Clinical Decision Support for Immunizations (CDSi) Project

Stuart Myerburg & Eric Larson

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National Center for Immunization & Respiratory Diseases (NCIRD)
Immunization Information System Support Branch (IISSB)

UPDATES

Initial Project Scope

Healthy children birth through 18 years

In Scope	Out of Scope
Current ACIP recommendations	Non-ACIP published rules
Compromised/sub-potent/expired doses	Adult vaccines
Vaccine recalls	Recommendations based on: • Precautions • Special indications • High, increased, or special risks • Travel
Wrong vaccine formulations	Occupation and/or facility-based recommendations
Underlying conditions related to contraindications in General Recs	Bio-terrorism vaccines
4-day grace period	Immune Globulin (IG)
	Route and body site administration
	Vaccine shortages
	Non-FDA approved vaccines (e.g., those in clinical trial)
	Schedule without 4-day grace period

Current Project Scope

Birth through death, including increased/high risk recommendations

In Scope	Out of Scope
Current ACIP recommendations	Non-ACIP published rules
Compromised/sub-potent/expired doses	Bio-terrorism vaccines
Vaccine recalls	Immune Globulin (IG)
Wrong vaccine formulations	Route and body site administration
Underlying conditions related to contraindications in General Recs	Vaccine shortages
4-day grace period	Non-FDA approved vaccines (e.g., those in clinical trial)
Adult vaccines	Schedule without 4-day grace period
Recommendations based on: • Precautions • Special indications • High, increased, or special risks • Travel	
Occupation and/or facility-based recommendations	

Current CDSi Project Accomplishments

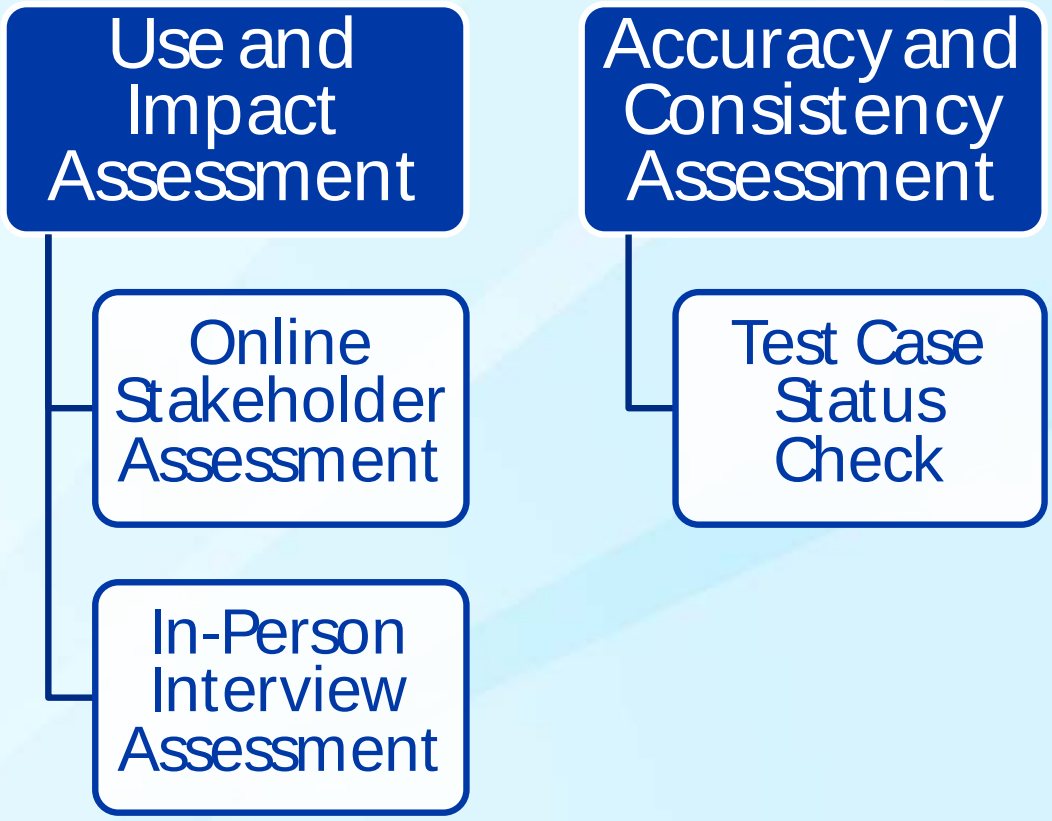
- Conducted multiple expert panel meetings including two multi-day, in-person sessions in Atlanta
- Refined existing CDSi terminology and domain model
- Translated ACIP recommendations across 18 vaccine groups into a single common format with traceability back to 63 online publications
- Developed a Test Case Management Tool and trained multiple members of immunization community members on its use
- Developed over 150 new test cases
- Began effort of translating ACIP recommendations into a list of discrete "underlying conditions" that can be evaluated and mapping these to existing code sets, such as SNOMED-CT
- Contributed technical guidance regarding dealing with vaccines mixed with an adjuvant at the point of administration

CDSi Resource Publication

The new CDSi resources (Logic Specification, Supporting Data, and Test Cases/Methodology) will be published in phases:

May 2015	July 2015	October 2015
Routine Adult Recommendations Will be incorporated into Logic Specification, Supporting Data, and Test Cases/Methodology	**Underlying Conditions** Mapping will be finalized and published, as appropriate	**Increased-Risk Recommendations** Will be incorporated into Logic Specification, Supporting Data, and Test Cases/Methodology

CDSi Resources Evaluation Research Questions



CDSi Evaluation Mixed Method Approach

In-Person Interviews

- Semi-structured interviewswith IIS community members
- 7 small groups (1-3 individuals)
- Total of 17 individuals interviewed

Online Assessment

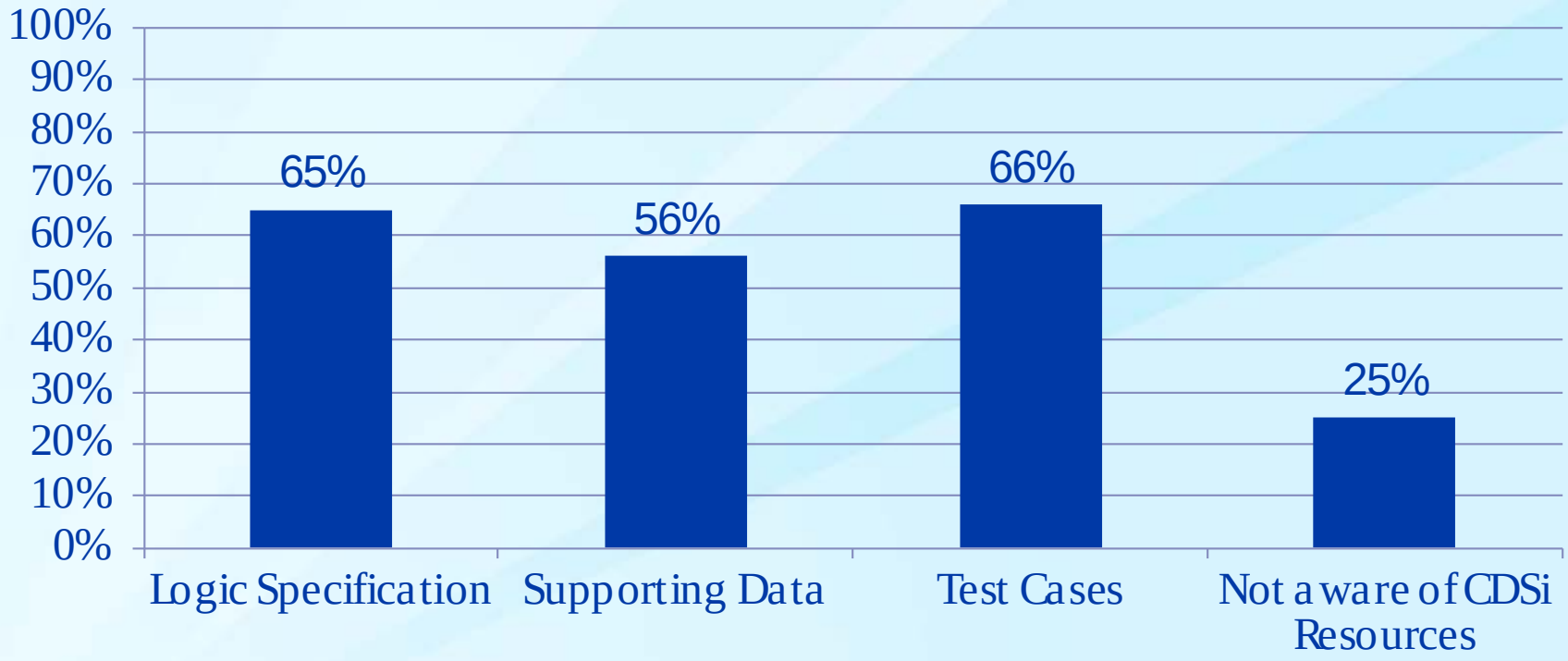
- Invited main and technical contacts from the 64 IIS grantees, IISvendors (8) independent consultants(3), and EHRvendors(15)
- 60 responsesfrom IISGrantees
- 11 responsesfrom Vendors/Consultants

Test Case Status Check

- System validation
- A subset of 12 test cases out of over 750 test cases were selected
- Sent to the 64 IIS grantees
- 29 responses received to date

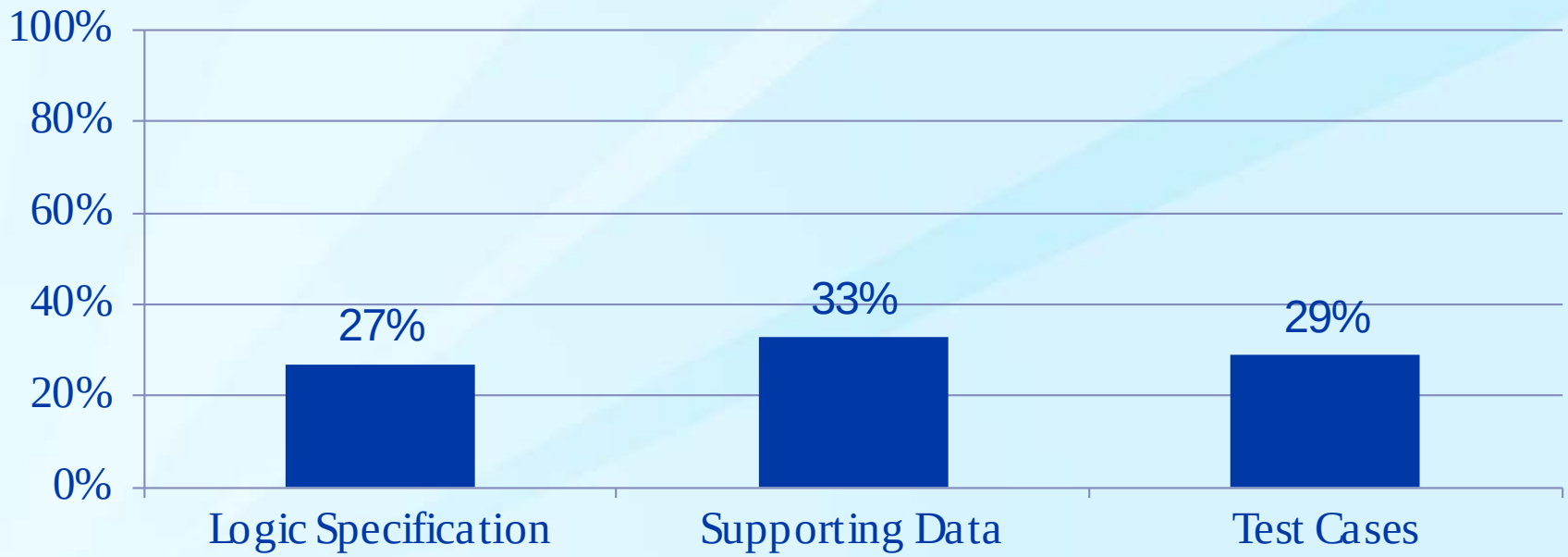
Online Assessment Preliminary Results
Awareness of CDSi Resources

Which of the following have you heard about?



Online Assessment Preliminary Results
Use of CDSi Resources

Have you used the CDSi resources to improve evaluation and forecasting of ACIP recommendations?



Continued Evaluation of CDSi Resources

- **In-person interviews**
  - Continue to code and analyze the qualitative data
- **Online Assessment**
  - Further data analysis of awareness, use, and impact of CDSi resources
- **Test Case Status Check**
  - Finalize data collection
  - Develop personalized reports for each state/jurisdiction to show how their CDS engine aligns with the CDSi expected answers
  - Data analysis of accuracy and consistency of IIS CDS engines across IIS grantees
- **Examine and triangulate the results of the evaluation**

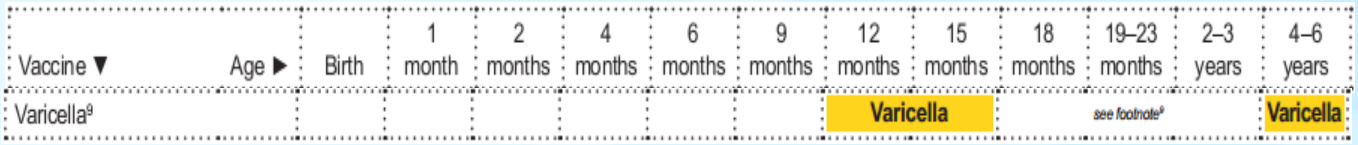
WORKSHOP

Goals for Today

- Gain an understanding of the different CDSi Resources
- Use CDSi resources to answer questions during small group exercises
- Review questions as a Large Group

ACIP Age Recommendations on Varicella

TABLE1. 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



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

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.

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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

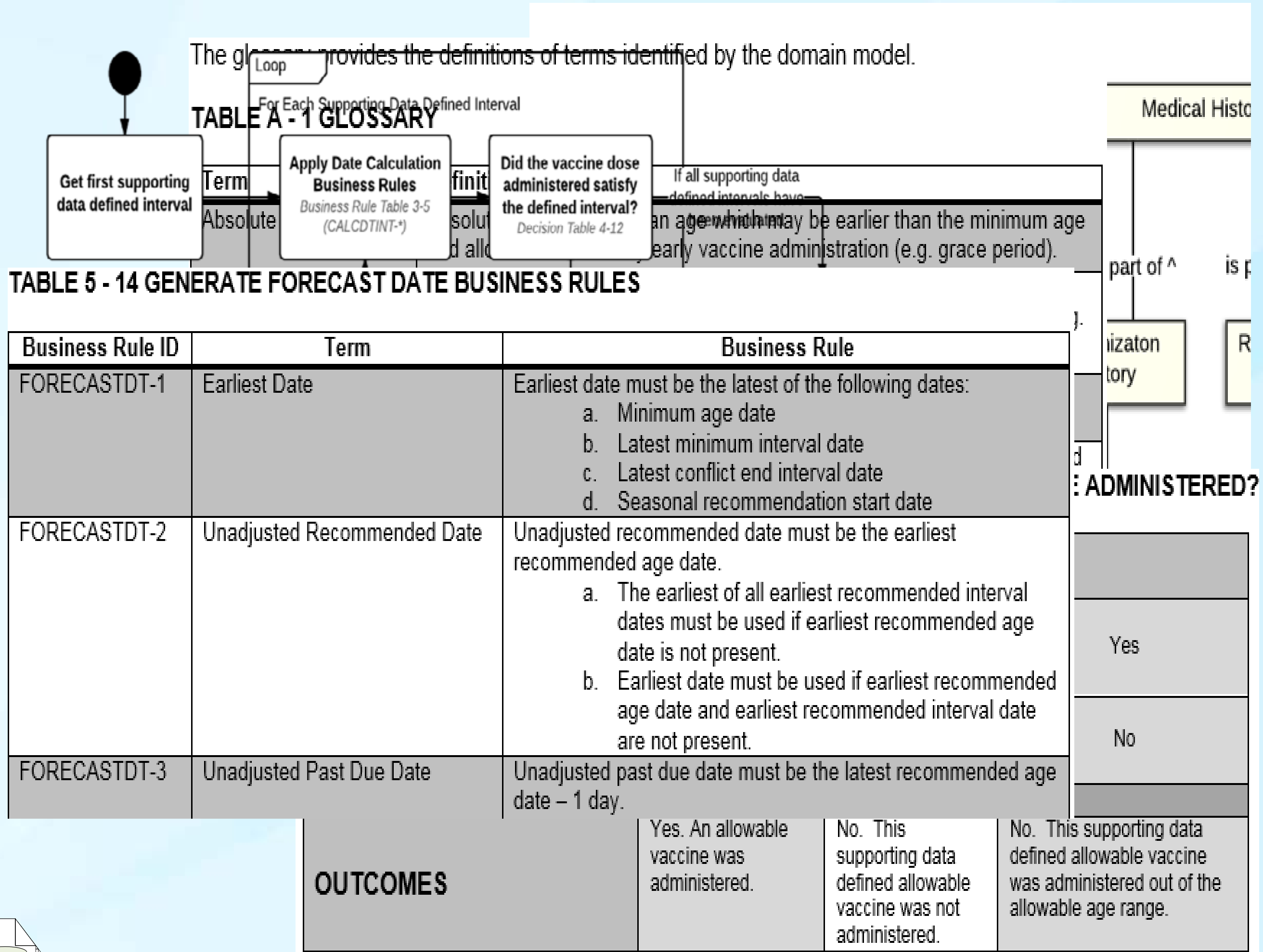
Business Rules

- 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.

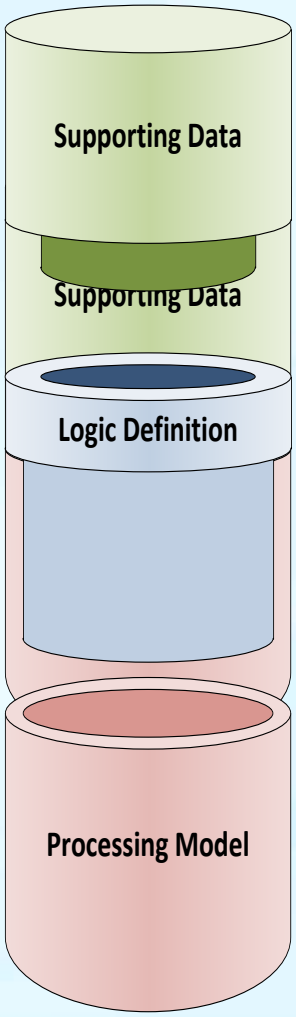
TABLE A - 1 GLOSSARY

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.

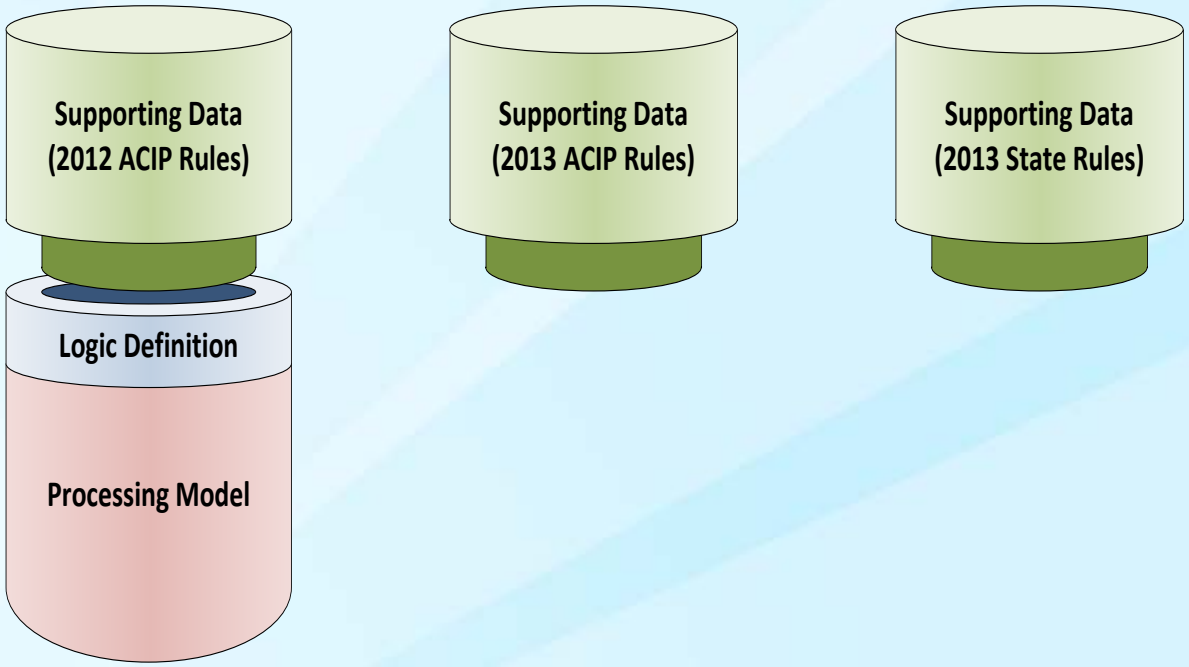
OUTCOMES	Yes. An allowable vaccine was administered.	No. This supporting data defined allowable vaccine was not administered.	No. This supporting data defined allowable vaccine was administered out of the allowable age range.

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



Workshop Exercise

- **Break into small groups (3 – 10 per group)**
  - The number in each group doesn't matter, but it should be small enough that each person can contribute
- **Research and answer each question using the CDSi handouts provided even if you know the answer.**
  - Confirm that you know the answer!
- **Make sure at least one person is jotting down the answers**
  - Does everyone agree? If not, jot down both answers
- **Take about 15 minutes and then reconvene to review**