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AMERICAN IMMUNIZATION
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Measures and Tests for IIS Validation

Clinical Decision Support
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Background and Context

Immunization information systems (IIS) supply health care providers with immunization clinical decision support (CDS) tools designed to automatically determine the recommended immunizations needed when a patient presents for vaccination. These recommendations are developed by the Advisory Committee on Immunization Practices (ACIP). In an effort to harmonize the outcomes of existing CDS tools, the Immunization Information Systems Support Branch (IISSB) at the CDC funded the Clinical Decision Support for Immunization (CDSi) Project to develop new clinical decision support resources for each vaccine-preventable disease in accordance with ACIP recommendations.¹

In 2016, AIRA convened the Measurement for Assessment and Certification Advisory Workgroup (MACAW) to develop and propose measures for IIS Assessment. CDS measures and tests are the fourth content area in the Measurement and Improvement Initiative (M&I) to be developed. These measures and tests are shared with the AIRA Board of Directors and the full AIRA community to ensure broad community input and agreement. A baseline measurement was taken during the second quarter of 2019 with remeasurements in each subsequent quarter. Aggregate results are published on the AIRA Repository.² MACAW is now recommending these measures be used for Validation.

Functional Standards and Operational Guidance Statements

The use of standardized CDS tools are referenced throughout the IIS Functional Standards (FS) v4.0, updated in 2018³ and Operational Guidance Statements (OGS). The revised IIS FS were developed by the IISSB, through a consensus-based process involving input from a variety of IIS managers and technical experts from across the U.S. They are intended to reflect the functionality an IIS should strive to attain to fully support program and stakeholder immunization-related goals. The OGS provide further guidance to the IIS community about how to achieve the FS and to inform the development of measures for achievement. The following FS and OGS are included – at some level – in the MACAW measures and tests defined in this document.

The updated IIS Functional Standards v5.0 and Operational Guidance Statements (OGS) were developed through a consensus-based process by CDC's Informatics and Data Analytics Branch (IDAB), formerly known as Immunization Information Systems Support Branch (IISSB) with input from a variety of IIS managers and technical experts nationwide. These standards describe the core functionality an IIS should strive to achieve in support of programmatic and stakeholder immunization goals.

¹ <https://www.cdc.gov/iis/downloads/func-stds-v4-2-resource-guide-508.pdf>

² <https://repository.immregistries.org/resource/iis-assessment-aggregate-status-report-clinical-decision-support/>

³ <https://www.cdc.gov/iis/functional-standards/introduction.html>

The following FS and OGS are applicable to Clinical Decision Support (CDS) functionality and are included in the MACAW measures and tests defined in this document.

Measures and tests are based on the IIS Functional Standards v5.0. CDS measures and tests are specifically based off the following:

Functional Standard C5.0: Manage interfaces for exchange and integration of data electronically between the IIS and other information systems in accordance with federal and jurisdictional standards.

Guidance Statement C5.1: The IIS exchanges data in accordance with current interoperability standards endorsed by CDC for message content, format, and transport.

Functional Standard D6.0: The IIS supports pediatric, adolescent, and adult immunization forecasts consistent with Advisory Committee on Immunization Practices (ACIP) recommendations.

Guidance Statement D6.1: The IIS establishes and maintains Clinical Decision Support (CDS) functionality consistent with ACIP recommendations.

Guidance Statement D6.2: The IIS establishes and maintains Clinical Decision Support functionality in alignment with CDSi resources published on the CDC website.

Functional Standard E7.0: The IIS ensures authorized users have access to patient demographic and vaccination data based on user roles and permissions.

Guidance Statement E7.5: The IIS supports authorized IIS partners' and providers' appropriate access to data in the IIS for public and population health purposes (e.g. childcare, schools, college, health plans, clinics).

The Assessment measures for CDS were approved in December 2018 and will be used for Validation. For more information on the Assessment measures, please see the CDS Assessment document on the AIRA website.⁴

⁴ <https://repository.immregistries.org/resource/test/>

Validation Stage

The *Immunization Information System (IIS) Measurement and Improvement: Testing and Discovery, Assessment and Validation Overview*⁵ document describes the Validation stage in detail and should be referenced for more information. At the highest level, the Validation stage uses the same (or a subset of) measures and tests which have been developed, vetted, and approved by the IIS community and AIRA Board for IIS Assessment. No new measures are introduced at Validation that have not already been measured in IIS Assessment.

Validation Levels

Clinical Decision Support contains two Validation Levels (Basic and Complete). Measures selected for Validation are reviewed and assigned a Level based on the following definitions.

- **Basic Level:** A level of Validation measurement that includes only essential measures to functionally meet the content area.
- **Complete Level:** A level of Validation measurement that includes conformance to all measures approved for Validation.

⁵ <https://repository.immregistries.org/resource/iis-measurement-and-improvement-testing-and-discovery-assessment-and-validation-overview/>

http://www.immregistries.org/initiatives/measurement/IIS_Measurement_and_Improvement_-Validation_Overview_11-2017_Final.pdf

The following table defines the requirements for both Basic and Complete levels of Validation.

Table 1: CDS Validation Levels

CDS Concept	Assessment Measure	Basic Validation	Complete Validation
Evaluation Status <i>Did the dose count?</i>	1) Supports Concept		X
	2) Pediatric Accuracy (0-6 years)		X
	3) Adolescent Accuracy (7-18 years)		X
	4) Adult Accuracy (19 years+)		X
Earliest Date <i>When could the next dose be given?</i>	5) Supports Concept	X	X
	6) Pediatric Accuracy (0-6 years)	X	X
	7) Adolescent Accuracy (7-18 years)	X	X
	8) Adult Accuracy (19 years+)	X	X
Recommended Date <i>When should the next dose be given?</i>	9) Supports Concept	X	X
	10) Pediatric Accuracy (0-6 years)	X	X
	11) Adolescent Accuracy (7-18 years)	X	X
	12) Adult Accuracy (19 years+)	X	X

Validation Statuses

Validation statuses are assigned based on the Assessment outcomes for the measures of interest (e.g., Meets, Deviates, Does Not Meet). More information on Assessment outcomes can be found in the *Measures and Tests for Assessments: Clinical Decision Support*.⁶

Basic and Complete Level Requirements

Table 2: Basic and Complete Level Requirements

Validation Status	Assessment Outcome Requirements
 Complete Validated  Basic Validated	The IIS Meets all measures which are identified to be part of the Basic or Complete Level in Table 1 above.
 Complete Minor Difference  Basic Minor Difference	The IIS Meets all measures which are identified to be part of the Basic or Complete Level in Table 1 above, except for differences that 1) are allowed within the measures and test, or 2) are meeting requirements due to local law or policy.
 Major Difference - Validation Not Met	The IIS fails to meet the requirements for Basic or Complete Validated.
 Not Measured	The IIS has communicated willingness to be measured but is not able to be tested at this time.
 Not Participating	The IIS has chosen not to be measured.

⁶ <https://repository.immregistries.org/resource/test/>