February 7, 2017

Jon White, MD
Acting National Coordinator for Health Information Technology
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Dr. White,

The 2017 Interoperability Standards Advisory Task Force (ISATF) convened on March 8, 2016, as part of a joint collaboration between the Health IT Policy Committee (HITPC) and Health IT Standards Committee (HITSC). The Task Force was charged to submit recommendations to the Health IT Standards Committee regarding revisions and enhancements ONC should consider as it creates the Draft 2017 Interoperability Standards Advisory (ISA), taking into account feedback from the public comment process. This transmittal offers these recommendations, which are informed by the deliberations among the Task Force members, and consideration of testimony from public and private industry stakeholders.

ISA Phase II Charge

In the second phase, the 2017 ISA Taskforce is charged to develop recommendations for the HITSC on the following:

- Review interoperability needs and standards listed for Sections II & III (not completed in Phase I)
- Discussion and recommendations around the TF's priority list for inclusion in the 2017 ISA's "Projected Additions" section.
- Develop explanatory content for topic areas where additional information for stakeholders would be beneficial for better understanding
    - Including: APIs, Observations/Observation Values, Research, Consumer/Patient Access, Nursing

Background:

The Interoperability Standards Advisory (ISA) was ONC's first deliverable in support of the Nationwide Interoperability Roadmap towards a Learning Health System. The document provides the industry with a single, public list of the standards and implementation specifications necessary to fulfill specific clinical health information technology interoperability needs. The ISA Documents known limitations, preconditions, and dependencies as well as known security patterns among referenced standards and implementation specifications when they are used to fulfill a specific clinical health IT interoperability need. It is a non-regulatory "advisory" document, using a straight-forward approach with an interactive and predictable process for updates.

The Interoperability Standards Advisory process represents the model by which ONC will coordinate the identification, assessment, and determination of the "best available" interoperability standards and implementation specifications for industry use to fulfill specific clinical health IT interoperability needs.

Phase II Recommendations

ISA Overarching Recommendations

- Base standards (e.g. CDA, etc.) that are listed for multiple interoperability needs should be re-located into a new section for "base standards" that can be referenced throughout the ISA.
    - These should be removed from individual interoperability needs within the ISA (unless they can be used alone to achieve the interoperability need) to avoid confusion by implementers.
- Standards listed throughout the ISA are and should remain varied by the use case or interoperability need they support (i.e., the "best" standard for one use case may not be "best" for a similar use case or may need to be profiled differently.)
    - Continued and expanded use of ONC's Interoperability Proving Ground to showcase actual use of standards and best practices directly from the ISA is encouraged.
- For areas where FHIR is listed, a notation should be added around the varying level of maturity for different FHIR resources. A link to the FHIR maturity model should be provided for reference.
- Where interoperability needs align with ONC Certification Criteria, these should be listed and linked appropriately so that stakeholders know what to certify to as things evolve. In addition, where interoperability needs relate to portions of MACRA/MIPS and Alternative Payment Models, links to educational resources should be provided.
- Security patterns listed for each interoperability need in Sections II &III are duplicative. They should be relocated to an appendix that deals with general security concerns.
- As the ISA grows to become a more robust tool for industry reference, it should also provide educational information about standards issues to support implementers. (e.g. observation/observation value pairings; emerging-API based standards; etc)
    - Recommended language from the Task Force in these areas is provided following the recommendations.
- A note should be added that standards alone are not always sufficient for interoperability. Governance and other policy considerations are often required.

Section II (Content/Structure) Recommendations

Section II-H: Electronic Prescribing

- A number of the SCRIPT V10.6 transaction types have incorrect information about the maturity/adoption level listed. These should be updated to reflect the current state of industry capabilities in support of e-prescribing transactions.

Section II-I: Family Health History (Clinical Genomics)

- FHIR's Sync for Genes should be mentioned as a project that will test out FHIR's clinical genomics resources.

Section II-J: Images

- If mature enough, the ISA should reflect ongoing work within Commonwell and Carequality surrounding narrative text portion of image exchange.

Section II-K: Laboratory

- The adoption level for the implementation specifications for receiving electronic lab results should be increased to at least 2 bubbles to reflect actual adoption and use.
- The "HL7 Version 2 Implementation Guide: Clinical Genomics Coded Reporting, Release 1, U.S. Realm" should be monitored and added to the ISA as an emerging standard once released as a balloted draft.

II-L: Medical Device Communication to Other Information Systems/Technologies

- A limitation should be added to reflect the variety of approaches and various use cases for "medical devices" that may be included as part of this interoperability need.
- Next year's ISA Task Force should include experts in this area to better support enhancing this interoperability need.

II-M: Patient Education Materials

- The SOA based implementation specification has an over-stated adoption level. The adoption level should be reduced to two dots.
- The context-aware knowledge retrieval (infobutton) release 4 should have an adoption level of four dots.
- A FHIR-based approach for patient education materials is currently being developed. This should be reflected in the ISA.

II-N: Patient Preference and Consent

- BPPC is not executable, just provides documentation of consent. Adoption level should be lowered to one star.
- A note should also be added that BPPC is being used for SSA Disability Determination requests, which may impact overall adoption level.
- A note should be added to reflect that Carequality has created a profile that provides additional information and context for consent and authorization preference that is conveyed through the SAML security header portion of a SOAP message.

II-O: Public Health Reporting

- For antimicrobial reporting, the CDA R2 HAI Reports Implementation Guide should have a higher adoption level as it is federally required. Increase to two bubbles.
- For Electronic Transmission of Reportable Lab Results, the adoption level for the ELR Implementation Specification should be increased to five bubbles.

II-P: Representing Clinical Health Information as a Resource

- A specific definition should be provided to distinguish between the use of FHIR as a "clinical resource" vs as an "API based approach" to interoperability.
    - Draft text to reflect this information has been provided following the recommendations

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II-R: Segmentation of Sensitive Information

- There is a federal send and receive requirement (partial data segmentation), which should be noted in limitations may be difficult for providers to accomplish. This has largely only been used in pilot settings with low adoption.
- In addition, the second standard (full data segmentation for privacy) which is in pilot with very low adoption.

II-S: Summary Care Record

- Resources for implementers should be provided, that provide lists of examples that are accessible from directly within the ISA (e.g. EDGE testing tool).
- Identifying and providing links within the ISA to CCDA example libraries that vendors/developers can use to ensure consistent adoption of CCDA and consistent representation of the clinical data within the CCDA would be a helpful addition.

Section III (Services) Recommendations

III-A: Push Exchange

- Implementation Specifications titled "NwHIN" should be updated to reflect change to "eHealth Exchange", a Sequoia Project Initiative.
    - The following specifications should also be referenced:
        - For general push of clinical data: Document Submission Production Specification
        - For general push of non-clinical data: Administrative Distribution production specification
        - For push of treatment and administrative data for CMS claims review: Electronic Submission of Medical Documentation production specification
    - Up to date URLs are available at: http://sequoiaproject.org/resources/exchange-specifications/
- The IHE Document Metadata Subscription (DSUB) standard, which controls the ability to manage subscriptions, should be added.
- The Interoperability Need for Push Communication of Vital Signs should be split into two, one for consumer devices (titled "Remote Single Monitoring of a Patient's Health Statistics') and one for in-facility medical device communications.
    - A note should be added for active efforts underway, including Devices on FHIR, IHE 11073, and HL7 V2.

III-B: Clinical Decision Support Services

- The relevant standards body or SDO should be added to the standards listed for this section.
- Both "CDS on FHIR" and CDS Hooks" should be included as different approaches for this interoperability need.
    - A note should be added for stakeholders that this is a rapidly evolving space, with the following links provided for stakeholder awareness of activities.
        - HL7 Wiki for CDS Hooks
        - HL7 CDS Workgroup
        - CDS Community (Google Group)

III-C: Image Exchange

- For "Exchanging Imaging Documents within a Specific HIE Domain", the adoption level for XDS should be increased.
- A note should be added that Sequoia has partnered with RSNA on a US initiative for testing XCA-I and XDS-I for this interoperability need.

III-D: Healthcare Directory, Provider Directory

- FHIR DSTU-2 should be updated to FHIR STU-3
- A note should be added about the emerging US National Extension for the IHE HPD specification, which will include clarifications, tweaks, and constraints to the IHE International Specification.
- A note should be added about the Argonaut Project work related to a FHIR based Provider Directory for organizations seeking to implement a provider directory based on FHIR rather than SOAP standards.
- A note should also be added that FHIR Based Health Provider Directory and Care Services Discovery will be the same standard, currently in the process of convergence.

III-E: Public Health Exchange

- For Query/Response for Immunization Reporting and Exchange, there is a need to clean up a number of items in the ISA table:
    - CDC should be added to the first specification: "CDC - EHR-IIS Interoperability Enhancement Project Transport Layer Protocol Recommendation Formal Specification, Version 1.2" for clarity.
    - The second row should be deleted as this is a pointer to a low-level specification already incorporated by the first row.
    - Add new row that has a coupling of 1 or more standards to do the query/response (HL7 v2/v3, or FHIR)

III-F: Publish and Subscribe

- A comment should be added that the NwHIN Specification will be deprecated in the future in favor of the IHE DSUB specification and/or the equivalent FHIR profile.

III-G: Query

- The MHD standard may have been modified in the most recent round of balloting – ONC should verify it is up to date.
- CareQuality and Commonwell specifications should be referenced here to acknowledge work by these entities in this area.

III-H: Resource Location

- This interoperability need should be changed to "Care Service Discovery Within the US" for a more accurate description.
- FHIR should be added as an emerging standard for this interoperability need. CareQuality's work in this area should also be referenced.
- A note should also be added that FHIR Based Health Provider Directory and Care Services Discovery will be the same standard, currently in the process of convergence.

Nursing Recommendations: Overarching

- The ISA TF recommends using consistent terminology throughout the document when referring to mapping, translating, or converting from one terminology to another.
    - Ex: Section I-L "Other ANA-recognized terminologies should be ~~converted to~~ mapped to SNOMED CT® for comparison across health systems and/or transmission."
- A forthcoming report on Nursing Terminology from ONC may help influence population of the "Adoption Level" fields for nursing standards.
- Currently a map is not available or easily accessible for mapping existing nursing terminologies to SNOMED & LOINC. ONC should work to identify a home where this mapping can be authoritatively curated over time, working with existing nursing terminology "owners" to ensure mapping is correct.

Nursing Recommendations: Representing Nursing Assessments

- The title of this interoperability need should changed to: "Representing Clinical/Nursing Assessments"
- In the preconditions/limitations field, the second sentence in the statement below is unclear and should be removed
- "Assessments are represented as question/answer (name/value) pairs. ~~They are not represented in other terminologies~~."
- LOINC should be used to represent the questions and SNOMED CT should be used to represent the answers (except when using validated scales):
    - Suggest adding two preconditions: "*codes should generally be chosen from two axes: Clinical finding and Situation with explicit context" and "When representing validated scales LOINC should be used for the question and LOINC answers (LA Codes) should be used for the answers*" (e.g. Braden Scale, Morse Falls Scale)
- Adoption level should be listed as low for both LOINC and SNOMED CT for this interoperability need.
- LOINC assessment panels should be added as starter sets
    - A note should be added to reflect that definitions of the panels are in LOINC.

Nursing Recommendations: Representing Nursing Interventions

- The Procedure axis of SNOMED CT is the terminology used for 'Nursing Interventions'.
- For nursing interventions, LOINC is not used and should be removed as a standard for this interoperability need.
- A resource for nursing intervention value set is the map set from ICNP to SNOMED CT can be found in this document: (http://www.icn.ch/images/stories/documents/pillars/Practice/icnp/ICNP_to_SNOMED_CT_Equivalency_Table_for_Intervention_Statements.pdf)

Nursing Recommendations: Representing Outcomes for Nursing

- SNOMED CT should be added as a standard for this interoperability need.
- Recommend that terminologies listed for the Interoperability Need 'Representing Nursing Outcomes' to follow the previous recommendation in the 'Nursing/Clinical Assessment' section

of the observation/observation value pairing.
- We agree for most circumstances that LOINC should represent the observations/questions and SNOMED CT should be used to represent the observation values/answers. However, when the outcomes are recorded as an assertion (e.g., normotensive, afebrile, etc) the terminology to be used is SNOMED CT

Nursing Recommendations: Representing Patient Problems for Nursing

- We agree with SNOMED CT being used for this interoperability need.
- The Limitations/Dependencies/Preconditions should be modified as follows:
- Add "The use of SNOMED CT® for this interoperability need, codes should generally be chosen from two axes: Clinical finding and Situation with explicit context."
- Add "Local and" to the beginning of the statement "Other ANA-recognized terminologies should be…"
- Recommend adding "Nursing Problem List Subset of SNOMED CT" as a starter set Applicable Value Set and Starter Set section.
- URL: https://www.nlm.nih.gov/research/umls/Snomed/nursing_problemlist_subset.html

Consumer Access Recommendations

- Recommendation 1: Add New Consumer/Patient Section to the ISA
- Recommendation 2: Add Educational Content with Guiding Text to the ISA for Diverse Stakeholders to Better Understand Interoperability in the Consumers/Patients Arena
- Recommendation 3: Initiate Work to Close Gaps on Existing Use Cases in Regulation for Patient Engagement
- Recommendation 4: Identify Emerging Use Cases that Will Need to Be Addressed and Monitored in ISA

Recommendation 1: Add New Consumer/Patient Section to the ISA

- Add a section to the ISA that informs stakeholders which standards support consumer access to health information and emerging needs like patient generated data
- Efforts should promote the entry of consumer technologies and outline how these emerging standards and use cases solve existing legacy problems for interoperability with patients.
- Efforts should include linkages to Patient Engagement Playbook (in formation)
- Include a new subheading in Section III
    - Interoperability Need: Consumer/Patient Access to Health Information Exchange
- Identified Standards to Include:
    - Direct
    - APIs
    - FHIR

Recommendation 1: Add New Consumer/Patient Section to the ISA

Identified Standards: Known Limitations, Dependencies, and Preconditions for Consideration

- Direct
  - For Direct, interoperability may be dependent on the establishment of "trust" between two parties and may vary based on the trust community(ies) to which parties belong.
  - The leading trust communities to enable communication amongst the most users include DirectTrust (for provider messaging and consumer-mediated exchange) and NATE (for consumer-mediated exchange).
  - Simply implementing technologies that are ONC 2014 or 2015 Edition Certified to meet the View, download, transmit to a third party criteria and/or support this functionality does not guarantee that patients will be able to transmit health information from their various portals, even in provider mediated exchange.
- APIs
  - The utilization of APIs is not new to the industry and they are widely used to exchange data. However, APIs are not standardized.
  - App developers will need to support Open API specs from each EHR to support vendor APIs in use for patients to access electronic health information to flow into their applications
- FHIR
  - While still in the early stages, FHIR has been identified as a rapidly emerging standard, and is currently garnering the most industry wide support to be adopted.
  - Not a regulatory requirement. However, many leading EHR vendors are implementing FHIR to meet regulatory API requirements
  - Links to FHIR communities can help inform APP
    - Argonaut
    - Sync 4 Science

Recommendation 2: Add Educational Content with Guiding Text to the ISA for Diverse Stakeholders to Better Understand Interoperability in the Consumers/Patients Arena

- ONC has identified that there is a low level of interaction with the ISA from consumer stakeholders (app developers, patient advocates, patient organizations, etc.)
- As the ISA expands to offer guidance to a more diverse group of stakeholders implementing, developing and/or leveraging technologies that are consumer facing, it is increasingly important to include guidance on available standards, adoption levels, use cases, and limitations
- Educational content with guiding text will help make the ISA more inviting to a diverse group of stakeholders and encourage involvement and understanding about the current state of consumer/patient access to electronic health information as it relates to industry standards
- Discuss emerging use cases like patient generated data and more (see use cases)

Recommendation 3: Initiate Work to Close Gaps on Existing Use Cases in Regulation for Patient Engagement

- Use Case 1: Defined by API Task Force
    - App Developer builds an app that can benefit from patient data accessed via an API-based connection to EHR data. The patient may choose any app that can interact with the open API (Open API) facilitated by the provider's offered portal
- Provide Context
    - The above use case was based on how EHR vendors interoperate to meet the API requirements in the 2015 Edition Certification
        - Plain language version of the API task force recommendations for the patient and consumer app developer or patient/consumer themselves
    - Identify existing work and initiate work to fill gaps
        - Progress: links to EHR/HIT vendors specifications
        - Gaps: Identity management, certification practice/needs, testing, interoperability and more
        - Relevant supporting work: ONC/OCR privacy and security work in OPEN API, Carequality, Exertia, CARIN, Commonwell, NATE and others

Recommendation 4: Identify Emerging Use Cases that Will Need to Be Addressed and Monitored in ISA

- Provide a forum in the ISA to suggest use cases and identify emerging work, standards, gaps and opportunities for patient/consumer/provider interoperability
- Monitor progress
- Use Case 2: Consumer wants to connect to various clinical providers using an app of their choice, or multiple apps of their choice to aggregate or access aggregated data
    - Central source: like HealthVault or healthbank
    - Record locator and federated query service: like Commonwell
    - Directory and account service: like Yodlee or MINT (in financial services)
- Use Case 3: At the request of the provider, a patient wants to annotate/respond to existing information within the provider EMR using an app of the patient's choice, and have those notes accepted by a synergistic app or functionality within the provider workflow
- Use Case 4: A provider endorses and prescribes an app of their choice to the patient for connection and use with the OPEN API
- Use Case 5: A patient has a medical device that connects to the OPEN API for data flow from the patient to the synergistic app or functionality within the provider workflow (device PGHD)
- Use Case 6: A patient has a medical device that connects to the OPEN API for necessary information for patient self care or monitoring
- Use Case 7: A patient has new unsolicited information to share with the provider from the app of their choice
- Use Case 8: A patient wants to communicate with their provider using secure email
    - NATE
    - Directtrust.org

- Use Care 9: A patient wants to communicate with their provider using secure texting
    - Directtrust.org
- Use Case 10: A patient, having been provided a unique digital identity wants to share this with their care team's systems
    - Knowledge based identity proofing
    - Provider generated identity proofing
    - Government issued identity proofing (USPS e.g.)
    - Industry collaborative identity proofing (Commonwell)
- Use Case 11: A patient participating in research wants to share information with the researcher directly from the provider EHR and to share information from the researcher to the provider system
- Use Case 12: A consumer organization (ie: non-profit) wants to provide an app or ecosystem of patient friendly tools to their patients and needs access to clinical data from EHRs across multiple sites throughout the country
- Use Case 13: A healthcare provider or a payer wants to know whether a person has an "advance directive" or an "advance care plan", or the person may simply want to share (unsolicited) such a document with the healthcare provider and/or alert the insurance company of the existence and location of his/her advance care plan.

Research Recommendations

- Recommendation 1: Add New Clinical Research Section to the ISA
- Recommendation 2: Initiate Work to Close Gaps on Existing Use Cases in Regulation for Clinical Research
- Recommendation 3: 2018 ISA Task Force should continue to build upon this work to expand the ISA's Research areas.

Recommendation 1: Add New Clinical Research Section to the ISA

- Add a section to the ISA that informs stakeholders which standards support Clinical Research needs.
- Define Clinical Research for stakeholders.
- Efforts should promote the use of standards which support clinical research across the research spectrum, both regulated and non-regulated research.
- Special focus should be given to work which is attempting to facilitate the use of data generated in healthcare delivery in regulatory decision-making.
- Identify Standards to be included.
    - CDISC Standards, IHE Profiles, FHIR-based approaches, etc.
- Adding context to common data models used in Clinical Research

Recommendation 2: Initiate Work to Close Gaps on Existing Use Cases in Regulation for Clinical Research

For Section I-Q Research:

1. Interoperability Need: Terminology Standards for Use with Submissions to FDA
2. Interoperability Need: Observational Research and Product Labeling (SNOMED CT and RxNorm)

For Section II-S Research:

1. Interoperability Need: Submission of Data to FDA and other regulatory authorities for regulatory decision-making purposes *[this would include NDAs, new indication, etc.]*
2. Interoperability Need: Extraction and use of data from electronic healthcare sources (including Electronic Data Capture Systems, Electronic Health Records, Clinical Data Warehouses, Mobile) for healthcare data exchange
3. Interoperability Need: Extraction and use of data from electronic healthcare sources (including Electronic Data Capture Systems, Electronic Health Records, Clinical Data Warehouses, Mobile) for submission to regulatory authorities.
4. Interoperability Need: Recognition, extraction and submission of medical products (drugs and devices) adverse event reports from electronic healthcare sources (including Electronic Data Capture Systems, Electronic Health Records, Clinical Data Warehouses, Mobile) to regulatory authorities.
5. Interoperability Need: Registering a Clinical Trial
6. Interoperability Need: Information Models for Observational and Clinical Research

Areas for 2018 ISA Task Force Focus

- Exploring how existing resources (e.g. SAFER guides, PCOR Technical Wiki, etc) can be best included in the ISA.
- Additional text and education to help guide stakeholders through the ISA and standards issues.
- Medical Device Communications to Other Systems or Technologies requires more subject matter expertise.
- Standards for research require more subject matter expertise and continued work.

We appreciate the opportunity to provide these recommendations and look forward to discussing next steps.

Sincerely yours,

/s/	/s/
Lisa Gallagher	Arien Malec
Co-Chair, Health IT Standards Committee	Co-Chair, Health IT Standards Committee

Appendix I – Draft Text for ISA Informational Resources

Understanding Observations and Observation Values

Many kinds of health data are represented as **observations**. A laboratory test result, a vital sign measurement, a pain scale rating, or recording the kind of exercise activity that a patient engaged in (e.g. running, walking, swimming, etc.) can all be considered observations. In this context, we use observation as a generic term. Depending on the domain of interest, you might call these tests, variables, or data elements, etc.

Within and among health IT systems, observations are communicated with a structure that has two key structural elements. The first element identifies *what the observation is*, e.g. diastolic blood pressure, hematocrit, tobacco smoking status, or pain intensity on a 0 to 10 scale. The second element carries *the result value of the observation*, e.g. 80 (mmHg), 40 (%), "current every day smoker", or 5. When used together, these two elements carry the instance of specific test result for a given patient.

Another way to think about this model is as questions and answers. This first element of the structure (the **observation)** is like the question, and the second element (the **observation value**) is like the answer. For example, the question might be: *What is this patient's blood type?* The answer then, might be *O Positive*.

When identifying Vocabulary/Code Sets/Terminology Standards for health data represented as **observations**, the ISA lists separately the different standards for the **observation** and the **observation value** because they fulfill different roles. Quantitative results don't need a standard code for the value: the observation value is simply a number (with its associated units of measure). On the other hand, nominal or ordinal results benefit from having a standard code.

A common pairing for many domains is to use LOINC as the standard code for the **observation** (that's what the O in LOINC stands for), and SNOMED CT as the standard code for the **observation value** when needed. This approach is endorsed by the developers of both of these terminologies and fits their design purpose. Yet, the choice of which vocabulary standard to use for these roles varies by domain. For example, when reporting the results of a validated patient assessment (e.g. the Morse Fall Scale), you may choose to use the LOINC Answer Codes as the **observation value** because they represent the exact text as it appears in that instrument. In contrast, a different approach may be needed when reporting genetic variant results. For example, when reporting a simple genetic variant you could pair the LOINC **observation** code [81252-9] for "Discrete genetic variant" with an **observation value** using an identifier from NCBI's ClinVar. Reporting a complex genetic variant may instead pair the LOINC **observation** code [81262-8] for "Complex variant HGVS name" with an **observation value** expressed in the HGVS nomenclature.

There are some situations where the structure of health IT system removes the need for the two-part observation structure. If an EHR has a "Problem" table where the records are instances or assertions of patient problems (conditions), then there is no need for an observation code. On the other hand, if the structure of the health IT system or the exchange format lacks such a structural element, the patient's problem list could be represented using the observation and observation value pattern.

Understanding Emerging API-Based Standards

A new generation of API-based interoperability standards is emerging. In contrast to traditional interface specifications, these new approaches focus on reuse of standardized APIs and other "building blocks" which can often be re-combined to address new high-level use-cases without requiring a "start from scratch" for each new use-case.

API access to Health IT systems is not new, but following the JASON report and the JASON Task Force recommendations to the HIT Standards and Policy Committees, there is growing interest into a standards-based API that could become widely supported across many kinds of Health IT. One particular emerging standard, HL7's Fast Healthcare Interoperability Resources (FHIR) shows promise as becoming a widely supported standard. Vendors and some large provider groups have created the Argonaut Project to define and publish implementation guides in an effort to standardize FHIR implementations across the Health IT community. The FHIR standard specifies many low-level data access services that can be used as "building blocks" to assemble more complex interoperability functionality.

API-based approaches to interoperability have the advantage that APIs can be assembled to rapidly create different kinds of aggregate functions. However, API-based interoperability still requires attention to important implementation details, similar to traditional interoperability specifications. In particular, given the flexibility of APIs, an API-based approach will need to address many required and optional constraints that are necessary to support a desired use-case. For example, if using FHIR as the base API specification, here are some of the constraints that should be considered:

- Which specific data resources are required for the intended interoperability use-case (e.g., patient, encounter, observation)?
- For each resource, what constraints are placed on the values that are allowed for the resource's data elements (e.g., LOINC, SNOMED)?
- What transport will be used to move the resources back and forth (e.g., HTTP, batch files)?
- Which API operations (e.g. GET (read), PUT (write)) are required?
- For each operation, what operational parameters are required (e.g., supported query parameters for GET)?
- What security model is used to handle authentication, authorization, and encryption (e.g., OAuth, TLS)?
- What other standards are necessary for the overall use-case to be deployed (e.g., HTML, JSON, etc.)?

A specific API-based interoperability use-case will probably need to specify, in the form of an implementation specification, most of the above categories. Some API standards, such as FHIR, contain formal mechanisms (Profiles, Conformance Statements) for specifying constraints, though even a comprehensive specification like FHIR will require that some of the constraints are documented outside of the standard's formal tools.

To give a more concrete example, consider the "SMART on FHIR" interoperability specification. SMART on FHIR defines a mechanism for interoperable "SMART Apps" that can be plugged in to EHRs and other Health IT systems. Each SMART App can expose a user interaction, and can access data in the underlying system. This presents a powerful way to extend EHR capabilities via "pluggable" app functionality. Dozens of SMART apps are available, with more expected in the future. These apps serve many different

clinical needs, yet they all use the same underlying FHIR-based API functionality. However, even though SMART apps are all based on the FHIR standard, it's not sufficient to simply say "use FHIR". Here are some of the additional specifications that are needed:

- Resources – Which FHIR resources are available to the App developer? Many EHR vendors are choosing to expose some of the resources defined in ONC's 2015 Edition Health IT Certification Criteria API requirement. Typical resources available include: Patient, Encounter, Condition, Observation, etc. Not all vendors will elect to expose the exact same set of resources, and some apps may require resources that are not contained in the 2015 Certification list, such as Schedule.
- Resource Profiles – For each supported resource, the FHIR implementation will follow some Profile that specifies how the data fields in the resource will be populated. The Profile will usually define the cardinality of the data (zero, one, or many instances allowed) as well as the Value Sets supported (e.g., LOINC, SNOMED, RxNorm, etc.) Note that formal use of FHIR Profiles is not widely supported at present, so the data constraints are often documented via spreadsheet or other informal means.
- Transport – SMART Apps use HTTP as the transport since they are designed to be interactive and need real-time access to EHR data. The FHIR specification contains a clear mapping of standard data operations (read, write, update, etc.) to the standard HTTP verbs (PUT, GET, etc.)
- API Operations – The 2015 Certification specification currently requires that EHRs support "read only" operations, using the HTTP GET operation. Some vendors have begun to support selected "write" operations using POST, PUT, or UPDATE. Note that the supported write operations may apply only to certain resources. For example, an app might be able to PUT a new Observation, but not be allowed to PUT a new Encounter.
- Parameters – for each resource and operation, the interoperability specification will need to specify which data access parameters are supported. Typically, these include the types of query functions supported by the GET operation. For example, some implementation will support "GET Patient" using the patient's medical record number, but might not support a "GET Patient" using the SSN or a hospital room number.
- Security Model – The SMART on FHIR specification makes heavy use of the OAuth 2 security standard to orchestrate the HTTP transactions. OAuth may be combined with OpenID Connect in order to cover both authentication and authorization. HTTPS (TLS) is required for on-the-wire encryption. Note that the OAuth 2 standard (which is managed by the IETF) requires its own implementation guide to constrain it for healthcare uses.
- Other Standards – SMART Apps can use HTML5 to control the visual expression of the app, so in some sense, HTML5 is part of the overall specification for SMART on FHIR.
- Trust Relationship – For interoperability using FHIR to work, a trust relationship must be established between entities (ie an EHR/clinical system and an app). This is currently being accomplished by establishing siloed ecosystems. Without an established trust relationship, access to information is not possible regardless of the standards used.

This example illustrates that even though API-based interoperability enables powerful new approaches, there is still a need to carefully specify and constrain each layer of the overall interface orchestration in order to achieve the desired degree of standardization and interoperability.