

IMMUNIZATION INFORMATION SYSTEM (IIS) ASSESSMENT AND CERTIFICATION ROADMAP

An initial process to measure IIS alignment with
standards and best practices

AIRA IIS Assessment Subject Matter Expert Panel
Version 3.0 - May, 2016

Sponsor and/or Funding Source: CDC/NCIRD/IISB
2014 Prevention and Public Health Funds
IP14-140902Cont15

History of Changes/Updates

Date	Changes/Updates	Version Number
2/19/2016	Consolidated Version Compiled	V0.1
2/29/2016	Version Reviewed and Approved by SME Panel	V1.0
3/10/2016	DRAFT Notes Removed, Final Formatting Updates	V2.0
5/15/2016	Swim Lane Document & T/D Map Modified	V3.0

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Acknowledgements

AIRA would like to acknowledge the many members of the community who contributed to the development of this document:

The IIS Assessment Subject Matter Expert Panel, who contributed significant expertise and review:

- Mike Bin, IIS Exchange Coordinator, Office of Immunization and Child Profile, Washington State Department of Health
- Danielle Hall, Planning and Research Associate, Maine Immunization Program
- LaTrece Harris, Health Scientist, Immunization Services Division, CDC
- Dina Hofer, NYSIIS and Vaccine Program Manager, New York State Department of Health Bureau of Immunization
- Aras Islam, KIDS Plus IIS Coordinator, Philadelphia Department of Public Health
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- Loren Rodgers, Evaluation Team Lead (acting), IIS Support Branch, CDC
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The AIRA Board of Directors, who reviewed and provided input at various stages of this effort:

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Executive Summary

Immunization Information Systems (IIS) have grown in both functionality and complexity over the last twenty years. Increasingly, IIS are viewed less as a collection of independent systems serving a catchment area, and more as a network of systems that need to share information and data within and beyond the IIS network. The American Immunization Registry Association's (AIRA's) Strategic Plan (2013-2016) includes an objective related to the exploration of IIS certification, including the evaluation of financial and strategic benefits and the necessary considerations for establishing a certifying body and governance structure. AIRA's 2014-2018 Cooperative Agreement with the Centers for Disease Control and Prevention (CDC) includes a goal to conduct formal evaluations of IIS practice or operations. Both of these initiatives support the exploration of an assessment and/or certification process for IIS.

Beginning in 2015, AIRA worked with IIS programs and vendors to test HL7 interfaces through an interoperability Testing and Discovery process. This early work provided valuable information regarding the community's adoption of standards and best practices. In parallel, a panel of Subject Matter Experts (SMEs) was gathered to evaluate strategic and financial benefits and barriers to IIS Assessment, and to develop an initial process for IIS Assessment and potential Certification.

A comprehensive IIS Assessment Communications Plan was also developed to ensure visibility, transparency, and inclusiveness throughout the project's progress. Although many key messages were identified, the overarching goal of this project is to:

Provide IIS with information to more fully align with IIS Functional Standards, while also developing a summary of where IIS are as an overall network in meeting standards and best practices.

This work will serve as groundwork for a new group being convened to inform measurement; the Measurement for Assessment and Certification Advisory Workgroup (MACAW) will include representatives from across the IIS program and vendor community, as well as representatives from critical partner organizations such as CDC. This ongoing group will develop metrics and oversee the process of moving from IIS Testing and Discovery to IIS Assessment and beyond.

Near-universal participation of IIS in the testing and discovery phase of this project signals that the need for measurement to assess alignment with standards is broadly recognized as a priority. Early tests and analysis have provided valuable information to use in the establishment of initial measures for IIS Assessment. Even in the first year of IIS Testing and Discovery, findings have increased awareness, incentivized enhancements, and highlighted critical areas where standards themselves are in need of further clarification. As the IIS community moves into formal IIS assessment, this early work will serve as a valuable base from which to develop meaningful measures of success and to meet collective priorities.

Background

Immunization Information Systems (IIS) have grown in both functionality and complexity over the last twenty years. Increasingly, IIS are viewed less as a collection of independent systems serving a catchment area, and more as a network of systems that need to share information and data within and beyond the IIS network. AIRA's Strategic Plan (2013-2016) includes an objective related to the exploration of IIS certification, including the evaluation of financial and strategic benefits and the necessary considerations for establishing a certifying body and governance structure. AIRA's 2014-2018 Cooperative Agreement with CDC includes a goal to conduct formal evaluations of IIS practice or operations. Both of these initiatives support the exploration of an assessment and/or certification process for IIS.

In April 2015, AIRA published a white paper entitled ***Summary and Environmental Scan of Assessment and Certification Models***¹, which explores models in public health and healthcare that can serve as examples to draw from for IIS assessment and certification. This paper highlights current examples that have already blazed trails in terms of measurement and metrics for evaluation. Based on the initial scan of assessment and certification models in use across the clinical health and public health arenas, there are excellent components of measurement processes to draw from.

One of the findings of the environmental scan was that, although certification may become a long-term goal, launching a formal assessment process to drive quality improvement and alignment with standards is believed to be a better immediate next step. This assessment process will also provide an opportunity to fine-tune standards and measures themselves, creating an iterative process of improvement of both IIS programs and the metrics used to assess them. The paper offered initial recommendations for consideration in planning and implementation of an IIS assessment process, and potential future certification program. Additional investigation, discussions, and considerations are needed to identify the ideal model for the IIS community.

AIRA also convened a collection of community experts at their National Meeting in New Orleans, Louisiana to gather community input and feedback regarding assessment and certification. On April 22nd, 2015, 155 IIS program staff, immunization program managers, IIS vendors, and interested stakeholders/partners participated in facilitated small group discussions to review and respond to the recommendations in the AIRA assessment white paper. Input was captured through two primary methods:

- Facilitators were asked to take summary notes of the group's discussion and input on the Facilitator's Guide. Twenty-two facilitators' notes pages were collected and summarized.

¹ Summary and Environmental Scan of Assessment and Certification Models:

[http://www.immregistries.org/resources/other-aira-resources/Summary and Environmental Scan of Assessment, Certification Models - Final.pdf](http://www.immregistries.org/resources/other-aira-resources/Summary%20and%20Environmental%20Scan%20of%20Assessment,%20Certification%20Models%20-%20Final.pdf)

- Participants were asked to provide more detailed and individualized input on the Participant Guides. One hundred and five participants' notes pages were collected and summarized.

The results of the roundtable meetings were written up in a summary paper² and released to the full AIRA membership following the meeting. The roundtable feedback heavily supported the development of an internally-facing, community driven IIS assessment process, and respondents were interested in exploring more formal certification at a later date. The full write-up is currently available on the AIRA website.

Approach/Framework

Per the Environmental Scan paper's recommendations and the Roundtable feedback, a Subject Matter Expert panel was convened to validate initial assumptions, and to draft next steps for the development of a formal assessment process. This group was initiated in August 2015, and has been assembled for approximately six months. The group is charged with reviewing the Environmental Scan paper and the Roundtable feedback, and validating key directions for an IIS assessment process. In addition, the group will have the opportunity to review information from the Interoperability Testing Project that is conducting testing and discovery activities in parallel with the SME group to better inform the assessment process. The group will also make recommendations on forming a Measurement Advisory Workgroup that will be charged with developing metrics and a measurement process for IIS Assessment/Certification. The Measurement Advisory Workgroup may or may not also serve as the assessing/certifying body for measurement, but this linkage will be explored with both the SME panel and with the AIRA Board of Directors.

This effort will draw heavily on relevant materials available across the community in developing both the process for assessment/certification as well as the metrics. The following standards and guidance materials will be leveraged as appropriate:

- IIS Functional Standards, including Core Data Elements³
- IIS Functional Requirements⁴
- HL7 Implementation Guide 2.5.1, Release 1.5⁵
- SOAP Web Services Recommendations⁶
- Clinical Decision Support (CDSi) Specifications⁷

² Summary of Roundtable Input on Assessment from the 2015 AIRA National Meeting:

http://www.immregistries.org/resources/Summary_of_Roundtable_Input_on_Assessment_from_the_2015_AIRA_National_Meeting_-_Final.pdf

³ IIS Functional Standards, 2013-2017: <http://www.cdc.gov/vaccines/programs/iis/func-stds.html>

⁴ Defining IIS Functional Requirements:

<https://phii.org/sites/default/files/resource/pdfs/IIS%20FINAL%2010302012.pdf>

⁵ HL7 Implementation Guide, 2.5.1, Release 1.5: <http://www.cdc.gov/vaccines/programs/iis/technical-guidance/downloads/hl7guide-1-5-2014-11.pdf>

⁶ Soap Web Services Guidance: <http://www.cdc.gov/vaccines/programs/iis/technical-guidance/SOAP/services.html>

⁷ Clinical Decision Support Specifications: <http://www.cdc.gov/vaccines/programs/iis/interop-proj/cds.html>

- MIROW Best Practice Guidelines⁸

In addition, work has been completed across the IIS community to develop metrics and measures in the past; this project will draw from the strongest among these tools and measures:

- IIS Annual Report metrics⁹
- AIRA IIS Self-Assessment Tool¹⁰
- PROW Standards¹¹
- Technical Working Group Archival Documents¹²

Partner Organizations and Other Stakeholders

NIST

The National Institute of Standards and Technology (NIST) is partnering with AIRA in the early part of the assessment process. One important role NIST plays is to develop conformance test tools for health information technology standards that support initiatives such as Meaningful Use (MU). As part of this effort, NIST has developed the 2014 Meaningful Use (MU) testing process for the transmission of immunization criterion. NIST is extending the testing capabilities of the test tool in a collaboration between NIST and the CDC to support future MU regulation. NIST has also been working with AIRA for several years to access domain experts in an effort to create software that verifies EHR software is following the IIS messaging standards for Meaningful Use. The tools that will be developed from NIST will be important components in the assessment/certification process as they may become centralized testing tools.

AIRA Board of Directors

The AIRA Board of Directors will be utilized in an oversight capacity to support the planning and implementation of an assessment process. The Board of Directors can also provide an informed outside perspective for the group, and can provide feedback on missing aspects in planning and/or implementation. All recommendations within the findings documents resulting from testing and discovery as well as IIS Assessment will be reviewed and approved by the AIRA Board of Directors.

CDC IISB Team

The CDC Immunization Information Systems Support Branch (IISB) has vast knowledge in statistical approaches and will provide their expertise in this area. In particular, the IISB Evaluation Team, in

⁸ MIROW Best Practice Guidelines: <http://www.immregistries.org/resources/aira-mirow>

⁹ IIS Annual Report: <http://www.cdc.gov/vaccines/programs/iis/annual-report-IISAR/index.html>

¹⁰ AIRA IIS Self-Assessment Tool: http://www.immregistries.org/about-aira/committees/Revised_Assessment_Version_Aug_16.pdf

¹¹ Programmatic Registry Operations Workgroup Guide: <http://www.immregistries.org/resources/prowstartupguide.pdf>

¹² Technical Working Group: http://www.immregistries.org/resources/twg_recommendation.pdf

conjunction with other Branch staff, will be asked to bring lessons from the Sentinel Site projects and the Trends in Immunization Practices System (TIPS) efforts to share with the Assessment process.

CDC IISB Leadership will also play an important role in strongly recommending participation in IIS Assessment, as well as encouraging IIS to implement findings of IIS Assessment to enhance and improve system functions.

Role and Scope of Workgroups

Assessment Subject Matter Expert Panel

The Assessment Subject Matter Expert Panel is made up of IIS and partner organization representatives. The group will discuss the following aspects of assessment/certification: strategic benefits and barriers, financial benefits and barriers, and implications of each.

The workgroup will:

- evaluate and designate the initial approach and early governance structure for formal uniform assessment of all IIS, evaluating and selecting strategies to mitigate strategic and financial risks and barriers.
- draft an initial Communications and Messaging Plan that includes a strong statement of support, both programmatic and financial, for the development of a formal assessment process from CDC as a primary IIS funder. The plan should focus on both external messaging and the solicitation of input from the full IIS community to ensure broad opportunities for influencing the process development.
- evaluate the feasibility of the assessment process transitioning into a formal certification process, and set milestones and triggers for a decision regarding this transition.
- define and conduct the selection process for an ongoing Planning/Steering Committee, at which point the IIS SME workgroup will disband.

Measurement Advisory Workgroup

The Measurement for Assessment and Certification Advisory Workgroup (MACAW) will include IIS community members and partners/stakeholders. This group will be charged with systematically researching and formulating key IIS assessment components, developing pilot metrics, and creating an Implementation Plan for IIS assessment. The Workgroup will also critically evaluate the feasibility and cost-benefit of transitioning to a formal certification process in accordance with the triggers/milestones set by the SME group. Dependent on the outcome of this evaluation, if a move to formal certification should go forward, this Workgroup may become the formal certifying body, or may appoint another organization or group to fill this role.

Evaluation of Benefits and Barriers

Initial strategic and financial benefits and barriers were generated in the Environmental Scan, expanded on by the IIS community at the Roundtable meetings and through the IIS Interoperability Pilot Project, and will be further validated by the SME Panel, with strategies and/or solutions generated as feasible.

Strategic Benefits

Assessment/certification has the potential to facilitate greater standardization and nationwide symmetry in IIS (e.g., design, operations, and functions) and to increase the development of, and adherence to, national IIS policy (e.g., data reporting and sharing, opt in/opt out). Improved symmetry would also provide the necessary framework for introducing increasingly succinct IIS data standards and relative markers (e.g., universal methodology for quantifying data and setting new and more advanced standards for data reporting/collection; data quality; data sharing and privacy related data security processes). Certifying IIS would produce community-wide IIS conformity and agreement for interoperability with both interstate IIS and EHRs, thereby increasing the use of IIS within health information exchange and supporting clinical decision support. Certified IIS systems would improve end-user acceptance, usage and system satisfaction and increase confidence in the systems' collection, retention and reporting of Protected Health Information (PHI). A certified IIS infrastructure would ensure all IIS are operating at a fundamental level of capacity. Measurable minimal IIS standards would pave the way for creation of a nationally cohesive and formalized IIS evaluation process, with the potential to minimize IIS deviation from established standards. A formalized evaluation process would:

- 1) assist in the identification of national-level IIS performance measures and improvement processes;
- 2) highlight best practices and opportunities for system enhancements;
- 3) assist in the creation of standardized system documentation, including clearly defined operational roles and responsibilities; and
- 4) aid in IIS risk analysis and management measures.

Strategic benefits of certification, as validated by the community, should be leveraged in communications and messaging to build broad support for and participation in the assessment effort.

Strategic Barriers

Along with broad variation in standards adoption across the IIS community, there is a current lack of uniform nationwide policy as well. Although challenging, the development of national IIS policy and adoption of standards could be supported by assessment/certification, which would vastly improve IIS reporting and data handling. National uniform policy would require the committed engagement of all entities charged with the ongoing monitoring and assessment of IIS, including:

- 1) IIS systems' abilities to meet (or exceed) and maintain common policies, legislation and system requirements;
- 2) IIS systems' abilities to adhere to and maintain these requirements and their assessment/certification standing;
- 3) the implications for those IIS systems unable to meet national standards and become certified; and
- 4) the periodic review, assessment and adjustment to IIS standards, policy and legislation, and assessment/certification endeavors.

The introduction of nationally defined assessment/certification standards and IIS policy would highlight the current diversity of IIS practices, potentially create the need to secure and maintain assessment/certification and/or the funding necessary to perform required system enhancement, redesign and/or operational maintenance. Assessment/certification and the

implementation of national level standards would impact current IIS operational processes, potentially impacting stakeholder-based expectations, including privacy and security concerns.

Financial Benefits

Many of the financial benefits to assessment and certification must be inferred, and may be indirect. Validation and verification of greater standards alignment will likely create a stronger, interoperable IIS network, which in turn may create opportunities for broader partnerships. These partnerships may lead to funding opportunities in the future. Similarly, stronger alignment with standards should streamline development and strengthen opportunities for shared services and collaborative development and implementation efforts.

As with strategic benefits, financial benefits of assessment and certification, as validated by the community, should be leveraged in communications and messaging to build broad support for and participation in the assessment effort.

Financial Barriers

Because assessment/certification has the potential to articulate the shortcoming of those systems not yet meeting standards, it is plausible that there would be significant financial ramifications to IIS programs. IIS currently receive state and federal funding for ongoing activities and objectives related to improved or enhanced system design, operation and function, and broader adoption of standards and best practices. Instituting a national IIS assessment/certification process will likely result in the need to both increase current funding streams and to explore and secure new funding streams to assist IIS in meeting the minimal requirements to achieve a certain level of standing. Given the current competing priorities and limited funding avenues available to the IIS, finding, securing and maintaining adequate funds to support the assessment/certification process may prove challenging. Without a doubt, there are foreseeable financial implications tied to IIS assessment/certification, including development (initial costs to meet standards), sustainment (ongoing IIS related costs), and maintenance (unexpected or newly acquired costs to meet revised standards). There are also financial implications connected to the process of becoming certified: 1) cost to certify, and 2) staff time for IIS project and IIS certifying body for the preparation, collection and processing of required documentation, and the demonstration of system function and capacity (including testing performance and implementing corrective measures). Decisions regarding which programs receive funding and for what assessment/certification related purposes should be made transparently and with significant IIS community input.

Although it is impossible to provide a comprehensive list of all strategic and financial benefits and barriers, it is evident that there are significant implications requiring further discussion and investigation, and which cannot be fully understood until an assessment process is planned and operationalized. As these benefits and barriers are evaluated, it may be beneficial to differentiate the very real barriers that need to be resolved from the potential risks to consider and/or to be cognizant of as we as a community move forward with assessment.

The table below represents a collective effort to develop strategies and solutions where possible for identified barriers and risks:

Barrier or Risk in Implementing IIS Assessment Process	Originally Cited By:	Potential Strategies/ Solutions to Mitigate Barrier or Risk
Lack of uniform alignment with standards (including local variation) (barrier)	Environmental Scan, Roundtables	<ul style="list-style-type: none"> • Use AIRA interoperability testing project to provide early feedback on needed enhancements and to identify local variations – map/categorize local policy variation vs. other differences. • Continue to promote adoption of standards and best practice guides to help influence change. • Consider development of a best practice guide for jurisdictional policies (opt-in/opt-out, lifespan capture, participation mandates, etc.) • Target areas of assessment where uniformity exists. Recognize the sites where uniformity can be stated and acknowledge where there are needs to improve. • Choose a set of priorities and goals that are achievable for all jurisdictions. This may require a jurisdiction-by-jurisdiction review to identify potential issues.
Lack of clarity within standards, time needed to come to agreement on standards (barrier)	IIS Interoperability Testing Process, Roundtables	<ul style="list-style-type: none"> • Leverage AIRA Interoperability discovery and testing process to inform clarification and/or improvement of standards. • Stand up ad hoc groups where needed to further develop standards. • Allow programs time to meet the standards. • Maintain stability of measures for a reasonable (and well-communicated) period of time. • Assess in a phased approach to targeted areas, where standards or measures can be agreed upon within realistic timeframes • Subsequent to the strategies listed above, the assessment process will likely be iteratively refined, beginning with a pilot and responding as lessons are learned. This process will likely highlight areas where additional clarification is needed. • Propose developing standards over time. Agree on initial set of standards; standards that are clear and achievable in the initial stages.
Lack of uniform nationwide IIS policy (barrier)	Environmental Scan	<ul style="list-style-type: none"> • Show evidence of/demonstrate need for nationwide policy through highlighting differences. • Partner with CDC, ASTHO, ONC and other stakeholders to clarify and influence best practice policies nationally and locally. • Explore linkages with IIS Strategic Plan’s focus on National Policy.

		<ul style="list-style-type: none"> • View assessment process as a means of evaluating system quality/maturity. The results of the assessment can help identify strategies or policies that would improve system quality. • Propose standards that are achievable across the IIS community without requiring major jurisdiction policy changes.
Concern of negative impact from highlighting differences/diversity among IIS (risk)	Environmental Scan, Roundtables	<ul style="list-style-type: none"> • Maintain internal focus of assessment until messaging and communications planning is drafted, vetted, and operationalized. • Respect political environments and needs of states/jurisdictions. • Focus on assessing system performance. In instances where performance variations are due to diversity among IIS, then comparisons could be useful in order to assess the impact of the system differences. • Use a phased approach to assessment strategies to help inform policy issues. • Communication is important here. Highlighting differences and diversity among each IIS will actually strengthen the IIS community as a whole. Diversity may lead to better ideas and practices as the assessment process moves forward.
Rapid operational changes with introduction of enhancements (risk)	Environmental Scan	<ul style="list-style-type: none"> • A phased approach, with an extended period of optional participation in assessment, should allow programs to implement enhancements at a manageable pace. A move to certification should not be planned on a timeline that would require unmanageable operational changes. • Provide guidelines on how to deal with rapid operational changes. • Provide technical and operational support to IIS to manage change and to educate users and partners
Stakeholder concerns about patient privacy/confidentiality being compromised by assessment (risk)	Environmental Scan	<ul style="list-style-type: none"> • Establish strong confidentiality agreements. • Utilize technologies for file transport and storage that are appropriately rated for PII. Document this in Data Sharing Agreements. • Consult other certification programs for lessons learned. • Limit the use of PII data for assessment purposes, use de identified data for data quality measures or test functional capacity with test cases with fictitious names.

		<ul style="list-style-type: none"> • Security and Confidentiality agreements have to be drafted with each IIS being assessed. The agreements must be signed by all parties involved. • Ensure assessment process needs no access to confidential patient data • Ensure communication and messaging emphasizes that test data will be used whenever possible, all data will be treated securely and confidentially, and only aggregate information will be shared
Competing priorities/limited staff time (barrier)	Environmental Scan, Roundtables	<ul style="list-style-type: none"> • Explore technology solutions that minimize the effort required to prepare files for assessment. Explore the possibility of working with vendors to determine the feasibility of facilitating the transfer of data from the IIS into an assessment tool. • Ensure that the process is flexible to staff time, and that deadlines are not within tight windows. • Reasonable efforts should be made to view the calendar and avoid critical time periods for competing immunization activities – i.e. don't ask for this to be completed when we are all working on our annual grant application or IIS strategic plan. • Minimize burden to program staff, provide technical assistance for interpretation of assessment results and planning for necessary enhancements when needed
Competitive grant process among sites needing funds for enhancements resulting from assessment could create or reinforce disparities across IIS community (risk)	Environmental Scan	<ul style="list-style-type: none"> • Grant process regarding assessment funds has to open to all IIS sites. • Funding support should come from Immunization Cooperative Agreement. Ideally meeting assessment goals would be a core grant objective and funded accordingly • Work with CDC to continue to support innovation among high performers • Fund base grants and non-competitive funds at sufficient level
Additional funds may be needed to prepare for assessment, or to fund enhancements highlighted as a result of assessment (barrier)	Environmental Scan, Roundtables	<ul style="list-style-type: none"> • See “Competing priorities/limited staff time (barrier)” to address preparation for an Assessment. • Grants have to be available so jurisdictions can develop the enhancements being targeted. • Funding support should come from Immunization Cooperative Agreement. Ideally meeting assessment goals would be a core grant objective and funded accordingly • Advocate for increased funds through current channels

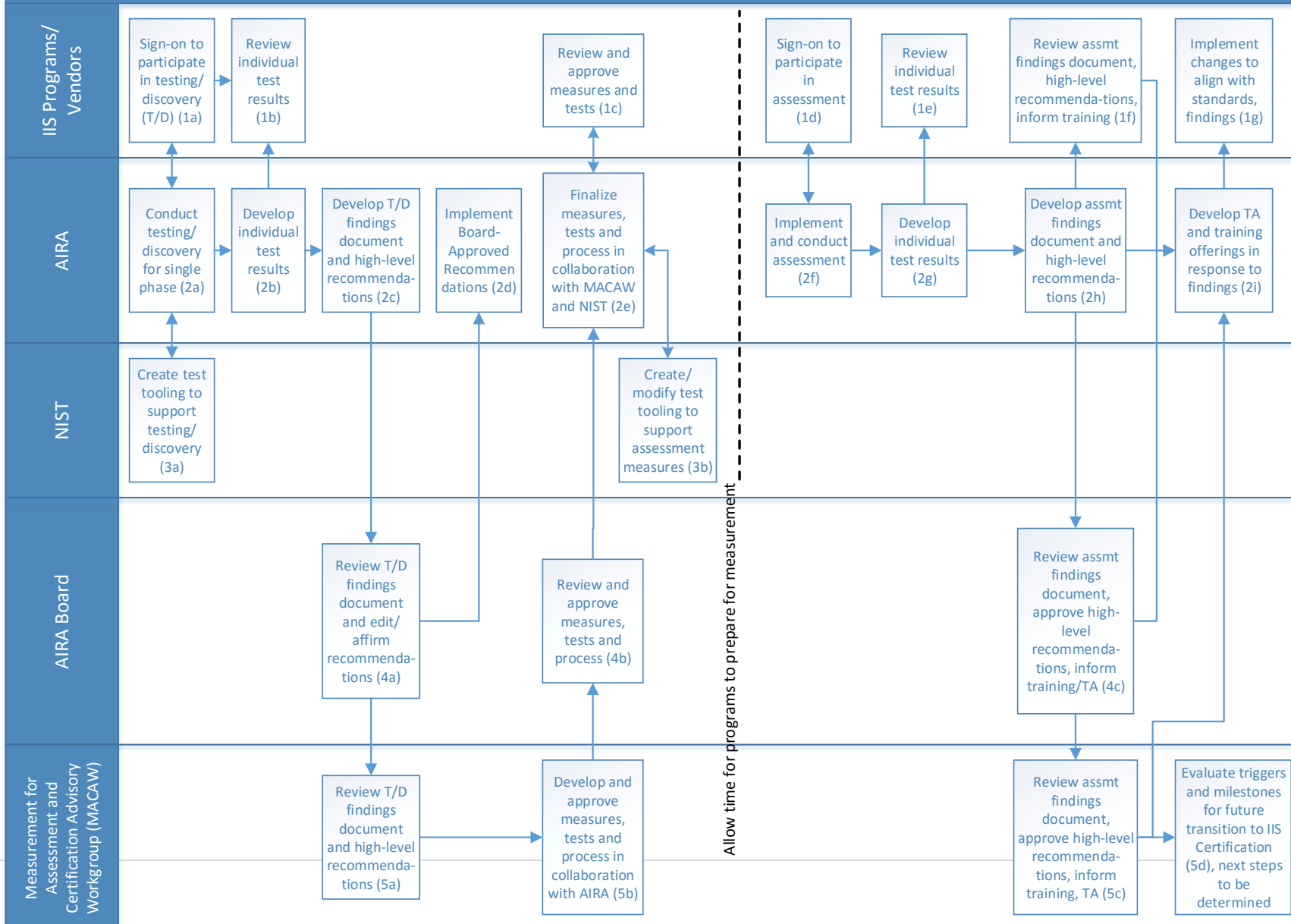
		<ul style="list-style-type: none"> • Advocate for additional funds through new potential channels, explore cost-efficient funding methods (i.e., joint development, shared services), quantify expected costs
Technical assistance may be needed to plan and/or implement enhancements (barrier)	Environmental Scan	<ul style="list-style-type: none"> • Appropriate planning for selected measure needs to factor in technical assistance needs from either CDC or AIRA. • Need to keep phased approach so that these needs are addressed and planned. • Vendor participation will be important here. Vendors will have to be included during the planning phase of the assessment process. Vendors will have to know if they have the technical capability to develop the enhancements needed. • AIRA committees/workgroups; sharing of FDDs/CRs across projects; support from shared vendors. • Collaborate across CDC, PHII, AIRA and IIS vendors to support programs in need of technical assistance
Consequences if IIS does not meet assessment goals (risk)	Roundtables	<ul style="list-style-type: none"> • By objectively defining gaps, programs can use resources to address limitations of the assessment. • Certain measures may be able to be leveraged as a contract performance measure or staff goal. • Need to communicate to the community what the consequences may be, if any. This has to be very clear (does it affect funding an issue, etc.) • Each IIS would need to develop timelines to meet assessment goals in strategic planning. 5 year timeline. Goals could be balance against funding – i.e. with this \$\$ level of financial support IIS can do W, X, Y, and Z. With this \$ level of financial support IIS can do Y and Z • Ensure focus remains on quality improvement, “raising the floor” for all IIS

Measurement Process

Formally, there are three potential planned stages of measurement: IIS Testing and Discovery, Assessment, and Certification. As outlined in the previous section, the assessment process includes multiple partners/stakeholders and multiple layers of review and approval. Phases of assessment will be rolling, with multiple phases in motion and overlapping. The graphic on the following page represents the process steps for the first two stages of measurement (IIS Testing and Discovery, IIS Assessment), and an evaluation point for a future Certification stage. The graphic is followed by an explanation of the individual activities and involvement of various actors within each step of the process:

Process for Three Planned Stages of Measurement: IIS Testing and Discovery, Assessment, Certification, V2

Process is for single phase, to be repeated for future phases - note that some processes will occur simultaneously



Actor or Swim Lane	Step in Process	Text Box	Additional Detail
IIS Programs/ Vendors	(1a)	Sign-on to participate in testing/discovery (T/D)	IIS and vendors are recruited to participate in testing and discovery through a variety of means, including community-wide webinars, direct emails, website recruitment, print and electronic materials, and targeted phone outreach to IIS Managers. AIRA's webpage includes detail about the Interoperability Project in general and about testing and discovery specifically. To sign-on to participate, programs need to provide credentials to allow AIRA and/or NIST access to the program's development platform. Testing and discovery will inform later phases of IIS assessment.
	(1b)	Review individual test results	Following testing/discovery, participating programs are provided with a link to a detailed, site-specific report and/or tool that includes test results and scores. The report was reviewed and vetted with the full IIS community, and continues to be modified and updated based on developing test procedures and user feedback. An enhanced reporting tool will be available early in 2016.
	(1c)	Review and approve measures and tests	Following their development by the Measurement for Assessment and Certification Advisory Workgroup, the measures and tests will be reviewed and approved by the full community through a community comments period followed by a webinar polling opportunity.
	(1d)	Sign-on to participate in assessment	Following a period of time for preparation, IIS will be asked to sign on to participate in a particular phase of development.
	(1e)	Review individual test results	Following assessment, IIS will have the opportunity to review individual test results via a report or online tool.
	(1f)	Review assmt findings document, high-level recommendations, inform training	The community will have an opportunity to review the findings document that results from the assessment testing process, as well as the high-level recommendations. This will serve as the jumping off point for the development of training and technical assistance that will be offered to ensure all IIS can progress toward meeting assessment measures. Detailed input and guidance on training and TA needs will be requested of the IIS community.
	(1g)	Implement changes to align with standards, findings	This step focuses on adopting and implementing changes to better align with standards. Training and TA will support this process.
AIRA	(2a)	Conduct testing/discovery (T/D) for single phase	AIRA staff will use the testing/discovery phase to gather initial findings about IIS status and functionality in each given phase.

	(2b)	Develop individual test results	Individualized results will be available for each IIS in a report and/or in an online tool format. These results may evolve over time as the tests are refined.
	(2c)	Develop T/D findings document and high-level recommendations	A T/D findings document will be created to share results of T/D testing as well as to socialize high-level recommendations resulting from the findings.
	(2d)	Implement Board-Approved Recommendations	AIRA will be one stakeholder among many charged with implementing the recommendations in the findings reports as approved by the AIRA Board.
	(2e)	Finalize measures, tests and process in collaboration with MACAW and NIST	AIRA staff will collaborate with MACAW and NIST in the development and finalization of measures and tests.
	(2f)	Implement and conduct assessment (2f)	Following a period of time for preparation, IIS will sign-on for participation, and AIRA staff will conduct assessment with each IIS.
	(2g)	Develop individual test results	Individualized results will be available for each IIS in a report and/or in an online tool format.
	(2h)	Develop assmt findings document and high-level recommendations	Following IIS assessment, a second findings report will be developed that will contain aggregate results of assessment, along with high-level recommendations.
	(2i)	Develop TA and training offerings in response to findings	In response to the findings documents, and informed by the IIS community, AIRA will develop specific training and TA offerings to help IIS meet assessment measures. These offerings will be available on a rolling basis and ongoing as additional phases of assessment are launched.
NIST	(3a)	Create test tooling to support testing/discovery	NIST is creating testing tools that AIRA will leverage throughout the testing/discovery and assessment process.
	(3b)	Create/modify test tooling to support assessment measures	Following testing/discovery, NIST will continue to modify their testing tools to support IIS assessment.

AIRA Board of Directors	(4a)	Review T/D findings document and edit/affirm recommendations	The AIRA Board will be asked to review and formally vote to approve the testing/discovery findings document and accompanying recommendations.
	(4b)	Review and approve measures and process	The AIRA Board will be asked to review and formally vote to approve the measures and process recommended by MACAW for IIS assessment.
	(4c)	Review findings document and approve high-level recommendations	The AIRA Board will be asked to review and formally vote to approve the assessment findings document and accompanying recommendations.
Measurement for assessment and certification Advisory Workgroup (MACAW)	(5a)	Review T/D findings document and high-level recommendations	The MACAW group will be asked to review in detail the testing/discovery findings document and accompanying recommendations.
	(5b)	Develop and approve measures, tests and process in collaboration with AIRA	The MACAW group will be asked to use the testing/discovery findings document and accompanying recommendations to develop actual measures and thresholds for IIS assessment.
	(5c)	Review assessment findings document and approve high-level recommendations, inform training/TA	The MACAW group will be asked to review in detail the testing/discovery findings document and accompanying recommendations. This will serve as the jumping off point for the development of training and technical assistance that will be offered to ensure all IIS can progress toward meeting assessment measures. Detailed input and guidance on training and TA needs will be requested of the MACAW group.
	(5d)	Evaluate triggers and milestones for future transition to IIS Certification	The MACAW group will use the triggers and milestones developed by the now-disbanded Assessment SME Panel to evaluate a rolling transition to IIS Certification.

Each IIS HL7 interface was categorized and analyzed based on transport layer offering and willingness to participate in the project. Varied analysis techniques were employed due to variation in transport layer offerings.

At the time of analysis (November 2015), it was determined that the CDC WSDL was being developed or was in use by 31 of the IIS HL7 interfaces. In the end, 17 IIS HL7 Interfaces passed CDC WSDL conformance completely. The project also identified that an additional 15 IIS HL7 interfaces are candidates to use the CDC WSDL based on business requirements expressed in their current transport layer offerings. For more details of the full analysis, please see the *AIRA Interoperability Findings Report – Transport Layer*.

Given the overall positive results of this analysis, external conversations, and trends of growing implementers, this report recommends continued education, outreach, and encouragement of CDC WSDL implementation for point-to-point exchange of information.

More specifically, the following actions could be taken to increase adoption:

- It may be worthwhile to encourage adoption by IIS HL7 interfaces who currently support either a Non-CDC WSDL or HTTPS POST where the business requirements show they are a candidate for CDC WSDL usage. These IIS would not be encouraged to shut down their existing transport layers rather they could offer up the CDC WSDL as another option for trading partners.
- IIS should publish and make available transport layer requirements for interoperability partners. The earlier and more easily accessible this information is, the better chance interoperability partners will have at meeting requirements during development time and not during the onboarding process.
- IIS and IIS vendors can and should use the NIST testing site¹⁴ to validate their CDC WSDL implementation.
- This analysis effort should be executed again in the future as the number of project participants grows and these recommendations are implemented. As the number of participants increase, the amount of participants in the least meaningful category should decrease providing a more accurate picture of the national landscape.
- Develop best practices around confidentiality and security including the use of client-side certificates.

Acknowledgement (ACK) Message Format Findings

Another area for testing focused on IIS alignment with standards for acknowledgement messages, referred to as ACK messages. Twenty-one IIS were provided an HL7 message containing three immunizations. The message was modified to meet local requirements allowing the IIS to accept the message. Then the same message was modified to remove one required field and resubmitted. In this particular case, the removed field was the vaccine type of the first immunization. That is, the message contained an immunization with a date, but no vaccine type (e.g., MMR, Varicella, and Hib). It is

¹⁴ <http://hl7v2-iz-r1.5-testing.nist.gov>

believed that this field is critical enough to all IIS that the immunization would not be accepted if this field were not populated.

The resulting acknowledgement (ACK) messages – which tell the sender if the message was accepted by the IIS – were analyzed for conformance against the National HL7 Implementation Guide (IG) and for general understanding as to if the IIS accepted the message or not based on the National IG definitions.

Of the 21 analyzed systems, the following high-level findings were discovered:

- 3 systems conformed to the national IG
 - 1 of these didn't provide any granularity to be useful operationally
- 18 systems failed to conform to the National IG
 - 3 of these met structure but used invalid or inappropriate values in required fields
 - Most failed for 1 of 2 reasons
 - Population of fields defined to be “Not Supported” in the HL7 guide
 - Omission of fields defined to be “Required” in the HL7 guide

For more details of the full analysis, please see the *AIRA Interoperability Findings Report – Acknowledgement (ACK) Message Format*.

Based on the variation and quality of ACK messages, the following recommendations are being provided for consideration.

- **ALIGNMENT:**
 - Encourage IIS to align with release 1.5 of the National IG. Even though release 1.5 can be improved, it is not going to change so drastically that this would be a wasted effort by IIS.
- **FOCUSED GUIDANCE:**
 - Provide a short and directed community-developed Guidance Document to aid IIS implementers as they improve their ACK messages to ensure consistent implementations. It is recommended that this work be vetted through SISC.
- **LONG TERM IMPROVEMENTS:**
 - Plan for updates to release 1.6 of the National IG to create tighter conformance statements. We are hopeful the improvements can come from the Guidance Document.
 - The current processing rules are built from a technical perspective and not a business perspective. In that, all fields that have a usage of Required (R) are treated as equal and the expectation is the same for those fields. Unfortunately, that has turned out to not be true. In some cases, an HL7 formatting field has a usage of Required (R), but is not nearly as important as a patient specific field such as the date of birth.
- **OTHER CONSIDERATIONS:**
 - Consider expanding the ACK message to provide information on partially successful (or accepted) information.

VXU Submission (Interoperability Status Check)

These report findings focused on VXU submissions to an IIS and serve as an update from the 2013 Interoperability Status Check project. The tests used for the 2013 report were repeated for this report during the fall of 2015. The seven test cases were developed by the IIS community based on release 1.4 of the HL7 version 2.5.1 Implementation Guide for Immunization Messaging¹⁵ and are still relevant based on the current landscape of interoperability.

The National Institute of Standards and Technology (NIST) used the seven messages as part of Meaningful Use (MU) Stage 2 certification tests for Electronic Health Records (EHRs). Under MU Stage 2, a certified EHR must be able to demonstrate support for the seven basic test cases.

At the time of this report, 46 (44 IIS and 2 IIS Vendors) had completed VXU Submission testing, with an additional nine working towards completion.¹⁶ In 2013, 33 completed testing with an additional 12 working towards completion.

Of the 46 participants who completed testing, 38 (36 IIS and 2 IIS vendors) allowed AIRA to directly connect and perform the status check while eight IIS performed a self-check. By comparison, 17 were directly connected and 16 performed a self-check in 2013.

Of the 46 participants who completed testing, 19 (17 IIS and 2 IIS vendors) accepted the seven NIST test cases without applying local requirements while 27 (59%) IIS have local requirements. By comparison, 22 out of 33 (67%) were deemed to have local requirements in 2013.¹⁷

The 2015 testing results identified many of the same alignment differences from the National IG as were found in the 2013 report. With increased participants from 2013, no new or never-before-seen issues were discovered. Progress was seen in IIS where active projects were underway to improve alignment with the National IG.

For more details of the full analysis, please see the *AIRA Interoperability Findings Report – VXU Submission - 2015*. For comparison of the 2013 results, see the *Immunization Information Systems Interoperability Status Check report*¹⁸.

This report is recommending IIS focus on the following key areas to improve interoperability through alignment with the National IG:

- **Fix Conflicts:** Conflicts (e.g., Requiring data not supported by the National IG, requiring non-standard HL7 formatting) are not allowed in the constrainable model used by the National IG.

¹⁵ <http://www.cdc.gov/vaccines/programs/iis/technical-guidance/downloads/hl7guide-1-4-2012-08.pdf>

¹⁶ “Working towards completion” can vary from participant-to-participant. Some are very close, while others are willing, but holding off for a bit due to various reasons (e.g., New IIS implementation, upgrading HL7 interface, etc.)

¹⁷ Further discrete criteria were developed between the 2013 report and this report so assignments of Local Requirement and None Found may have shifted slightly between the two reports. Given that, comparing 2013 to this report should be done with caution.

¹⁸ http://www.immregistries.org/resources/aira-initiatives/interoperability-testing-pilot/IIS_Interoperability_Status_Check_Final_Report_v1.0.pdf

These conflicts are often the most difficult to address by an EHR designed to meet the base HL7 standard and the National IG.

- **Vaccine Refusals:** Despite being a core data element and defined in the National IG, many IIS reject messages when the message contains a vaccine refusal. IIS should not reject messages that contain refusals and work to incorporate these data as part of the consolidated information about a patient.
- **History of Disease:** Despite being a core data element and defined in the National IG, many IIS reject messages when the message contains a history of disease. IIS should not reject messages that contain history of disease and work to incorporate this data as part of the consolidated information about a patient.
- **Review/Validate Constraints:** Each IIS should take time to take a fresh look at the constraints they place on the National IG. Each constraint should be considered carefully as each constraint can hamper interoperability and extend on-boarding processes.
- **Acknowledgement (ACK) Message Alignment:** As noted in the ACK Findings Report, the variation that exists in the ACK message makes analysis and understanding of IIS requirements difficult. IIS should focus on aligning with current guidance for ACK messages.
- **Testing Support:** NIST has a test suite where immunization specific messages can be validated for conformance against release 1.4¹⁹ and 1.5²⁰ of the National IG. This tooling is being actively used by EHR developers and is available for use by IIS developers. The tooling is free to use without installation or registration.

In addition to recommendations for IIS, the National IG should consider the following for community discussion:

- **Adult vs. Child:** Several IIS have slightly different requirements for children than they do for adults. This makes logical sense when considering topics like patient consent, patient vs. responsible person address, and funding eligibility. The current National IG may need to consider the differences at some level so that a structured and consistently documented approach is available for local requirements.
- **File and Batch segments:** The National IG allows for the use of – and defines – file and batch headers, but does not promote their use. A limited number of IIS are using file and/or batch segments in varying ways. Any use of these segments is considered a Major Constraint, but the usage of these segments varies amongst IIS. Based on further community discussions, the national IG should explicitly allow or discourage the use of these segments in real-time transactions.

¹⁹ <http://hl7v2-iz-testing.nist.gov/mu-immunization/>

²⁰ <http://hl7v2-iz-r1.5-testing.nist.gov/iztool/#/home>

QBP-RSP – Currently Under Review

Future Considerations:

Milestones and Triggers for Evaluating IIS Certification

The IIS community has been clear in their support of an internally-facing assessment process that allows for third-party measurement of alignment with standards²¹. What has been more nuanced is the community's readiness for a later stage that would involve an externally-facing certification process²². There was concern voiced during the 2015 community roundtable forum that there is still lack of clarity in how to quantify and measure standards, and that IIS credibility could be harmed by prematurely publishing outcomes via an external process. As such, the Assessment Subject Matter Expert (SME) Panel was charged with drafting a set of milestones or triggers to use in considering a future shift to a Certification stage. The following subject areas and milestones offer areas for the Measurement for Assessment and Certification Advisory Workgroup (MACAW) to consider regarding a future transition to Certification.

For additional context, it may be helpful to recognize that there will likely be three distinct stages of AIRA's full standards measurement process:

- Stage 1) IIS Testing and Discovery (underway since mid-2015)
- Stage 2) IIS Assessment (planned to begin in early 2016)
- Stage 3) IIS Certification (potential future stage)

Development of Metrics

The MACAW group will convene in early 2016. This group will be charged with developing formal metrics for IIS Assessment. The development of metrics will be a phased, rolling process, with each phase being released individually. Given that the process of participation is voluntary, IIS will determine which phase(s) of formal assessment they will participate in and when.

Metrics will be informed heavily by the outcomes from the testing and discovery stage that has been underway since Q2, 2015. The first three planned phases of testing and discovery are:

- 1) Message Transport
- 2) HL7 Message Format (VXU, including acknowledgement (ACK) messaging)
- 3) HL7 Message Format (QBP/RSP)

Prior to considering a move from IIS Assessment to IIS Certification, it is critical that clear and quantifiable metrics have been defined for each phase of Assessment.

²¹http://www.immregistries.org/resources/other-aira-resources/Summary_and_Environmental_Scan_of_Assessment,_Certification_Models_-_Final.pdf

²²http://www.immregistries.org/resources/Summary_of_Roundtable_Input_on_Assessment_from_the_2015_AIR_A_National_Meeting_-_Final.pdf

Community Participation

Over and above defined metrics, it is recommended that a threshold be met regarding the proportion of IIS programs participating in a given phase of Assessment. As cited above, IIS will need to volunteer to be included in the denominator for a given phase of Assessment. As a community, the MACAW group may want to see a certain proportion, for example, 80% participation in Assessment prior to considering a shift from Assessment to Certification for a particular phase.

Note that volunteering to participate in IIS Assessment does not necessarily equate with readiness to meet a given measure. There may be additional information and/or technical assistance available to IIS who participate in Assessment, regardless of their readiness to meet a measure. As such, all IIS should be encouraged to participate in IIS Assessment at the earliest possible point.

Achievement of Metrics

A third and final consideration in the move from Assessment to Certification may involve a quantitative threshold of IIS actually meeting given metrics across those IIS participating in Assessment. Among the IIS participating in Assessment, it may be beneficial to see, at minimum, 75% achieving a certain set of metrics that make up a phase of Assessment prior to considering a shift from Assessment to Certification.

Additional Testing Methods

Early phases of testing and discovery, as well as planned phases of IIS assessment, rely on testing IIS pre-production systems through back-end connections. This method of testing has many benefits:

- Once permissions and credentials are gathered from participating IIS, the burden for continued participation is minimal
- AIRA staff can conduct the testing and analysis relatively independently from the program and vendor staff, with the expectation that the testing process will be visible and transparent to participating programs, and test results will be made available to participants.
- Tests can be rerun frequently to provide rapid information on changes and improvements

However, this method also has its limitations:

- Test results are dependent on clear and accurate acknowledgement (ACK) or response (RSP) messaging
- Some findings could get distorted through the HL7 interface
- Although this method works well for interoperability phases, it is not clear how future phases to test deduplication, data quality, data use etc. might be best tested.

The work needed in these early testing areas is still abundant, but in the near future, it is likely that alternative methods of testing will need to be explored. These may include a locally installed application such as the Data Quality Assessment (DQA) tool, an extract of data similar to the Trends in Immunization Practices System (TIPS) within the Sentinel Site program, or other means. Regardless of the method, it is important that future testing approaches continue to move beyond historic methods of IIS self-report to ensure full credibility and comparability.

Conclusion

Near-universal participation of IIS in the testing and discovery phase of this project signals that the need for measurement to assess alignment with standards is broadly recognized as a priority. Early tests and analysis have provided valuable information to use in the establishment of initial measures for IIS Assessment. Even in the first year of IIS Testing and Discovery, findings have increased awareness, incentivized enhancements, and highlighted critical areas where standards themselves are in need of further clarification. As the IIS community moves into formal IIS assessment, this early work will serve as a valuable base from which to develop meaningful measures of success and to meet collective priorities.