

Conquering the Challenges of CDSi

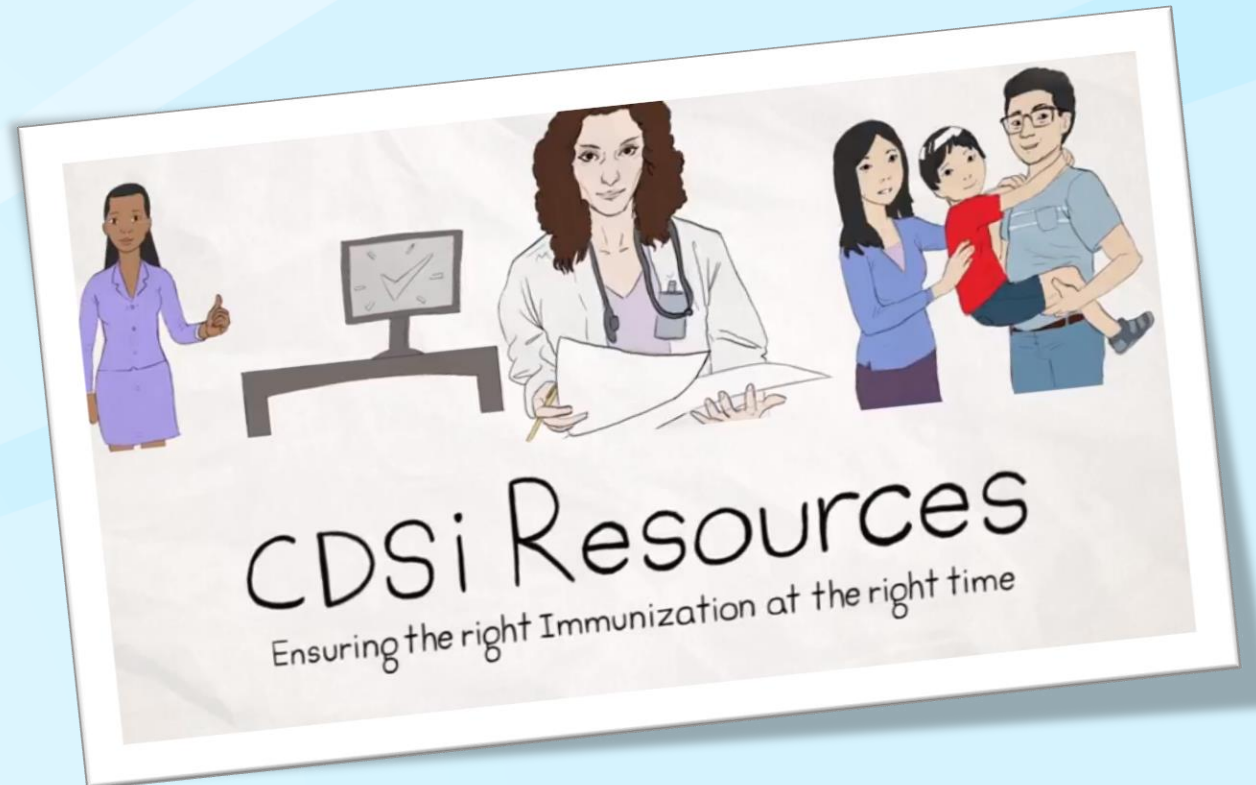
Eric Larson

Northrop Grumman contractor to CDC



Takeaways from Today

- ❑ Overview of CDSi
- ❑ ACIP Changes in CDSi
- ❑ Test Case Management
- ❑ Future Directions
- ❑ Getting Involved

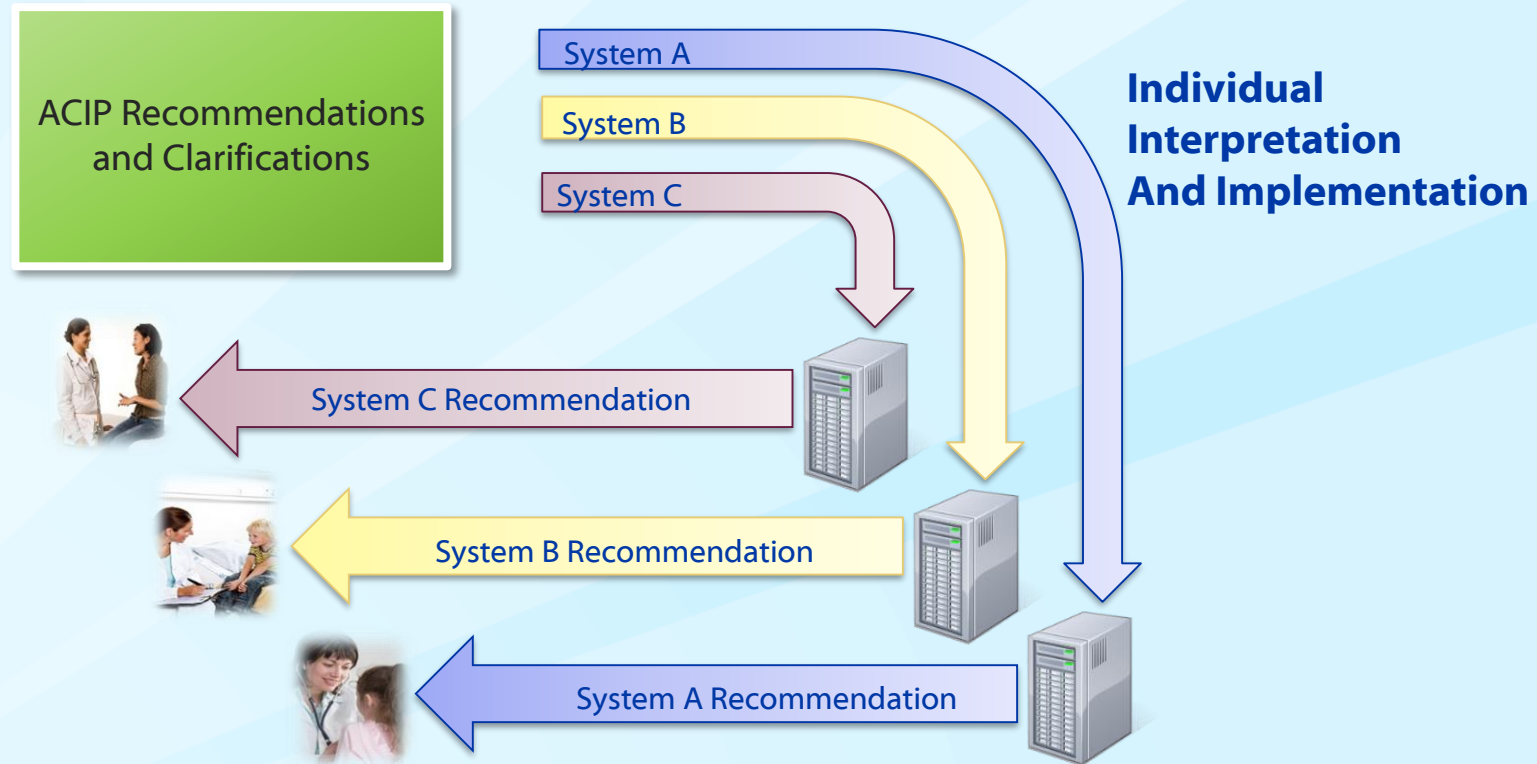


OVERVIEW OF CDSI

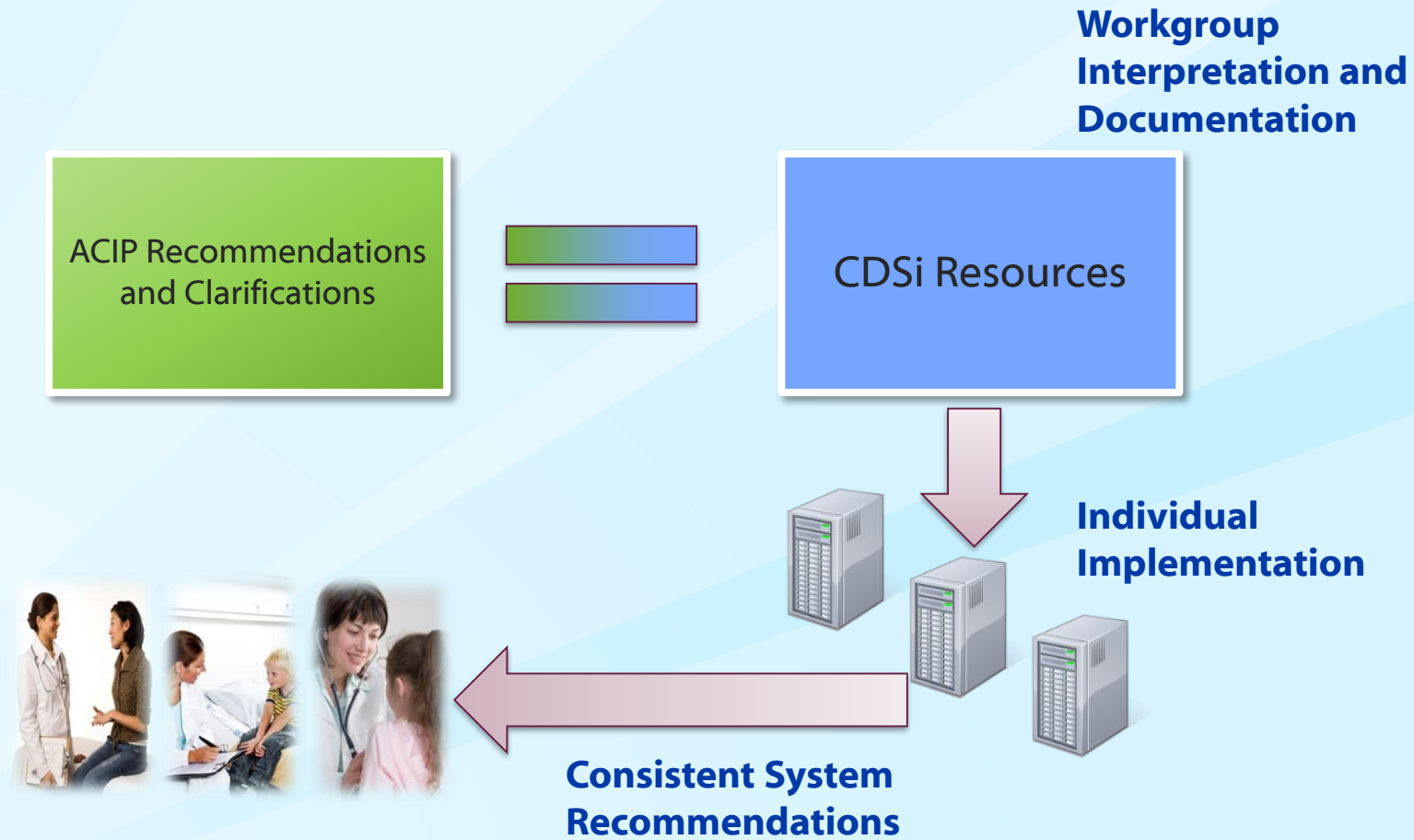
CDSi

- ❑ CDSi = Clinical Decision Support for Immunization
- ❑ CDC created and managed set of resources
- ❑ Designed to map ACIP recommendations into IT-friendly resources
- ❑ Goal = Consistent implementations aligned with ACIP recommendations

Before CDSi

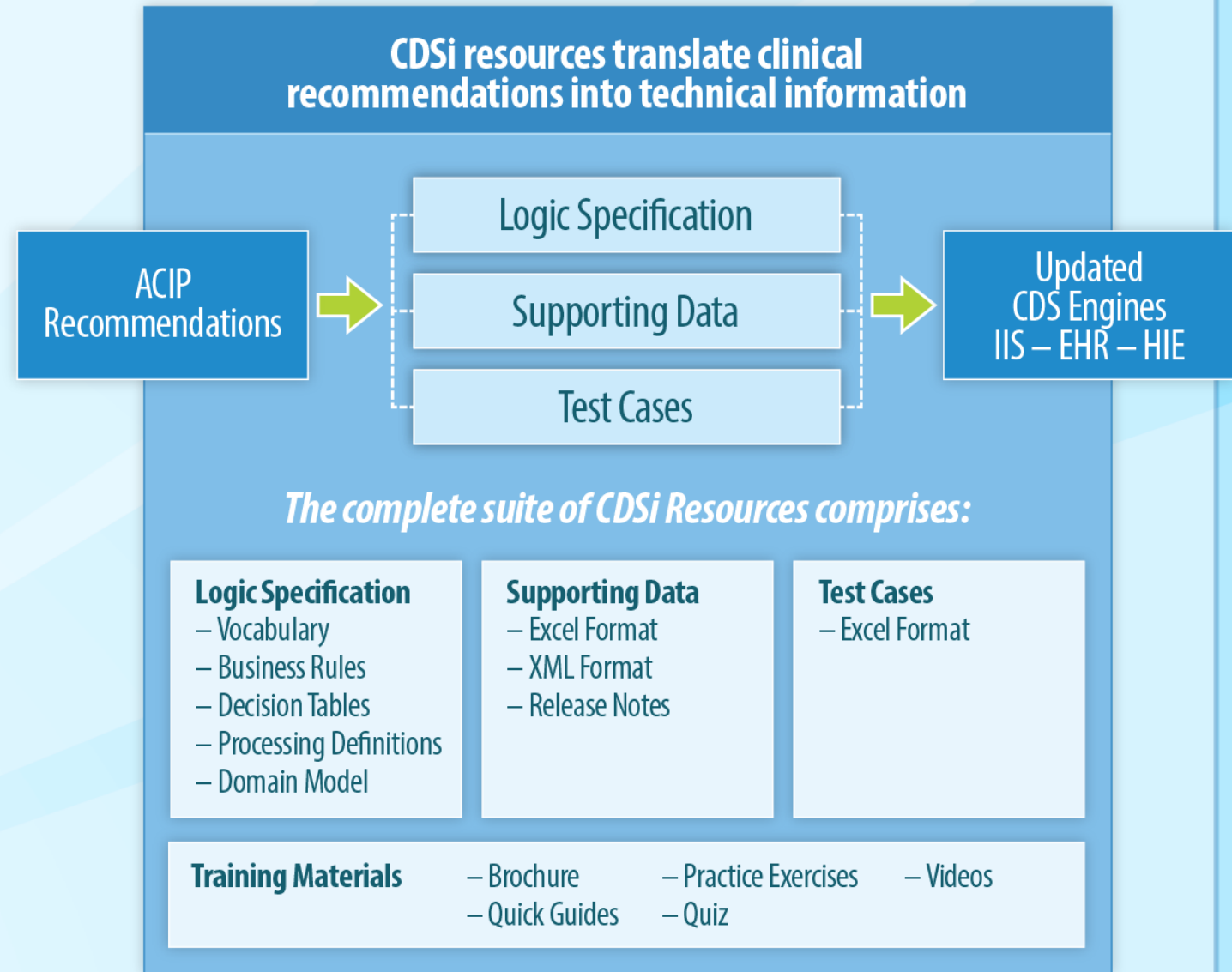


With CDSi



CDSi Resources

- The CDSi project focuses on documenting ACIP recommendations and test cases.
- The CDC does not have or maintain a CDS engine.



ACIP CHANGES IN CDSI

ACIP Changes since last AIRA National Meeting (April 2017)

2017

- **Meningococcal Vaccine**
Patton ME, Stephens D, Moore K, MacNeil JR. [Updated Recommendations for Use of MenB-FHbp Serogroup](#)
[Committee on Immunization Practices, 2016](#)
Source: *MMWR*. 2017;66(19):509-13.
- **Oral Cholera vaccine**
Wong KK, Burdette E, Mahon BE, Mintz ED, Ryan ET, Reingold AL. [Recommendations of the Advisory Com](#)
[Cholera Vaccine](#)
Source: *MMWR*. 2017;66(18):482-5.

General Best Practice Guidelines for Immunization Course



At a Glance

General Best Practice Guidelines for Immunization was published on April 20, 2017. Continuing education is available until April 20, 2019.

2018

- **Quadrivalent Live Attenuated Influenza vaccines (2018-19 season)**
Grohskopf LA, Sokolow LZ, Fry AM, Walter EB, Jernigan DB. [Update: ACIP Recommendations for the Use of Quadrivalent Live Attenuated Influenza Vaccine \(LAIV4\) — United States, 2018–19 Influenza Season](#)
Source: *MMWR*. 2018;67(22):643-5.
- **DTaP/Tdap/Td vaccine**
Liang JL, Tiwari T, Moro P, Messonnier NE, Reingold A, Sawyer M, et al. [Prevention of Pertussis, Tetanus, and Diphtheria with](#)
[Tdap Vaccines: Recommendations of the Advisory Committee on Immunization Practices \(ACIP\)](#)
Source: *MMWR*. 2018;67(RR-2):1-44.
- **HepB Vaccine**
Schillie S, Harris A, Link-Gelles R, Romero J, Ward J, Nelson N. [Recommendations of the Advisory Committee on Immunization](#)
[Hepatitis B Vaccine with a Novel Adjuvant](#)
Source: *MMWR*. 2018;67(15):455-8.
- **Adult immunization schedule**
Kim DK, Riley LE, Hunter P. [Advisory Committee on Immunization Practices Recommended Immunization Schedule for Adults](#)
[— United States, 2018](#)
Source: *MMWR*. 2018;67(5):158-60.
- **Child/adolescent immunization schedule**
Robinson CL, Romero JR, Kempe A, Pellegrini C, Szilagyi P. [Advisory Committee on Immunization Practices Recommended](#)
[Children and Adolescents Aged 18 Years or Younger — United States, 2018](#)
Source: *MMWR*. 2018;67(5):156-7.
- **Herpes Zoster vaccine (Shingles)**
Dooling KL, Guo A, Patel M, Lee GM, Moore K, Belongia EA, et al. [Recommendations of the Advisory Committee on Immunization](#)
[Herpes Zoster Vaccines](#)
Source: *MMWR*. 2018;67(3):103-8.
- **Measles, Mumps and Rubella**
Marin M, Marlow M, Moore KL, Patel M. [Recommendation of the Advisory Committee on Immunization Practices for Use of](#)
[Virus-Containing Vaccine in Persons at Increased Risk for Mumps During an Outbreak](#)
Source: *MMWR*. 2018;67(1):33-8.
- **Hepatitis B**
Schillie S, Vellozzi C, Reingold A, Harris A, Haber P, Ward JW, et al. [Prevention of Hepatitis B Virus Infection in the United States](#)
[the Advisory Committee on Immunization Practices](#)
Source: *MMWR*. 2018;67(1):1-33.

2011 General Recommendation

TABLE 1. Recommended and minimum ages and intervals between vaccine doses**†

Vaccine and dose number	Recommended age for this dose	Minimum age for this dose	Recommended interval to next dose	Minimum interval to next dose
HepB-1 [§]	Birth	Birth	1–4 months	4 weeks
HepB-2	1–2 months	4 weeks	2–17 months	8 weeks
HepB-3 [§]	6–18 months	24 weeks	—	—
DTaP-1 [§]	2 months	6 weeks	2 months	4 weeks
DTaP-2	4 months	10 weeks	2 months	4 weeks
DTaP-3	6 months	14 weeks	6–12 months	6 months**††
DTaP-4	15–18 months	12 months	3 years	6 months**

** Calendar months.

†† The minimum recommended interval between DTaP-3 and DTaP-4 is 6 months. However, DTaP-4 need not be repeated if administered at least 4 months after DTaP-3

2017 General Best Practices

TABLE 3-1. Recommended and minimum ages and intervals between vaccine doses^{(a),(b),(c),(d)}

Vaccine and dose number	Recommended age for this dose	Minimum age for this dose	Recommended interval to next dose	Minimum interval to next dose
DTaP-1 ^(e)	2 months	6 weeks	8 weeks	4 weeks
DTaP-2	4 months	10 weeks	8 weeks	4 weeks
DTaP-3	6 months	14 weeks	6–12 months ^(f)	6 months ^(f)
DTaP-4	15–18 months	15 months ^(f)	3 years	6 months

^(f) The minimum recommended interval between DTaP-3 and DTaP-4 is 6 months. However, DTaP-4 need not be repeated if administered at least 4 months after DTaP-3. This is a special grace period of 2 months which can be used if evaluating records retrospectively. An additional 4 days should not be added to this grace period prospectively, but can be added retrospectively.

Supporting Data Version 3.3

Series Dose	Dose 4							
Age	Absolute Minimum Age	Minimum Age	Earliest Recommended Age	Latest Recommended Age (less than)	Maximum Age (less than)			
	12 months - 4 days	12 months	15 months	19 months + 4 weeks	n/a			
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)
	Y	n/a	n/a	n/a	6 months - 4 days	6 months	6 months	13 months + 4 weeks
Allowable Interval	From Immediate Previous Dose Administered? Y/N	From Target Dose # in Series	Absolute Minimum Interval					
	Y	n/a	4 months					

Supporting Data Version 3.4

Series Dose	Dose 4							
Age	Absolute Minimum Age	Minimum Age	Earliest Recommended Age	Latest Recommended Age (less than)	Maximum Age (less than)			
	12 months - 4 days	15 months	15 months	19 months + 4 weeks	n/a			
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)
	Y	n/a	n/a	n/a	6 months - 4 days	6 months	6 months	13 months + 4 weeks
Allowable Interval	From Immediate Previous Dose Administered? Y/N	From Target Dose # in Series	Absolute Minimum Interval					
	Y	n/a	4 months - 4 days					

Release Notes and Change History Tracking

Supporting Data Release Notes – 3.4

June 19, 2017

Overview

Schedule Specific Supporting Data Changes

Table 1: Schedule Specific Supporting Data Changes

Supporting Data	Change
Live Virus Conflict	<ul style="list-style-type: none">Reference to Cholera vaccine removed

Antigen Series Supporting Data Changes

Table 2: Antigen Series Specific Supporting Data Changes

Supporting Data	Change
Diphtheria	<ul style="list-style-type: none">Moved Minimum Age on Dose 4 from 12 months to 15 monthsAdded Grace Period on Dose 4 allowable interval
Hep A	<ul style="list-style-type: none">Added Maximum Age for Dose 1 of 2-dose standard series

Version	3.4				
Change	Change #	Area	Previous	Change	Reason for Change
	1	Dose 4 Minimum Age	12 Months	15 Months	Moved from 12 months to 15 months per 2017 harmonized schedule and 2017 General Best Practice Guidelines.
	2	Dose 4 Allowable Interval	4 Months	4 Months - 4 days	Clarification from CEB - and subsequent update to 2017 General Best Practice Guidelines - now allows for the grace period to be used here.

TEST CASE MANAGEMENT

The Need for a New Test Case Management System

- ❑ **CDSi Test Cases were managed using spreadsheets since version 1.0**
- ❑ **Challenges**
 - Easy to make mistakes
 - Difficult to maintain
 - Required a Maintenance Spreadsheet (where CDSi team worked) and a publication spreadsheet with a cumbersome process
 - Test Cases were becoming dated

The New Test Case Management System

- ❑ **CDC Worked with the National Institute of Standards and Technology (NIST)**
- ❑ **Goals of the new system were**
 - Ability to create and change test cases within a single user interface
 - Ability to extract test cases into CDSi format
 - Ability to create “Relative” test cases
 - Ability to execute test cases against IIS (or CDS Engines)
 - Open for all to use – not just CDSi project team

Forecasting for Immunization Test Suite (FITS)

<https://fits.nist.gov/>

- Free to Use
- No Install Needed
- Requires User Account
- Create and Manage your own test cases
- CDSi Test Cases Always Available

The screenshot shows the NIST FITS 1.0-beta website. The header is dark blue with the title 'NIST - Forecasting for Immunization Test Suite (FITS)' in white and yellow, followed by '1.0-beta' in red. Below the header is a yellow navigation bar with links: Home, Test Plans, Validation, Documentation, About, and Issues. The main content area has a white background with a red heading 'Welcome to the NIST Forecasting for Immunization Test Suite (FITS)'. Below this is a light blue box with an information icon and the text 'Beta Note'. The note states that FITS is a beta pre-release for feedback, that it is very close to production but cannot guarantee no data loss during redeployment, and that exporting test cases to XML is the best way to ensure data safety. Below the note are two columns. The left column, titled 'FITS Overview', describes FITS as a web-based application for testing immunization CDS engines against ACIP recommendations, creating and managing test cases, running and validating test cases, creating reports in standardized formats, and providing standardized (FHIR) and non-standardized (proprietary) interfaces to CDS engines. It also states that FITS can be used to validate immunization CDS engines independently of the system in which the CDS resides or is associated (e.g., an FHR or IIS) and that FITS will contain a set of test cases authored and maintained by NIST. The right column, titled 'Have a Question?', states that a Google Group FITS has been established for discussion/feedback and that a Google account is required for posting. It provides the site URL 'https://groups.google.com/forum/#!forum/fits-immunization-testing' and the email address 'fits-immunization-testing@googlegroups.com'.

NIST - Forecasting for Immunization Test Suite (FITS) 1.0-beta

Home Test Plans Validation Documentation About Issues

Welcome to the NIST Forecasting for Immunization Test Suite (FITS)

Beta Note

FITS is currently provided as a beta pre-release in order to gather feedback from the larger community. While very close in look, feel, and function to the production release, but we cannot guarantee no data may be lost if the database is reloaded during redeployment. Exporting test cases to the file system in XML is the best way to ensure the :

FITS Overview

FITS (Forecasting for Immunization Test Suite) is a web-based application for testing immunization CDS engines against ACIP recommendations. FITS creates and manages test cases, runs and validates the test cases, creates reports in standardized formats, and provides standardized (FHIR) and non-standardized (proprietary) interfaces to the CDS engines.

FITS can be used to validate immunization CDS engines independently of the system in which the CDS resides or is associated (e.g., an FHR or IIS). FITS will contain a set of test cases authored and maintained by NIST.

Have a Question?

A Google Group **FITS** has been established for discussion/feedback. A Google account is required for posting.

- Site: <https://groups.google.com/forum/#!forum/fits-immunization-testing>
- Email: fits-immunization-testing@googlegroups.com

FUTURE DIRECTIONS

Last 3.x Release

- ❑ **Once Flu Recommendations come out (any day now)**
 - Version 3.8 of Supporting Data will be released
 - Version 3.5 of Test Cases will be released

- ❑ **This will be the last version 3.x before moving to version 4.0**

CDSi 4.0

❑ **Historical Recommendations**

- This will incorporate important ACIP recommendations from the past which may impact evaluation of older records administered under previous ACIP recommendations (e.g., Polio, HPV, MenB)

❑ **Conditional Skip Context**

- Not all skipping of doses should be done in both Evaluation AND forecasting.
- This will allow for more controlled skipping so that skipping of doses can be controlled depending upon the context (i.e., only in evaluation, only in forecasting)
- Helpful for situations like the 6 doses before 7 years in DTaP

❑ **Blending Series**

- Version 3.0 created “Series Groups” for different types of recommendations (e.g., Standard, Risk)
- This can result in more than one “Best Series”
- Blending will provide one picture of the entire Evaluated History and Forecast

CDSi 4.0 Cont'd

❑ **Timeline**

- This work is slated to complete by the end of the year

❑ **Changes to Resources**

- New Logic Specification
- New Supporting Data with updated Structure
- Test Cases will be updated as necessary, but trying not to change structure of Test Case Spreadsheet

GETTING INVOLVED

Using and Improving CDSi

❑ Join the CDSi Informational Workgroup

- 100% remote participation
- Anyone and Everyone is welcome
- Minimally meets 3-times per year following each ACIP meeting
- May meet more as needed/desired
- Focus: Recent ACIP votes, recent CDSi changes, Future CDSi changes

❑ Use CDSi Resources

- Training Material (designed to be short)
- Test Cases
- Supporting Data
- Logic Spec

❑ Improve CDSi

- Communicate with CDSi project team on questions, improvements, etc.

Questions

Stuart Myerburg

jyz0@cdc.gov

CDC Project Lead

Eric Larson

vev5@cdc.gov

Informatics Specialist

Craig Newman

yuo9@cdc.gov

Informatics Specialist

Patricia Speights

ysq2@cdc.gov

Informatics Specialist

<https://www.cdc.gov/vaccines/programs/iis/cdsi.html>

Or Google “CDC CDSi”

For more information please contact Centers for Disease Control and Prevention

1600 Clifton Road NE, Atlanta, GA 30333

Telephone, 1-800-CDC-INFO (232-4636)/TTY: 1-888-232-6348

E-mail: cdcinfo@cdc.gov Web: www.cdc.gov

National Center for Immunization & Respiratory Diseases (NCIRD)

Immunization Information System Support Branch (IISSB)

