUATE FOR AN ALLOWABLE VACCINE PROCESS MODEL

#### **TABLE 6-31 ALLOWABLE VACCINE ATTRIBUTES**

Attribute Type	Attribute Name	Assumed Value if Empty	
Vaccine dose administered	Date Administered	-	
Vaccine dose administered	Vaccine Type	-	
Supporting data (Allowable Vaccine)	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 6-32 WAS THE SUPPORTING DATA DEFINED ALLOWABLE VACCINE ADMINISTERED?

CONDITIONS	RULES			
Is the vaccine type of the vaccine dose administered the same as the vaccine type of the allowable vaccine?	Yes	No	Yes	
Is the 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 6-33 ALLOWABLE VACCINE BUSINESS RULES**

Business Rule ID	Business 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.

Business Rule ID	Business Rule
CALCDTALLOW-1	A patient's allowable vaccine type begin age date must be calculated as the patient's date of birth plus the vaccine type begin age of an allowable vaccine.
CALCDTALLOW-2	A patient's allowable vaccine type end age date must be calculated as the patient's date of birth plus the vaccine type end age of an allowable vaccine.

## 6.10 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.

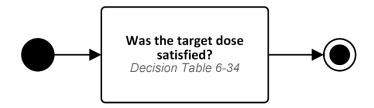


FIGURE 6-23 SATISFY TARGET DOSE PROCESS MODEL

#### **TABLE 6-34 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 preferable or allowable interval?	Yes	-	-	No	-	-
Was the vaccine dose administered in conflict with any previous live virus vaccine doses administered?	No	-	-	-	Yes	-
Did the patient receive either a preferable or allowable vaccine?	Yes	-	-	-	-	No

CONDITIONS	RULES						
OUTCOMES	Yes. The target dose status is "satisfied."	No. The target dose status is "not satisfied."	No. The target dose status is "not satisfied."	No. The target dose status is "not satisfied."	No. The target dose status is "not satisfied."	No. The target dose status is "not satisfied."	
	Evaluation status is "valid" with possible evaluation reason(s).	Evaluation status is "extraneous" with possible evaluation reason(s).	Evaluation status is "not valid" with evaluation reason(s).				

# 7 FORECAST DATES AND REASONS

A CDS engine uses a patient's medical and vaccine history to forecast immunization due dates for a series. 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 7-1 FORECAST DATES AND REASONS PROCESS STEPS

Section	Activity	Goal
7.1	Evaluate Conditional Skip	The goal of this step is to determine if the target dose can be skipped due to a patient's age at assessment or immunization history.
7.2	Determine Evidence Of Immunity	The goal of this step is to determine if the patient has evidence of immunity.
7.3	Determine Contraindications	The goal of this step is to determine if any patient series are contraindicated.
7.4	Determine Forecast Need	The goal of this step is to determine if the patient should receive another dose.
7.5	Generate Forecast Dates And Recommended Vaccines	The goal of this step is to generate forecast dates for the next target dose.
7.6	Validate Recommendation	The goal of this step is to ensure the forecast makes chronological sense (e.g, the earliest date isn't after the latest date)

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

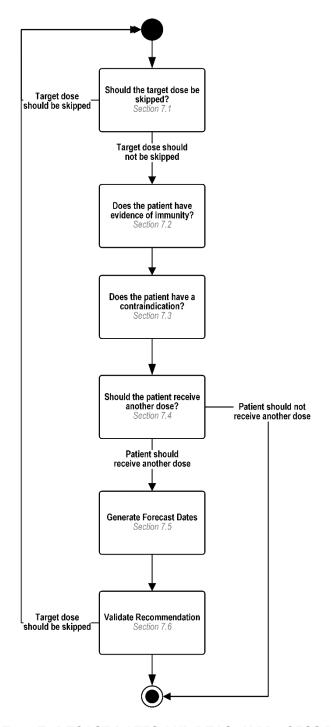


FIGURE 7-1 FORECAST DATES AND REASON PROCESS MODEL

## 7.1 EVALUATE CONDITIONAL SKIP

Evaluate Conditional Skip addresses times when a target dose can be skipped. A dose should be considered necessary unless it is determined that it can be skipped. The most common scenarios for skipping a dose are:

- Catch-up doses where the patient is current with their administrations and does not need to catch-up
- The patient is behind schedule and the total number of doses needed to satisfy the patient series can be reduced
- The previously administered dose(s) negates the need for the current target dose

Only Conditional Skip Instances with a context of Forecast or Both should be used. In cases where a target dose does not specify Conditional Skip attributes, the target dose cannot be skipped.

The process model, attribute table, and decision table are used to determine if the target dose can be skipped is the same as described in Chapter 6.2.

## 7.2 DETERMINE EVIDENCE OF IMMUNITY

Determine evidence of immunity assesses the patient's profile to determine if the patient is already potentially immune to the target disease, negating the need for additional doses. A patient may be considered immune due to their clinical history or if they were born before a defined date for the given target disease. For example, for measles, a patient is considered immune if they have a clinical finding of "Measles immune" or if they were born before 01/01/1957. Additional patient attributes, such as occupation or pregnancy status, may supersede the birth date logic.

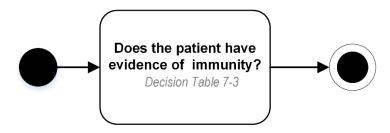


FIGURE 7-2 EVIDENCE OF IMMUNITY PROCESS MODEL

**TABLE 7-2 IMMUNITY ATTRIBUTES** 

Attribute Type	Attribute Name	Assumed Value if Empty
Patient Data	Date of Birth	-
Patient Data	Country of Birth	-
Calculated date (CALCDTAGE-1)	Maximum Age Date	12/31/2999
Supporting Data (Clinical History Immunity)	Immunity Guideline	-
Supporting Data (Birth Date Immunity)	Immunity Birth Date	-
Supporting Data (Birth Date Immunity)	Immunity Exclusion Condition	-
Supporting Data (Birth Date Immunity)	Immunity Country of Birth	-

## TABLE 7-3 DOES THE PATIENT HAVE EVIDENCE OF IMMUNITY?

CONDITIONS	RULES				
Does the patient history contain one of the supporting data defined immunity guidelines?	Yes	No	No	No	No
Is the patient's date of birth < the supporting data defined immunity birth date?	-	Yes	Yes	Yes	No

CONDITIONS		RULES					
Does this patient have an immunity exclusion condition?	-	Yes	No	No	-		
Is the patient's country of birth the same as the supporting data defined immunity country of birth?	-	-	Yes	No	-		
OUTCOMES		No. The patient does not have evidence of immunity.	Yes. The patient has evidence of immunity.	No. The patient does not have evidence of immunity.	No. The patient does not have evidence of immunity.		

## 7.3 DETERMINE CONTRAINDICATIONS

Determine contraindications assesses if any or all series for an antigen are contraindicated for the patient. Contraindications may be applied at either the antigen or vaccine level.

Given the complex nature of contraindications, it may not always be possible to conclusively determine if a contraindication applies to a patient. To minimize missed doses, in the case where a contraindication cannot be definitively determined to be relevant for a patient, the contraindication will not be applied, but a notification should be made to a clinician alerting them to the presence of the possible contraindication which could not be resolved.

The following process model is used to assess contraindications.

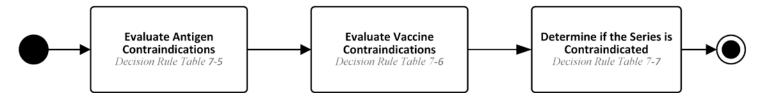


FIGURE 7-3 CONTRAINDICATION PROCESS MODEL

#### **TABLE 7-4 DETERMINE CONTRAINDICATION ATTRIBUTES**

Attribute Type	Attribute Name	Assumed Value if Empty
Supporting Data (Contraindication Code)	Contraindication	-
Processing data	Assessment Date	current date
Calculated date (CALCDTCI-1)	Contraindication Begin Age Date	01/01/1900
Calculated date (CALCDTCI-2)	Contraindication End Age Date	12/31/2999

An antigen contraindication prevents all series for that antigen from applying to the patient. That is, no series for the antigen should be forecast for the patient.

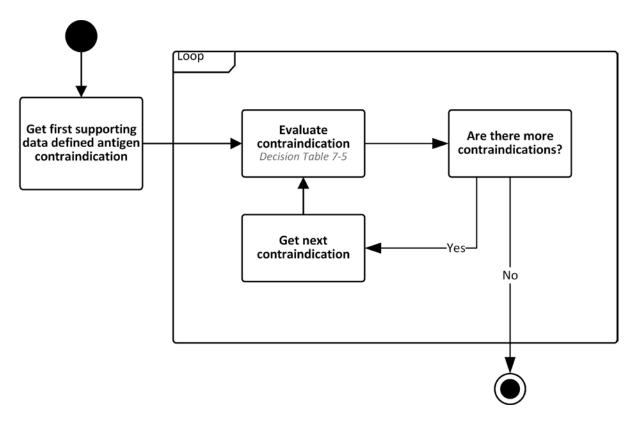


FIGURE 7-4 ANTIGEN CONTRAINDICATION PROCESS MODEL

TABLE 7-5 DOES THE ANTIGEN CONTRAINDICATION APPLY TO THE PATIENT?

CONDITIONS			RULES	
Does the antigen contraindication describe any active patient observations?	Yes	No	-	Unknown
Is the contraindication begin age date ≤ assessment date < contraindication end age date?	Yes	-	No	Yes
OUTCOMES	Yes. The antigen contraindication applies to the patient.	No. The antigen contraindication does not apply to the patient.	No. The antigen contraindication does not apply to the patient.	No. It could not be determined if the antigen contraindication applies to the patient; however, the Contraindication Text Description should be made available to the clinician for manual determination.

A vaccine contraindication eliminates a specific vaccine from being forecast for the patient.

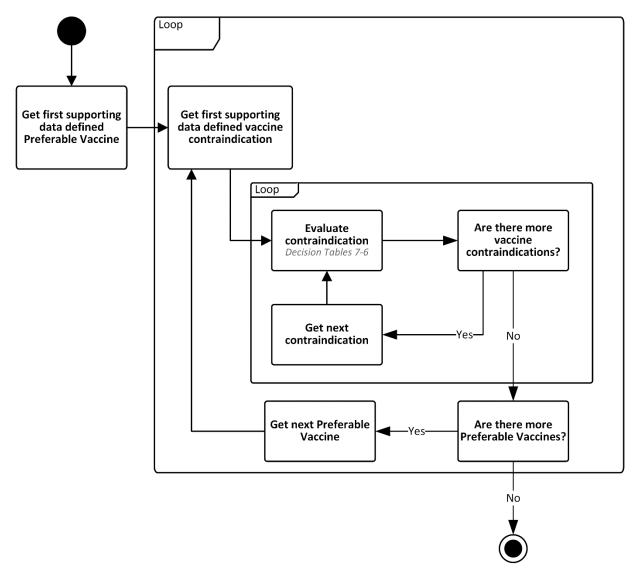


FIGURE 7-5 VACCINE CONTRAINDICATION PROCESS MODEL

TABLE 7-6 DOES THE VACCINE CONTRAINDICATION APPLY TO THE PATIENT?

CONDITIONS	RULES				
Does the vaccine contraindication describe any active patient observations?	Yes	No	-	Unknown	
Is the contraindication begin age date ≤ assessment date < contraindication end age date?	Yes	-	No	Yes	
Is the vaccine type of the preferable vaccine one of the contraindicated vaccine types for the contraindication?	Yes	-	-	Yes	
OUTCOMES	Yes. The vaccine contraindication applies to the patient.	No. The vaccine contraindication does not apply to the patient.	No. The vaccine contraindication does not apply to the patient.	No. It could not be determined if the vaccine contraindication applies to the patient; however the Contraindication Text Description should be made available to the clinician for manual determination.	

A series should not be forecast if either an antigen contraindication exists, or if all Preferable Vaccines are contraindicated.

TABLE 7-7 IS THE PATIENT SERIES A CONTRAINDICATED PATIENT SERIES?

CONDITIONS	RULES				
Are there any antigen contraindication that apply to the patient?	Yes	-	No		
Do all preferable vaccines for the patient series have at least one vaccine contraindication that applies to the patient?	-	Yes	No		
OUTCOMES		-	No. The patient series is not a contraindicated patient series.		

## 7.4 DETERMINE FORECAST NEED

Determine forecast need determines if there is a need to forecast dates. This involves reviewing patient data, antigen administered records, and patient series. This is a prerequisite before a CDS engine can produce forecast dates and reasons.

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

#### FIGURE 7-6 DETERMINE FORECAST NEED PROCESS MODEL

## **TABLE 7-8 DETERMINE FORECAST NEED ATTRIBUTES**

Attribute Type	Attribute Name	Assumed Value if Empty
Immunization history	Vaccine Dose(s) Administered	-
Immunization history	Adverse Reactions	-
Patient 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	Immunity	-

## TABLE 7-9 SHOULD THE PATIENT RECEIVE ANOTHER TARGET DOSE?

CONDITIONS		RULES					
Does the patient have at least one target dose with a target dose status of "not satisfied"?	Yes	No	No		-	-	-
Does the patient have at least one target dose with a target dose status of "satisfied'?	-	Yes	No		-	-	-
Does the patient have evidence of immunity?	No	•	-	Yes	-	-	-
Is the patient series a contraindicated patient series?	No	-	-	-	Yes	-	-
Is the assessment date < the maximum age date?	Yes	-	-	-	-	No	-

CONDITIONS		RULES							
Is the 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 "Not Recommende d"  Forecast reason is "not recommended at this time due to past immunization history"	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 "Contraindicat ed"  Forecast reason is "patient has a contraindicatio n."	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 recommendati on end date."		

## 7.5 GENERATE FORECAST DATES AND RECOMMENDED VACCINES

Generate forecast dates and recommend vaccines determines the forecast dates for the next target dose and identifies one or more recommended vaccines if the target dose warrants specific vaccine recommendations. Additional detail, such as administrative guidance for providers may also be included. 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 next target dose. Figure 7-7 below provides an illustration of how forecast dates appear on the timeline.

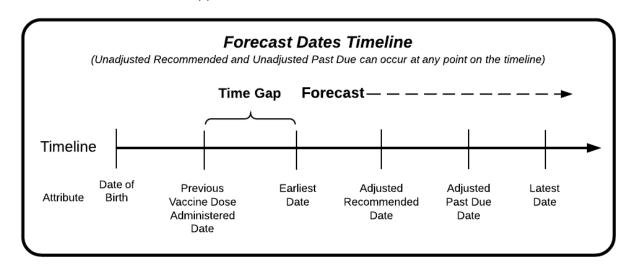


FIGURE 7-7 FORECAST DATES TIMELINE

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 7-8 GENERATE FORECAST DATES AND RECOMMENDED VACCINE PROCESS MODEL

#### TABLE 7-10 GENERATE FORECAST DATE AND RECOMMENDED VACCINE 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)	Seasonal Recommendation Start Date	01/01/1900
Supporting Data (Preferable Vaccine)	Vaccine Type (CVX)	-
Supporting Data (Preferable Vaccine)	Forecast Vaccine Type	N

#### TABLE 7-11 GENERATE FORECAST DATE AND RECOMMENDED VACCINE BUSINESS RULES

Business Rule ID	Business Rule
CALCDTAGE-1	A patient's maximum age date must be calculated as the patient's date of birth plus the maximum age.
CALCDTAGE-2	A patient's latest recommended age date must be calculated as the patient's date of birth plus the latest recommended age.
CALCDTAGE-3	A patient's earliest recommended age date must be calculated as the patient's date of birth plus the earliest recommended age.
CALCDTAGE-4	A patient's minimum age date must be calculated as the patient's date of birth plus the minimum age.
CALCDTINT-4	A patient's minimum interval date must be calculated as the patient's reference dose date plus the minimum interval.
CALCDTINT-5	A patient's earliest recommended interval date must be calculated as the patient's reference dose date plus the earliest recommended interval.
CALCDTINT-6	A patient's latest recommended interval date must be calculated as the patient's reference dose date plus the latest recommended interval.

Business Rule ID	Business Rule
CALCDTLIVE-4	A patient's latest conflict end interval date must be the latest date of all calculated conflict end interval dates for a given target dose.
FORECASTDT-1	The earliest date must be the latest of the following dates:  • Minimum age date  • Latest minimum interval date  • Latest conflict end interval date  • Seasonal recommendation start date  • Latest inadvertent administration date  • Date Administered of the most recent vaccine dose administered
FORECASTDT-2	The unadjusted recommended date must be one of the following:  The earliest recommended age date.  The latest of all earliest recommended interval dates if the earliest recommended age date is not present.  The forecast earliest date if the earliest recommended age date and earliest recommended interval date are not present.
FORECASTDT-3	The unadjusted past due date must be one of the following:  The latest recommended age date – 1 day.  The latest of all latest recommended interval dates – 1 day if the latest recommended age date is not present.  The unadjusted past due date must be empty if latest recommended age date and latest recommended interval date(s) are not present.
FORECASTDT-4	The latest date must be the maximum age date – 1 day if present.
FORECASTDT-5	The adjusted recommended date must be the later of the earliest date and unadjusted recommended date.
FORECASTDT-6	The adjusted past due date must be one of the following:  The later of the earliest date and the unadjusted past due date if the unadjusted past due date is present.  Empty if the unadjusted past due date is not present.
FORECASTGUIDANCE-1	Administrative guidance pertaining to a forecast made for a patient must include all of the following: <ul> <li>administrative guidance pertaining to the antigen series of the antigen in the forecast</li> <li>administrative guidance pertaining to any indications which apply to the patient</li> </ul>
FORECASTRECVAC-1	A vaccine must be considered a recommended vaccine for a patient if all the following are true:  The vaccine is a preferable vaccine  • The forecast vaccine type is "Y"  • There is no vaccine contraindication that applies to the patient for this vaccine

# 7.6 VALIDATE RECOMMENDATION

Validation Recommendation interrogates the forecasted earliest date to ensure the forecast makes logical sense. Two scenarios for a recommendation being invalid or illogical and thus in need of a complete re-forecasting or an adjustment are the following:

• The forecasted dates are beyond the conditional skip requirements of the target dose being forecasted resulting in a different forecast when the patient returns for vaccination. To prevent erroneous recommendations, this section prospectively ensures the recommendation remains valid at the earliest date. If the recommendation is found to be invalid, re-forecasting for the next target dose is required.

- For example, a patient is behind on Hib and has just received a first dose at 11 months and 1 week of age. The patient is then recommended for a catch-up dose in four weeks, shortly after the 12-month mark. However, upon returning to the provider office four weeks later, the freshly updated forecast skips the previously forecasted target dose and now forecasts the patient return 8 weeks after the previous dose.
- The earliest date is greater than the latest date for the series, thus negating the need for future doses.
  - For example, when the previous dose of rotavirus was administered close to the maximum age date of 8 months and the next target dose is forecasted for later than 8 months.

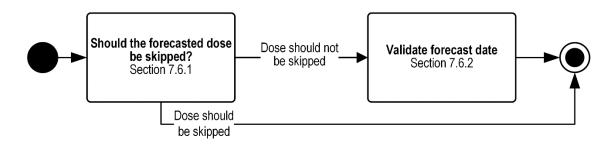


FIGURE 7-9 VALIDATE RECOMMENDED DOSE PROCESS MODEL

#### 7.6.1 Conditional Skip

The process model, attribute table, and decision table are used to determine if the target dose can be skipped is the same as described in Chapter 6.2. Only Conditional Skip Instances with a context of Forecast or Both should be used. In cases where a target dose does not specify Conditional Skip attributes, the target dose cannot be skipped. In CONDSKIP-2, the Earliest Date is used.

#### 7.6.2 Validate Forecasted Dates

#### **TABLE 7-12 VALIDATE FORECASTED DATES BUSINESS RULES**

Business Rule ID	Business Rule
VALIDATEREC-1	A forecast with an earliest date on or after the latest date must be modified to indicate all the following:  Patient series status is "Aged Out'  Forecast reason is "Patient is unable to finish the series prior to the maximum age"  There is no forecast earliest date  There is no forecast adjusted recommended date  There is no forecast adjusted past due date  There is no forecast latest date

## 8 SELECT PATIENT SERIES

Select Patient Series involves reviewing all potential patient series which might satisfy the goals of an antigen and determining the one or more series which best fits the patient needs based on several important factors.

The basic steps of this process are listed in table 8-1. This process is repeated for each Series Group after which the remaining prioritized series are further compared and selected. In some cases, the best series from one Series Group may negate the need for the best series from another, equivalent series group, but in other cases, multiple best series may be needed to fully protect the patient. The final section of this chapter deals with identifying the smallest possible set of best patient series needed to meet the patient needs.

**TABLE 8-1 SELECT PATIENT SERIES PROCESS STEPS** 

Section	Activity	Goal
8.1	Pre-Filter Patient Series	The goal of this step is to determine if any series within a Series Group should be excluded from consideration for Best Patient Series.
8.2	Identify One Prioritized Patient Series	The goal of this step is to determine if one patient series is superior to the other entire patient series for each series group.
8.3	Classify Scorable Patient Series	The goal of this step is to classify where the patient is in the overall path to immunity and pass those 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.
8.4	Complete 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 prioritized 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 scorable 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 Series Group, only one set of these scoring business rules will be applied to each scorable patient series.
8.5	In-Process 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 prioritized 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 scorable 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 Series Group, only one set of these scoring business rules will be applied to each scorable patient series.
8.6	No Valid Doses	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 prioritized 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 scorable 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 Series Group, only one set of these scoring business rules will be applied to each scorable patient series.

Section	Activity	Goal
8.7	Select Prioritized Patient Series	The goal of this step is to evaluate the scored patient series and determine which of the scorable patient series is the one and only best patient series for the series group.
8.8	Determine Best Patient Series	The goal of this step is to identify final set of best patient series that apply to the patient.

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

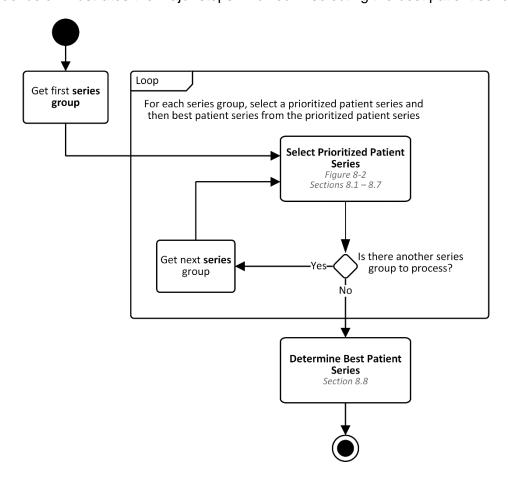


FIGURE 8-1 SELECT PATIENT SERIES PROCESS MODEL

The process model below illustrates for a Series Group the major steps involved in selecting the prioritized patient series.

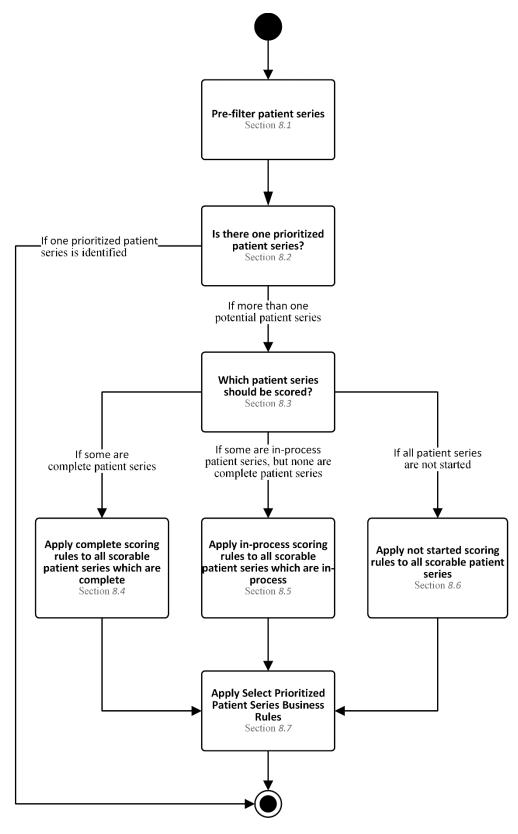


FIGURE 8-2 SELECT PRIORITIZED PATIENT SERIES PROCESS MODEL

## 8.1 Pre-filter Patient Series

*Pre-filter patient series* examines each of the patient series for a given Series Group to determine if any series should be removed from consideration for best patient series. If a Series Group contains relevant patient series of different priorities, only the set of highest priority patient series should be considered when determining the best patient series for the Series Group.

**TABLE 8-2 PRE-FILTER PATIENT SERIES BUSINESS RULES** 

Business Rule ID	Business Rule
SELECTSCORE-2	<ul> <li>A relevant patient series must be considered a scorable patient series if one of the following is true:</li> <li>All the following are true for the relevant patient series</li> <li>The Series Type is 'Risk'</li> <li>The series priority is the same or greater series priority as any relevant patient series within the same series group.</li> <li>All the following are true for the relevant patient series</li> <li>The Series Type is 'Standard'</li> <li>The patient has at least one vaccine dose administered associated with the relevant patient series</li> <li>The first vaccine dose administered associated with the relevant patient series with an evaluation status of 'Valid' has a date administered before the maximum age to start date.</li> </ul>

## 8.2 IDENTIFY ONE PRIORITIZED PATIENT SERIES

*Identify one prioritized patient series* examines all of the patient series for a given Series Group to determine if one of the patient series is superior to all other patient series and can be considered the prioritized patient series.

TABLE 8-3 IDENTIFY ONE PRIORITIZED PATIENT SERIES BUSINESS RULES

Business Rule ID	Business Rule
SELECTB-6	A patient series must be considered a complete patient series if the patient series status is "complete."
SELECTB-7	A patient series must be considered the default patient series if the supporting data defined default series is "Yes."
	An in-process patient series must be a patient series with at least one target dose status "satisfied" and the patient series status "not complete."

# TABLE 8-4 IS THERE ONE PRIORITIZED PATIENT SERIES AMONG SCORABLE PATIENT SERIES IN THE SERIES GROUP?

CONDITIONS	RULES					
Series Group contains 0 scorable patient series but 1 relevant patient series is identified as the default patient series for the Series Group?	Yes	No	No	No	No	No

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

## 8.3 CLASSIFY SCORABLE PATIENT SERIES

Classify scorable patient series is an attempt to reduce the total number of patient series within a Series Group to only those which have a chance to be selected as the prioritized patient series.

## TABLE 8-5 CLASSIFY SCORABLE PATIENT SERIES BUSINESS RULES

Business Rule ID	Business Rule
SELECTB-6	A patient series must be considered a complete patient series if the patient series status is "complete."
	An in-process patient series must be a patient series with at least one target dose status "satisfied" and the patient series status "not complete."

#### TABLE 8-6 WHICH SCORABLE PATIENT SERIES SHOULD BE SCORED?

CONDITIONS	RULES					
Are there 2 or more complete patient series?	Yes	No	No			

CONDITIONS	RULES			
Are there 2 or more in- process patient series and 0 are complete patient series?	-	Yes	No	
Do 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.	

# 8.4 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 8-7 COMPLETE PATIENT SERIES BUSINESS RULES**

Business Rule ID	Business Rule
SELECTB-1	The actual finish date of a complete patient series must be the date administered of the latest vaccine dose administered with an evaluation status "valid."
SELECTB-2	A patient series has all valid doses if all doses administered have an evaluation status "valid."
SELECTB-8	A complete patient series must be considered to be the earliest completing if the actual finish date is before the actual finish date for all other complete patient series.
SELECTB-19	A patient series has the most valid doses if the number of valid doses is greater than the number of valid doses in all other patient series.
SELECTB-21	The number of valid doses must be the count of Target Doses with the status "satisfied."
SELECTB-23	A patient series must be considered a product patient series if the product path is "Yes."

# TABLE 8-8 HOW MANY POINTS ARE AWARDED TO A COMPLETE PATIENT SERIES WHEN 2 OR MORE SCORABLE PATIENT SERIES ARE COMPLETE?

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

## 8.5 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 8-9 IN-PROCESS PATIENT SERIES BUSINESS RULES**

Business Rule ID	Business Rule
SELECTB-2	A patient series has all valid doses if all doses administered have an evaluation status "valid."
SELECTB-3	A patient series must be considered completable if the forecast finish date is less than the maximum age date of the last target dose.
SELECTB-5	A patient series must be the considered the closest to completion if the number of not satisfied target doses is less than the number of not satisfied target doses in all other patient series.
SELECTB-11	A patient series can finish earliest if the patient series is completable and the forecast finish date is earlier than the forecast finish date in all other completable patient series.
SELECTB-12	The forecast finish date for a patient series must be calculated as the forecast earliest date plus the latest minimum interval from the remaining target dose(s).
SELECTB-17	The maximum age to start date must be calculated as the patient's date of birth plus the Select Patient Series Maximum Age to Start.
SELECTB-19	A patient series has the most valid doses if the number of valid doses is greater than the number of valid doses in all other patient series.
SELECTB-20	The number of not satisfied target doses must be the count of Target Doses with the status "Not Satisfied."
SELECTB-21	The number of valid doses must be the count of Target Doses with the status "satisfied."
SELECTB-23	A patient series must be considered a product patient series if the product path is "Yes."

# TABLE 8-10 HOW MANY POINTS ARE AWARDED TO AN IN-PROCESS PATIENT SERIES WHEN 2 OR MORE SCORABLE PATIENT SERIES ARE IN-PROCESS AND NO SCORABLE PATIENT SERIES ARE COMPLETE?

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

## 8.6 No Valid Doses

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

**TABLE 8-11 NO VALID DOSES BUSINESS RULES** 

Business Rule ID	Business Rule
SELECTB-3	A patient series must be considered completable if the forecast finish date is less than the maximum age date of the last target dose.
SELECTB-23	A patient series must be considered a product patient series if the product path is "Yes."
SELECTB-13	The start date for a patient series must be the forecast earliest date if the number of valid doses for the patient series is 0.
SELECTB-14	A patient series must be considered start earliest if the start date is before the start date for all other patient series with a start date.

# TABLE 8-12 HOW MANY POINTS ARE AWARDED TO A SCORABLE 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 scorable patient series		If this condition is not true for the scorable patient series
A scorable patient series can start earliest.	+1	0	-1
A scorable patient series is completable.	+1	n/a	-1
A scorable patient series is a product patient series.	-1	n/a	+1

## 8.7 SELECT PRIORITIZED PATIENT SERIES

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

#### **TABLE 8-13 SELECT PRIORITIZED PATIENT SERIES BUSINESS RULES**

Business Rule ID	Business Rule	
SELECTBEST-1	The scorable patient series score must be the sum of all points awarded to the scorable patient series.	
SELECTBEST-2	The prioritized patient series must be one of the following:  • The scorable patient series with the highest scorable patient series score.  • The scorable patient series with the best ranked series preference if more than one scorable patient series are tied for the highest scorable patient series score.	

## 8.8 DETERMINE BEST PATIENT SERIES

Determine best patient series provides the business rules to be applied to the set of prioritized patient series, one per Series Group, determined above. This step only happens after one prioritized patient series has been selected for each Series Group for the antigen. After this process, one or more non-redundant best patient series will remain. Each of these best patient series are necessary to fully protect the patient.

**TABLE 8-14 IS THE SERIES A BEST PATIENT SERIES?** 

CONDITIONS			RULES		
Is the series status "complete"?	Yes	No	No	No	No
Is there a series in an equivalent series group with a status of "complete"?	-	Yes	No	No	No
Is the series type "risk"?	-	-	Yes	No	No
Is there a series in an equivalent series group that is of series type "risk"?	-	-	-	No	Yes
OUTCOMES	Yes. The series is a best patient series.	No. The series is not a best patient series.	Yes. The series is a best patient series.	Yes. The series is a best patient series.	No. The series is not a best patient series.

## 9 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 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 9-1 IDENTIFY AND EVALUATE VACCINE GROUP PROCESS STEPS

Section	Activity	Goal
9.1	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.
9.2	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.
9.3	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.

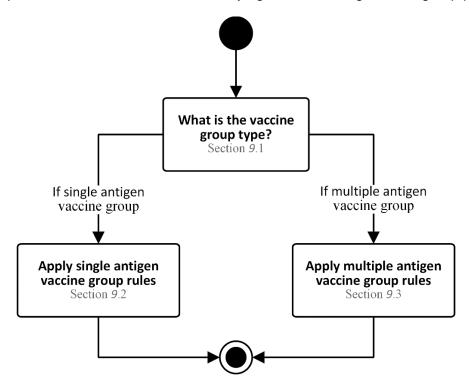


FIGURE 9-1 IDENTIFY AND EVALUATE VACCINE GROUP PROCESS MODEL

## 9.1 CLASSIFY VACCINE GROUP

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

## **TABLE 9-2 WHAT IS THE VACCINE GROUP TYPE?**

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

# 9.2 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 9-3 SINGLE ANTIGEN VACCINE GROUP BUSINESS RULES

Business Rule ID	Business Rule
SINGLEANTVG-1	The vaccine group status for a single antigen vaccine group must be the patient series status of the best patient series.
SINGLEANTVG-2	The vaccine group forecast earliest date for a single antigen vaccine group must be the best patient series forecast earliest date.
SINGLEANTVG-3	The vaccine group forecast adjusted recommended date for a single antigen vaccine group must be the best patient series forecast adjusted recommended date.
SINGLEANTVG-4	The vaccine group forecast adjusted past due date for a single antigen vaccine group must be the best patient series forecast adjusted past due date.
SINGLEANTVG-5	The vaccine group forecast latest date for a single antigen vaccine group must be the best patient series forecast latest date.
SINGLEANTVG-6	The vaccine group forecast unadjusted recommended date for a single antigen vaccine group must be the best patient series forecast unadjusted recommended date.
SINGLEANTVG-7	The vaccine group forecast unadjusted past due date for a single antigen vaccine group must be the best patient series forecast unadjusted past due date.
SINGLEANTVG-8	The vaccine group forecast reason for a single antigen vaccine group must be set the best patient series forecast reason.
SINGLEANTVG-9	The vaccine group forecast antigens needed for a single antigen vaccine group must be the best patient series target disease.
SINGLEANTVG-10	The vaccine group forecast recommended vaccines for a single antigen vaccine group must be the best patient series forecast recommended vaccines.

# 9.3 MULTIPLE ANTIGEN VACCINE GROUP

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

TABLE 9-4 WHAT IS THE VACCINE GROUP STATUS OF A MULTIPLE ANTIGEN VACCINE GROUP?

CONDITIONS	RULES					
Is there at least one best patient series status of "Not Complete"?	No	No	-	Yes	Yes	-
Are all best patient series status "immune"?	No	No	No	No	No	Yes
Is there at least one best patient series status of "Contraindicated"?	No	Yes	Yes	No	-	-
Is the recommendation for the vaccine group to administer full vaccine group?	-	No	Yes	Yes	No	-
OUTCOMES	Complete	Contraindicated	Contraindicated	Not Complete	Not Complete	Immune

## TABLE 9-5 MULTIPLE ANTIGEN VACCINE GROUP BUSINESS RULES

Business Rule ID	Business Rule
MULTIANTVG-1	<ul> <li>A vaccine group forecast earliest date for multiple antigen vaccine groups must be one of the following:</li> <li>The latest of all best patient series forecast earliest dates if each best patient series interval priority flag is "n/a" for the target dose being forecast.</li> <li>The later of the following dates if the interval priority flag is "override" for the target dose being forecasted: <ul> <li>The earliest of all best patient series forecast earliest dates</li> <li>The latest of all dates administered for the vaccine doses administered associated with the vaccine group.</li> </ul> </li> </ul>
MULTIANTVG-2	A vaccine group forecast adjusted recommended date for multiple antigen vaccine groups must be the latest of the following dates:  • The earliest of all best patient series forecast adjusted recommended dates.  • The vaccine group forecast earliest date.
MULTIANTVG-3	A vaccine group forecast adjusted past due date for multiple antigen vaccine groups must be the latest of the following dates:  • The earliest of all best patient series forecast adjusted past due date  • The vaccine group forecast earliest date
MULTIANTVG-4	A vaccine group forecast latest date for multiple antigen vaccine groups must be the earliest of all best patient series forecast latest dates.
MULTIANTVG-5	A vaccine group forecast unadjusted recommended date for multiple antigen vaccine groups must be the earliest of all best patient series forecast unadjusted recommended dates.
MULTIANTVG-6	A vaccine group forecast unadjusted past due date for multiple antigen vaccine groups must be the earliest of all best patient series forecast unadjusted past due dates.
MULTIANTVG-7	A vaccine group forecast reason for multiple antigen vaccine groups must include all the forecast reasons from each best patient series.

Business Rule ID	Business Rule
MULTIANTVG-8	An antigen must be considered an antigen needed in a vaccine group forecast if one of the following is true:  • the antigen is in a vaccine group where all the following are true:  • administer the full vaccine group is "Yes" for the vaccine group  • the antigen is for a best patient series with a patient series status of "not complete"  • the antigen is in a vaccine group where all the following are true:  • administer the full vaccine group is "n/a" for the vaccine group  • the antigen is for a best patient series with a patient series status of "not complete"  • the antigen is for a best patient series with a forecast earliest date which is equal to or earlier than any forecast earliest date in a best patient series belonging to the vaccine group
MULTIANTVG-9	The vaccine group forecast recommended vaccines for multiple antigen vaccine groups must be the collection of best patient series forecast recommended vaccines.

## APPENDIX A: DOMAIN MODEL AND GLOSSARY

DOMAIN MODEL (CONCEPT MODEL, VOCABULARY) OVERVIEW

## **Purpose**

The purpose of employing a domain model (i.e. concept 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, Figure A-3 and Figure A-4)
- 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.

## **How to Read the Domain Model Diagrams**

The following figure and glossary provide:

- A legend for the symbols used the Domain Model diagrams
- Definitions for what the symbols represent as well as definitions clarifying related terms.

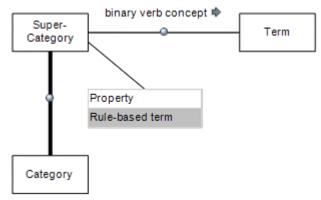


FIGURE A-1 NEIGHBORHOOD

The glossary below provides some basic terms related to the methodology used to generate the Domain Model. The terms in *bold italics* relate to the symbols on the diagram above.

**TABLE A-1 DOMAIN MODEL GLOSSARY** 

Term	Definition	
Binary Verb Concept	a verb concept that involves exactly two noun concepts	
Business Rule	a rule that is practicable and that is under business jurisdiction	
Category	a general concept whose meaning is more restrictive, but otherwise compliant with, another general concept (the super-category)	
Concept	a notion in a person's mind that is a unit of knowledge created by a unique combination of definitional criteria	
Concept Model	a set of concepts structured according to the relations among them	
Concept Model Diagram	a graphical representation of a concept model	
General Concept	a noun concept that classifies potentially many things on the basis of common properties	
Neighborhood	a section of a concept model diagram separated for convenience	
Noun Concept	a concept that is the meaning of a noun or noun phrase	
Property	a quality or trait belonging to a thing itself	
Rule	a guide for conduct or action; one of a set of usually official regulations by which an activity (as a sport) is governed; a standard on which a decision or judgment may be based [MWUD 1a, 1f and [criterion] 2]	
Rule-based Term	a term for a concept for which some explicit definitional rule(s) is/are specified separately from the concept's definition	
Super-Category	a general concept that is broader than its related category/ies	
Synonym	a word (or phrase) having the same meaning as another word (or phrase)	
Term	a designation for a general concept	
Verb Concept	the meaning of a verb phrase (including optional prepositions) along with one or more noun concepts in specific relation to that verb phrase	

## DESCRIPTION OF THE DOMAIN MODEL DIAGRAMS

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

#### **Patient Neighborhood**

The *patient neighborhood* (Figure A-2) focuses on the patient and the patient's history. The patient's history is composed of two distinct items of importance. The first is the set of patient observations which may not be directly related to a previous immunization event. This includes observations about relevant medical, environmental, occupational and behavioral factors for the patient. The second is the immunization history which is composed of vaccine doses administered and adverse reactions.

### **Schedule Neighborhood**

A schedule is the highest level entity encompassing a collection of recommendations and which is composed of antigen series. The schedule neighborhood (Figure A-3) focuses on components that relate directly to the schedule rather than to a specific antigen series or dose. These include:

- Immunity considerations which may negate the need for vaccination of the patient
- Contraindications which may alter the risk benefit analysis for a given vaccination, contraindications may be either at the antigen or vaccine level
- Live virus conflicts which indicate adverse interactions between doses of live virus containing vaccines

## **Series Neighborhood**

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. The *series neighborhood* (Figure A-4) 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.

## **Evaluation and Forecasting Neighborhood**

The evaluation and forecasting neighborhood (Figure A-5) is the result of merging the patient neighborhood with the series and schedule neighborhoods and applying the recommendations of ACIP. That is, it is the result of evaluating vaccine doses administered against the ACIP recommendations and creating the forecast for when the next vaccine dose should be administered according to the ACIP recommendations.

While the schedule, antigen series, and series doses from the *series* and *schedule neighborhoods* encompass 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 recommendations 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 MODEL DIAGRAMS AND GLOSSARY				
that may make the digital. The time below these consecut which the find the digital is the start the administration.				

FIGURE A-2 CDSI DOMAIN DIAGRAM: PATIENT NEIGHBORHOOD

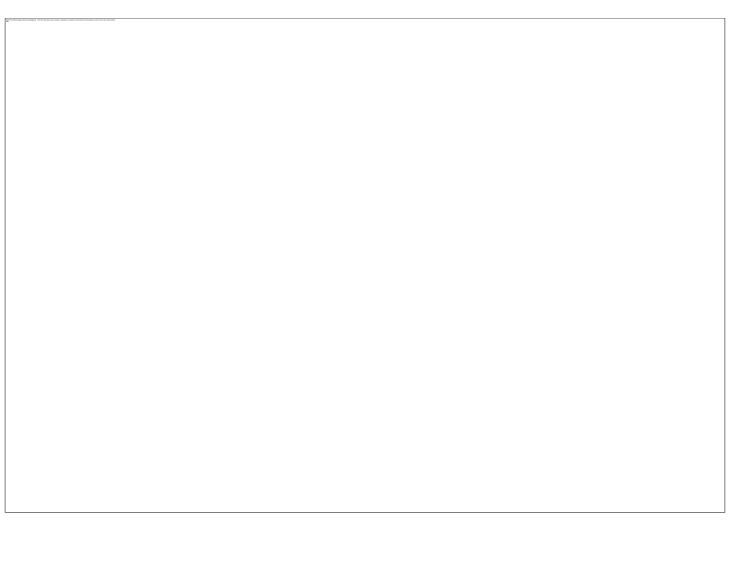


FIGURE A-3 CDSI DOMAIN DIAGRAM: SCHEDULE NEIGHBORHOOD

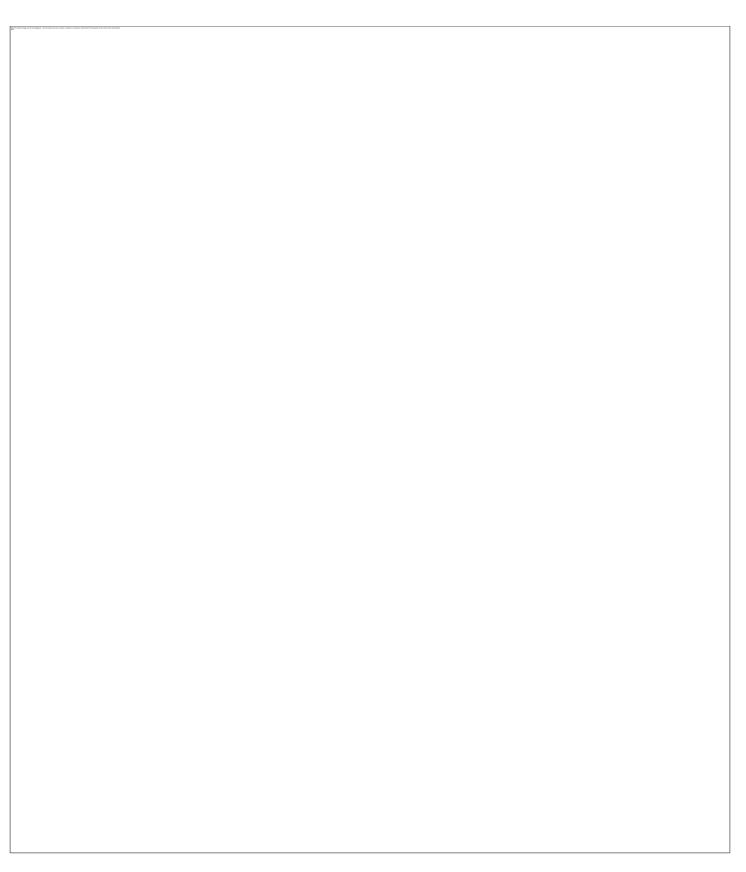


FIGURE A-4 CDSI DOMAIN DIAGRAM: SERIES NEIGHBORHOOD



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

# **TABLE A-2 GLOSSARY**

Term	Definition
Absolute Minimum Age	an age which may be earlier than the minimum age and allows for a vaccine dose administered to be considered valid when administered abnormally early (e.g. grace period)
Absolute Minimum Interval	an interval which maybe shorter than the minimum interval and allows for a vaccine dose administered to be considered valid when administered abnormally early (e.g. grace period)
Active Patient Observation	A patient observation that is applicable to a patient at the time of an evaluation or forecast
Adjusted Past Due Date	the date at which the next target dose for the patient is considered overdue
	Defined by the rule: The adjusted past due date must be one of the following:  • The later of the earliest date and the unadjusted past due date if the unadjusted past due date is present.  • Empty if the unadjusted past due date is not present.
Adjusted Recommended Date	the date at which the next target dose should be given  Defined by the rule:  The adjusted recommended date must be the later of the earliest date and unadjusted recommended date.
Administrative Guidance	text conveying additional information pertaining to an antigen series or an indication
Adverse Reaction	a negative health consequence experienced by a patient related in time to administration of vaccine (s). NOTE: "In time" means that it happens in some reasonable time after the vaccination event. It might not be attributable to a specific vaccine dose administered, especially in cases when the patient receives several vaccines in one visit.
Age	the length of time from birth to a specified time
Aged Out	A patient series status that indicates the patient exceeded the maximum age prior to completing the patient series
Allowable Interval	an interval that is outside of the preferable interval, but still counts towards immunity
Allowable Vaccine	a vaccine which is administered outside of the preferable vaccine recommendations, but still count towards immunity
Allowable Vaccine Type	a list of vaccines that are allowed to be administered to a patient if a preferable vaccine is not available
Antigen	a foreign (non-self) substance which can cause an immune response. In a vaccine, an antigen can be a live organism (such as viruses and bacteria), an inactivated organism or a component proteins and/or polysaccharides.
Antigen Contraindication	a contraindication which applies to all current formulations of vaccine for a given antigen (e.g. all formulations of hepatitis a vaccine are contraindicated for a patient with a hypersensitivity to alum)
Antigen Series	one possible path to achieve presumed immunity against a target disease
Antigen Supporting Data	supporting data for a specific antigen
Antigens Needed	the antigens from a vaccine group which the patient is in need of receiving
Assessment Date	the date for which the forecast is created
Best Patient Series	the prioritized patient series which apply to the patient.

Term	Definition
Birth Date Immunity	an immunity that may provide protection if a patient was born before an established immunity birth date within a country of birth
Cessation Date	the ending date after which a logical component instance is no longer appropriate to use
Clinical Guideline Observation	an observation defined by an organization (e.g., ACIP) that impacts a patient's immunization recommendations
Clinical History Immunity	an immunity that may provide protection based on patient history
Complete	A patient series status that indicates the patient has met all of the ACIP recommendations for the patient series
Conditional Skip	a situation where, based on a patient's immunization history or age, the patient may not need a particular dose of vaccine.
Conditional Skip Begin Age	For Conditions of Type Vaccine Count by Age, the Begin Age defines the beginning point of the age range to be considered.
Conditional Skip Condition	a fact about a patient which may impact a patient's need for a particular dose of vaccine.
Conditional Skip Condition ID	a numeric identifier for a condition within a set
Conditional Skip Condition Logic	When a set consists of more than 1 condition, the Condition Logic determines if all conditions must be met or just a single one in order for the set to be met.
Conditional Skip Condition Logic - AND	When the Condition Logic is "AND", all conditions in the set must be met in order for the set to be met.
Conditional Skip Condition Logic - OR	When the Condition Logic is "OR", only a single condition in the set must be met for the set to be met.
Conditional Skip Context	The circumstances in which conditional skip rules should be applied during the Evaluation and Forecasting process
Conditional Skip Description	a textual description of the intent of the condition
Conditional Skip Dose Count	For Condition of Types of Vaccine Count by Age or Vaccine Count by Date, the Dose Count indicates the critical number of doses for the Condition. The Dose Count works together with Dose Type and Dose Count Logic to fully define the Condition.
Conditional Skip Dose Count Logic	For Condition of Types of Vaccine Count by Age or Vaccine Count by Date, the Dose Count Logic indicates for the Condition whether the patient's dose count must be greater than, less than or equal to the Dose Count. The Dose Count Logic works together with Dose Count and Dose Type to fully define the Condition.
Conditional Skip Dose Type	For Condition of Types of Vaccine Count by Age or Vaccine Count by Date, the Dose Type indicates for the Condition whether or not counted doses must be valid doses for the series or not. The Dose Type works together with Dose Count and Dose Count Logic to fully define the Condition.
Conditional Skip End Age	For Conditions of Type Vaccine Count by Age, the End Age defines the ending point of the age range to be considered.
Conditional Skip End Date	For Conditions of Type Vaccine Count by Date, the End Date defines the ending point of the date range to be considered.
Conditional Skip Interval	For Conditions of Type of Interval, the Interval defines the minimum space of time since the last satisfied target dose.
Conditional Skip Series Group	For Conditions of Type of Completed Series, indicates for the condition which series group needs to contain a completed series for the condition to be met

Term	Definition			
Conditional Skip Set	A set is one or more conditions which need to be considered together when determining if a patient can skip a particular dose of vaccine.			
Conditional Skip Set ID	a numeric identifier for a set of conditions that may lead to the skipping of a series dose			
Conditional Skip Set Logic	When The Conditional Skip section contains more than 1 set, The Set Logic determines if all sets must b met or just a single one in order for the dose to be skipped.			
Conditional Skip Set Logic - AND	When the Set Logic is "AND", all Sets must be met in order for the Dose to be skipped			
Conditional Skip Set Logic - OR	When the Set Logic is "OR", only a single Set must be met for the Set for the Dose to be skipped.			
Conditional Skip Start Date	For Conditions of Type Vaccine Count by Date, the Start Date defines the beginning point of the date range to be considered.			
Conditional Skip Type	The Type specifies the nature of the condition			
Conditional Skip Type - Age	If the patient's age at the time of dose administration or forecast is equal to or greater than the Begin Age, then the condition is met.  Required Parameters: Begin Age			
Conditional Skip Type - Completed Series	If the patient has completed a series in the specified Series Group, then the condition is met.  Required Parameters: Series Group			
Conditional Skip Type - Interval	If the interval from the administered date of the last satisfied target dose equals or exceeds the Interval, then the condition is met. Required Parameters: Interval			
Conditional Skip Type – Vaccine Count by Age	· · · · · · · · · · · · · · · · · · ·			
Conditional Skip Type – Vaccine Count by Date	, ,			
Conditional Skip Vaccine Type	the specific types of vaccine dose administered.			
Conflict Begin Interval	an interval which identifies the start of a live virus conflict			
Conflict End Interval	an interval which identifies the end of a live virus conflict			
Conflicting vaccine dose administered at without appropriate spacing from and administered vaccine.				
	Defined by the rule: A current vaccine dose administered must be considered to be a conflicting vaccine dose administered if it is in conflict with any previous vaccine doses administered.			

Term	Definition			
Contraindicated	A patient series status that indicates no further vaccines should be administered at this time for the patient series			
Contraindicated Patient Series	A patient series for which there are one or more contraindications that apply to a patient			
Contraindication	a clinical guideline observation rendering a vaccination inadvisable for a patient due to a condition in the patient that increases the risk of a serious adverse reaction			
Contraindication Begin Age	the earliest age that a contraindication applies to			
Contraindication End Age	the latest age that a contraindication applies to			
Contraindication Text Description	a recommended action for a clinical guideline observation where there is a contraindication			
Country of Birth	the birth country where an individual was born			
Current Vaccine Type	the vaccine type of the vaccine dose administered currently undergoing evaluation			
Date Administered	the date of the vaccine dose administered			
Date of Birth	a patient 's date of birth			
Default Series	an antigen series which best describes the standard recommendations of the ACIP			
Dose Condition	the state of the vaccine dose administered with respect to producing a strong immune response to protect against a target disease			
Dose Count	the number of vaccine doses administered			
Dose Number	the ordinal dose position in the antigen series			
Earliest Date	the earliest point in time at which the next target dose could be given  Defined by the rule: The earliest date must be the latest of the following dates:  • Minimum age date • Latest minimum interval date • Latest conflict end interval date • Seasonal recommendation start date • Latest inadvertent administration date • Date Administered of the most recent vaccine dose administered			
Earliest Recommended Age	the preferred age a vaccine should be administered			
Earliest Recommended Interval	the lower bound within a range for a preferable interval at which point a patient is recommended to receive their next target dose			
Effective Date	the starting date at which point a logical component instance is appropriate to use			
Equivalent Series Group	A series group which provides the same protection as another series group within the same antigen			
Evaluation	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.			
<b>Evaluation Reason</b>	provides reasons why a vaccine dose administered is or is not valid			
Evaluation Status	indicates validity of a vaccine dose administered in relation to a specific target dose			
Evidence of Immunity	the proof or written documentation that indicates a patient may have immunity			

Term	Definition			
Extraneous	An evaluation status that indicates 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)			
Forecast	the result of the process of applying rules for the next series dose. The outcome of the forecasting proce would be dates for the next target dose.			
Forecast Reason	provides reasons why a target dose is or is not recommended to be administered			
Forecast Vaccine Type	a specific vaccine type that should be administered for a vaccine series			
From Immediate Previous Dose Administered	indicates the interval is applied from the date of the previous vaccine dose administered within the antigen series			
From Most Recent (CVX List)	see From Most Recent Vaccine Type			
From Most Recent Vaccine Type	a vaccine type for which an interval is determined from the date administered of the most recent occurrence of that vaccine type			
From Relevant Observation Code	the clinical guideline observation from which the interval is determined			
From Target Dose Number in Series	indicates the interval is applied from the date of the vaccine dose administered which satisfied the defined target dose			
Gender	patient's sex			
Immune	A patient series status that indicates the patient has evidence of immunity indicating no further vaccines are needed for the patient series			
Immunity	a condition of being able to resist a particular disease			
Immunity Birth Date	the date that suggests when a patient may have protection from a specific disease			
Immunity Country of Birth	the country where a patient must have been born in order for a birth date immunity to apply			
Immunity Exclusion Condition	a patient factor which precludes a patient from being considered immune without vaccination			
Immunity Guideline	a statement defined by an organization (e.g., ACIP) that can be used to help determine whether clinical history immunity is applicable			
Immunization	the process of being made immune or resistant to an infectious disease typically by the administration of a vaccine			
Immunization History	a collection of information detailing more vaccination events for a patient			
Inadvertent Vaccine	a vaccine that should not have been administered			
Indication	a clinical guideline observation signifying the need for an antigen series because of an increased risk of disease			
Indication Begin Age	the earliest age that an indication applies to			
Indication End Age	the latest age that an indication applies to			
Indication Text Description	a recommended action for a clinical guideline observation where there is an contraindication			
Interval	a period of time between instances, typically between vaccine doses administered			
Interval Priority Flag	wal Priority Flag when forecast the next target dose for a vaccine group, the Interval Priority Flag allows an override of the combined forecast dates by an antigen			

Term	Definition			
Latest Date	the latest point in time at which the next target dose could be given			
	Defined by the rules: The latest date must be the maximum age date – 1 day if present.			
	A vaccine group forecast latest date for multiple antigen vaccine groups must be the earliest of all best patient series forecast latest dates.			
	The vaccine group forecast latest date for a single antigen vaccine group must be the best patient series forecast latest date.			
Latest Recommended Age	the age a vaccine must be administered before the patient is considered overdue			
Latest Recommended Interval	the upper bound within a range for a preferable interval after which a patient is considered overdue for their next target dose			
Live Virus Conflict	a condition when two live virus vaccines are administered at too close of an interval			
Live Virus Vaccine	a vaccine that is made with a weakened or attenuated form of a virus or bacteria			
Logical Component	a set of related logical component elements that contribute to the supporting data (e.g. Age, Preferable Interval, Allowable Interval and Conditional Skip)			
Logical Component Element	a single concept contained as part of a Logical Component (e.g. elements of the Age logical component include Absolute Minimum Age, Minimum Age and Earliest Recommended Age)			
Lot Expiration Date	the date at which point the lot of vaccine is no longer considered potent			
Manufacturer	an organization that develops and distributes a vaccine			
Maximum Age	the latest age a vaccine may be administered			
Maximum Age To Start	the latest age an antigen series may be started			
Minimum Age	the earliest age a vaccine may be administered			
Minimum Age To Start	the earliest age an antigen series may be started			
Minimum Conflict End Interval	an interval which identifies the absolute earliest end of a live virus conflict			
Minimum Interval	the shortest interval between two vaccine doses administered			
Multiple Antigen Vaccine Group	a vaccine group containing more than one antigen designed to protect against more than one disease (e.g. MMR, DTaP/Tdap/Td)			
Not Complete	A patient series status that indicates the patient has not yet met all of the ACIP recommendations for th patient series			
Not Recommended	A patient series status that indicates the patient's immunization history provides sufficient protection against a disease and there's no recommended action at this time			
Not Satisfied	A target dose status that indicates no vaccine dose administered has met the goals of the target dose			
Not Valid	An evaluation status that indicates the vaccine dose administered was not administered according to ACIP recommendations and must be repeated at an appropriate time in the future			
Observation	a notation of a medical, environmental, behavioral, or occupational situation			
Observation Code	a unique identifier for a clinical guideline observation			
Observation Date	the date which a clinician determined the patient observation occurred or will occur			
Observation Title	a name for a clinical guideline observation			

Term	Definition			
Patient	an individual who is the actual or potential recipient of a vaccine dose administered			
Patient History	a narrative or record of current and/or past events and circumstances that are or may be relevant to a patient's current state of health			
Patient Observation	an observation specific to a patient			
Patient Series	tracks the patient's progress towards the completion of an antigen series.			
Patient Series Status	indicates whether the patient has met the goals for the Patient series			
Preferable Interval	an interval defined by ACIP best practices			
Preferable Vaccine	a vaccine which follows the recommended ACIP guidelines for administering a specific vaccine			
Previous Vaccine Type	the vaccine type of the vaccine dose administered during a previous vaccine dose administered			
Prioritized Patient Series	the patient series within a series group that best meets the patient's need  Defined by the rule: The prioritized patient series must be one of the following:  • The scorable patient series with the highest scorable patient series score.  • The scorable patient series with the best ranked series preference if more than one scorable patient series are tied for the highest scorable patient series score.			
Product Path	an antigen series which specifically targets a product, vaccine type, and or trade name			
Reason	a rationale or justification for an outcome			
Recurring Dose	indicates a target dose is to be repeated endlessly			
Relevant Patient Series	a series that is selected and created for the appropriateness of the patient based on criteria such as standard recommendations, patient gender, and observations			
Required Gender	the gender that a patient should be in order to consider an antigen series relevant			
Risk Series	an antigen series which outlines immunization recommendations based on underlying indications a patient may have			
Satisfied	A target dose status that indicates a vaccine dose administered has met the goals of the target dose			
Schedule	a collection of guidelines defined by an organization (e.g. ACIP) recommending under what circumstances someone should or should not receive a vaccine			
Schedule Supporting Data	supporting data which span antigens including:  clinical guideline observation used to identify indications, immunity, and contraindications  a CVX to Antigen map which links individual CVX codes to antigen supporting data  a list of Vaccine Groups  a Vaccine Group to Antigen map to identify the Antigens which make up a Vaccine Group  a Live Virus Conflict table to identify situations where the timing of administration of live virus vaccine may be impacted			
Seasonal Recommendation	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	the last day a seasonal vaccine should be recommended			
Seasonal Recommendation Start Date	the first day a seasonal vaccine should be recommended			
Select Patient Series	the process of reviewing all potential patient series which might satisfy the goals of an antigen and determining the one or more series which leads to the best path to immunity for the patient			

Term	Definition			
Series Dose	an individually defined dose within an antigen series			
Series Group	a set of related antigen series which fulfill the same purpose such as protecting against underlying risk conditions or being the standard series			
Series Group Name	a meaningful identifier for a series group			
Series Name	a meaningful identifier for an antigen series			
Series Preference	a ranking given to antigen series within a series group.			
Series Priority	a ranking given to antigen series within a single series group. The series priority is considered when selecting relevant patient series to evaluate as a potential best patient series			
Series Type	indicates if the series is a standard series or a risk series			
Single Antigen Vaccine Group	a vaccine group containing one antigen designed to protect against one disease (e.g., Hib, HepB, Polio)			
Skipped	A target dose status that indicates 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.			
Standard Series	an antigen series which outlines routine immunization recommendations			
Sub-standard	An evaluation status that indicates 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			
Supporting Data	a structured representation of ACIP recommendations			
Target Disease	a disease where a vaccine can be administered to a patient to reduce the risk of contracting the disease working with the body's natural defenses to help it develop an immunity to the disease			
Target Dose	a patient-specific dose required to satisfy a recommendation of the ACIP			
Target Dose Status	indicates whether or not a vaccine dose administered has met the goals of the target dose			
Total Count of Valid Doses	the total number of valid doses regardless of age			
Trade Name	the manufacturer's proprietary name, and in some cases, its intended use (e.g. adults, pediatrics)			
Unadjusted Past Due Date	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  Defined by the rule: The unadjusted past due date must be one of the following:  • The latest recommended age date – 1 day.  • The latest of all latest recommended interval dates – 1 day if the latest recommended age date is not present.  • The unadjusted past due date must be empty if latest recommended age date and latest recommended interval date(s) are not present.			
Unadjusted Recommended Date	the static recommended date a patient should receive the next target dose regardless of patient's current age and previous vaccine doses administered  Defined by the rule: The unadjusted recommended date must be one of the following:  • The earliest recommended age date.  • The latest of all earliest recommended interval dates if the earliest recommended age date is not present.  • The forecast earliest date if the earliest recommended age date and earliest recommended interval date are not present.			
Vaccination	the use of vaccines to produce immunity to a disease			

Term	Definition		
Vaccine	a dose of substance administered during a vaccination event		
Vaccine Contraindication	a contraindication which is specific to a particular vaccine (e.g. a prefilled syringe with a latex plunger would trigger a vaccine contraindication for patients with a latex allergy but other formulations of vaccine for the same antigen may be safe to give)		
Vaccine Dose Administered	a medical occurrence of administering one Vaccine to a Patient		
Vaccine Group	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	the forecast for a vaccine group		
Vaccine Group Status	indicates whether the patient has met the goals for the Vaccine group		
Vaccine Type	the specific type of vaccine dose administered		
Vaccine Type Begin Age	the earliest age the vaccine type can be administered		
Vaccine Type End Age	the latest age the vaccine type can be administered. Vaccine type end age date is derived from vaccine type end age.		
Valid	An evaluation status that indicates the vaccine dose administered was administered according to ACIP recommendations		
Volume	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		
DT	Diphtheria and tetanus toxoids adsorbed (children)		
DTaP	Diphtheria and tetanus toxoids and acellular pertussis vaccine adsorbed		
EIPB	Education, Information and Partnership Branch		
EHR	Electronic Health Record		
FDA	Federal Drug Administration		
Hib	Haemophilus influenza type b conjugate vaccine		
HIE	Health Information Exchange		
HIS	Health Information System		
НерА	Hepatitis A vaccine		
НерВ	Hepatitis B vaccine		
HIV	Human Immunodeficiency Virus		
HPV	Human papillomavirus vaccine		
IIS	Immunization Information System		
IISSB	Immunization Information Systems Support Branch		
Flu	Influenza		
MMR	Measles, Mumps, and Rubella vaccine		
MMRV	Measles, Mumps, Rubella, and Varicella vaccine		
MCV	Meningococcal conjugate vaccine		
MMWR	Morbidity and Mortality Weekly Report		
NCIRD	National Center for Infectious Diseases		
PCV	Pneumococcal conjugate vaccine		
PPSV	Pneumococcal polysaccharide 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		
DHHS	U.S. Department of Health and Human Services		

Term	Meaning
VZ	Varicella vaccine

# **APPENDIX C: RETIRED ITEMS**

The table below provides a list of terms, rules and tables used in previous versions of the document but which are no longer in use.

#### **TABLE C-1 RETIRED ITEMS**

Version	Item	Name	Motivation
4.1	Term	Observation Description	Term was replaced by Indication Text Description and Contraindication Text Description which are used in Supporting Data.
4.1	Term	Vaccination Administrative Guidance	Retired term due to update to rule FORECASTGUIDANCE-1 which no longer references the term.
4.0	Business Rule	SELECTSCORE-1	Rule was retired and condensed into one rule in SELECTSCORE-2.
4.0	Term	Organization	Term is not used anywhere.
4.0	Term	Relevant Behavioral Observation	The term is not being used.
4.0	Term	Relevant Environmental Observation	The term is not being used.
4.0	Term	Relevant Medical Observation	The term is not being used.
4.0	Term	Schedule Name	Term is not used anywhere.
3.0	Business Rule	SELECTB-10	This rule is no longer needed and therefore was retired in version 3.0.
3.0	Business Rule	SELECTB-15	This rule is no longer needed as gender consideration was moved to the create relevant series section.
3.0	Business Rule	SELECTB-22	The Rule was retired when the term "candidate patient series" was replaced by "scorable patient series".
3.0	Business Rule	SELECTB-4	The Rule was retired when the term "candidate patient series" was replaced by "scorable patient series".
3.0	Decision Table	Is the Patient's Gender One of the Required Genders?	The decision table was retired when the gender logic was incorporated into the selection of relevant patient series.
3.0	Term	Candidate Patient Series	The term was retired when replaced by "scorable patient series" when the evolution of patient series was rethought.
3.0	Term	CVX List	Has no clear definition and is only a descriptor of Supporting Data elements
3.0	Term	Date Administered of First Satisfied Target Dose	Is only a conglomeration of individual terms
3.0	Term	Exceeded Maximum Age To Start	This term is no longer needed and therefore was retired in version 3.0.
3.0	Term	First Dose Begin Age	Not used in version 3.0. It should have been removed/retired in version 2.1.
3.0	Term	First Dose End Age	Not used in version 3.0. It should have been removed/retired in version 2.1.
3.0	Term	Gender-Specific Patient Series	This rule is no longer needed as gender consideration was moved to the create relevant series section.

Version	Item	Name	Motivation
3.0	Term	Medical History	Replaced in version 3.0 by Patient History.
3.0	Term	Preferable Vaccine Trade Name	The term was retired because Trade Name is an attribute of Vaccine of which there are two flavors, preferable and allowable. See the term Trade Name for a definition.
3.0	Term	Preferable Vaccine Volume	The term was retired because Volume is an attribute of Vaccine of which there are two flavors, preferable and allowable. See the term Volume for a definition.
3.0	Term	Select Best Patient Series	Replaced with Select Patient Series in V3.0
3.0	Term	Vaccine Type Begin Age Date	This is a duplicate of Preferable Vaccine Type Begin Age Date
3.0	Term	Vaccine Type End Age Date	This is a duplicate of Preferable Vaccine Type End Age Date.
2.1	Business Rule	CALCDTCOND-1	The rule was no longer needed in the Logic Specification due to the newly added conditional skip logic.
2.1	Business Rule	CALCDTCOND-2	The rule was no longer needed in the Logic Specification due to the newly added conditional skip logic.
2.1	Business Rule	CALCDTSKIP-1	The rule was no longer needed in the Logic Specification due to the newly added conditional skip logic.
2.1	Business Rule	CALCDTSKIP-2	The rule was no longer needed in the Logic Specification due to the newly added conditional skip logic.
2.1	Business Rule	CALCDTSUB-1	The rule was no longer needed in the Logic Specification due to the newly added conditional skip logic. It was replaced with CALCDTSKIP-3 rule.
2.1	Business Rule	CALCDTSUB-2	The rule was no longer needed in the Logic Specification due to the newly added conditional skip logic. It was replaced with CALCDTSKIP-4 rule.
2.1	Business Rule	CONDNEED-1	The rule was no longer needed in the Logic Specification due to the newly added conditional skip logic.
2.1	Business Rule	CONDNEED-2	The rule was no longer needed in the Logic Specification due to the newly added conditional skip logic.
2.1	Business Rule	Number of Doses Remaining	The rule was no longer needed in the Logic Specification due to the newly added conditional skip logic.
2.1	Business Rule	SELECTBEST-3	The rule was incorporated into SELECTBEST-2.
2.1	Business Rule	SUBDOSE-1	The rule was no longer needed in the Logic Specification due to the newly added conditional skip logic.
2.1	Business Rule	SUBDOSE-2	The rule was no longer needed in the Logic Specification due to the newly added conditional skip logic.
2.1	Decision Table	Can Target Doses Be Substituted? (Evaluation)	The decision table was retired in favor of new conditional skip logic.
2.1	Decision Table	Can Target Doses Be Substituted? (Forecast)	The decision table was retired in favor of new conditional skip logic.
2.1	Decision Table	Is the Condition Met?	This decision table was retired in favor of new Conditional Skip logic.
2.1	Decision Table	Is the Target Dose Conditionally Needed?	This decision table was retired in favor of new Conditional Skip logic.

Version	Item	Name	Motivation
2.1	Term	Conditional Begin Age	The term was replaced with the Conditional Skip term.
2.1	Term	Conditional Begin Age Date	The term was replaced with the Conditional Skip term.
2.1	Term	Conditional End Age	The term was replaced with the Conditional Skip Begin Age term.
2.1	Term	Conditional End Age Date	The term was replaced with the Conditional Skip term.
2.1	Term	Conditional End Date	The term was replaced with the Conditional Skip Condition term.
2.1	Term	Conditional Need	The term was replaced with Conditional Skip Type- Vaccine Count by Age term.
2.1	Term	Conditional Need Dose Count	The term was replaced with the Conditional Skip Dose Count term.
2.1	Term	Conditional Need Vaccine Count	The term was replaced with the Conditional Skip term.
2.1	Term	Conditional Need Vaccine Type	The term was replaced with the Conditional Skip term.
2.1	Term	Conditional Set	The term was replaced with the Conditional Skip Type-Vaccine Count by Date term.
2.1	Term	Conditional Start Date	The term was replaced with Conditional Skip Vaccine Types (CVX List) supporting data concept.
2.1	Term	Conditionally Needed Administrations	The term was replaced with Number of Conditional Doses Administered rule.
2.1	Term	First Dose Begin Age Date	The term was replaced with Conditional Skip.
2.1	Term	Forecast Status	The term was retired because it is not used anywhere (except on Domain model for versions 1.3) in the Logic Specification.
2.1	Term	Number of Doses Remaining	The term was replaced with Conditional skip.
2.1	Term	Number of Target Doses to Substitute	The term was replaced with Conditional Skip.
2.1	Term	Skip Target Dose	The term was replaced with the Conditional Skip.
2.1	Term	Substitute Dose	This term was replaced with Conditional Skip.
2.1	Term	Substituted	This term was replaced with Conditional Skip.
2.1	Term	Target Doses with a Target Dose Status "Satisfied"	This term was replaced with Conditional Skip.
2.1	Term	Trigger Age	The term was replaced with Conditional Skip.
2.1	Term	Trigger Age Date	The term was replaced with Conditional Skip.
2.1	Term	Trigger Doses Administered	The term was replaced with Conditional Skip.
2.1	Term	Trigger Interval	The term was replaced with Conditional Skip.
2.1	Term	Trigger Interval Date	The term was replaced with Conditional Skip.
2.1	Term	Trigger Target Dose	The term was replaced with Conditional Skip.

Version	Item	Name	Motivation
1.7	Term	Conflict End Date	The term was replaced with Conflict End Interval Date term.
1.5	Business Rule	SATISFIEDVG-1	The rule was retired due to restructuring of Chapter 7 in v1.5.
1.5	Business Rule	SATISFIEDVG-2	The rule was retired due to restructuring of Chapter 7 in v1.5.
1.5	Business Rule	SATISFIEDVG-3	The rule was retired due to restructuring of Chapter 7 in v1.5.
1.5	Business Rule	SATISFIEDVG-4	The rule was retired due to restructuring of Chapter 7 in v1.5.
1.5	Business Rule	UNSATPARTVG-1	The rule was retired due to restructuring of Chapter 7 in v1.5.
1.5	Business Rule	UNSATPARTVG-2	The rule was retired due to restructuring of Chapter 7 in v1.5.
1.5	Business Rule	UNSATPARTVG-3	The rule was retired due to restructuring of Chapter 7 in v1.5.
1.5	Business Rule	UNSATPARTVG-4	The rule was retired due to restructuring of Chapter 7 in v1.5.
1.5	Business Rule	UNSATPARTVG-5	The rule was retired due to restructuring of Chapter 7 in v1.5.
1.5	Business Rule	UNSATPARTVG-6	The rule was retired due to restructuring of Chapter 7 in v1.5.
1.5	Business Rule	UNSATPARTVG-7	The rule was retired due to restructuring of Chapter 7 in v1.5.
1.5	Business Rule	UNSATPARTVG-8	The rule was retired due to restructuring of Chapter 7 in v1.5.
1.5	Business Rule	UNSATPARTVG-9	The rule was retired due to restructuring of Chapter 7 in v1.5.
1.5	Decision Table	What is the Type and Condition of the Vaccine Group?	The decision table was retired and replaced by 'What is the Vaccine Group Type?'
1.5	Decision Table	What Is the Vaccine Group Forecast?	The decision table was retired and replaced by 'What is the Vaccine Group Status?'
1.5	Term	Satisfied Patient Series	The tern was retired due to redesign of chapter 7 in v1.5
1.5	Term	Satisfied Vaccine Group	The term was retired due to redesign of chapter 7 in v1.5

# APPENDIX D: ACKNOWLEDGEMENTS

#### **Subject Matter Experts**

#### • 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.

#### • **Greg Anderson,** Connexin Software

#### • **Judy Anderson**, Hewlett Packard (HP)

Judy Anderson has nearly 8 years of hands-on immunization registry experience that includes direct interaction with the Georgia registry users, in-depth knowledge of the immunization schedules, requirement analysis, and test case development. Past projects have included data exchange and inventory management/reporting enhancements, in addition to a supporting role on the current VTrckS implementation for the Georgia registry. One of her strengths, as a member of the HP Immunization Evaluator Workgroup, is to interpret CDC/ACIP recommendations into logical solutions that can be implemented across the WIR-based registries. She is a graduate of Loyola University of Chicago with a Bachelor of Arts degree in Communication Arts/Mass Media.

#### • Regina Austin, HLN Consulting

Regina Austin has over 20 years of healthcare-related experience and expertise in analysis, requirement elicitation, writing, testing, and training in her current position as Senior Analyst and Project Specialist with HLN Consulting. Her focus in recent years has been assisting public health clients with the development and deployment of customized, cutting-edge software meeting the latest standards in healthcare IT. She is current the lead business analyst on several major HLN immunization-related projects. Regina attends and participates in key industry conferences, most recently as a facilitator of HL7 2.5.1 and clinical decision support round-table discussions at the 2012 and 2013 AIRA conferences. Regina is also a member of American Immunization Registry Association's (AIRA) Standards and Interoperability Steering Committee (SISC). Among her recent

publications is a white paper in the HIMSS Journal of Healthcare Information Management on open source clinical decision support for immunizations.

# • 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.

# • 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.

• 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.

### • **Kahil Branton,** Advanced Strategies

Kahil Branton has had an 18+ year career in the Information Technology industry, with experience in business requirements analysis, JDA facilitation, systems architecture, software development, and user interface design. Kahil has facilitated groups through the development of business object models (aka. conceptual data models), architectural designs and business process models. Kahil also has extensive experience in event, location and socio-political modeling. As a Senior Consultant with Advanced Strategies, Inc., Kahil teaches courses on business analysis and consults with government and private sector organizations. He has facilitated numerous sessions for public health and healthcare organizations, including: The CDC, AIRA, and Hospital Corporation of America. Kahil has both a Master's and Bachelor's degree in Computer Science and Engineering from Massachusetts Institute of Technology.

#### • Nathan Bunker, Dandelion Software & Research, LLC

Nathan Bunker 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.

John Canning, Physicians Computer Company (PCC)

#### • 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.

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

#### Rachel Cunningham, MPH, Texas Children's Hospital

Rachel M. Cunningham, MPH, is the immunization registry and educational specialist at Texas Children's Hospital in the Immunization Project. Rachel is the primary author of *Vaccine-Preventable Disease: The Forgotten Story* of which more than 130,000 copies have been distributed. Rachel also worked with Nathan Bunker and other Immunization Project staff to develop the TCH Immunization Forecaster and TCH Forecast Tester. The TCH Immunization Forecaster is used through Texas Children's Hospital as well as its private pediatric network, Texas Children's Pediatrics (TCP), which has 48 practices throughout the greater Houston area. The TCH Immunization Forecaster is also currently being utilized by Indian Health Services and the Virginia

Department of Health while the TCH Forecast Tester is being utilized by multiple organizations across the U.S. Rachel has been at Texas Children's since 2007. She earned her Bachelor of Science degree from Oral Roberts University and has a master's in public health from The University of Texas Health Science Center at Houston.

#### • **Gail DeCosta,** Advanced Strategies

Gail DeCosta has had a 30+ year career in the Information Technology industry, with experience in business requirements analysis, JDA facilitation, software development, and project management. She has facilitated groups through the documentation of current business processes and the transformation to a desired future state of "To-Be" business process models. Additionally, Gail also has extensive experience in event, location, socio-political, and business object/data modeling and project management. Gail is employed by Advanced Strategies, Inc. and both teaches courses on business analysis and consults with government and private sector organizations. She has facilitated numerous sessions for public health and health care organizations, including: The CDC, AIRA, MN Department of Health, Hospital Corporation of America and the National Cancer Institute. Gail holds a Bachelor of Arts degree in Psychology from Brown University and a Master's degree in Education from Georgia State University.

## • 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.

# • Kristen Forney, MPH, New York Citywide Immunization Registry (CIR)

Kristen Forney is a public health professional who has led a variety of health IT projects for the Citywide Immunization Registry at the New York City Department of Health and Mental Hygiene. She has participated in the Immunization Calculation Engine (ICE) project as the lead analyst for New York City. As lead analyst for NYC, Kristen co-facilitated the subject matter expert workgroup responsible for developing and documenting the rules and test cases used to implement the ICE algorithm.

# • Anita Geevarughese, MD, New York Citywide Immunization Registry (CIR)

Dr. Anita Geevarughese serves as the Adult Immunization Medical Specialist for the Bureau of Immunization at the New York City (NYC) Department of Health and Mental Hygiene. In this role, Dr. Geevarughese works on a variety of programmatic and policy initiatives to support immunizations in NYC, including improvement of healthcare personnel influenza vaccination coverage, development of school-located influenza vaccination programs and utilization of electronic health record data to create feedback reports for adult providers on practice-level influenza and pneumococcal vaccination coverage. Dr. Geevarughese assists in the development of

both public and provider communications and offers provider education on a number of topics related to adult immunization. She current serves on the executive committee for the National Adult Immunization Coordinators Partnership and has previously served as the principal NYC contact for a CDC-sponsored pilot to field test the National Quality Forum measure on standardized reporting of healthcare personnel influenza vaccination.

# • 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.

# • 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 Bachelor's 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.

#### • **Amy Groom, MPH,** Indian Health Service (IHS)

Amy Groom is a Public Health Advisor with the Centers for Disease Control and Prevention, assigned to work with the Indian Health Service's Division of Epidemiology and Disease Prevention. She has served as the National IHS Immunization Program manager since 2001. In this capacity, she works with IHS and tribal immunization programs across the country to develop immunization policy, implement immunization programs, and monitor immunization coverage. In addition, she is the lead for the development of the IHS clinical decision support software for immunizations, and provides training to end-users on the use of the sofwtare. She is the ex-officio representative for IHS on both the Advisory Committee on Immunization Practices and the National Vaccine Advisory Committee. She holds a Masters in Public Health from Boston University.

#### • 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.

# • **Chip Hart,** Physician's Computer Company (PCC)

Chip Hart is the Director of PCC's Pediatric Solutions and author of the blog "Confessions of a Pediatric Practice Consultant" (chipsblog.pcc.com). Chip's two decades of pediatric practice management expertise have been focused on the support and development of independent pediatric practices. Chip spends nearly all of his time working in and with private practices around the country. He has worked as a consultant for the American Academy of Pediatrics (AAP) and the AAP Section on Administration and Practice Management (SOAPM). Chip leads educational seminars and consults for pediatric professionals nationwide for organizations like the AAP, state chapter AAP programs, the MGMA, and various physician and hospital organizations around the country. Chip was a member of the CCHIT Child Health Work Group and the CDC Clinical Decision Support working group. Chip contributes articles on practice management and health care information technology for Pediatric Coding Alert, the AAP's SOAPM Newsletter, and Medical Group Management Association.

#### • Mari Hilleman, Hewlett Packard (HP)

Mari Hilleman is a business analyst with Hewlett Packard and has been focused on statewide immunization information systems for 11 years. Mari has worked with five different State immunization programs to define requirements and test plans for the development of enhancements to their Immunization Information Systems. Currently Mari is supporting the Idaho Immunization Reminder Information System in the implementation and testing of the Wisconsin Immunization Evaluator module used for forecasting and evaluation of Idaho's ACIP schedule as well as school and childcare eligibility.

# • Robert Hopkins, Jr., MD, FACP, FAAP, American College of Physicians (ACP)

Dr. Hopkins is Professor of Internal Medicine and Pediatrics and director of the division of the Division of General Internal Medicine at the University of Arkansas for Medical Sciences. He has active teaching and faculty practices in Internal Medicine and Pediatrics at UAMS and also directs the Combined Internal Medicine-Pediatrics residency at UAMS. He is recognized nationally as an expert in adult immunization, clinical practice guidelines review and development, medical education and quality improvement and has published well over 100 articles on these topics. He is the immediate past governor of the Arkansas Chapter of the American College of Physicians and has served on numerous national ACP committees in addition to his roles at the University of Arkansas for Medical Sciences. Currently, he serves on the Adult Immunization Technical Advisory Committee and the ACP Performance Measurement Committee and the Arkansas Department of Health Vaccine Medical Advisory Committee.

# • Paul Hunter, MD, American Academy of Family Physicians (AAFP)

As Associate Medical Director of the City of Milwaukee Health Department (MHD), Dr. Paul Hunter focuses on clinical aspects of local public health, especially immunizations, sexually transmitted diseases, tuberculosis, and obesity. He writes the medical orders that MHD nurses use to vaccinate Milwaukeeans. He represents MHD on the Wisconsin Council on Immunization Practices and on the Immunization Work Group of the National Association of County and City Health Officials. He helped develop Immunize Milwaukee! (IM!), a coalition of stakeholders from health systems, health departments, schools, neighborhood centers, health insurers, and others, which focuses on raising vaccination rates of all residents of Metro-Milwaukee. As an Assistant Professor of Family Medicine at the University of Wisconsin School of Medicine and Public Health, he teaches medical and public health students about practical aspects of implementing community health interventions. Dr. Hunter practiced family medicine for 19 years in underserved neighborhoods in Milwaukee and Rockford.

# • **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).

# • **Erin Kennedy, DVM, MPH,** Centers for Disease Control and Prevention (CDC)

Dr. Erin Kennedy is a Medical Officer in the Immunization Services Division, National Center for Immunization and Respiratory Diseases at the Centers for Disease Control. Dr. Kennedy has a DVM and Masters in Anatomy and Neurobiology from Colorado State University and an MPH in Epidemiology from Emory University. Dr. Kennedy first joined the CDC as a fellow on the Rabies Team and then became an Epidemic Intelligence Service Officer in 2008 where she worked primarily on 2009 H1N1 pandemic influenza surveillance. Her career in public health has included research and policy on vaccine preventable diseases, pandemic preparedness, and improving coverage for recommended adult vaccines.

# • Brady Kerr, RN, Texas Children's Hospital

Brady Kerr is a graduate of the University of Utah with a bachelor's degree in Nursing. He is currently working as the Health Education Nurse for the Immunization Project at Texas Children's Hospital. An important part of his role in the Immunization Project is working to maintain, improve and promote the immunization forecaster for Texas Children's Hospital. Previous roles have included caring for geriatric patients as a Home Health RN Case Manager and working as an Immunization Nurse for the Salt Lake County Health Department.

# • **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.

#### • Alean Kirnak, Software Partners (SWP), LLC

#### • **Chandra Klein,** Envision Technology

Chandra Klein works with Envision Technology Partners, Inc. as a Subject Matter Expert. She has developed test cases for the forecast feature of the WebIZ immunization registry. Chandra has been a public health nurse for over 10 years. She has worked in many areas of public health including Tuberculosis Case Management, Perinatal Hep B Case Management, and Immunizations. Most recently she was the Immunization Program Supervisor for the Larimer County Health Department in Fort Collins, Colorado.

#### • 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.

#### • Carl Lauter, MD, FACP, American College of Physicians (ACP)

Dr. Carl Lauter, currently the Governor of the Michigan Chapter, American College of Physicians, graduated from Wayne State University and Wayne State University School of Medicine. He completed his residency in internal medicine followed by a NIH fellowship in infectious diseases and subsequently a fellowship in allergy and immunology. He is board certified in all three specialties. He was on the full time faculty of Wayne State University School of Medicine from 1973 – 1980 and has been at William Beaumont Hospital, Royal Oak, Michigan, since that time. In the past, Dr. Lauter was an internal medicine residency director in two different programs and Chief, Department of Medicine at William Beaumont Hospital for ten years. He is Professor of Medicine at Oakland University School of Medicine and Section Head of Allergy and Immunology, as well as Clinical Professor of Medicine at Wayne State University. Dr. Lauter is an editorial reviewer for several peer reviewed journals. He is a contributor to the medical literature. At the national level he sits on the Immunization Technical Advisory Committee of the American College of Physicians and the Primary Immunodeficiency Committee and the Altered Immune Response Committee of the American Academy of Allergy, Asthma and Immunology. His clinical and teaching interests involve immunology, immunodeficiency and adverse and allergic reactions to vaccinations.

# • Susan Lett, MD, MPH, Massachusetts Department of Health

Dr. Susan Lett has been the medical director of the Massachusetts Immunization Program for over 25 years and has played a key role in the development of the Massachusetts Immunization Information System (MIIS). For the past 5 years, she has co-lead with Dr. Bill Adams, the MIIS immunization decision support team. The MIIS uses a web-service based immunization forecasting module (IFM) which is supported by Drs. Lett and Adams, and their technical team. The IFM includes forecasting rules for children and adults and also supports advanced decision support related to clinical features such as contraindications, immunities, and special indications. All MIIS IFM rules are based on ACIP recommendations. The team has also developed an extensive set of test cases designed to provide comprehensive, automated testing of rules. Dr. Lett is also an internist who has served as a voting member on the Advisory Committee for Immunization Practices (ACIP). She is currently active on 4 ACIP working groups: Adult Schedule, Harmonized (Childhood)

Schedule, General Recommendations on Immunization and Influenza. Susan also helped to review phase 1 of the Logic Specification for ACIP Recommendations.

• **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)
- 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.

• **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.

- **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.
- Shadkashara "Shad" Rajashekarappa, General Electric (GE) Healthcare
- 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.
- Bobby Sanchez, New Mexico Statewide Immunization Information System (NMSIIS)
- Rob Savage, Northrop Grumman Corporation
  - Rob Savage has been involved in the Immunization Information Systems arena since 1989, playing a number of roles including system architect, developer, business analyst and technical writer. While working on the development of the Wisconsin Immunization Registry (WIR), he was the architect of the CDS engine evaluating immunization history and forecasting next doses due. He has been involved in HL7 standards development since 2005. He represented the American Immunization Registry Association for a number of years. He continues to be involved as a Northrup Grumman contractor to the Immunization Information Systems Support Branch at CDC. He is the author of the Version 2.5.1 Implementation Guide for Immunization Messaging. In this role he provided consultation to NIST for their development of Meaningful Use Certification. Rob is a cochair of the Public Health and Emergency Response workgroup and participates in a number of other work groups. Based on his experience in public health and immunization messaging, he has presented tutorials and seminars on the role of HL7 in supporting public health and on implementing Version 2.5.1 immunization messaging.
- 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 11 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 the WIR-based Immunization Evaluator Workgroup and the WIR Consortium. Eric was also a member of the Phase I Clinical Decision Support for Immunizations Expert Panel for childhood vaccinations.

- Richard Shiffman, MD, MCIS, Yale University School of Medicine
- Rosalyn Singleton, MD, MPH, Alaska Native Tribal Health Consortium (ANTHC)

Dr. 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. Shane was also a member of the Clinical Decision Support for Immunizations Expert Panel for childhood vaccinations in 2011 and 2012.

• **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.

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.

- Narasimha Velagaleti, Epic Systems Corporation
- Bryan Volpp, MD, Veterans Health Administration

Dr. Bryan Volpp is an Infectious Diseases Physician at the VA Northern California Healthcare System and the Chief Health Informatics Officer for the regional office. Dr. Volpp attended Duke University Medical School and did his residency and fellowship training at the University of Iowa. Dr. Volpp has been involved with the implementation of the VA EHR and the decision support tools in the VA EHR since 1994. Dr. Volpp has served on the VA/DOD National Clinical Practice Guideline Council and has built, tested and supported most of the existing National VA clinical reminders and all of the regional reminders which include reminders for many immunizations.

• **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.

• 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).

• Gary Wheeler, Hewlett Packard (HP)

# Communication and Education Branch (CEB) Liaison

• Andrew Kroger, Center for Disease Control and Prevention (CDC)

#### **Current CDSi Project Team**

- **Stuart Myerburg, JD,** Centers for Disease Control and Prevention (CDC)
- Eric Larson, Northrop Grumman Corporation
- Lauren Shrader, MA, Northrop Grumman Corporation
- Patricia Speights, MPH, Northrop Grumman Corporation

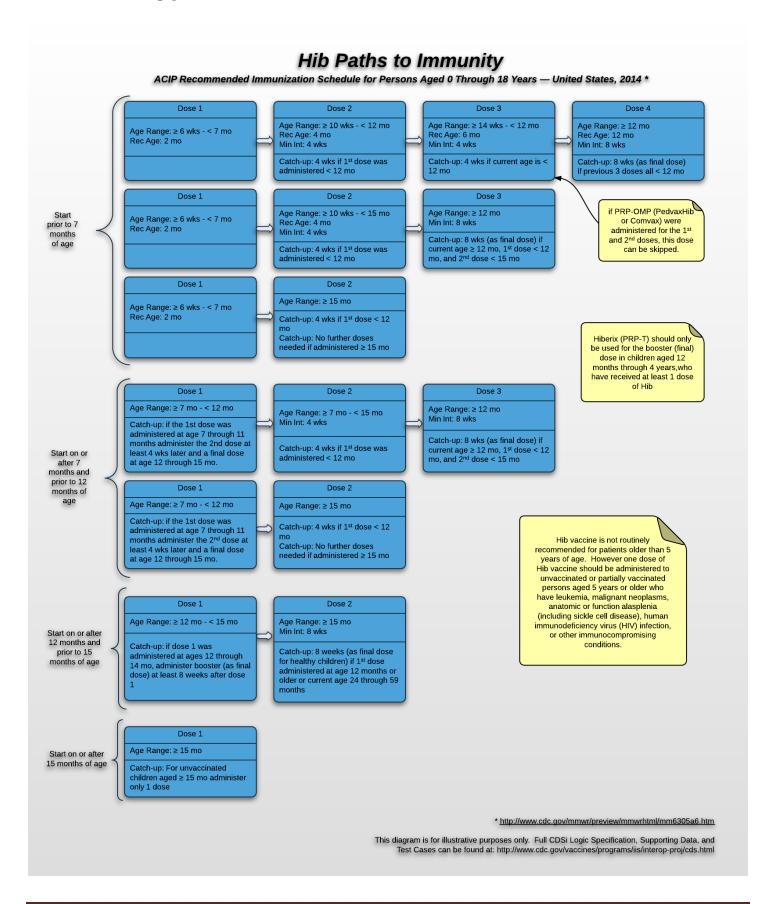
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# APPENDIX F: SUPPLEMENTAL MATERIAL



# **APPENDIX G: 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	Select Best Patient Series language clarifications  Sections 6.1, 6.2, 6.3, 6.5, and 6.6  Select Best Patient Series Decision Table correction  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.  Section 3.4  Assessment date was added to the domain model and a typo was corrected in the definition of the term assessment date  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.  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.  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  Section 3.4	1.3
01/09/14	E. Larson	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.  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.  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.  Changes to Sections 3.2, 5, 5.3 (New), 5.4 (previously 5.3)  Document editorial consistency improvements  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.  Sections 4.2, 5.1, Appendix A	1.4
03/20/14	E. Larson	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.  o Chapter 7  Updated inconsistencies found in Supplemental Material graphics.  o Appendix E	1.6

Date	Changed By	Comments	Version #
		Added Business Rule to Calculate Dates to ensure consistent application of	
		date calculations  o Section 3.4 – See CALCDT-6 Business Rule	
08/14/14	E. Larson	Updated definition of Maximum Age to Start	1.7
		o Section 6.1	
		Added/improved diagrams and process models o chapters 4, 5, 6, 7, 8 and appendices	
		Updated attribute tables to cross-reference with date calculation business rules	
		o chapters 4 and 5	
		Added a new Patient Series Status and associated usage of new "Aged Out"	
		status.  o Section 3.2 and chapters 5 and 6	
		Improved decision table and business rule language to fully utilize vocabulary.	
		o Chapters 5 and 6	
		Assigned Patient Series Status to outcomes section of decision table.  o Section 5.4	
		New Evaluation section was added to accommodate clarifications from EIPB on	
		Hep A intervals after a not valid dose.	
		Section 4.6 was created (Allowable Interval).	
		<ul> <li>Other updates due to this were in the chapter 4 process model, section 4.11, and Appendix A.</li> </ul>	
12/16/14	E. Larson	Added support for maximum doses by age (i.e.: 6 doses by 7 years in DTaP	1.8
		Section 5.1 and Appendix A	
05/11/15	P. Speights, E. Larson	Added Zoster to the Vaccine Groups in Table 1-1 Added Age base Adult Recommendations to the Additional Items in scope	2.0
	L. Laison	include.	
		Added Not Recommended status and definition in Table 3-3	
		Updated Table 3.5 to include business rule CALCDTINT-8, CALCDTCOND-1,	
		and CALCDTCOND-2 Added From Most Recent explanation under the Relationship to ACIP	
		Recommendation in Section 4.5	
		Added Figure 4-10 From Most Recent timeline in section 4.5	
		Added Supporting data "From Most Recent" to table 4-11 Updated the Activity and Goal in Table 5-1 to incorporate sections 5.4	
		Updated the processing model in Figure 5-1 to add section 5.4	
		Added the new Immunity section in section 5.4	
		Updated Table 5-7 to add supporting data for Begin and End Age Date.	
		Updated Table 5-14 to add Not recommended status info.  Added the term Minimum Age to Start Date and Definition in table 6.2	
		Updated Table 7-3 to add business rule SINGLEANTVG-10	
		Updated Table 7-4 to add business rule MULTIANTVG-9	
		Updated the Figure 8-2 Updated the Domain models Figure A-1, Figure A-2, and Figure A-3	
		Added new terms and definitions to the Table A-1 Glossary section. Included	
		are Conditional begin age, Birth Date Immunity, Clinical History Immunity,	
		Country of Birth, Conditional End Age, Exclusion Condition, Forecast Vaccine Type, From Most Recent, Immunity Date, Immunity Guideline, Minimum Age to	
		Start, and Recommended Vaccine,	
12/22/15	C. Newman,	Updated the fourth paragraph in Background and Goals 1.1.	2.1
	P. Speights,	Updated text in section 2.4.	
	E. Larson	Updated text in the first paragraph of section 3.1. Removed Substituted from Target Dose Statuses Table 3.2	
		Updated Supporting Data text in 3.3	
		Updated Logical Component Date Rules in Table 3-5	
		Added Table 3-8 What Exercises Should I do today in section 3.5.	
		Updated Evaluation Process Steps in Table 4-1 Updated Evaluation Process Model in Figure 4-1	
		Species Evaluation (190000 model in Figure 7)	

Date	Changed By	Comments	Version #
		Removed Skip Target Dose section and replaced with Evaluate Conditional Skip in section 4.2. Removed Substitute Target dose section Updated Evaluate Interval in Section 4.4. Updated Live Virus Conflict Business Rules in Table 4-23 of section 4.6 Updated Forecast Dates and Reasons Process steps in Table 5-1. Updated Forecast Dates and Reason Process Model in Figure 5-1. Replaced Skip Target dose with Evaluate Conditional Skip in section 5.1. Removed Substitute Target Dose section. Updated text in Determine Evidence of Immunity section 5.2. Updated decision table 5-3: "Does the patient have evidence of immunity?" Updated Generate Forecast Date and Recommended Vaccine Business rules in Table 5-7. Updated Select Best Patient Series Vocabulary/Definition in Table 6-2. Updated Select Best Patient Series Business Rules in Table 6-8. Updated Organize Immunization History Process Model in Figure 8-2. Updated the CDSI Domain Diagram: Patient Neighborhood in Figure A-1. Updated the CDSI Domain Diagram: Vaccine and Schedule Neighborhood in Figure A-2. Updated the CDSI Domain Diagram: Evaluation and Forecasting Neighborhood in Figure A-3. Updated the Glossary in Table A-1. Added PPSV to the Acronym's and Abbreviations in Appendix B.	
6/20/16	C. Newman, P. Speights, E. Larson	Expanded scope to include coded contraindications and series based on patient risk  Updated description of CDSi resources in Section 1.4  Moved Processing Model description from Chapter 8 to Chapter 4  Updated Patient Series descriptions to include Relevant, Scorable, Prioritized and Best Patient Series  Enhanced Create Patient Series discussion in the Processing Model Inserted a new Create Relevant Patient Series chapter (Chapter 5)  Inserted a new Evaluate for Inadvertent Vaccine section (Section 6.3)  Updated references to Interval to Preferable Interval to distinguish from Allowable Interval  Updated From Most Recent interval type accommodate a list of CVX codes in Section 6.5  Added a new interval type of From Relevant Observation in Section 6.5  Moved Evaluate Gender logic from Chapter 6 to Chapter 5  Inserted a new Determine Contraindications section (Section 7.3)  Updated Select Patient Series Business Rules (Table 8-2)  Inserted a new Pre-Filter Patient Series section (Section 8.2)  Enhanced Patient Series selection in Chapter 8 to include Series Groups  Split the Vaccine and Schedule neighborhood into separate Schedule and Series neighborhoods in Appendix A  Updated Table A-1 Glossary  Created new Appendix to contain the new Retired Items table	3.0
02/22/19	C. Newman, P. Speights, E. Larson	Added support for Historical Recommendation Supporting Data Added support for conditional skip context to control when skipping occurs (e.g., only in evaluation, only in forecast, both evaluation and forecast) Updated the location of the business rules in Chapter 8 Updated the description of the Supporting Data Updated processing model in section 4.6 (Identify and Evaluation Vaccine Group) Added section 7.6 for validating recommendations Updated Decision Table 6-8 Updated CALCDTSKIP-5	4.0

Date	Changed By	Comments	Version #
		Consolidated SELECTSCORE-1 and SELECTSCORE-2 into one rule to eliminate unnecessary referencing. This also resulted in the retirement of a term (Exceeded Maximum age to start).	
06/02/20	P. Speights, E. Larson	<ul> <li>Substantive Improvements         The following rules and decision tales were improved based on implementer feedback and will result in improved consistency/accuracy.         FORECASTDT-1: Added additional date for calculating the earliest date         MULTIANTVG-1: Better logic for selecting logical dates for forecasting         MULTIANTVG-8: Better logic for selecting antigens needed         SELECTBEST-2: Better logic to define how to break a tie         </li> <li>SELECTSCORE-2: The previous version was ambiguous with regards to starting age requirements and was incorrectly excluding series which should not have been excluded.</li> <li>Evaluate Age and Evaluate Preferable Interval Decision Tables were refined to allow grace period to be used following an invalid dose if it has been at least 1 year.</li> </ul> <li>Additional Improvements         The following improvements will improve the overall consistency of the Logic Specification, but should not change any rules, decisions, or processing. The domain model is was redrawn using a new tool which gives it a new look. A new section was added in Appendix A entitled "How to read the Domain Model Diagram". As part of this process improvements were made to the domain model, terminology, and definitions. These improved terms were then used within the logic specification rules and decision tables. </li>	4.1