AIRA Education Steering Committee

Clinical Decision Support for Immunization (CDSi) 101

Stuart Myerburg

Eric Larson

National Center for Immunization & Respiratory Diseases

Immunization Information Systems Support Branch

Learning Objectives

- What CDSi is and what CDSi isn't
- CDSi Artifacts
- Getting Started with CDSi
- CDSi Compliance

What CDSi is and What CDSi isn't

CDSi isn't:

- **Creating vaccine recommendations or replacing ACIP's role**
- **Producing an application:**
  - No CDS software
  - No automated test suite
- **Replacement for current software applications**

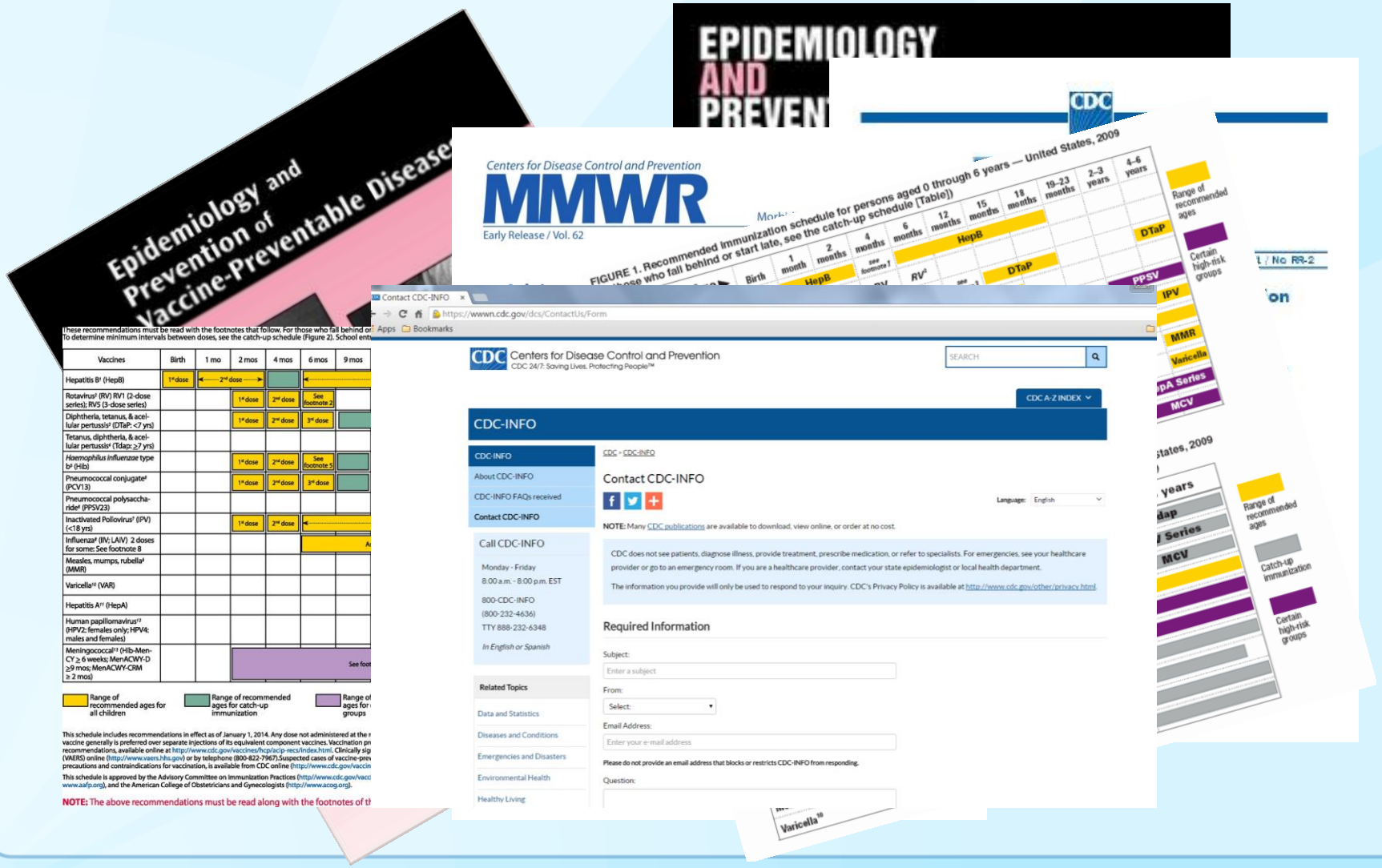
CDSi is:

- **A bridge between ACIP recommendations and IIS/EHRs:**
  - Documentation of logic and supporting data
  - Formalized communication mechanism and process
- **Providing guidance for groups who want to implement the panel's deliverables**
- **Establishing a communication mechanism between immunization community and ACIP**

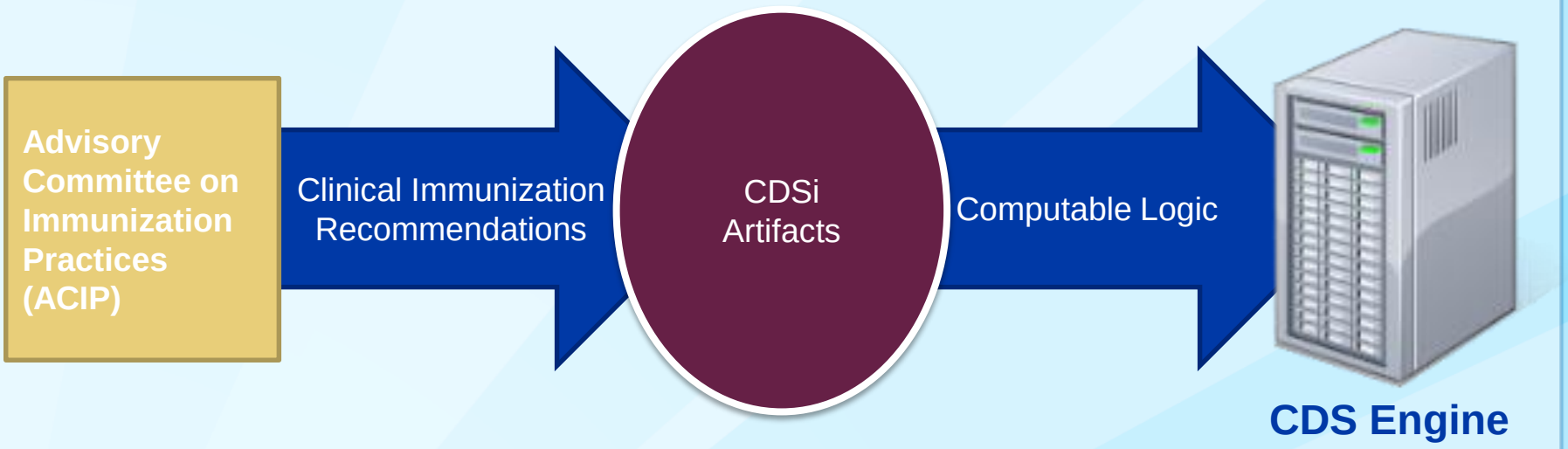
Translating ACIP Recommendations

- Translation of scientific language to technical logic is complex and time-consuming
- Uniform interpretation is challenging:
  - Mostly happened independently within each health information system
  - Significant variance in system outputs
  - Outputs frequently didn't match expectations of clinical SMEs

Sources of Knowledge



Bridging the Gap



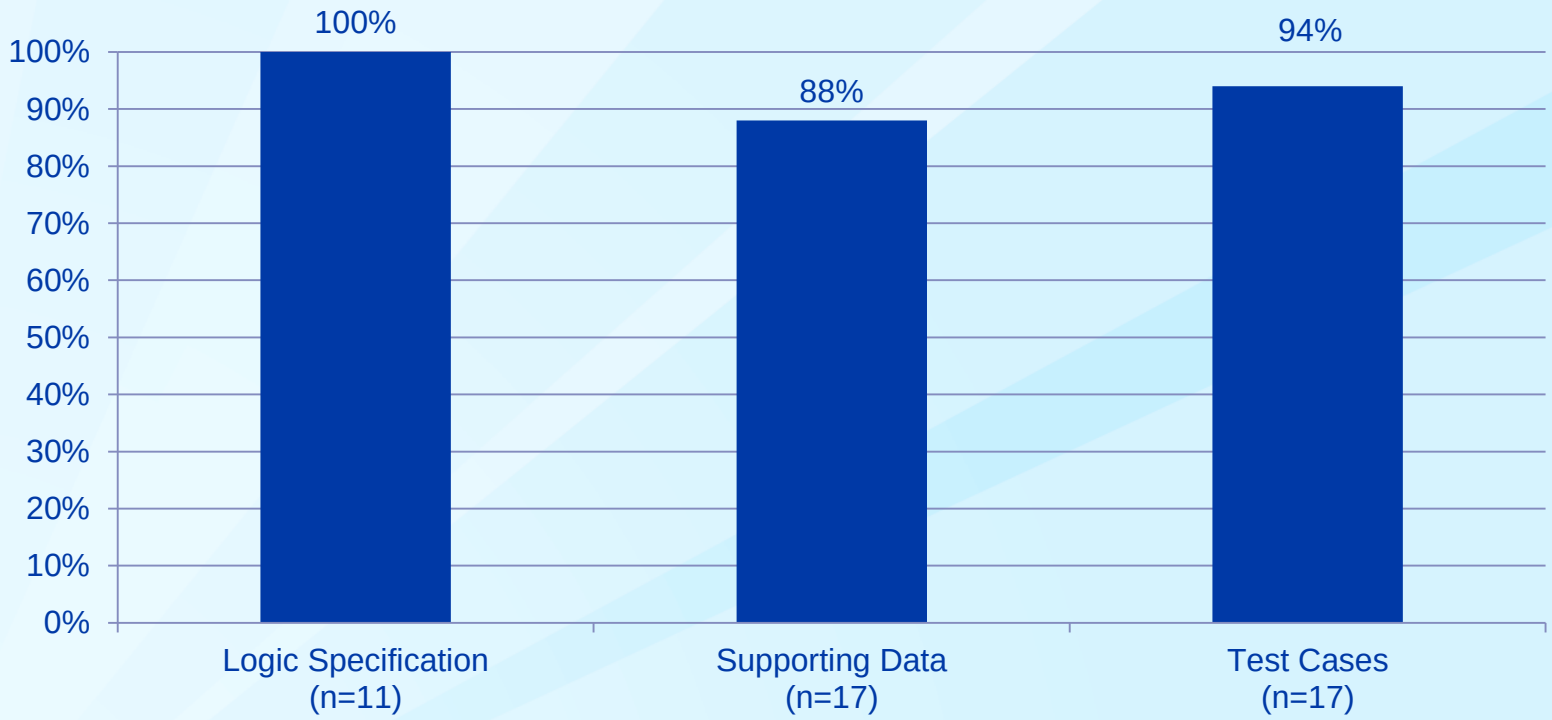
- Increase the accuracy and consistency of immunization evaluation and forecasting
- Improve the process of accommodating new and/or changed ACIP recommendations
- Make it easier to develop and maintain immunization evaluation and forecasting products
- Ensure patients get “the right immunization at the right time”

Project Phases

	Phase 1	Phase 2	Phase 3
Foundation	Current ACIP Recommendations		
Scope	Healthy children, birth through 18 years	Healthy people, birth to death	Birth to death, with: • Precautions • Special indications • High, increased, or special risks • Travel
Resources Created	• Logic Specification • Supporting Data • Test Cases	• Logic Specification • Supporting Data • Test Cases	• Logic Specification • Supporting Data • Test Cases • Code Set for Precautions, Special Indications, etc.
Publication Date	November 2013	June 2015	Estimated: first half of 2016

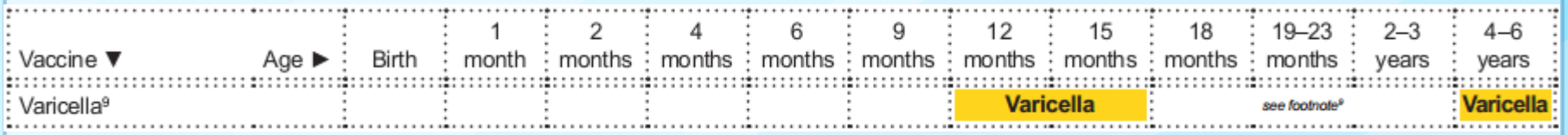
Business Rules in CDSi

Of those who have used the CDSi resources, do you plan to use them in the future?



ACIP Age Recommendations on Varicella

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**
Varicella-1†††	12—15 months	12 months
Varicella-2†††	4—6 years	15 months



Vaccine ▼ Age ►	Birth	1 month	2 months	4 months	6 months	9 months	12 months	15 months	18 months	19–23 months	2–3 years	4–6 years
Varicella[9]							Varicella		see footnote[9]			Varicella

9. Varicella (VAR) vaccine. (Minimum age: 12 months)

- The second dose may be administered before age 4 years, provided at least 3 months have elapsed since the first dose.
- For children aged 12 months through 12 years, the recommended minimum interval between doses is 3 months. However, if the second dose was administered at least 4 weeks after the first dose, it can be accepted as valid.

Doses administered too close together or at too young an age can lead to a suboptimal immune response. However, administering a dose a few days earlier the minimum interval or age is unlikely to have a substantially negative effect on the immune response to that dose. Vaccine doses administered ≤4 days before the minimum interval or age are considered valid.

http://www.cdc.gov/mmwr/pdf/rr/rr6002.pdf

http://www.cdc.gov/vaccines/schedules/downloads/child/0-18yrs-11x17-fold-pr.pdf

Structured Age Representation of Varicella

Dose #	Absolute Min Age	Min Age	Earliest Recommended Age	Latest Recommended Age (less than)	Max Age (less than)
1	12m – 4d	12m	12m	16m + 4w	n/a
2	12m + 4w	15m	4y	7y + 4w	n/a

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1	12m – 4d	12m	12m	16m + 4w	n/a
2	12m + 4w	15m	4y	7y + 4w	n/a

More Structured Age Representations

Series	Dose #	Absolute Minimum Age	Minimum Age	Earliest Recommended Age	Latest Recommended Age (less than)	Maximum Age (less than)
HepA	1	12m – 4d	12m	12m	24m +4w	n/a
Rotavirus	2	10w – 4d	10w	4m	5m + 4w	8m + 1d
MCV	1	2y – 4d	2y	11y	13y + 4w	n/a

http://www.cdc.gov/mmwr/pdf/rr/rr6002.pdf
http://www.cdc.gov/vaccines/schedules/downloads/child/0-18yrs-11x17-fold-pr.pdf

Supporting Data

Series Dose	Dose 2					
Age	Absolute Minimum Age	Minimum Age	Earliest Recommended Age	Latest Recommended Age (less than)	Maximum Age (less than)	
	12 Months + 4 weeks	15 Months	4 years	7 years + 4 weeks	n/a	
Interval	From Immediate Previous Dose Administered? Y/N	From Target Dose # in Series	Absolute Minimum Interval	Minimum Interval	Earliest Recommended Interval	Latest Recommended Interval (less than)
	Y	n/a	12 weeks - 4 days	12 weeks	3 years	6 years + 4 weeks
Allowable Interval	From Immediate Previous Dose Administered? Y/N	From Target Dose # in Series	Absolute Minimum Interval			
	Y	n/a	4 weeks			
Preferable Vaccine	Vaccine Type (CVX)	Vaccine Type Begin Age	Vaccine Type End Age (less than)	Trade Name (MVX)	Volume (in ml)	
	Varicella (21)	12 Months	n/a	n/a	0.5	
	MMRV (94)	12 Months	13 Years	n/a	0.5	
Allowable Vaccine	Vaccine Type (CVX)	Vaccine Type Begin Age	Vaccine Type End Age (less than)			
	Varicella (21)	12 Months - 4 days	n/a			
	MMRV (94)	12 Months - 4 days	n/a			
	Zoster (121)	12 Months - 4 days	n/a			
Skip Dose	Trigger Age	Trigger Interval	Trigger Target Dose	Trigger Doses Administered		
	n/a	n/a	n/a	n/a		
Recurring Dose	Recurring Dose (Yes/No)					
	No					
Conditional Need	Condition Set	Start Date	End Date	Dose Count (less than)	CVX List	
	n/a					
Seasonal Recommendation	Start Date	End Date				
	n/a					
Substitute Dose	total count of valid doses	First Dose Begin Age	First Dose End Age (less than)	number of target doses to substitute		
	n/a					
Gender	Required Gender					
	n/a					

Logic Specification Documentation Techniques

Domain Model, Vocabulary, and Glossary

- Used to drive consistency, understanding of terms, and relationship between terms

Decision Tables

- Used to convey conditional logic and outcomes

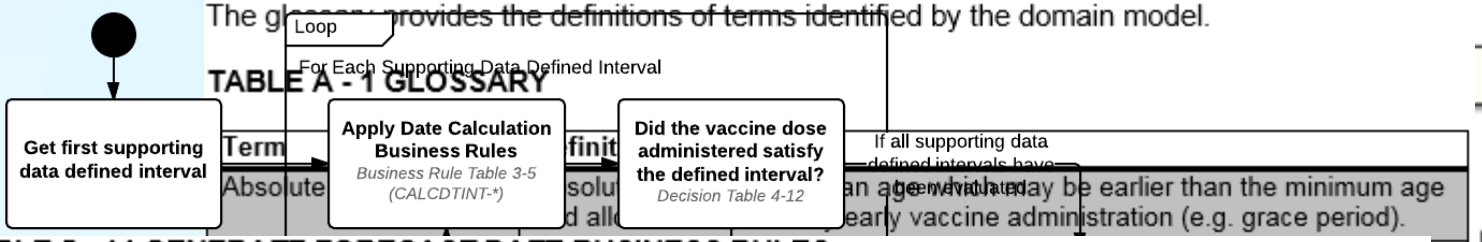
Business Rules

- Used to express date calculations and declarative rules.

Process Models

- Used to chain decisions and/or business rules together.

Logic Specification Samples



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

TABLE A - 1 GLOSSARY

Term	Definition
Absolute	an age which may be earlier than the minimum age and allowable early vaccine administration (e.g. grace period).

TABLE 5 - 14 GENERATE FORECAST DATE BUSINESS RULES

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

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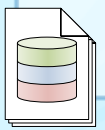
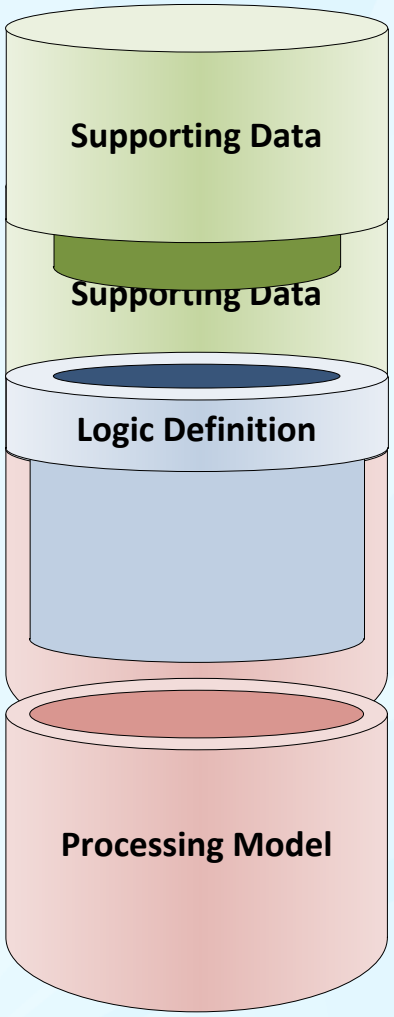
ADMINISTERED?

	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.



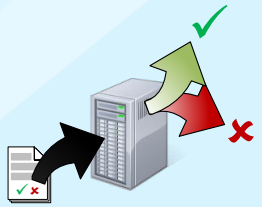
Logic Specification Components



- **Abstracted attributes and values**
  - Standard data table definitions
  - Antigen specific values
  - Static definitions
  - Dynamic values
- **Functionality for evaluation/forecasting**
  - Thin process models
  - Decision tables
  - Business rules
  - Static
- **Processing Model**
  - Activity diagrams
  - Static

Dynamic vs. Static

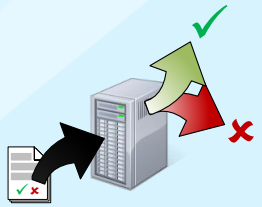
Test Cases



- **GOAL:**
  - Create a representative set of consensus-based systematic test cases that can be used by an immunization evaluation and forecasting engine
- **~765 Test Cases**
- **Published in an Excel spreadsheet for easy usage**
- **Each Test Case:**
  - Focuses on one unique problem (e.g.: minimum age only)
  - Provides the answer (e.g.: expected outcome; usually a forecast)
  - Is classified by vaccine group, evaluation test type, and forecast test type

Test Case Sample

Hib – Dose #2 at 10 weeks – 5 days



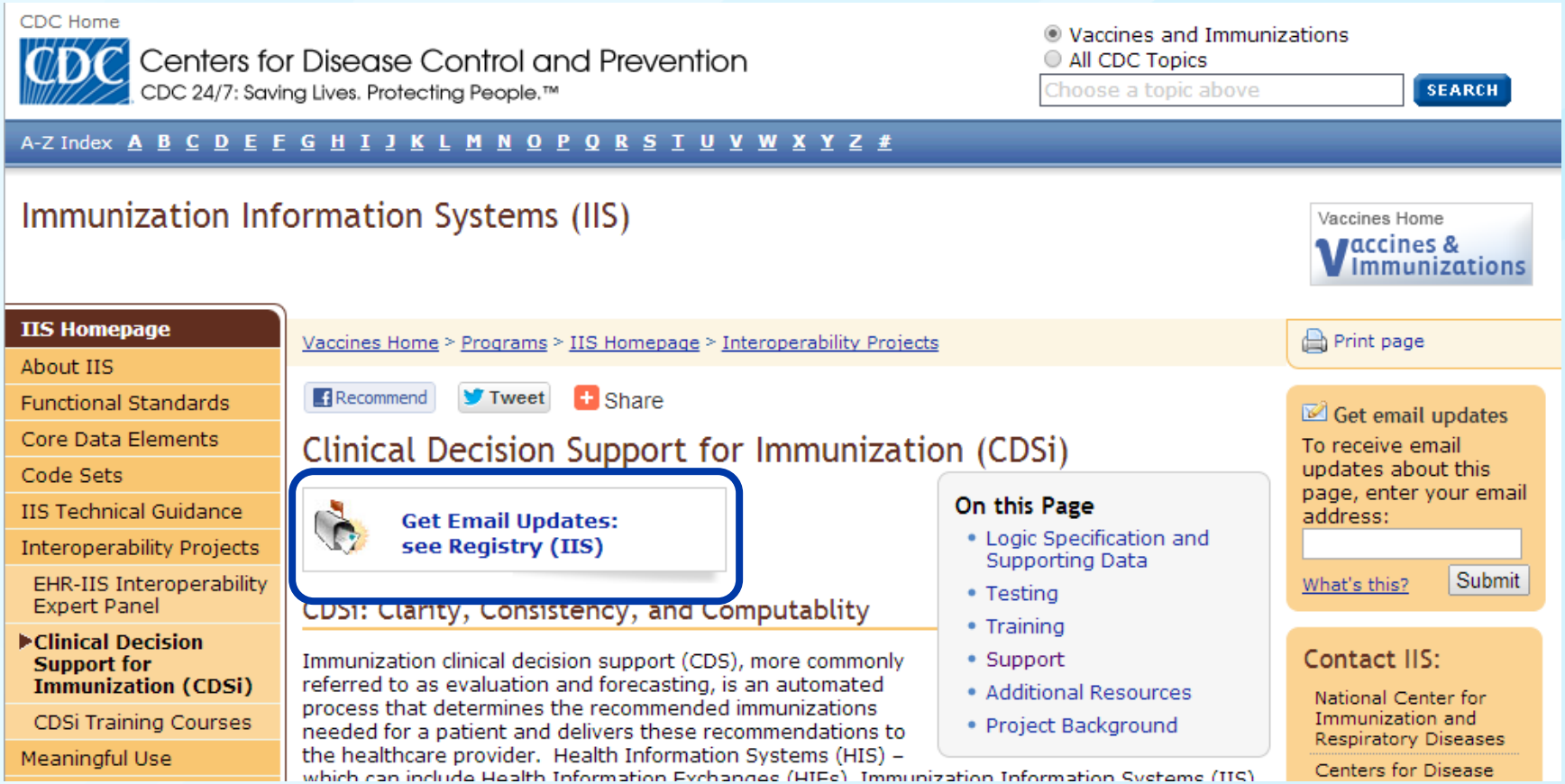
- **Test Case Scenario**

Birth Date	01/01/2010
Dose #1	Admin: 02/08/2010 Age: 5 weeks 3 days ACTHIB
Dose #2	03/07/2010 Age: 9 weeks 2 days ACTHIB

- **CDSi Expected Result**

Birth Date	01/01/2010
Dose #1	Eval Status: **Valid**
Dose #2	Eval Status: **Not Valid** Reason: **Age too young**
Forecast	Earliest Date: 04/04/2010 Rec Date: 05/01/10 Latest Date: 6/28/10

Sign up for CDSi updates



Using CDSi Resources

From minor to major engagement

- **Research specific ACIP Recommendation**
  - < 1 hour: Individual research or supported by CDSi project team
- **Take training courses**
  - < 1 hour: per course
- **Execute and compare the test cases expected results against CDS engine's actual results**
  - < 1 day: Manually execute a handful of test cases
  - < 1 month: Automate all test cases
- **Compare CDSi supporting data against CDS engine's supporting data**
  - < 1 week: Per vaccine group
- **Develop/Improve CDS engine logic based on CDSi Logic Specification**
  - Really depends on scope of development and improvement

CDSi Alignment

- **CDSi Status Check**
  - 38 participants
  - Each Participant received an individualized report
  - Aggregate data showed better alignment for users of CDSi
  - Limitation: 12 test cases
  - Limitation: All tests were edge cases
    - e.g., day before valid, day of valid dose, etc.

- **Test Cases**
  - Community vetted
  - Updated with new/changed ACIP recommendations
  - Limitation: Self-Assessment
  - Limitation: Representative sample

CDSi Compliance

- No formal or official CDC compliance testing exists.
- CDC in very early stages of exploring what – if anything – can be done.

Questions

Stuart Myerburg
(404) 639-1813
jyz0@cdc.gov
CDC Program Management

Eric Larson
(608) 385-8535
vev5@cdc.gov
Northrop Grumman Corporation
Sr. Informatics Specialist

http://www.cdc.gov/vaccines/programs/iis/interop-proj/cds.html
Or simply 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