Clinical Decision Support for Immunization: Test Cases for ACIP Recommendations

National Center for Immunization and Respiratory Diseases (NCIRD)

Immunization Information Systems Support Branch (IISSB)

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1 Overview

1.1 Background and Goals

In 2010, approximately 82% (18.8 million) of U.S. children under the age of six participated[1] in an Immunization Information System (IIS), an increase from 78% (18.0 million) in 2009. Further, a total of 11,536 public and 36,512 private provider sites also participated[2] in an IIS.[3] Given this widespread IIS participation, it is important that each patient's immunization record is consistent and up-to-date within an IIS.

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

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

In an effort to harmonize the outcomes of existing HIS CDS tools, the Immunization Information System Support Branch (IISSB) at the CDC funded the Clinical Decision Support for Immunization (CDSi) Project to develop new clinical decision aids[4] for each vaccine on the children's immunization schedule to:

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

[1] Participation was defined as having at least two recorded vaccinations in an Immunization Information System (IIS).
[2] Participation was defined as having submitted data to the IIS in their state or city in the previous six months (i.e. from July 1 through December 31, 2010), indicating recent submissions.
[3] All data derived from the 2010 Immunization Information Systems Annual Report (IISAR). 54 of 56 Centers for Disease Control and Prevention (CDC) Immunization Program grantees/IIS reported. For further information, see: http://www.cdc.gov/vaccines/programs/iis/annual-report-IISAR/index.html.
[4] Aids refer to manual support mechanisms and in no way imply that an automated system is being developed or provided. These aids can, however, be used to refine existing or develop new automated systems.

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

1.2 Approach

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

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

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

- **Logic Specification Panel (LSP)** – Developed the **Logic Specification for ACIP Recommendations**, which captures ACIP recommendations in an unambiguous manner and improves both the uniform representation of vaccine decision guidelines as well as the ability to automate vaccine evaluation and forecasting

- **Validation and Testing Panel (VTP)** – Created the **Testing Methodology** to extensively test the compliance of CDS logic representation within CDS engines with ACIP recommendations

- **Process, Communication and Sustainability Panel (PCSP)** – Produced a **Sustainability Plan** to ensure the long-term viability of the Clinical Decision Support for Immunization (CDSi) resources

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

1.3 Scope

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

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

Additional items in scope include:

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

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

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

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

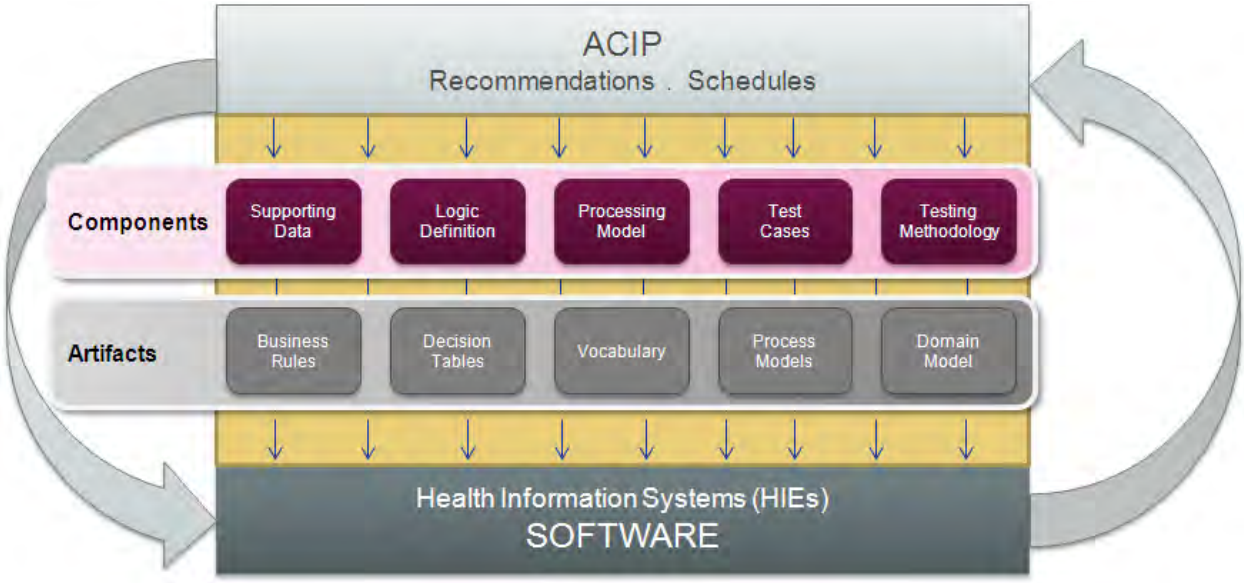
1.4 Products

1.4.1 Logic Specification

The panel developed the Logic Specification which captures ACIP recommendations in an unambiguous manner and improves both the uniform representation of vaccine decision guidelines as well as the ability to automate vaccine evaluation and forecasting. The Logic Specification provides a single, authoritative, implementation-neutral foundation for development and maintenance of clinical decision support engines. It increases the accuracy and consistency of forecasting and evaluation across the HIS community and improves the timeliness of HIS accommodation of new and changed rules.

The objectives of the Logic Specification are to:

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



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

The Logic Specification consists of the following three components:

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

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

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

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

1.4.2 Testing Methodology

The panel developed a Testing Methodology to extensively test the compliance of CDS logic representation within CDS engines with the ACIP recommendations. The panel created test cases and expected results which can be

processed against an immunization evaluation and forecasting engine to validate or test its algorithm against the Logic Specification.

The Testing Methodology consists of the following two components:

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

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

1.4.3 Sustainability Plan

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

The Sustainability Plan consists of the following four components:

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

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

1.4.4 Document Organization

This document is organized using a "spiral down approach." This means the topics earlier in the document will be broader and more applicable to a broader audience, and as the document progresses, the topics will be more detailed for implementers looking to use the test cases in their immunization evaluation and forecasting engine.

More specifically, the document contains the following Chapters:

Chapter 2: Background Information

The background information chapter provides background material and core concepts that lay the foundation for the remainder of the document and the accompanying test cases.

Chapter 3: Test Case Creation Methodology

The test case creation methodology chapter provides information on the systematic approach to creating the representative sample of test cases.

Chapter 4: Test Case Structure

The test case structure chapter provides the details of an individual test case that is used for the entire complement of test cases.

Chapter 5: Test Case Usage

The test case usage chapter provides the file layout for predefined test case extracts, information for those wishing to create their own extract format, and high level information on executing the test cases and validating the results.

2 Background Information

2.1 Background Material

Creating a representative sample of test cases for immunization evaluation and forecasting purposes requires a sound understanding of the ACIP recommendations and the Logic Specification created by the project. The Logic Specification Document can be found on the CDSi homepage (CDC CDSi Homepage). The Logic Specification is designed to provide computational clarity to the ACIP scientific language. It also provides a common vocabulary and domain model used by this project.

ACIP recommendations exist in a few different formats. The expert panel focused on the following artifacts:

Artifact	Location
General Recommendations on Immunizations – (1/28/2011)	http://www.cdc.gov/mmwr/pdf/rr/rr6002.pdf
Recommended Immunization schedule for Persons Aged 0 Through 18 years – United States, 2013 – (01/28/2013)	http://www.cdc.gov/mmwr/pdf/wk/mm62e0128.pdf
Recommended Immunization Schedules for Persons Aged 0 Through 18 Years – United States, 2012 – (02/10/2012)	http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6105a5.htm

Artifact	Location
Recommended Immunization Schedules for Persons Aged 0 Through 18 Years – United States, 2011 – (02/11/2011)	http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6005a6.htm
DTaP	http://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/dtap.html http://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/hib-dtp.html
Hepatitis A	http://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/hepa.html
Hepatitis B	http://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/hepb.html
Haemophilus Influenzae type B (Hib)	http://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/hib.html http://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/hib-dtp.html
Human Papillomavirus (HPV)	http://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/hpv.html
Influenza	http://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/flu.html
Measles, Mumps, Rubella (MMR)	http://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/mmr.html http://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/mmrv.html
Meningococcal	http://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/mening.html
Pneumococcal (PCV)	http://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/pneumo.html
Polio	http://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/polio.html
Rotavirus	http://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/rotavirus.html
Tdap	http://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/tdap-td.html
Varicella	http://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/varicella.html http://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/mmrv.html

2.2 Core Concepts

2.2.1 Evaluation and Forecasting

Evaluation and Forecasting are often lumped together in conversation to describe the entire process of looking at a patient's history and determining what immunizations should be given today or in the future. In defining logic and creating test cases, it is important to separate these two concepts.

2.2.2 Evaluation

For the purpose of the project, evaluation was defined as: the result of applying rules for a given Series Dose. It is the outcome of the evaluation process that determines whether a Vaccine Dose Administered is valid. Evaluation is sometimes referred to as screening or validation.

Proper evaluation of an immunization history is essential to creating an accurate set of forecast dates for the next administration.

2.2.3 Forecasting

For the purpose of the project, forecast was defined as: the result of applying rules for the next Series Dose. The outcome of the forecasting process is dates for the next Target Dose.

2.2.4 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 rules of ACIP. Until a Target Dose is satisfied, the patient is not allowed to move to the next Target Dose in the patient series. In other words, until a patient has a valid dose administered, which in turn satisfies the Target Dose, the patient remains on the unsatisfied Target Dose.

This concept can be seen graphically below in Figure 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 series. The patient must have doses administered on or after these minimum ages to be considered valid. A valid dose administered will satisfy a Target Dose and allow movement to the next Target Dose. A 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 1 by looking at "Target Dose 2" and vaccine doses administered "Dose 2" and "Dose 3." "Dose 2" was administered too early and was deemed "Not Valid". A "Not Valid" vaccine dose administered means the Target Dose was not satisfied and must be repeated. Vaccine Dose Administered "Dose 3" was given at an appropriate age to be a "valid" dose administered and thus satisfy the goals of "Target Dose 2." This allows movement onto "Target Dose 3" which is subsequently satisfied by Vaccine Dose Administered "Dose 4."

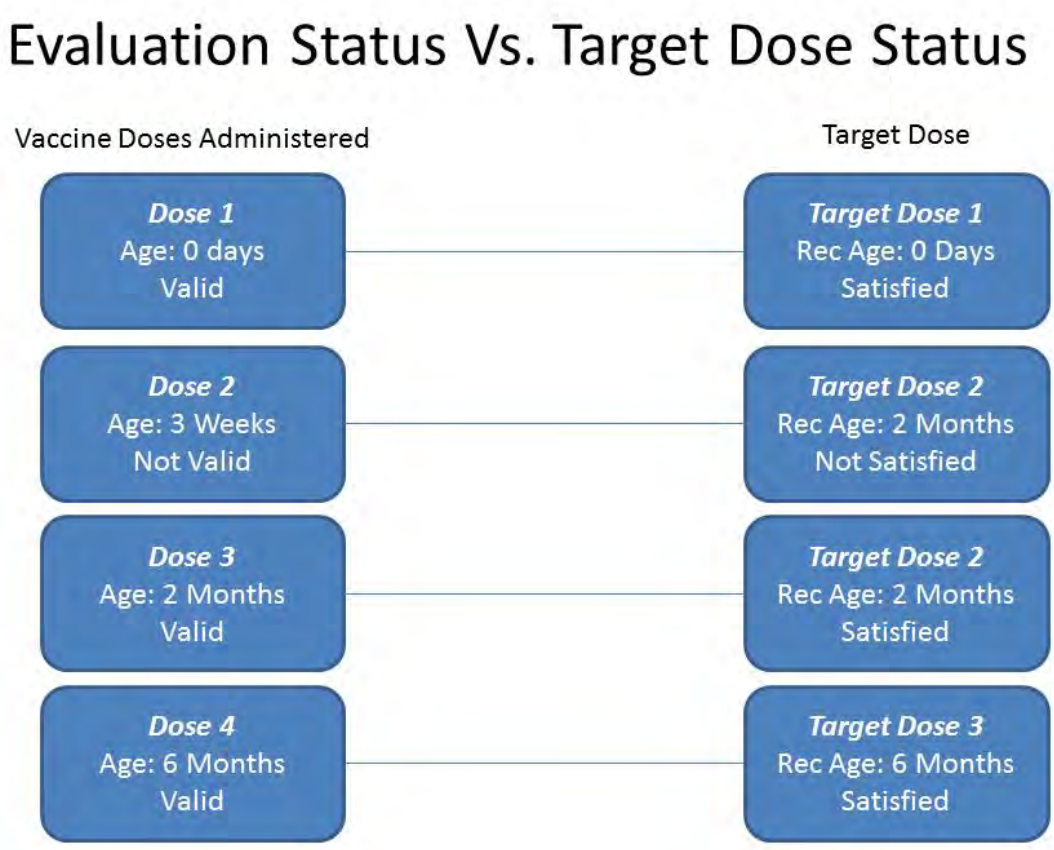


Figure 1: Vaccine Doses Administered Satisfy Target Doses

The Target Dose concept is a critical aspect of both evaluation and forecasting. It helps to understand which dose in a series is attempting to be satisfied, where the patient is in the process towards immunity, and which dose should be forecasted.

3 Test Case Creation and Validation Methodology

The subject matter experts on the panel researched published papers and peer-reviewed presentations to create a consensus-based approach to test case creation. Through this process, the panel created a methodology to systematically create test cases, focusing on the boundaries between valid and not valid vaccine doses administered.

Immunization evaluation and forecasting test cases can be created several different ways to exercise an evaluation and forecasting engine. Two of the most common approaches involve either examining the set of test cases by Vaccine Group (family) or by product. Both approaches have advantages and disadvantages which were explored by the panel.

Aligning test cases based on product provides the following advantages and disadvantages:

1) Advantages
    a. Combination vaccines can quickly cover multiple Vaccine Groups with fewer tests.
    b. Enables easier Product specific path test cases.
2) Disadvantages
    a. ACIP recommendations are, for the most part, Vaccine Group recommendations rather than product-specific recommendations. So, approaching test cases at the product level does not best align with the recommendations of ACIP.
    b. IIS and other health information systems do not always know the specific product and will label the vaccine as unspecified formulation.
    c. While a combination vaccine can quickly cover multiple Vaccine Groups, doing this also adds complexity to a test case because it must contain multiple expected evaluation statuses per vaccine dose administered and multiple forecasts to address each Vaccine Group contained in the combination shot.

Aligning test cases based on Vaccine Groups provides the following advantages and disadvantages:

1) Advantages
    a. ACIP recommendations are, for the most part, Vaccine Group recommendations. This allows test cases to closer mimic the ACIP recommendations by focusing on one specific Vaccine Group per test case.
    b. Vaccine Group test cases allow for a single evaluation per vaccine dose administered and a single forecast per Vaccine Group being tested allowing for a simpler test case structure.
    c. Vaccine Group test cases closely represent the clinical and business perspective by focusing on the goals of immunity against a disease rather than product lines available for administration.
    d. Vaccine Group test cases provide an outlet to capture unspecified formulation vaccine tests.
2) Disadvantages
    a. Test cases involving combination vaccines only test a single component of the combination vaccine associated with the Vaccine Group being tested. This means test cases involving combination vaccines must be replicated to address the other components. This results in test cases which appear as duplicates, but test different Vaccine Groups.

Based on the advantages and disadvantages, the VTP opted to base their tests on Vaccine Groups. It should be acknowledged that either approach could be successful, and possibly a hybrid approach may also be taken to create test cases.

With the foundation laid, the panel focused on how to systematically create the test cases. The panel created a set of conditions which should be considered for each Vaccine Group when applicable. The conditions focused on areas where a vaccine dose administered changed statuses from valid to not valid. For example, vaccine doses administered 5 days prior to the minimum age in the ACIP general recommendations are considered not valid. At 4 days prior to the minimum age, the vaccine dose administered is considered valid. This systematic approach was carried out for other factors used in evaluation and are shown in Table 1.

Table 1: Systematic approach to Test Case Creation

Conditions Considered	Example Scenario
Minimal Age – 5 days	DTaP #1 at age 6 weeks-5 days
Minimal Age – 4 days	DTaP #1 at age 6 weeks-4 days
Minimal Age	DTaP #1 at age 6 weeks
Maximum Age	Rotavirus Max Age: 8 months (Rotateq)
Minimal Interval – 5 days	PCV Dose 1 to dose 2 interval 28-5 days.
Minimal Interval – 4 days	PCV Dose 1 to dose 2 interval 28-4 days
Minimal Interval	PCV Dose 1 to dose 2 interval 28 days
Catch-Up rules	Hib late start
Multiple vaccination events (scenarios of invalid doses between valid doses)	IPV Invalid dose 3 (age) in midst of others. The next dose was at age 4 and ≥ 6 months since previous dose. Series complete.
Product specific	2-dose Recombivax-HB Adult for 11 – 15 years old.
Gender specific	HPV #1 @ 11 yrs - 0 days, male, Cervarix
Skip doses	First Dose of MCV administered after age 16 years.
Off Label Usage	Kinrix at age 4 months as dose 2 of DTaP. Off label but counts as valid.
Live Virus	MMR and Varicella Live Interval
Non-Adjacent Interval	HPV #3 with interval of 24 weeks - 5 days from #1

After creating the conditions found in Table 1, the panel created a representative set of test scenarios for each Vaccine Group based on the conditions in the table. The scenarios are similar to the example scenarios found in Table 1.

A key acknowledgement of the panel is the notion of a representative set of test cases rather than a comprehensive or exhaustive set of test cases. Immunization evaluation and forecasting testing is a challenge which can always be improved. The representative test cases provide a solid beginning and a methodology to expand as the need arises.

Test scenarios based on the Table 1 conditions were created and peer reviewed by members of the panel. Once the test scenarios were completed, detailed test cases were populated based on the test scenario data.

Finally, the test cases went through several different forms of validation to ensure accuracy. The different forms of test case validation included:

- Test case execution and validation against existing IIS evaluation and forecasting engines
- Detailed question and answer correspondence with the project ACIP liaison
- Self-review improvement cycles
- Peer-review improvement cycles
- Validation against the Logic Specification Supporting Data

Through this creation and validation process, the panel created over 850 test cases spanning the 12 Vaccine Groups in scope for the project.

4 Test Case Structure

Each test case can be broken into four major sections:

1) Test Case Information
2) Patient Data
3) Immunization History
4) Forecast

4.1 Test Case Information

The following fields are found in the Test Case Information section. These fields provide high-level information about the test case.

Table 2: Test Case Fields

Field	Description
CDC_Test_ID	Test ID is a simple numerical identifier for the test case.
Test_Case_Name	Test Name is a human-readable test name to briefly describe the test case.
Assessment_Date	Assessment Date is the date which should be used during evaluation and forecasting rather than the current date. This is used to help with test cases which would become invalid over time.
Vaccine_Group	Vaccine Group is the Vaccine Group being tested with the test case.
Series_Status	Series Status is the measure of the patients status in relationship to presumed immunity. Series Status values are: • Not Complete • Complete • Immune • Contraindicated
Evaluation_Test_Type	Evaluation Test Type is used to categorize the test case. This will allow testers to focus in on categories of tests as needed. Evaluation test types are: • Age: Below Absolute Minimum • Age: At Absolute Minimum • Age: At Minimum • Age: At Recommended • Age: Too Old

Field	Description
	• Interval: Below Absolute Minimum • Interval: At Absolute Minimum • Interval: At Minimum • Interval: At Recommended • Gender: Invalid Administration • No Doses Administered • Single Antigen Administration • Vaccine: Invalid Usage • Vaccine: Off Label • All Valid: Forecast Test • Extra Doses
Forecast_Test_Type	Forecast Test Type is used to categorize the test case. This will allow testers to focus on categories of tests as needed. Forecast test types are: • Recommended based on age • Recommended based on interval • Recommended based on minimum interval from invalid dose • Recommended based on minimum interval from previous dose (catch-up) • Recommended based on minimum interval from live virus vaccine • Recommended based on seasonal start date • Not Recommended: series complete • Not Recommended: too old • Not Recommended: contraindication • Not Recommended: immune
Date_Added	This is the date the test case was created. The format is MM/DD/YYYY. (e.g.: 01/01/2000)
Date_Updated	This is the date the test case was changed. The format is MM/DD/YYYY. (e.g.: 01/01/2000)
Reason_For_Change	As test cases are changed, this field is used to document the reason the test case was changed.
Changed_In_Version	This field documents the version number the test case was last changed.

4.2 Patient Data

The following fields are found in the Patient Data section. These fields provide specific non-immunization related data important to the test case.

Table 3: Patient Data Fields

Field	Description
DOB	DOB is the date of birth of the patient. The format of the DOB is MM/DD/YYYY. (E.g.: 01/01/2000)
Gender	Gender is the gender of the patient. Gender is either M or F (Male or Female)
Med_History_Text	Medical History Text is the human readable description of a known relevant medical history associated with this patient which may indicate a contraindication or immunity
Med_History_Code	Medical History Code is the coded value which represents the medical history text.
Med_History_Code_Sys	Medical History Code System is the coding system associated with the coded value. In alignment with the CDC Implementation guide for HL7 messaging the coding systems

Field	Description
	include SNOMED CT (identified as SCT) and PHINVADS (identified as CDCPHINVS).

4.3 Immunization History

For each immunization within a test case, the following fields are found in the Immunization History section. These fields provide the patient's immunizations and expected evaluation status for each immunization. Each field ends in _X in the following table. The _X is a placeholder for _1 through _7 for each vaccine dose administered and the data associated with it. Vaccine Names, CVX codes, and MVX codes are based on the following CDC resource: IIS Vaccine Code Sets.

Table 4: Immunization History Fields

Field	Description
Date_Administered_X	Administration Date is the date vaccine dose was administered. The format is MM/DD/YYYY. (e.g.: 01/01/2000)
Vaccine_Name_X	Vaccine Name is the human readable trade name or the unspecified formulation of the vaccine.
CVX_X	CVX is the coded value to define the type of vaccine. Together with MVX the trade name can be inferred.
MVX_X	MVX is the coded value to define the manufacturer of the vaccine. Together with CVX the trade name can be inferred. If an unspecified formulation is used, no MVX is specified.
Evaluation_Status_X	Evaluation Status is the expected evaluation status (Valid, Not Valid, Extraneous) of the vaccine dose administered based on the ACIP recommendations. In the case of a combination shot, the Expected Evaluation Status is related to the Vaccine Group targeted by the particular test case. The other components of the combination vaccine are tested in their respective Vaccine Group test cases.
Evaluation_Reason_X	Evaluation Reason provides further information as to why the dose administered was not valid. In the case of a combination shot, the reason is related to the Vaccine Group targeted by the particular test case. The other components of the combination vaccine are tested in their specific Vaccine Group test cases.

4.4 Forecast

The Forecast section provides the patient's forecasted dates, if appropriate, for the next Target Dose in the patient series. Since each test case is focused on a single Vaccine Group, there will be one set of forecasted dates for the Vaccine Group.

Table 5: Forecast Fields

Field	Description
Forecast_#	Forecast_# is the target Dose being forecasted. If Target Doses 1 and 2 have been satisfied, the Target Dose Number being forecasted would be Target Dose Number 3. If

Field	Description
	the patient no longer requires a dose (complete, immune, contraindication), the forecast_# is set to "-".
Earliest_Date	Earliest Date is the earliest point in time at which the next vaccine dose could be administered and still be considered valid. This does not include the 4-day grace period. The format of the date is MM/DD/YYYY. (E.g.: 01/01/2000)
Recommended_Date	Recommended Date is the date at which the next vaccine dose administered should be given. The format of the date is MM/DD/YYYY. (E.g.: 01/01/2000)
Past_Due_Date	Past Due Date is the date at which the patient is considered overdue for their immunization. The format of the date is MM/DD/YYYY. (E.g.: 01/01/2000)

5 Test Case Data and Usage

Test cases created by the panel are provided in Excel Spreadsheet format.

The Excel spreadsheet has one test case per row. The first row of the spreadsheet is the column headers describing the columns.

The layout of the spreadsheet is as follows.

Column	Field Name
A	CDC_Test_ID
B	Test_Case_Name
C	DOB
D	Gender
E	Med_History_Text
F	Med_History_Code
G	Med_History_Code_Sys
H	Series_Status
I	Date_Administered_1
J	Vaccine_Name_1
K	CVX_1
L	MVX_1
M	Evaluation_Status
N	Evaluation_Reason
O – AX	Vaccine Doses Administered 2 through 7. This is a repetition of fields I – N.
AY	Forecast_#
AZ	Earliest_Date
BA	Recommended_Date
BB	Past_Due_Date
BC	Vaccine_Group
BD	Assessment_Date
BE	Evaluation_Test_Type
BF	Date_Added
BG	Date_Updated
BH	Forecast_Test_Type
BI	Reason_For_Change
BJ	Changed_In_Version

With the power and flexibility of Excel, additional extracts can be created should the supplied format not align with the CDS engine being tested.

5.1 Test Case Execution

The wide range of technical solutions and varied implementations of evaluation and forecasting engines eliminates the ability to provide detailed step-by-step guidance to execute the test cases. However at the high-level, the following steps can be followed to ensure proper execution and validation of the results.

Step	Notes
Determine the test cases to execute	The test cases developed by the panel provide the ability to be used in several different ways. The entire set of test cases can be selected, a specific Vaccine Group can be selected, a type of evaluation test can be selected, and/or a type of forecast test can be selected. Using Excel, the work to filter the test cases of interest prior to extracting them into a file format can be done quickly and easily.
Prepare the test case data	To prepare the test case data, either use an extract provided or format the data into a layout consumable by the evaluation and forecasting engine.
Execute the test cases	This step could vary greatly between systems. Some systems may be able to directly call their evaluation and forecasting engine, while other systems may require data to be loaded prior to executing the test cases in their evaluation and forecasting engine.
Validate the results	The Test ID column can be used to validate the actual result of a test case against the expected result provided in the test case.

6 Conclusion

The work of the panel provides a representative sample of immunization evaluation and forecasting test cases. In addition to the test cases, the methodology used by the panel can serve as insight and a best practice guide in creating additional test cases in local environments.

Appendix A: Acknowledgements

Subject Matter Experts – Logic Specification Panel

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

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

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

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

- **Shaun Grannis, MD, MS, FAAFP,** Regenstrief Institute / Indiana University
  Dr. Shaun Grannis is a Research Scientist at Regenstrief Institute, Inc. and Assistant Professor of Family Medicine at the Indiana University School of Medicine. He received an Aerospace Engineering degree from the Massachusetts Institute of Technology, and underwent post-doctoral training in Medical Informatics and Clinical Research at Regenstrief Institute. He joined Indiana University in 2001 and collaborates closely with national and international public health stakeholders to advance the technical infrastructure and data-sharing capabilities. He is a member of World Health Organization (WHO) Collaborating Center for the Design, Application, and Research of Medical Information Systems, where he provides consultancy on issues related to health information system identity management and implementing automated patient record matching strategies.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Subject Matter Experts – Process, Communication and Sustainability

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

- **Amy Groom, MPH,** Indian Health Service (IHS)

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

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

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

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

Subject Matter Experts – Validation / Testing

- **Greg Anderson,** Connexin Software

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

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

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

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

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

- **Narasimha Velagaleti,** EPIC Systems Corporation

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

External Reviewers

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

- **Blackford Middleton, MD,** Partners Healthcare

- **John Canning,** Physicians Computer Company (PCC)

- **Mark Dente, MD**, General Electric (GE) Healthcare
  Dr. Dente's informatics career spans over 19 years, focusing on new approaches to increase patient safety and creating new methods to implement evidence-based medicine.

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

- **Ruth Gubernick, MPH**, HLN Consulting, LLC
  Ruth Gubernick is an independent consultant. For over 15 years, she has been part of a consulting team with HLN, LLC which has performed needs assessments regarding immunization registries in WA, UT, KY, NH and VT. She has been involved as a subject matter expert (SME) in registry planning in MN and LA and registry evaluation and enhanced development in CA, RI, OH, New York City and Philadelphia.

  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. Ruth has worked with the NJ Academy of Family Physicians (NJAFP) and Horizon Healthcare Innovations, a subsidiary of NJ Horizon BC/BS, as a practice facilitator and coach to assist family physicians in practice transformation and achievement of NCQA recognition as Patient Centered Medical Homes (PCMH).

Ruth consulted on the development of All Kids Count (AKC)'s "Increasing Private Provider Participation in Immunization Registries: A Toolkit and Guide" and also with the Public Health Informatics Institute (PHII) on the "Integration of Newborn Screening and Genetic Service Systems with Other Maternal & Child Health Systems: A Sourcebook for Planning and Development." She has been a participant, as a SME, on the American Immunization Registry Association (AIRA)'s Modeling Immunization Registry Operations Workgroup (MIROW).

Prior to becoming a full-time consultant, Ruth worked for the Camden County Dept. of Health and Human Services for 14 years. She is a NJ licensed Health Officer and Registered Environmental Health Specialist. She is currently a doctoral student at the Thomas Jefferson University School of Population Health.

- **Alean Kirnak**, Software Partners (SWP), LLC

- **Susan Lett, MD, MPH**, *Massachusetts* Immunization Information Systems (MIIS)

- **Shadkashara "Shad" Rajashekarappa,** General Electric (GE) Healthcare

- **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 immunogenicity of influenza, polio, measles and pneumococcal vaccines; studies on the impact of spatial clustering of vaccine refusers; and clinical trials to evaluate drug regimens to reduce mother-to-child transmission of HIV in Africa. Dr. Omer is the principal investigator for the Georgia site of the Vaccine Safety Datalink -based at Kaiser Permanente, Georgia. He is also the principal investigator of a cohort study in Georgia (United States) for evaluating the impact of influenza vaccine receipt in pregnancy and fetal/birth outcomes. He was awarded the Maurice Hilleman Early-stage Investigator award in vaccinology by the National Foundation of Infectious Diseases.

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

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

- **Gary Wheeler**, Hewlett Packard (HP)

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- **Andrew Kroger,** Centers for Disease Control and Prevention (CDC)

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- **Eric Larson,** Northrop Grumman
- **David Lyalin,** Centers for Disease Control and Prevention (CDC), Subject Matter Expert
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- **Darrin O'Dell,** Northrop Grumman
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Appendix B: Document Management

Date	Changed By	Comments	Version #
01/30/2013	E. Larson	Initial Publication	1.0
07/17/2013	E. Larson	• Updated References for 2013 Harmonized Schedule and remapped existing links to ACIP's new URLs (Section 2.1) • Added two new fields to track changes to test cases. (Sections 4.1 and 5)	1.1