HIT Standards Committee
NwHIN Power Team - Update

Dixie Baker, Chair

May 24, 2012

NwHIN Power Team 2012

- Dixie Baker (SAIC)
- Tim Cromwell (VA)
- Floyd Eisenberg (National Quality Forum)
- Ollie Gray (DOD)
- David Groves (HealthBridge REC)
- David Kates (Navinet)
- David McCallie (Cerner)
- Nancy Orvis (DOD)
- Marc Overhage (Siemens)
- Wes Rishel (Gartner)
- Cris Ross (SureScripts)
- Arien Malec (Relay Health)

★ Supported by Avinash Shanbhag, Ellen Lengermann, and Matthew Rahn (ONC)

Agenda

- Progress on defining criteria and metrics
- NwHIN Power Team work represented in Governance RFI
- NwHIN Power Team assignments in Governance RFI Review
- Next steps

NwHIN Power Team Assignment

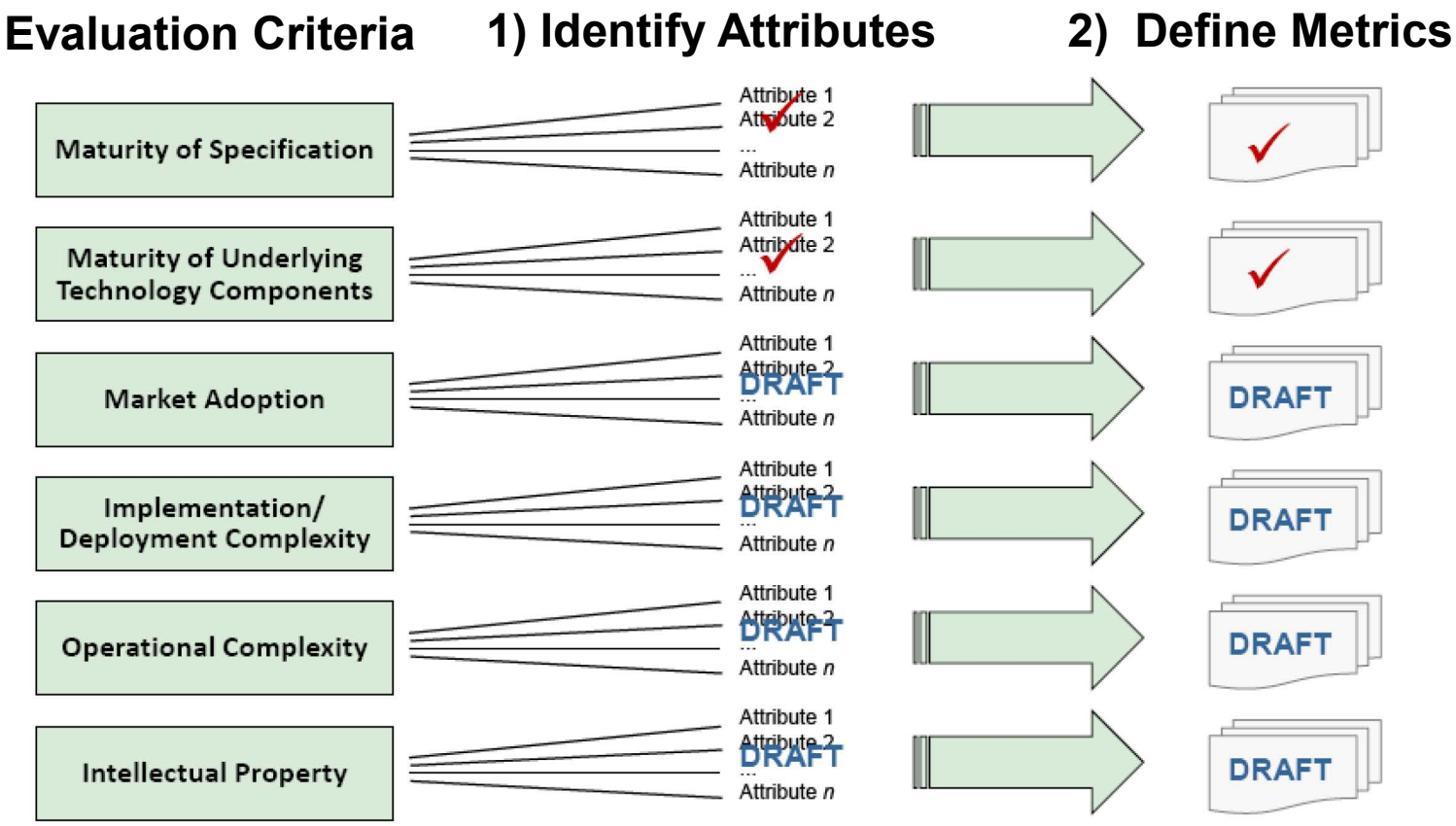
- **Scope:** Develop comprehensive, objective, and to the extent practicable, quantitative criteria for evaluating the readiness of technical specifications for adoption as national standards in the following classes:
  - Pilot/domain specific (specifications that could further develop or merge to become “Emerging”)
  - Emerging (toward readiness)
  - Ready for national adoption
- **Approach:**
  - Start with criteria and grid approach defined by the “Summer Camp 2011” NwHIN Power Team
  - Scales of Low, Moderate, High for each criterion
  - Define attributes for each criterion, and metrics for measuring the attributes
  - Objective and unambiguous attributes and metrics to be applied to specifications in predictable way
  - Common set of criteria and process to evaluate any standard

Roadmap and Progress to Date

Evaluation Criteria

Need	Remove “Need” as criterion – will be factor considered by ONC in determining what specifications are evaluated
Maturity of Specification	
Maturity of Underlying Technology	Added “Components” to clarify that a specification is likely to incorporate more than one technology component
Market Adoption	
Implementation/ Deployment Complexity	Split “Deployment/Operational Complexity” into two separate criteria
Operational Complexity	
Intellectual Property	Add “Intellectual Property” as new criterion

Roadmap and Progress to Date



See Appendix A for work to date – comments are welcome!

NwHIN Power Team Work Represented in Governance RFI

- NwHIN Power Team "Summer Camp" activity included in historical context discussion in Section 3, "Health Information Exchange and the Nationwide Health Information Network in Brief"
- **Section F. CTE Processes and Standards and Implementation Specification Classifications**
  - 2. Interoperability Conditions for Trusted Exchange – Technical Standards and Implementation Specifications Classification Process
    - Proposes to include as part of governance mechanism, a formal and transparent process to classified technical standards and implementation specifications that could ultimately be adopted within the Interoperability category of CTE
    - Annual review and assessment process
    - 3 categories of specifications
      1. Emerging
      2. Pilot
      3. National

NwHIN Power Team Work Represented in Governance RFI

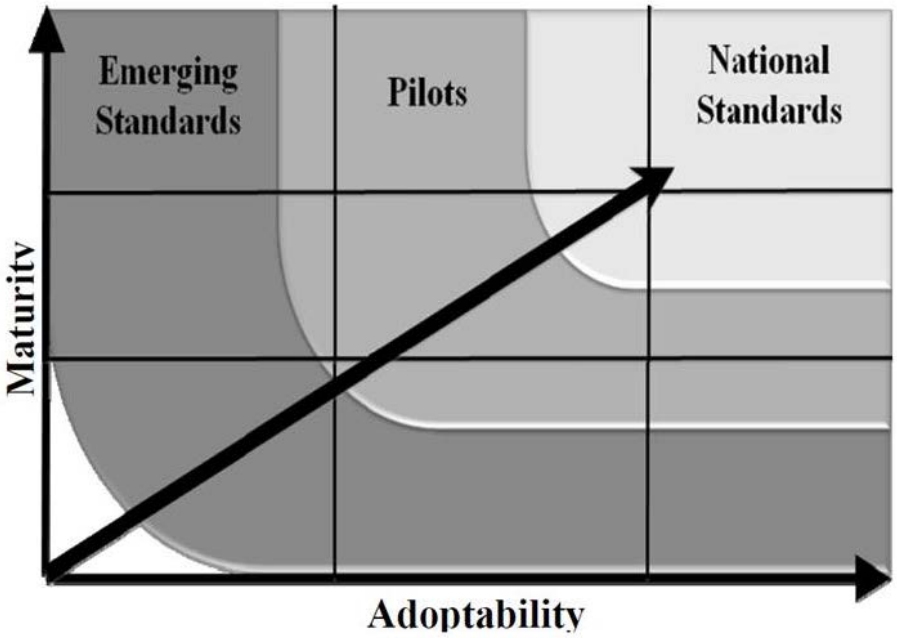


Figure 1. Standards and Implementation Specifications Classification Grid

- **Question 63:** What would be the best way(s) ONC could help facilitate the pilot testing and learning necessary for implementing technical standards and implementation specifications categorized as Emerging or Pilot?

NwHIN Power Team Work Represented in Governance RFI

- Technical Standards and Implementation Specifications Classification Criteria
  - Annual process to identify, review, and assess standards and implementation specifications
  - Discrete set of objective criteria to assess when a standard or specification should be reclassified
  - HIT Policy Committee would have key role in prioritizing needs
  - HIT Standards Committee could have integral role in advising ONC about how to classify technical standards and implementation specifications
- **Question 64:** Would this approach for classifying technical standards and implementation specificationd be effective for updating and refreshing Interoperability CTEs?
- **Question 65:** What types of criteria could be used for categorizing standards and implementation specifications for Interoperability CTEs? We would prefer criteria that are objective and quantifiable and include some type of metric.

NwHIN Power Team Assignment in RFI Review

- RFI poses a total of 66 questions, 22 of which have been assigned to the NwHIN Power Team to develop draft responses – 5 completed to date; see Appendix B for remaining questions
  - 7 questions address technology standards (e.g., transport, certificate discovery)
  - 5 questions address policy and process for selecting national standards and CTEs
  - 10 questions address broad NwHIN governance policy
- General comments
  - RFI does not effectively convey an overall vision for the NwHIN
  - RFI does not adequately define terminology – e.g., RFI defines NVE "validation" as encompassing both accreditation and certification, without defining any of these terms
  - Governance process described in the RFI mixes policy-level requirements and processes, with technical-implementation-level requirements and processes
    - Some CTEs are too specific (e.g., transport standards, certificate discovery standards) – and likely to change more often than policy
    - We think validation of NVEs against governance policies should be separated from certification of conformance against technical specifications – though both processes may be considered parts of an overall governance model

Question 39: NVE Availability

Condition [S-7]: An NVE must operate its services with high availability.
Question 39: What standard of availability, if any, is appropriate?
NwHIN PT Comments: Availability requirements are service-specific; so it would not be realistic to specify a single availability level across all services and NVEs. We question whether there is a market failure that really compels a standard for availability. We think transparency is more important than establishing a specific availability floor; especially publication of actual availability over time. Better to leave specific availability level as a contract provision.

Questions 45-46: Transport Methods

Condition [I-1]: An NVE must be able to facilitate secure electronic health information exchange in two circumstances: 1) when the sender and receiver are known; and 2) when the exchange occurs at the patient's direction.

Question 45: What types of transport methods/standards should NVEs be able to support? Should they support both types of transport methods/standards (i.e., SMTP and SOAP), or should they only have to meet one of the two as well as have a way to translate (e.g., XDR/XDM)?

NwHIN PT Comments:

1. The Condition does not address all the reasonable circumstances for exchange and does not use language commonly used in other regulations. The conditions under which it is appropriate to exchange health information are specified elsewhere and should not be included in the Governance regulation.
2. Trust fabric should be decoupled from the transport mechanisms. Transport standards should not be specified in this Governance regulation. However, the Governance regulation should require transparency with regard to the transport protocols that an NVE supports, and how it supports those protocols.

General Comment: An NVE's implementation of its transport specifications (for example the Direct specification) should be certified through a process that is separate from the overall NVE validation process. The RFI states that "In our use of the term validation throughout this document, we mean it to encompass both accreditation and certification." We think it would be a mistake to include certification as part of the validation process. While acknowledging that the use of certified technology may be a consideration in validating an NVE, the actual certification of that technology should be accomplished through a separate process (though both processes may be part of a single governance model).

Question 46: If a secure "RESTful" transport specification is developed during the course of this rulemaking, should we also propose it as a way of demonstrating compliance with this CTE?

NwHIN PT Comments:

See response to question 45

Questions 47-48: Certificate Discovery

Condition [I-2]: An NVE must follow required standards for establishing and discovering digital certificates.
Question 47: Are the technical specifications (i.e., Domain Name System (DNS) and the Lightweight Directory Access Protocol (LDAP)) appropriate and sufficient for enabling easy location of organizational certificates? Are there other specifications that we should also consider?
NwHIN PT Comments: Yes, these specifications are appropriate for use, but we do not think the Governance regulation should specify these approaches as exclusive. There may be other ways to discover certificates, and we do not believe a Governance regulation should specify protocols for certificate discovery. We believe questions 45-47 are at a much more granular level than is appropriate for a Governance regulation.
Question 48: Should this CTE require all participants engaged in planned electronic exchange to obtain an organizational (or group) digital certificate consistent with the policies of the Federal Bridge?
NwHIN PT Comments: This is a policy question and will be looked at by the Privacy and Security Tiger Team.

In our use of the term validation throughout this document, we mean it to encompass both accreditation and certification.

APPENDIX A

Criteria, Attributes, and Metrics

Classification Criteria and Attributes (1 of 3)

Classification Criteria	Attributes
Maturity of Specification	• Breadth of Support • Stability • Degree of Interoperability among a number of independent and non-coordinated implementations (interfaces, data models, data sets, well defined, limited degrees of freedom) • Adoption of Specification
Maturity of Underlying Technology Components	For each technology component used by the specification: •Breadth of Support • Stability • Degree of Interoperability among a number of independent and non-coordinated implementations • Adoption of Technology • Platform Support • Integration of technology into larger solutions • Maturity of the technology within its life cycle

Classification Criteria and Attributes (2 of 3)

Classification Criteria	Attributes
Implementation/ Deployment Ease	• Effort for average developer to implement using existing infrastructure • Effort for average developer to build from scratch • Availability of off-the-shelf infrastructure to support implementation • Deployment Costs • Conformance criteria and tests • Complexity of Specifications • Availability of reference implementations • Quality/Clarity of specification documentation • Degree to which specification uses familiar terms to describe “real-world” concepts • Ease of use of Specifications • Number of interfaces with external components or services • Degree of optionality
Operational Ease	• Comparison of targeted scale of deployment with scale for which specification is actually deployed • Number of operational issues identified in deployment • Degree of peer-coordination needed • Big O notation for operational scalability (i.e., operational impact of adding a node) • Cost • Dependencies on external services • Fit to Purpose

Classification Criteria and Attributes (3 of 3)

Classification Criteria	Attributes
Market Adoption	• Installed User Base • Future projections and anticipated support • Investments in Customer Learning • Inclusion in other standards
Intellectual Property	• Openness • Accessibility and Fees • Licensing Policy • Copyrights • Patents

Maturity of Specification – Metrics (1 of 2)

Attributes	Metrics: Low	Metrics: Moderate	Metrics: High
Breadth of Support	• No contributing community or without activity • 1 organization supporting authorship • No support services other than public forums or mail lists • No implementation/ training services	• Existing community with notable activity • 2-5 organizations supporting authorship • Single organization provides support service • Single organization provides implementation/ training services	• Strong community with numerous contributors and advocates throughout industry • 5+ organizations supporting authorship • Multiple organizations provide support services • Multiple organizations provide implementation/ training services
Stability	• Unstable with numerous releases generating side effects • Standard has history of several known problems which can be prohibitive for adoption • Age of oldest known conforming implementation is less than 3 months	• Stabilized release process but difficulties with development process to respond to industry required changes • No known history of major problems or crisis • Age of oldest known conforming implementation is 3 months – 3 years	• Stabilized releases providing minor corrections to core standard. New core functionality changes in response to industry required changes • History of good management of crisis situations • Age of oldest known conforming implementation is 3 years or more

Maturity of Specification – Metrics (2 of 2)

Attributes	Metrics: Low	Metrics: Moderate	Metrics: High
Degree of Interoperability among independent non-coordinated implementations	• 0 - 1 non-coordinated implementations • Degree of interoperability is undetermined	• 2 - 4 non-coordinated implementations • Some indications of interoperability between at least 2 implementations	• 5+ non-coordinated implementations • Interoperability established for entire standard between at least 2 implementations
Adoption of Specification	• No references (informal blogs to formal papers) identified of the standard's specification in use • Existing specification with indications of decline (moved from "Declining" under Maturity of Specification criteria): - Existing community but no or little activity in last year - Reduced organizations supporting authorship - No new implementations - Critical programs analyzing replacement or upgrades options - Lacking support for new or emerging technology or products	• Few references of use on non-critical programs (i.e. in pilot)	• Numerous references of use in production for critical programs

Maturity of Underlying Technology Components – Metrics (1 of 3)

Attributes	Metrics: Low	Metrics: Moderate	Metrics: High
Breadth of Support	• No contributing community or without activity • 1-2 individuals leading development or not clearly defined • Less than 3 developers or not clearly identified • No support services other than public forums or mail lists • No implementation/ training services	• Existing community with notable activity • 2-5 individuals leading development • 4-7 developers or more, but turnover high • Single organization provides support services • Single organization provides implementation/ training services	• Strong community with numerous contributors and advocates throughout industry • 5+ individuals leading development • 7+ developers with low turnover • Multiple organizations provide support services • Multiple organizations provide implementation/ training services
Stability	• Unstable with numerous releases generating side effects • Standard has history of several known problems which can be prohibitive for adoption • Age of oldest known conforming implementation is less than 3 months	• Stabilized release process but difficulties with development process to respond to industry required changes • No known history of major problems or crisis • Age of oldest known conforming implementation is 3 months – 3 years	• Stabilized releases providing minor corrections to core standard. New core functionality changes in response to industry required changes • History of good management of crisis situations • Age of oldest known conforming implementation is 3 years or more

Maturity of Underlying Technology Components – Metrics (2 of 3)

Attributes	Metrics: Low	Metrics: Moderate	Metrics: High
Degree of Interoperability among independent non-coordinated implementations	• 0 - 1 non-coordinated implementations • Degree of interoperability is undetermined	• 2 - 4 non-coordinated implementations • Some indications of interoperability between at least 2 implementations	• 5+ non-coordinated implementations • Interoperability established for entire standard between at least 2 implementations
Adoption of Technology	• No references of standard identified • Existing technology with indications of decline: - Existing community but no or little activity in last year - Reduced development staff with high turn over - No new implementations - Critical programs analyzing replacement or upgrades options - Lacking support for new or emerging technology or products - Technology readiness stalled or stopped before TRL-9	• Few references of use on non-critical programs (i.e. in pilot)	• Numerous references of use in production for critical programs
Platform Support	• Supports only one platform	• Supports multiple platforms but requires additional effort or expertise	• Support multiple platforms with no or minimal effort

Maturity of Underlying Technology Components – Metrics (3 of 3)

Attributes	Metrics: Low	Metrics: Moderate	Metrics: High
Maturity of the technology within its life cycle	• Technology Readiness Level (TRL) 1-7 TRL 1: Basic principles observed and reported. Research begins. TRL 2: Technology concept and/or application formulated. Prototyping begins. TRL 3: Analytical and experimental critical function and/or characteristic proof of concept. Active R&D initiated, including analytical studies and lab studies to physically validate technology. TRL 4: Component and/or breadboard validation in a lab environment. Technological components are integrated in "low fidelity" setting. TRL 5: Component and/or breadboard validation in relevant environment. Technological components integrated with reasonably realistic supporting elements in an increased fidelity and simulated environment. TRL 6: System/subsystem model or prototype demonstration in relevant environment. Prototype is tested in relevant and "high-fidelity" simulated environment. TRL 7: System prototype demonstrated in operational environment.	• TRL 8 TRL 8: Actual system completed and qualified through test and demonstration. Technology has been proven to work in its final form and under expected conditions.	• TRL 9 TRL 9: Actual system proven through successful mission operations. Actual application of technology in its final form and under mission conditions.

Market Adoption – Metrics

Attributes	Metrics: Low	Metrics: Moderate	Metrics: High
Installed User Base	• Very few user bases other than the developers of the standard or pilots	• Detectable references of use outside of developers of pilots	• Numerous users and numerous references to large user bases • 35% or more in market
Future projections and anticipated support	• No roadmap, future projections, or announcements • Well established standard, projecting decline in future use	• Future announcements of releases and community activities are provided to limited audience on an irregular basis	• Roadmap and future announcements of releases are tightly coupled and are provided to a broad audience (members and public) on regular basis • Standard in broad use, projecting to continue
Investments in user training	• Few users investing in training on use of standard	• Limited user investment in learning , primarily through indirect means such as discussion boards	• Active user investments in training • Multiple training modes available, such as code-a-thons, webinars, classroom training
Inclusion in other standards	• Not referenced in other standards or in standards with low installed user base	• Referenced in at least one other standard with at least moderate installed user base	• Referenced in at least one standard with high installed user base

Intellectual Property – Metrics

Attributes	Metrics: Low	Metrics: Moderate	Metrics: High
Openness	• Closed to few individuals or entities	• Limited to only members or contributing organizations	• Open to public
Accessibility and Fees	• Fees associated with accessing standard specifications • High costs for use and documentation which are deemed prohibitive for high adoption	• No fee for accessing standard specifications but fees or restrictions on referenced specifications (e.g. Vocabularies) • Nominal costs to use standard and documentation	• No fees for accessing standard or referenced specifications • No costs to use standard and standard documentation
Licensing Policy	• Highly restricted use based on type	• Restricted to only non-commercial • Negotiated agreement for use (i.e. SNOMED)	• Unrestricted for any use (commercial, academic, governmental) • Perpetual use rights • Derivative work allowed • Unlimited number of users or instances
Copyrights	• Rights held by numerous individuals, making relicensing very difficult	• Rights held by a few individuals or entities	• Rights held by a legal entity whom the community trusts and relicensing process is clear and streamlined
Patents	• Patent encumbered: Known or anticipated patented methods required for conformance to standard	• RAND terms: Contributors to standard agree to reasonable and non-discriminatory (RAND) terms for their contributed material	• No known or anticipated patents required to implement any portion of the specification (not subject to “patent ambush”)

Ease of Implementation/Deployment – Metrics (1 o

Attributes	Metrics: Low	Metrics: Moderate	Metrics: High
Effort for average developer to implement from scratch	• Under Research	• Under Research	• Under Research
Effort for average developer to implement with existing infrastructure	• Under Research	• Under Research	• Under Research
Availability of off-the-shelf infrastructure to support implementation	• Few off-the-shelf infrastructure components are available or can be purchased to support implementation	• Some of supporting infrastructure components can be purchased off-the-self	• Most of supporting infrastructure components can be purchased off-the-self
Deployment Costs	• Evidence of deployments exceeding over 30% of original estimates for cost	• Evidence of deployments exceeding 10-30% of original estimates for cost	• Minimal overages in cost during deployment (10% or less over original cost estimates)
Conformance Criteria and Tests	• No conformance criteria or tests documented or available	• Conformance criteria exists but prescribed conformance testing tools are not available	• Well established and understood conformance criteria and prescribed conformance testing tools available
Availability of Reference Implementations	• No reference implementations	• Well-established reference implementations on a limited set of platforms	• Multiple reference implementations on multiple platforms

Ease of Implementation/Deployment – Metrics (2 c

Attributes	Metrics: Low	Metrics: Moderate	Metrics: High
Complexity of Specification	• Composition is monolithic and cannot be decomposed to smaller parts without complete loss of context • Over 6 other standards are incorporated into specification and few are easily accessible	• Some modularity in composition but requiring additional references for context • 4-6 other standards are incorporated into specification and most are easily accessible	• Modular composition such that a large specification is easily decomposed to simpler smaller parts • Fewer than 3 other standards are incorporated into specification and all are easily accessible
Quality and Clarity of Specifications	• Semantics not well defined and no evidence of interoperability • No support for detecting inconsistencies and ambiguities • Concepts are not defined for user's point of view and environment	• Defined semantics but evidence of some difficulty interoperating with other systems or networks • Little support for detecting inconsistencies and ambiguities • Concepts are loosely defined for user's point of view and environment	• Precisely defined semantics and providing evidence of interoperability with other systems or networks • Support for detecting inconsistencies and ambiguities • Concepts in specification expressively describe user's point of view and environment
Ease of use of specification	• Requires highly specialized expertise to read and understand specification • Maintenance activities are extensive and unique for each implementation	• Requires both domain and technical expertise to read and understand specifications • With little effort specification can be used as a starting point for maintenance	• Easily read and understood by domain experts • Easily used as a starting point for maintenance activities • Providing navigation links or indexed

Ease of Implementation/Deployment – Metrics (3 c

Attributes	Metrics: Low	Metrics: Moderate	Metrics: High
Degree to which specification uses familiar terms to describe “real-world” concepts	• Few concepts in standard are based on terminology currently used in industry	• Some to majority of concepts in standard are based on terminology currently used in industry	• Most concepts in standard are based on terminology well established in the industry
Number of interfaces with external components or services	• Under Research	•Under Research	•Under Research
Degree of Optionality	• Under Research	•Under Research	•Under Research

Ease of Operations – Metrics

Attributes	Metrics: Low	Metrics: Moderate	Metrics: High
Comparison of targeted scale of deployment to actual scale deployed	• No documented or advertised scale at which standard is intended to be deployed	• Scale is documented in standard but no evidence that the scale as been achieved in operations	• Scale is documented in standard and evidence that scale has been achieved or exceeded in operations
Number of operational issues identified in deployment	• Several critical issues identified during deployment and are high risks to operations	• Several issues identified during deployment but all mitigated through operational activities	• Few issues identified during deployment
Degree of peer-coordination needed	• Peer-coordination of technical experts required on daily basis	• Peer-coordination on frequent periodic basis	• Minimal peer-coordination required on as needed basis
Big O notation for operational scalability (i.e. operational impact of adding a single node)	• Addition of nodes creates exponential impacts to operational effort or complexity • Worse than O(n)	• Addition of nodes creates linear impacts to operational effort or complexity • O(n)	• Addition of nodes has little to no additional impacts to operational effort or complexity • O(1)
Cost	• Benefit-to-cost ratio under 1 BCR = cost-savings benefits/ cost	• Benefit-to-cost ratio of 1	• Benefit-to-cost ratio (BCR) over 1
Fit to Purpose	• x% of operational needs are met by use of the standard and specifications	• x% of operational needs are met by use of the standard and specifications	• 100% of operational needs are met by use of the standard and specifications

APPENDIX B

RFI Questions Remaining To Be Addressed

Questions To Be Addressed: Technology

- **Question 49:** Should we adopt a CTE that requires NVEs to employ matching algorithms that meet a specific accuracy level or a CTE that limits false positives to certain minimum ratio? What should the required levels be?
- **Question 50:** What core data elements should be included for patient matching queries?
- **Question 51:** What standards should we consider for patient matching queries?

Questions To Be Addressed: Process for Classifying and Selecting Standards and CTEs

- **Question 60**: What process should we use to update CTEs?
- **Question 62**: Should we consider a process outside of our advisory committees through which the identification and development to frame new CTEs could be done?
- **Question 63**: What would be the best way(s) ONC could help facilitate the pilot testing and learning necessary for implementing technical standards and implementation specifications categorized as Emerging or Pilot?
- **Question 64**: Would this approach for classifying technical standards and implementation specification be effective for updating and refreshing Interoperability CTEs?
- **Question 65**: What types of criteria could be used for categorizing standards and implementation specifications for Interoperability CTEs? We would prefer criteria that are objective and quantifiable and include some type of metric.

Questions To Be Addressed: NwHIN Governance Policy (1 of 2)

- **Question 3:** How urgent is the need for a nationwide governance approach for electronic health information exchange? Conversely, please indicate if you believe that it is untimely for a nationwide approach to be developed and why.
- **Question 4:** Would a voluntary validation approach as described above sufficiently achieve this goal? If not, why?
- **Question 8:** We solicit feedback on the appropriateness of ONC's role in coordinating the governance mechanism and whether certain responsibilities might be better delegated to, and/or fulfilled by, the private sector.
- **Question 9:** Would a voluntary validation process be effective for ensuring that entities engaged in facilitating electronic exchange continue to comply with adopted CTEs? If not, what other validation processes could be leveraged for validating conformance with adopted CTEs? If you identify existing processes, please explain the focus of each and its scope.

Questions To Be Addressed: NwHIN Governance Policy (2 of 2)

- **Question 10:** Should the validation method vary by CTE? Which methods would be most effective for ensuring compliance with the CTEs? (Before answering this question it may be useful to first review the CTEs we are considering to adopt, see section "VI. Conditions for Trusted Exchange."
- **Question 11:** What successful validation models or approaches exist in other industries that could be used as a model for our purposes in this context?
- **Question 17:** What is the optimum role for stakeholders, including consumers, in governance of the nationwide health information network? What mechanisms would most effectively implement that role?
- **Question 56:** Which CTEs would you revise or delete and why? Are there other CTEs not listed here that we should also consider?
- **Question 61:** Should we expressly permit validation bodies to provide for validation to pilot CTEs?