AIRA AMERICAN IMMUNIZATION REGISTRY ASSOCIATION

Immunization Information Systems for a New Era

Summary and Environmental Scan

of Assessment and Certification Models

AIRA White Paper

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Executive Summary

The nation's Immunization Information Systems (IIS) have made significant advancements over the past 20 years. IIS have transitioned from state-based childhood immunization repositories into multi-faceted "confidential, computerized, population-based systems"[1] capable of consolidating health information, providing clinical decision support and aggregate data reporting, supporting vaccine inventory ordering and accountability, and aiding in the improvement of quality health care. Interoperability with Electronic Health Records (EHRs) has become a driving priority as IIS fulfill an increasing number of complex functions across the private and public healthcare system.

IIS have led the Public Health community in the development and adoption of standards. IIS programs, in collaboration with the Centers for Disease Control and Prevention (CDC), the Public Health Informatics Institute (PHII), and the American Immunization Registry Association (AIRA), have published numerous guidance documents on topics such as the standards and framework for IIS core data elements, functional standards and requirements, operational processes, and messaging format and transport.

Despite common objectives and generally applied constructs of IIS infrastructure, some operational, functional and technical variances exist within the IIS community. While some variation may stem from state-specific law or policy, other differences may be the result of a range of interpretations or varied timelines for implementing standards. The available standards documents provide valuable qualifying markers for IIS function and operation, but none of these documents provide detailed measures for verifying or certifying IIS performance or adherence to the documented standards/recommendations.

Assessment is defined as an evaluation or measurement of the nature, quality or ability of a system or the data housed within that system. Certification is the measure of a system's ability to conform to a set of predetermined standards, the outcome of which is the written attestation (certificate) of the tested matter's ability to effectively meet or exceed the required standards. For the purposes of this paper, both assessment and certification will be used to discuss potential processes for exploration by the IIS community. The process of assessment or certification testing includes a review and analysis of pre-determined, quantifiable measures relative to the standards deemed critical to overall system operation. New standards would need a window of time for adoption and agreed-upon expectations of timelines for adoption and method of measurement. The implementation of a community-driven IIS assessment/certification process would formalize core IIS functional and operational capacity, support adoption of standards, and provide quantifiable measures for validating IIS system compliance.

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. This document, *Summary and Environmental Scan of Assessment and Certification Models*, provides an

[1] Centers for Disease Control and Prevention. *Progress in Immunization Information Systems – United States, 2012*. (CDC., Dec. 13, 2013). Retrieved from http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6249a4.htm

exploration of various assessment and certification processes used by other organizations in the public health/medical market space and outlines the potential considerations for creating an assessment and/or certification program for IIS.

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. 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 better fine-tune standards and measures themselves, creating an iterative process of improvement of both IIS programs and the metrics used to assess them.

The following initial recommendations are offered for consideration in planning and implementation of an IIS assessment process, and potential certification program. Additional investigation, discussions and considerations will be needed to identify the ideal model for the IIS community. It will be imperative for these efforts to be instituted with appropriate consideration to current IIS functional capacity, CDC-based IIS objectives, current limitations of IIS operational function and technical capacity, and funding constraints.

Given that IIS assessment efforts focused on testing and validating alignment with interoperability standards are currently underway, these efforts will provide early building blocks for a formal assessment process.

■ *Recommendation #1*

The IIS community should be engaged to discuss the strategic benefits and barriers to a phased approach for IIS assessment and certification, and have an opportunity to provide input toward its development. This input should be documented and used to develop planning efforts. The current work on interoperability testing and assessment should continue, and lessons learned should be leveraged to formalize the assessment process. There are a broad range of perspectives on these concepts; every effort should be made to be transparent and inclusive throughout the planning effort.

■ *Recommendation #2*

An appointed, limited duration IIS Subject Matter Expert (SME) workgroup, including IIS and partner organization representatives, should convene to discuss the following aspects of assessment/certification: strategic benefits and barriers, financial benefits and barriers, and implications of each. This workgroup should 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.

Leveraging broad input, this group should evaluate and designate the initial approach and early governance structure for formal uniform assessment of all IIS, evaluating and selecting strategies to mitigate risks and barriers. This SME group should also evaluate the feasibility and cost-benefit of the assessment process transitioning into a formal certification process, and set milestones and triggers for this transition. In outlining the governance structure for assessment, a primary component should include defining and conducting the selection process for an ongoing Planning/Steering Committee, at which point the IIS SME workgroup will disband.

■ *Recommendation #3*

An ongoing Assessment Planning/Steering Committee should be initiated through the appointment of IIS community members and partners/stakeholders, according to the recommendations outlined by the SME workgroup (Recommendation #2). 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 Implementation Plan should strongly consider employing a phased approach to assessment with the staged introduction of standards and measures. It should also be cognizant of the range in size and resources of IIS across the community, and be scalable to meet the needs of both large and small IIS. The Committee should 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 Committee may become the formal certifying body, or may appoint another organization or group to fill this role. Clear community support must exist prior to finalizing the decision to launch an external certification process.

■ *Recommendation #4*

Technical assistance, consultation, and, where needed, financial support should be available to assist IIS in all phases of both assessment and certification, including preparation for the process, implementation and measurement of metrics, as well as responses and enhancements as a result of assessment/certification findings. Additional financial support may also be needed to facilitate the development and maintenance of the assessment/certification governance structure as well. Decisions regarding which programs receive funding and for what assessment/certification related purposes should be made transparently and with significant IIS community input. Appropriate resources will be essential to ensure a process with broad acceptance and sustainability.

This document is not intended as a comprehensive IIS assessment and/or certification reference guide. The information contained herein should be viewed as the foundation upon which a national-level assessment and/or certification model strategic plan could be created and implemented, with the inclusion of added insights and direction by the IIS community, AIRA, CDC, and related stakeholders. Further discussion is warranted before proceeding, as there are a significant number of variables requiring IIS community input and consensus.

Introduction and Background

The nation's Immunization Information Systems (IIS) have made significant advancements over the past 20 years. Once known as "registries," IIS have transitioned from state-based childhood immunization repositories into multi-faceted "confidential, computerized, population-based systems"[1] capable of consolidating health information, providing clinical decision support and aggregate data reporting, supporting vaccine inventory ordering and accountability, and aiding in the improvement of quality health care. As increased efforts focus on achieving a national-level health information exchange (HIE) infrastructure, IIS are becoming increasingly recognized as an integral component in the electronic health information interoperability movement, including the requirement for electronic health records to report to IIS as part of Meaningful Use (MU) attestation.

Despite common objectives and generally applied constructs of IIS infrastructure, some operational, functional and technical variances exist within the IIS community. The Centers for Disease Control and Prevention (CDC) Immunization Information System Support Branch's (IISSB) *IIS Functional Standards* were created in an effort to aid in identifying "operational, programmatic, and technical capacities that all IIS should achieve." [2] The Public Health Informatics Institute's (PHII) *Defining Functional Requirements for Immunization Information Systems* document defines "a full range of important IIS functions." [3] The American Immunization Registry Association's (AIRA) Modeling of Immunization Registries Workgroup (MIROW) has developed several documents to be used as IIS road maps. The MIROW documents provide best practice guidelines in the form of IIS business rules and processes, along with general recommendations for "challenges to and solutions for implementing" [4] IIS functions and operations for selected topics.

These resources created by CDC IISSB, PHII and AIRA MIROW are actively referenced and leveraged by IIS projects as the basic framework for current IIS architecture and ongoing development. Although the documents provide valuable qualifying markers for immunization information system function and operation, none of these documents provide detailed measures for verifying or certifying IIS performance or adherence to the documented standards/recommendations. The CDC defines a fully operational IIS as one that "meets all IIS functional standards and in turn, allows IIS programs to effectively receive, use, and share immunization data in an efficient, consolidated manner." [5] Thus far, the CDC definition has aided the IIS community in general system development and prioritization of emerging business needs; but in order to build the necessary framework for ensuring national-level IIS comparability and functional capacity, IIS will require a greater level of standardization in technical capacity and operational functions for matrices to be developed, and a transparent, uniform method for assessing adherence with standards is essential.

[2] Centers for Disease Control and Prevention. *IIS Functional Standards, 2013-2017*. (CDC., N.d.). Retrieved from http://www.cdc.gov/vaccines/programs/iis/func-stds-table.pdf

[3] Public Health Informatics Institute. *Defining Functional Requirements for Immunization Information Systems*. (Public Health Informatics Institute. N.d.). Retrieved from http://www.phii.org/sites/default/files/resource/pdfs/IIS%20FINAL%2010302012.pdf

[4] American Immunization Registry Association. *MIROW Best Practices*. (AIRA., N.d.). Retrieved from http://www.immregistries.org/resources/aira-mirow

[5] Centers for Disease Control and Prevention. *IIS Functional Standards, 2013-2017*. (CDC., N.d.). Retrieved from http://www.cdc.gov/vaccines/programs/iis/func-stds.html

Similar to the collaborative efforts between the Centers for Medicare and Medicaid Services (CMS) and the ONC-Approved Accreditor (ONC-AA) which resulted in the development of ONC-based standards for electronic health records (EHR) standardization and assessment/certification, exploratory efforts should be initiated within the IIS community and among related immunization information system stakeholders to increase IIS consistency and adoption of technical and functional standards. The implementation of an IIS assessment/certification process would formalize core IIS functional and operational capacity, standardize system design, and provide quantifiable measures for validating IIS system compliance.

AIRA's Strategic Plan (2013-2016) includes an objective related to the exploration of IIS assessment/certification, including the evaluation of financial and strategic benefits and the necessary considerations for establishing a certifying body and governance structure. This document provides an exploration of various assessment/certification processes used by other organizations in the public health/medical market space and outlines the potential benefits of creating an assessment/certification program for immunization information systems. This exploratory effort was performed between June and December 2014. The findings in this document represent the first step of exploring possible assessment/certification models, but additional discussion and investigation will be needed for the preparation, planning and commencement of a national IIS measurement process.

Assessment/Certification and Environmental Scan

Assessment is defined as an evaluation or measurement of the nature, quality or ability of a system or the data housed within that system. Certification is considered to be a mark of proficiency, an official recognition. Terms commonly used in conjunction with "certification" include accreditation, attestation, or conformance testing. Certification is the measure of a system's ability to conform to a set of predetermined standards, the outcome of which is the written attestation (certificate) of the tested matter's ability to effectively meet or exceed the required standards (e.g. Gold Star, Good Housekeeping Seal, Stamp of Approval).

Assessment or certification can be performed by an external or internal body. For the purposes of this paper, both assessment and certification will be used to discuss potential processes for exploration by the IIS community. The process of either assessment or certification testing includes a review and analysis of pre-determined, quantifiable measures relative to the standards deemed critical to overall system operation. New standards would need a window of time for adoption and agreed-upon expectations of timelines for adoption and method of measurement. IIS assessment/certification could potentially be accomplished on two fronts: 1) system assessment/certification, and 2) data assessment/certification.
System assessment/certification (also known as conformance testing) focuses on functional aspects of an application and how well a system performs those functions. System assessment/certification is comprised of a series of universally applied tests that an application must adequately perform to produce a specified result. If a system can perform the function

with the desired result, a passing score is awarded. If a passing score is awarded for all of the required tests, the system may then be acknowledged as being certified, or of meeting a certain assessment/certification level (e.g., silver, gold, platinum). Assessment/certification may be recognized for the system as a whole or for functional areas (e.g. vaccine ordering and inventory management). Assessment/certification may be a one-time event, or may be assessed more often as new core requirements emerge or as technology evolves. Tests are defined by a panel of experts, and each test details a specific functional element (e.g. adding a lot number). A test unit is generally comprised of a test description, how the test will be conducted, what data is needed to perform the test, and what the expected outcome must be to pass the test. Testing is typically performed by an external, authorized entity that has been specially trained in how to administer and evaluate the various assessment/certification tests.

Data assessment/certification can be accomplished through validation of data entry professionals, data import profiles or import file data, and/or the quality of the data/database based on an established national benchmark as an incentive to achieve and maintain the highest data standards. Data assessment/certification may be performed in-house through self-assessment, through the use of standardized and/or centralized assessment tools, or through a process performed by an authorized third party entity.

The following environmental scan explores current assessment and certification models used across the clinical health and public health arenas that could potentially be adapted to meet the needs of an IIS certification program. This scan was performed between June and December 2014 and included assessments of models for certifying electronic health systems, data, organizations and individuals. A summary of the electronic health systems, data and organizational assessment/certification processes has been provided below. Although models for certifying individual personnel provide information that should be considered for IIS assessment/certification policy development, they have not been summarized in this section as these models more directly impact end users and are more relevant to state-level initiatives. More detailed documentation on all assessment/certification models and processes can be found in the Public Health Assessment and Certification Models spreadsheet, created as a companion piece to this document.

The following summary provides initial insights into assessment/certification structuring, including development and formalization, creation of minimal standards and testable measures, and required certifying and governance bodies. The information included below, and in the Public Health Assessment and Certification Models spreadsheet, is not intended to be a comprehensive compilation of all available clinical and public health assessment/certification models; rather, it is a summary of those models considered most applicable to IIS assessment/certification (e.g. structuring, standards and measures development, and governance and certifying body structures).

System Assessment and Certification Models

System Assessment and Certification Models include those that certify a software system and/or functional elements of a software system. The environmental scan included a review of the following:

- National Institute of Standards and Technology (NIST)
- Certification Commission for Health Information Technology (CCHIT)
- Surescripts

National Institute of Standards and Technology (NIST)

The National Institute of Standards and Technology (NIST) is focused on actively pursuing the standards and measurement research necessary to achieve the goal of improving healthcare delivery through information technology. NIST has been tasked with establishing functional and conformance testing requirements, test cases and test tools in support of EHR applications wishing to pursue voluntary certification of defined meaningful use requirements.

NIST has developed an extensive set of approved test procedures focused on various functional standards of EHR performance. The tests designed by NIST must be performed by an authorized testing and certification body. These entities have applied to The Office of the National Coordinator for Health Information Technology (ONC) and demonstrated the ability and competency to administer the certification tests. A list of approved certification bodies is provided on the ONC website. The authorized tester will then work with the vendor who is responsible for supplying the data and demonstrating the required function(s). After an EHR has been certified, it is listed on the ONC's Certified Health IT Product List and posted to the ONC website.

NIST provides testing guidance, tools, environments and resources to support the certification process. NIST does not establish the standards, perform the actual certification, or conduct any of the functional/operational testing. NIST is responsible for taking existing standards, developing tools to test conformance with the standards, and providing these tools/guidance to the approved certification bodies.

ONC provides administrative oversight and governance of the NIST certification activities. EHR vendors are not required to certify their product; however, the NIST certification is an indication to prospective consumers that the product has met or exceeded the ONC/NIST functional standard conformance.

Table 1. High-Level Summary Evaluation: NIST as a Model for IIS Certification

Pros /Benefits	Cons/Barriers
■ Testing tools are designed based on federal standards and can be applied to any EHR product/environment ■ Approved test procedures are posted to the NIST website for easy review and access ■ Established ONC process for certifying the certification bodies ■ Certified personnel work with the vendors/developers to perform certification testing ■ Voluntary participation ■ Both certified certification bodies and certified EHR products are posted on the ONC website for easy access/review ■ Division of governance/oversight, test procedure development, and performance of certification activities minimizes potential conflicts of interest	■ Cost to certify is borne by the vendors/developers - these costs are not regulated by ONC and are determined by the individual certification entities ■ Voluntary participation

The NIST certification model could be applied to IIS assessment/certification by leveraging similar tools and methods for validating IIS functional competence for common IIS standards and business processes.

Certification Commission for Health Information Technology (CCHIT)

The examination below is based on the Certification Commission for Health Information Technology's (CCHIT) role as the sole EHR certifying body for Health Information Technology for Economic and Clinical Health (HITECH) Act and Meaningful Use (MU) attestations [prior to the announcement in January 2014 that the Office of the National Coordinator for Health Information Technology (ONC) would be implementing an Approved Accreditor's (ONC-AA) process for certifying the ONC Authorized Certification Bodies (ONC-ACBs)].

While CCHIT was responsible for certifying/overseeing EHR MU attestation, the organization was governed by the Board of Commission – a panel of primary users and constituents formally appointed by the board and serving multiple-year terms, including formerly chartered CCHIT staff with no voting rights or authority. The Board was responsible for defining the scope, standards and necessary testing for electronic health record vendor certification.

Reporting to the board was a pool of jurors (users, medical directors, practicing physicians and licensed clinicians), all of whom were appointed to serve one-year terms and were randomly and anonymously assigned to perform three-juror panel EHR certification processes. A CCHIT appointed-proctor collected the jurors' findings and presented them to the CCHIT Board of Commission for final approval and certification ruling. All certification processes, e.g., demonstration and corrective measures, were performed virtually and within a required eight-hour period, to minimize cost. Prior to performing the processes for certification, EHR vendors were required to prepare and submit a written attestation statement and provide proper support documentation.

The entire EHR certification process was prepared by the Board, with open public feedback, published comment and expressed modifications. The Certification Commission for Health Information Technology's certification process was a detailed three-year road map with a required 18-month prior notification for changes or modification to the certification standards and testing.

Table 2. High-Level Summary Evaluation: CCHIT as a Model for IIS Certification

Pros /Benefits	Cons/Barriers
■ Transparent process, open to published public feedback and comment ■ 3-year roadmap with required notification for revisions	■ 100% virtual certification process could be difficult to implement ■ Cost for jurors and required certification documentation ■ Board defined certification scope, standards and testing, absent of stakeholder involvement, i.e., potential oversight of variances in state-defined legislation and policy

The CCHIT certification model could be applied to IIS assessment/certification by leveraging seasoned IIS community members to serve on the assessment/certification panel and conduct certification activities for a specified number of projects (i.e. a peer reviewed certification process).

Surescripts

Surescripts is reportedly the nation's largest health information data exchange and messaging network. Surescripts enables the sharing of prescription benefits and routing, as well as client medication and immunization histories, between healthcare clinics, physicians and pharmacies. Surescripts acts as a third-party facilitator of data between two or more entities serving as a data hub. Surescripts ensures that data is "served" to the receiving entity using industry-approved messaging formats and content.

Specifically for e-prescribing, Surescripts has developed a software certification process for vendors interested in connecting through the Surescripts network. In order for a provider to participate in e-prescribing, they must use either specialized e-prescribing software or an EMR product that has been certified to connect through Surescripts. The certification process "validates that the software is able to send and receive electronic messages in accordance with industry standards and that it is providing open choice for medication selection and dispensing location"[6]. The Surescripts certification focuses on the functional requirements of generating and transmitting the data file, not the overall software product.

Although the National Council for Prescription Drug Programs' (NCPDP) Board of Trustees is the final authority on all industry standards, the Standardization Committee is responsible for the development and maintenance of the council's standards documents. Public comment is solicited on proposals for new and revised standards, and involves a membership ballot process. The NCPDP is accredited by American National Standards Institute (ANSI), the ONC HIT approved accreditor for Meaningful Use attestation and certification. Members of the NCPDP Board of Trustees, Work Group and Standardization Co-Chairs and Committee members are required to sign a confidentiality and non-disclosure agreement.

Surescripts certified vendor software is tested and approved (certified) by documentation and certification tools designed by the Surescripts Board (certifying body). All software vendor applications must be developed to meet the specifications and qualitative measures dictated in the Surescripts Implementation Guide, based on the NCPDP Script Standards. The software vendor is solely responsible for development, testing and quality assurance. The certification process can take between 3-6 months.

Table 3. High-Level Summary Evaluation: Surescripts as a Model for IIS Certification

Pros/Benefits	Cons/Barriers
■ Nationwide system (network, hub) ■ Shared environment ■ Stakeholder feedback and involvement ■ Membership ballot approach	■ Board-defined national-level standards and testing/ stakeholders provided opportunity for public comment but not included in initial development ■ Lack of congruency with state legislation and policy ■ Software vendor solely responsible for testing

The Surescripts certification model could be applied to IIS certification by adopting this method to "certify" EHR systems for IIS data imports. Many IIS projects are already doing this to some degree, but adopting the Surescripts model would formalize this process on a national level.

[6]Surescripts. What is Surescripts Certification? (Surescripts FAQ, N.d.). Retrieved from http://surescripts.com/support/faqs/technology-vendors/detail/what-is-surescripts-certification

Data Assessment and Certification Models

Data Assessment and Certification Models include those that evaluate and certify data in a public health system, or inbound data from external sources, based on the common data quality principles of completeness, accuracy and timeliness. The environmental scan included a review of the following Data Assessment and Certification Models:

- National Association for Public Health Statistics and Information Systems (NAPHSIS)
- North American Association of Central Cancer Registries (NAACCR)
- BioSense 2.0

National Association for Public Health Statistics and Information Systems (NAPHSIS)

The National Association for Public Health Statistics and Information Systems (NAPHSIS) "is the national nonprofit organization representing the state vital records and public health statistics offices in the United States." The NAPHSIS mission is "to provide national leadership for both vital records and related information systems in order to establish and protect individual identity and improve population health."[7] NAPHSIS and the National Center for Health Statistics (NCHS) work collaboratively to identify the requirements for the Vital Statistics Cooperative Program (VSCP) contracts and to negotiate funding for each state's reported birth, death and fetal death data. This data is used for national statistics. States do not receive funding until the required statistics have been reported.

Each state establishes laws and regulations regarding vital records and vital statistics reporting based on: 1) NAPHSIS' Model Law, created to help define and establish improved uniformity in data procedures and reporting; and 2) the U. S. Standard Certificates of Birth, Death and Fetal Death, first created in 1989 (current version, 2003).

From 2011-2012, a voluntary workgroup, composed of NAPHSIS members and representatives from NCHS, developed the **101 Vital Statistics Standards**. The standards were formally approved by NAPHSIS members in 2012 and intended to be a more expansive guide for vital records and vital statistics operations. The standards are broken into 10 focus areas, including: data collection, data transmission, data analysis and data preservation. Each data standard includes a Target (e.g., 98% of data should be reported electronically), a Reference (e.g., national best practice or guideline) and a Documentation (e.g., measure). The 101 Vital Statistics Standards is a voluntary, self-assessment tool. There is currently no formalized process for the review and/or revision of the standards.

In early 2015, NAPHSIS will begin work with the Public Health Accreditation Board (PHAB) to develop a standardized data reporting model, based on NAPHSIS' 101 standards and modeled after PHAB's accreditation processes. NAPHSIS is the first public health program to collaborate with PHAB to develop a public health program-specific accreditation model for standardizing data reporting. Draft proposals from this work are expected to be finalized by May 2015 and presented for NAPHSIS membership review during the annual NCHS conference in Pittsburgh (June 2015).

[7]National Association for Public Health Statistics and Information Systems. *About NAPHSIS.* (NAPHSIS., N.d.). Retrieved from http://www.naphsis.org/about-naphsis

Table 4. High-Level Summary Evaluation: NAPHSIS as a Model for IIS Certification

Pros/Benefits	Cons/Barriers
■ 101 Data Standards are approved by NAPHSIS members ■ States' contract requirements are included within the data standards ■ Each data standard includes a description with an example (e.g., guideline or best practice) and a target (i.e., measure) ■ Voluntary self-assessment tool	■ State established laws and regulations ■ Voluntary self-assessment tool ■ Currently no certification process for vendor systems, i.e., no standardized system in use by each states' Vital Records

The NAPHSIS certification model could be applied to IIS assessment/certification through implementation of a voluntary, self-assessment of data quality (or IIS functional standards). The AIRA Assessment Steering Committee explored early efforts for self-assessment with their IIS Assessment Tool, but uptake was not widespread.

North American Association of Central Cancer Registries (NAACCR)

The North American Association of Central Cancer Registries (NAACCR) is a "professional organization that develops and promotes uniform data standards for cancer registration; provides education and training; certifies population-based registries; aggregates and publishes data from central cancer registries; and promotes the use of cancer surveillance data and systems for cancer control and epidemiologic research, public health programs, and patient care to reduce the burden of cancer in North America."[8] The NAACCR registry certification process is conducted annually by the Registry Certification committee (the NAACCR certifying body), a subcommittee of what was formerly known as the Data Evaluation and Certification Committee (DECC). Once certified, a registry is authorized to use the official NAACCR certification logo, respective to the level of certification received – Gold (highest standard) or Silver (high standard). All 50 states currently participate in the NAACCR's voluntary registry certification process and receive a Gold or Silver certification mark.

The initial NAACCR certification criteria and measures were established by the DECC, tested by the registries, and revised as necessary. After the required revisions, the certification criteria and measures were presented for public comment and any necessary final modifications were made before being presented to the NAACCR Board of Directors for approval. The entire process took approximately 18 months. This formal vetting process was not leveraged as part of the certification criteria and measures adoption process; it was not deemed necessary because the certification criteria and measures were developed by registry personnel for the registries. Additional information on the NAACCR certification criteria and measures can be found within the Public Health Certification Models spreadsheet.

NAACCR does not have a formal or ongoing review process for certification criteria and measures. The initial certification criteria and measures adoption process guaranteed the

[8]North American Association of Central Cancer Registries. *North American Association of Central Cancer Registries, Inc. Bylaws.* (NAACCR., N.d.). Retrieved from http://www.naaccr.org/AboutNAACCR/Bylaws.aspx

incorporation of requirements which met the lowest common denominator for all registries, independent of outside influence, while emphasizing data completeness, accuracy and timeliness. When certification concerns do arise, the NAACCR Board of Directors issues a call for the formation of a voluntary committee to address and resolve certification issues.

The NAACCR Board of Directors governs the NAACCR certification process. Board participants carry staggered terms and members include the president (2 year term), past president (2 year term), executive director, treasurer and sponsoring member organizations' representatives, which include national organizations such as the National Cancer Society and exclude those federal agencies funding the registries.

NAACCR offers a mentor fellowship program worthy of additional investigation by AIRA. The mentor program is designed "to provide one-on-one, hands-on training in a registry operation to central registry staff (or other comparable work site) with another central registry acting as the mentor. The goal is to provide an opportunity for an in-depth, on-site, and interactive experience in cancer registry operations."[9] It is presumed the mentor would also be used to provide technical support and assistance, and to assist the mentee organization in preparing for the process of certification.

Table 5. High-Level Summary Evaluation: NAACCR as a Model for IIS Certification

Pros/Benefits	Cons/Barriers
■ Voluntary, i.e., encourages community engagement ■ Certification process emphasizes lowest common denominator for all cancer registries ■ Certification process, criteria and measures were/are developed/supported by the registries ■ Ability to leverage voluntary certification participation for the acquisition of new/added funding streams ■ Uniformed, minimal data standards ■ Official certification achievement recognition – Gold and Silver Standards ■ Mentor Fellowship Program	■ Voluntary, i.e., ability to opt out of participation ■ Extensive resources necessary for performing the annual certification process ■ No formalized process for the ongoing review of and modifications/additions to certification criteria/measures

The NAACCR certification model could be applied to IIS data assessment/certification by leveraging similar methods for conducting a uniform IIS data quality assessment through the use of a centralized testing tool and data specification, combined with a uniform timeframe for conducting the assessment of all projects. Certification levels would then be determined based on the data quality score of each project.

[9]North American Association of Central Cancer Registries. *Mentor Fellowship Program: Description of Program.* (NAACCR., January 2010). Retrieved from http://www.naaccr.org/LinkClick.aspx?fileticket=a_B263QJWUY%3d&tabid=102&mid=442

BioSense 2.0

BioSense 2.0 is a national, cloud-based syndromic surveillance system which "gives participating health departments easily managed, on-demand access to a shared pool of configurable computing resources such as networks, servers, software, tools, storage, and services, with limited need for additional IT support. Through the use of these common resources, BioSense users gain significant efficiency, cost reduction, and information-sharing capabilities. With distributed cloud computing, each BioSense participant controls its portion of the cloud and its data. BioSense also provides local and state users free secure data storage space, an easy-to-use data display dashboard, and, most importantly, a shared environment where users can collaborate and advance public health surveillance practice. BioSense is the only public health surveillance system that enables state and local health departments and CDC to quickly share health information with each other across city, county, or state jurisdictions."[10]

BioSense users must be approved for data submission through data testing with their state/local health jurisdiction and must submit a Data Usage Agreement (DUA) with the Association of State and Territorial Health Officials (ASTHO). There is no cost to users of the BioSense application, although there are financial implications tied to the process of onboarding, ongoing data submission and monitoring, and the necessary jurisdictional management of the DUA.

The use of BioSense 2.0 is completely voluntary. Approximately two-thirds of those jurisdictions participating in BioSense continue to rely on their own public health system as their primary surveillance source, due to familiarity and comfort, and a concern about BioSense data quality. Data added to BioSense 2.0 is organized into jurisdictional "lockers." The jurisdictions control their own data and authorize data sharing with other jurisdictions and/or the CDC. Jurisdictions are not required to send syndromic surveillance (SS) data, nor SS summary data, to the CDC. The concept of jurisdictional data lockers enables each jurisdiction to make their own determination regarding any legal rights, including state and local laws, to share data with the CDC.

Thirty-two data elements form the BioSense 2.0 standards and measures, as determined by the application's vendor. These standards and measures were taken from the International Society for Disease Surveillance (ISDS) Meaningful Use Workgroup's Core Process and EHR Requirement for Public Health Syndromic Surveillance document (2011) and are categorized into the three main data element categories: Treatment Facility Identifiers, Patient Demographics and Patient Health Indicators. There is no formalized process for certifying system capabilities to exchange data with BioSense. Each state/local health department jurisdiction is responsible for establishing their own reporting requirements. Meaningful Use reporting requirements provide general guidance and conformity to messaging standards, but do not address issues with the jurisdictional variances in data reporting formats and structures (e.g., duplication, data quality).

The users preside over BioSense 2.0 employing a representative governance model with participation by ASTHO, the Council of State and Territorial Epidemiologists (CSTE), the International Society for Disease Surveillance (ISDS), the National Association of County and City Health Officials (NACCHO), the U.S. Department of Defense (DoD), the U.S. Department of

[10]Centers for Disease Control and Prevention. *BioSense Features*. (CDC., N.d.). Retrieved from http://www.cdc.gov/biosense/features.html

Veteran's Affairs (VA), CDC and local non-public health data providers (e.g., hospitals, EHR vendors, etc.). The BioSense Governance Group is facilitated by the CDC and charged with strategic planning; constituent representation, including relaying recommendations and resolving disputes; and the identification and recommendation of new data and functionality standards, through the creation of workgroups.

The BioSense charter specifies the authorities and policies of the elected governance body. "Associated Organizations" (e.g., health jurisdiction, individual health facilities and/or hospitals) are the 'certifying' bodies of BioSense and mediate onboarding and data submissions, per the DUA, within their jurisdictions.

Table 6. High-Level Summary Evaluation: Biosense 2 as a Model for IIS Certification

Pros/Benefits	Cons/Barriers
■ Nationwide system (Network/Hub) ■ Federal standards ■ Shared environment ■ Uniform application structure, i.e., tables ■ National-level IT support ■ No cost for system access ■ No cost, secure data storage ■ Jurisdictional control of data, with ability to assign permission rights to data ■ Voluntary process	■ CDC facilitation may create perception of top-down governance ■ Jurisdictional variances in reporting requirements, i.e., no 'true' certifying body or fully standardized process ■ Continued reliance on own surveillance system as primary, i.e., voluntary BioSense reporting ■ Costs for jurisdictional onboarding, data submission and monitoring ■ Voluntary process

The BioSense certification model is less applicable to IIS assessment/certification, but more applicable to building a case for centralized, platform neutral development of shared functions (e.g. forecasting, vaccine ordering). An IIS could then be "certified" to connect with or leverage these national tools.

Organizational Assessment and Certification Models

Organizational Assessment and Certification Models focus on certifying an organizational entity based on compliance with an agreed upon set of standards and/or performance measures. The environmental scan included a review of the following:

- Public Health Accreditation Board (PHAB)
- The Joint Commission
- American Association of Cardiovascular and Pulmonary Rehabilitation (AACVPR)

Public Health Accreditation Board (PHAB)

As part of their 2004 Futures Initiative, the CDC determined accreditation of public health agencies was a "key strategy for strengthening public health infrastructure."[11] As a result of CDC's position, a group of national public health stakeholders convened and agreed to investigate a voluntary accreditation program. In 2005, the Exploring Accreditation Steering Committee and sub-workgroups designed and proposed an accreditation model which was presented to public health officials for feedback and comment in 2006, and resulted in the steering committee's conclusion that accreditation was both necessary and achievable. The Public Health Accreditation Board (PHAB) was formed to oversee national public health department accreditation and in 2007, program development began.

The Public Health Accreditation Board is a partnership of the American Public Health Association (APHA), the Association of State and Territorial Health Officials (ASTHO), National Association of County and City Health Officials (NACCHO), the National Association of Local Boards of Health (NALBOH), the National Indian Health Board (NIHB), the National Network of Public Health Institutes (NNPHI), and the Public Health Foundation (PHF). National-level public health department accreditation is based on a set of standards and measurements which are comprehensive and encompass all governmental health department structures, e.g., tribal, state, local or territorial. The accreditation program is overseen by the PHAB Board of Directors (a panel of national public health leaders) and facilitated by the Accreditation Committee.

A draft version of the performance-based accreditation standards and measures was prepared in 2009 and available for public comment, for three months. The PHAB Standards Development Workgroup reviewed over 4,000 comments, proposed necessary modifications, and prepared the revised standards and measures for beta testing with 30 public health departments across the United States. During beta testing, the public health departments provided PHAB with crucial feedback which was used to revise the accreditation process a final time. In 2011, the PHAB Standards Development Workgroup and the PHAB Assessment Process Workgroup released the finalized documentation and launched the accreditation process.

Public health department accreditation is voluntary with a 5 year approval status. The accreditation standards and measures are maintained by PHAB's Assessment Process and Standards Development workgroups, which consist of state and local public health professionals, national and federal public health experts, public health researchers and other technical experts. All accreditation standards and measures are approved by the PHAB Board of Directors following required revisions.

[11]Public Health Accreditation Board. *Public Health Department Accreditation Background*. (PHAB., N.d.). Retrieved from http://www.phaboard.org/about-phab/public-health-accreditation-background/

Table 7. High-Level Summary Evaluation: PHAB as a Model for IIS Certification

Pros /Benefits	Cons/Barriers
■ Stakeholder feedback and involvement ■ Inclusive to all public health department structures ■ Certification Beta Testing ■ Voluntary process	■ Inclusive to public health department structure / does not consider private healthcare sector ■ 7 years of preparation and planning-initiation to official launch ■ Voluntary process

The PHAB certification model could be applied to certifying an IIS Program's compliance with basic awardee objectives and performance measures.

The Joint Commission

The Joint Commission, formerly The Joint Commission on Accreditation of Health Care Organizations (JCAHO), accredits national health care organizations (e.g., hospitals, Ambulatory Health Care, Behavior Health Care and laboratory services), and certifies national health care organization-based programs (e.g., asthma, diabetes and heart disease). Requirements and standards are based on organization function specific to the Health Care Organization (HCO) or HCO program being accredited/certified. Specific standards are developed with input by government agencies, professionals and subject matter experts within the area of specialty, employers and consumers, and created with considerations to scientific literature and expert consensus.

Draft standards and core measures are prepared for input by external task forces, focus groups, experts and stakeholders, reviewed by Professional and Technical Advisory Committees (PTACs), and then distributed for national review and comment. Following national feedback, the PTACs make final revisions approved by the Standards & Survey Procedures (SSP) Committee and publish the standards and measures, unless the Board of Commissioners request additional discussions and considerations. Modifications to the standards are identified through scientific literature, the Joint Commission's standing committees and advisory groups, accredited organizations, professional associations and consumer groups. All HCO and HCO program standards are approved by the Board of Commissioners.

The typical process includes an application submitted to The Joint Commission along with the specified fee. The requesting entity then performs a self-assessment to prepare for the official visit. An onsite survey is then conducted by The Joint Commission that concludes with a survey summary and post survey activities. After the post survey activities have been completed, the entire package is reviewed for certification/accreditation approval.

Accredited HCOs and certified HCO programs receive The Joint Commission's Gold Seal. Accreditation is awarded for three years (some exclusions apply) and certification is for two

years, with related fees charged annually; cost varies and includes considerations for the number of HCO locations and the volume of individuals served. Both the accreditation and certification processes are voluntary.

Table 8. High-Level Summary Evaluation: The Joint Commission as a Model for IIS Certification

Pros /Benefits	Cons/Barriers
■ Stakeholder feedback and involvement ■ Receive Gold Seal for certification ■ Require repeat accreditation/certification every 2-3 years ■ Cost varies, based on size/volume ■ Ongoing monitoring for required standardization revisions ■ Voluntary process	■ Extensive resources necessary for performing the annual certification process ■ Cost to certify is borne by the requesting entity ■ Voluntary process

The Joint Commission's certification model provides another example of how an IIS Program could be certified based on compliance with basic awardee objectives and performance measures.

American Association of Cardiovascular and Pulmonary Rehabilitation (AACVPR)

The American Association of Cardiovascular and Pulmonary Rehabilitation (AACVPR) offers two levels of certification – one for facility level certification and one for certification of medical professionals (*not covered here*). The facility, or program, level certification is "designed to review individual facilities for adherence to standards and guidelines developed by the AACVPR and other professional societies"[12].

The certification program is overseen by the AACVPR Board of Directors. The certification process follows a peer-review format administered by the Program Certification Committee. Initial certification cost is around $730 for new certifications and $620 for recertification. These fees help to cover costs of administering the program. The AACVPR certification program is comprised of four panels/teams staffed by volunteer personnel:

- Expert Panel: reviews and establishes the standards for certification
- Application Review Panel: reviews all certification applications for conformance with basic guidelines and requirements
- Mentorship Team serves to assist programs that want to become certified to prepare their programs for the certification process
- Remediation Team that assists programs with deficiencies to address issues and prepare for a secondary review

[12]American Association of Cardiovascular and Pulmonary Rehabilitation (AACVPR., N.d.). Retrieved from http://www.aacvpr.org/Certification/AACVPRProgramCertification/tabid/856/Default.aspx

AACVPR certification is voluntary, but certification demonstrates that the program aligns with required guidelines for the appropriate and effective care of patients. Certification assures standards of care, increases physician referrals and improves patient confidence. Certification is issued by the AACVPR Program Certification Committee based on review of a completed application and optional site visit. Certification is valid for a period of 3 years.

Table 9. High-Level Summary Evaluation: AACVPR as a Model for IIS Certification

Pros/Benefits	Cons/Barriers
■ Recertification every 3 years ■ Different panels/teams to facilitate the certification process and provide program assistance ■ Voluntary process ■ In the future will include certification of professionals as part of the program certification process	■ Certification program is staffed entirely by volunteers ■ Voluntary process

The AACVPR certification model provides another example of how an IIS Program (or possibly even end users) could be assessed or certified based on compliance with basic awardee objectives and performance measures; however, the fee structure and four panel/team model warrants additional consideration for an IIS program.

Individual Assessment and Certification Models

As previously noted, programs focused on certification of individual personnel were investigated as part of the environmental scan but have not been summarized in this document. For more information on the following organizations that have implemented Individual Assessment and Certification Models, refer to the Public Health Assessment and Certification Models spreadsheet.

- American Association of Cardiovascular and Pulmonary Rehabilitation (AACVPR)
- American Association of Critical Care Nurses (AACN)
- American Trauma Society Registrar Certification Board (ATSRCB)
- National Cancer Registrars Association's (NCRA) Council on Certification
- National Council of State Boards of Nursing (NCSBN)

Developing an IIS Assessment/Certification Program

Establishment of a national IIS assessment and eventual certification program would help to 1) minimize functional and technical variations between the numerous IIS products/platforms, 2) improve adoption of standards and functional requirements, and 3) provide measurable performance standards for IIS technical and operational abilities. However, considerations for implementing an IIS assessment/certification process would not be complete without an analysis

of both the potential benefits and the potential barriers of implementation. Assessment/certification programs also require appropriate infrastructure to administer and oversee program operations. As such, establishment of a governance structure and ongoing assessment/certification body are also important considerations for establishing an IIS program. The following section addresses these issues.

Benefits and Barriers of Assessment/Certification

This information is based on the initial environmental scan of assessment/certification models and is not intended to be a comprehensive representation of all existing programs. Additional evaluation and discussion is warranted prior to moving forward with IIS assessment/certification design, development and implementation, particularly in the areas of policy development, operational modifications and the technical changes needed to support this process.

Primary Benefits

Assessment/certification has the potential to facilitate greater standardization and nationwide symmetry in immunization information systems (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 immunization information systems 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 immunization information systems 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 Barriers

There is a current lack of uniform nationwide policy across the IIS community. One of the benefits of assessment/certification is the potential opportunity it offers toward the introduction

of national immunization information system policy and adoption of standards, 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 Considerations

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 the IIS. Although virtually impossible, at this point, to produce a comprehensive list of all known financial benefits and barriers to IIS assessment/certification pre-implementation, it is feasible to hypothesize the impacts. Immunization information systems 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.

No 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's impossible to provide a comprehensive list of all assessment/certification-based 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 after the preliminary groundwork has been laid and post-preliminary pilots are concluded.

Governance Structure and Certifying Body

All of the assessment/certification processes reviewed as part of this environmental scan had two common elements, 1) an organization that administers and sponsors the assessment/certification effort (governance), and 2) a certifying body responsible for overseeing the adoption of standards and establishment of measurements. The following sections look at the common attributes necessary for establishing the infrastructure needed for an IIS assessment/certification program.

Governance Structure

Governance for an assessment/certification process is typically provided in the form of a national organization, federal agency, or a Board/Steering Committee housed within a larger organization/agency. The governing entity provides oversight and structure to the assessment/certification process. In order for the IIS community to be fully invested and engaged, the governance structure should be developed/assigned with the following attributes in mind:

Table 10. Governance Structure Considerations

Requirement*	**Attributes**
National organization	■ National-level recognition and credibility ■ Aligned with related national-level affiliates and stakeholders with subject matter expertise in immunizations and IIS ■ Collaborate and work with federal agencies, e.g., CDC, CMS, National Institute of Standards and Technology (NIST) and ONC ■ Ongoing engagement, representation and support from the IIS community ■ Ongoing involvement in IIS initiatives and the documentations and practices related to IIS core functional elements
Representative of IIS (organization or individuals)	■ Endorsement, advocacy and support of IIS priorities, initiatives, challenges and advancements, at the local, state and national levels

Expert-level involvement from IIS Subject Matter Experts (SME)	■ In-depth knowledge of IIS operational and technical capacity, including objectives, initiatives and challenges at the local, state and national levels ■ An intuitive understanding of IIS' needs

**The requirements listed are not intended as an inclusive list of IIS assessment/certification body attributes.*

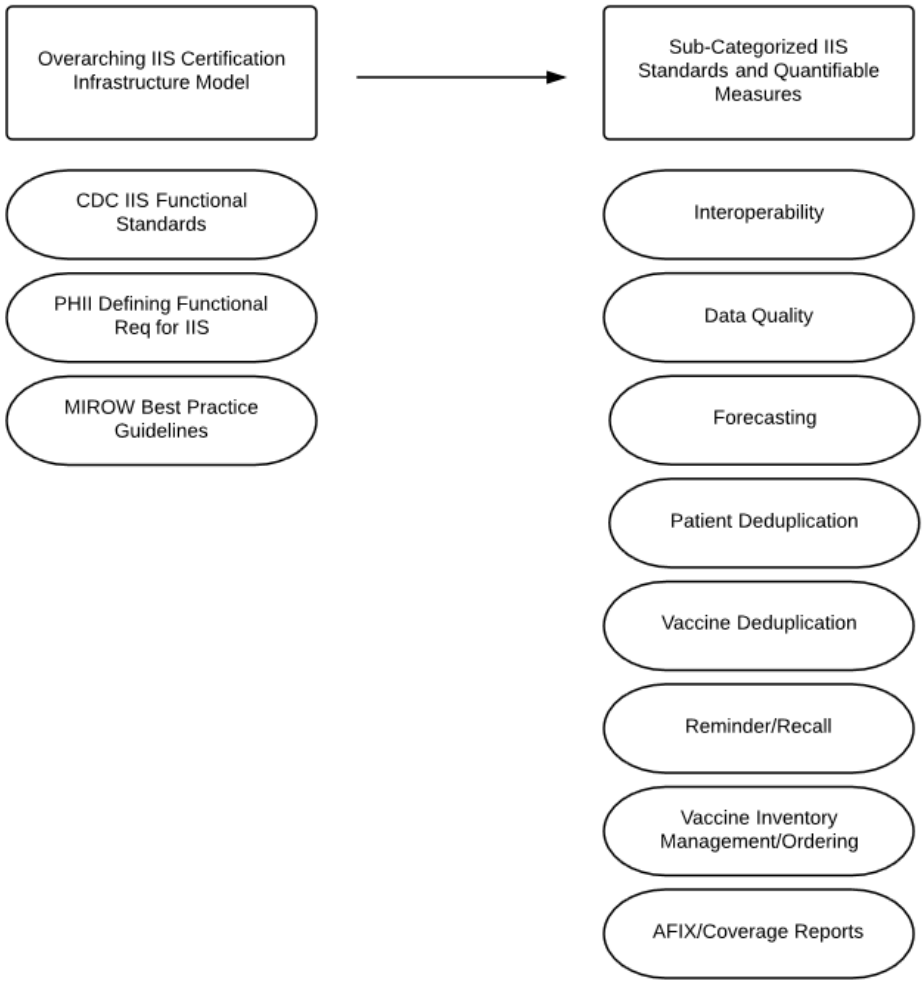
As the primary organization representing the interests of the IIS community and related stakeholders, AIRA is likely the best candidate to assume the role of the governing agency with the collaboration of members, partners, CDC, and other stakeholders.

It may be beneficial to create an interim governance body within AIRA to develop the initial structure for governance and decision-making, followed by a more permanent entity/infrastructure who will implement and oversee the long term assessment/certification process.

Assessing/Certifying Body

The assessing/certifying body is responsible for overseeing the adoption of standards, establishment of measurements, and ultimately the approval to issue standing or "certification" to entities that meet or exceed the standards criteria. Due to the complexity of IIS, an assessment/certification process will likely require a tiered approach, consisting of an overarching IIS infrastructure model and a series of smaller measures. This could possibly be accomplished through the use of an Assessment/Certification Planning/Steering Committee and smaller workgroups focused on specific subject matter. Determining the appropriate structure will be a crucial component of IIS assessment/certification development. An example of a potential structure is provided below.

Figure 1. Potential IIS Assessment/Certification Development Structure



Based on the assessment/certification models and associated governance structures identified during the environmental scan, the list below conveys recommendations for the creation of an IIS assessment/certification body and relevant considerations for membership/staffing.

Table 11. IIS Assessment/Certification Considerations for Membership/Staffing

Requirement *	**Attributes**
Required appointment	■ Serve terms
Participation at all stakeholder levels	■ Federal organizations and affiliates ■ Governmental organizations and affiliates ■ IIS projects ■ IIS vendors/implementers ■ IIS stakeholders ■ IIS users

**The requirements listed are not intended as an inclusive list of IIS assessment/certification body attributes.*

Members of the certifying body would ultimately be charged with: 1) IIS assessment/certification oversight, direction, and execution; 2) continual assessment and recommendations of required revisions; 3) ensuring proper and adequate alignment with new and forthcoming initiatives, and; 4) ensuring IIS assessment/certification sustainability.

General Recommendations

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. 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 better fine-tune standards and measures themselves, creating an iterative process of improvement of both IIS programs and the metrics used to assess them.

The following initial recommendations are offered for consideration in planning and implementation of an IIS assessment process, and potential certification program. Additional investigation, discussions and considerations will be needed to identify the ideal model for the IIS community. It will be imperative for these efforts to be instituted with appropriate consideration to current IIS functional capacity, CDC-based IIS objectives, current limitations of IIS operational function and technical capacity, and funding constraints.

IIS assessment efforts focused on testing and validating alignment with interoperability standards are currently underway; these efforts will provide early building blocks for a formal assessment process.

■ *Recommendation #1*

The IIS community should be engaged to discuss the strategic benefits and barriers to a phased approach for IIS assessment and certification, and have an opportunity to provide input toward its development. This input should be documented and used to develop planning efforts. The current work on interoperability testing and assessment should continue, and lessons learned should be leveraged to formalize the assessment process. There are a broad range of perspectives on these concepts; every effort should be made to be transparent and inclusive throughout the planning effort.

■ *Recommendation #2*

An appointed, limited duration IIS Subject Matter Expert (SME) workgroup, including IIS and partner organization representatives, should convene to discuss the following aspects of assessment/certification: strategic benefits and barriers, financial benefits and barriers, and implications of each. This workgroup should 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.

Leveraging broad input, this group should evaluate and designate the initial approach and early governance structure for formal uniform assessment of all IIS, evaluating and selecting strategies to mitigate risks and barriers. This SME group should also evaluate the feasibility and cost-benefit of the assessment process transitioning into a formal certification process, and set milestones and triggers for this transition. In outlining the governance structure for assessment, a primary component should include defining and conducting the selection process for an ongoing Planning/Steering Committee, at which point the IIS SME workgroup will disband.

■ *Recommendation #3*

An ongoing Assessment Planning/Steering Committee should be initiated through the appointment of IIS community members and partners/stakeholders, according to the recommendations outlined by the SME workgroup (Recommendation #2). 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 following topic areas and decision points should be addressed by this Committee:

Assessment Policy and Process	■ Voluntary or mandatory ■ One-time process or ongoing ■ Incentives – seal of recognition ■ Cost/funding ■ Policy
Assessment Standards	■ Minimal requirements ■ Methods for performing assessment ■ Periodic assessment for required revisions ■ Supporting documentation ■ IIS community readiness ■ Phased implementation approach ■ Guidance or Best Practice document for implementation
Assessment Measures/ Metrics	■ Quantifiable measures ■ Assessment oversight structure and appointment ■ Pilot testing of all measures
Pre-Assessment/Assessment Support and Readiness	■ IIS community readiness assessment ■ IIS mentorship and technical assistance

The Implementation Plan should strongly consider employing a phased approach to assessment with the staged introduction of standards and measures. A phased assessment process will allow for an iterative approach, leveraging community input to develop and fine-tune an optimal

process by which systems are evaluated based on agreed upon, prioritized functionality which is deemed achievable. An example of the phased assessment process might include interoperability/HL7 messaging as the Phase One goal, with data quality, vaccine forecasting, vaccine inventory accountability, and AFIX/coverage reports occurring in later phases of the assessment/certification effort. A modular, incremental process will allow for high-priority and timely topics such as validation of interoperability functions to launch swiftly, while also providing opportunities to fine-tune process steps for upcoming modules. It should also be cognizant of the range in size and resources of IIS across the community, and be scalable to meet the needs of both large and small IIS.

The Assessment Planning/Steering Committee should initiate the creation of additional workgroups and sub-workgroups, with appointed members, as necessary. The Committee should 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 Committee may become the formal certifying body, or may appoint another organization or group to fill this role. Clear community support must exist prior to finalizing the decision to launch an external certification process.

■ *Recommendation #4*

Technical assistance, consultation, and, where needed, financial support should be available to assist IIS in all phases of both assessment and certification, including preparation for the process, implementation and measurement of metrics, as well as responses and enhancements as a result of assessment/certification findings. Additional financial support may also be needed to facilitate the development and maintenance of the assessment/certification governance structure as well. Decisions regarding which programs receive funding and for what assessment/certification related purposes should be made transparently and with significant IIS community input. Appropriate resources will be essential to ensure a process with broad acceptance and sustainability.

Conclusions

It will be imperative for the IIS community to collectively support, engage in, and direct the planning process for both assessment and certification. Local IIS champions will be crucial to ensure the rapid adoption of a uniform measurement process. Once community wide engagement has been achieved to pursue assessment, then the immunization information system community must begin the task of pursuing agreement regarding the process, required standards, test measures and methodology, and potential outcomes. Considerations must also be given to the timeframe needed for necessary discussions and development which are vital to the creation of an agreeable process and preparation for assessment readiness.

It is essential to secure funding to ensure: 1) a formal, representative body is formed and available to support and/or perform assessment and potentially certification; 2) coverage of any costs associated with actual IIS assessment and/or certification activities, and 3) resources are available for all IIS to achieve defined standards through appropriate development and enhancement efforts.

This document is not intended as a comprehensive IIS assessment and/or certification reference guide. The information contained herein should be viewed as the foundation upon which a national-level assessment and/or certification model strategic plan could be created and implemented, with the inclusion of added insights and direction by the IIS community, AIRA, CDC, and related stakeholders. Further discussion is warranted before proceeding, as there are a significant number of variables requiring IIS community input and consensus.

Appendix: Citations

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