# Health Information Technology Advisory Committee
## Meeting Summary
### October 17, 2018, 9:30 a.m. – 12:30 p.m. ET
### Virtual

The October 17, 2018, Health IT Advisory Committee (HITAC) meeting was called to order at 9:32 am ET by Lauren Richie, Designated Federal Officer (DFO), Office of the National Coordinator for Health IT (ONC).

**ROLL CALL**
(Members in attendance, representing)
**Carolyn Petersen**, Individual, HITAC Co-chair
**Robert Wah**, DXC Technology, HITAC Co-chair
Christina Caraballo, Audacious Inquiry
Cynthia A. Fisher, WaterRev, LLC
Brad Gescheider, PatientsLikeMe
Valerie Grey, New York eHealth Collaborative
Kensaku Kawamoto, University of Utah Health
Steven Lane, Sutter Health
Arien Malec, Change Healthcare
Clem McDonald, National Library of Medicine
Aaron Miri, The University of Texas at Austin, Dell Medical School and UT Health Austin
Brett Oliver, Baptist Health
Terrence O'Malley, Massachusetts General Hospital
Raj Ratwani, MedStar Health
Steve L. Ready, Norton Healthcare
Sasha TerMaat, Epic
Andrew Truscott, Accenture LLP
Sheryl Turney, Anthem BCBS
Denise Webb, Marshfield Clinic Health System
Michael Adcock, University of Mississippi Medical Center
Tina Esposito, Advocate Health Care

**Federal Representatives**
Ram Sriram, National Institute of Standards and Technology (NIST)

**Members not in attendance:**
Kate Goodrich, Centers for Medicare & Medicaid Services (CMS)
Anil Jain, IBM Watson Health
John Kansky, Indiana Health Information Exchange
Leslie Lenert, Medical University of South Carolina

Denni McColm, Citizens Memorial Healthcare
Chesley Richards (CDC)
Patrick Soon-Shiong, NantHealth
Lauren Thompson, Department of Defense/Department of Veterans Affairs (DoD/VA)

**ONC Senior Staff**
Steve Posnack, Executive Director, Office of Technology
Elise Sweeney Anthony, Executive Director, Office of Policy
John Fleming, Deputy Assistant Secretary for Health Technology Reform
Seth Pazinski, Director, Office of Planning, Evaluation and Analysis
Lauren Richie, Designated Federal Officer

## Welcome Remarks
*Elise Sweeney Anthony, Executive Director, Office of Policy (ONC)*

**Elise Sweeney Anthony** welcomed the Health Information Technology Advisory Committee (HITAC) and thanked the committee on behalf of Dr. Rucker. She welcomed representatives from the National Committee on Vital and Health Statistics (NCVHS) who will be sharing information about their work. She also thanked the Interoperability Standards Priority Task Force (ISPTF) and the Annual Report Workgroup (ARWG) for the work they are doing to move forward their objectives and charges.

Elise shared that ONC's rule is now under consideration by the Office of Management and Budget (OMB) and noted that ONC looks forward to releasing the rule in the near term. Once released, the HITAC will review and provide feedback.

Elise also shared that the EHR reporting program request for information (RFI) has been out for some time and ONC is looking forward to hearing from the public. Comments are due today, October 17, 2018, by 5:00 pm. The feedback will be brought back to the HITAC once consolidated and summarized for consideration.

On behalf of Steve Posnack, Elise gave a plug for his blog regrading Fast Healthcare Interoperability Resources (FHIR). She also noted that the security risk assessment tool has been updated and can be found on ONC's website.

ONC's annual meeting is on November 29-30, 2018 and it will be a combination of plenary and break-out sessions. The public is encouraged to register as soon as possible.

In closing, Elise thanked the committee for the work that they do, especially in a volunteer capacity.

She turned the meeting over to **Carolyn Petersen**.

**Carolyn Petersen** reviewed the agenda for the meeting.

**Vote to Approve Minutes**
**Carolyn Petersen** called for a vote to approve the minutes from the September 5, 2018 meeting. No comments or amendments were offered; and the minutes were approved.

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### Overview of Heat Wave ONC blog post on FHIR
*Wes Barker, Analyst, Office of Technology (OTECH)*

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**Wes Barker** presented an overview of the recent ONC blog post on FHIR. He shared details regarding the underlining analysis presented in the blog.

- ONC reviewed the API documentation for all 2015 Edition products certified to 170.315(g)(8) ("Application access-data category request").
- Documentation is available on developers' public websites.
  - Links to documentation (webpages and PDFs) are available on the CHPL: https://chpl.healthit.gov/#/collections/apiDocumentation.
- Documentation was reviewed by ONC staff to determine the syntax of the certified API. It was determined whether the API used FHIR (release 2 or 3), a non-FHIR RESTful API, or another API.
- Medicare EHR Incentive Program attestation data were used to approximate developer market share.
- Data were merged to approximate availability of FHIR among hospital and office-based practices, given most recently reported certified technology.
- These measurements approximate FHIR availability if health care providers upgraded their certified technology to 2015 Edition.

Results
- 32% of the health IT developers certified to 170.315(g)(8) published that they are using FHIR Release 2.
- Nearly 51% of health IT developers are using a version of FHIR combined with OAuth 2.0.
- The specific version of FHIR could not be determined in all cases. Unless the version was explicitly stated in the documentation, it was documented as "some version of FHIR."
- Although approximately one in three developers uses FHIR Release 2 and half use any version of FHIR, the market impact is much greater.
- 87% of hospitals and 69% of clinicians are served by health IT developers with product(s) certified to any FHIR version.

- 82% of hospitals and 64% of clinicians use certified technology from the ten developers with the largest market share.
  - All ten of these developers have certified APIs that use FHIR.

Ten developers with the largest market share and their use of FHIR is presented below:

| Ten Developers with the Largest Market Share | API standard Referenced | % of Hospitals Report Using | % of Clinicians Report Using |
|---|---|---|---|
| Allscripts | FHIR Release 2 | 5% | 9% |
| athenahealth | FHIR Release 2 | <1% | 5% |
| Cerner | FHIR Release 2 | 21% | 5% |
| CPSI | FHIR Release 2 | 10% | - |
| eClinicalWorks | FHIR Release 3 | - | 7% |
| Epic | FHIR Release 2 | 21% | 27% |
| GE | FHIR Release 2 | <1% | 5% |
| MEDHOST | FHIR Release 2 | 5% | - |
| Meditech | FHIR Release 2 | 20% | <1% |
| NextGen | FHIR Release 2 | <1% | 6% |
| Total | | 82% | 64% |

Looking at these ten developers, the overall market impact can be seen.

Wes also reviewed two maps that were presented to demonstrate geographic FHIR use. Hospital referral regions (HRRs) were used to display the information.  HRR's are boundary lines in healthcare used to show healthcare referrals, patient sharing, and healthcare coverage.  It provides a boundary line that county or state lines don't provide.

Two maps were shared one for hospital data and another for clinician data.  The percentage of hospitals with FHIR enabled with the 2015 Edition were approximated.  Only two HRRs would not be enabled with FHIR.  For clinicians, there are a few additional regions not covered for those on the 2015 Edition.  In summary, most of the country and over half of clinicians would have a certified electronic health record (EHR) enabled with FHIR.

The API documentation is available on CHPL:
https://chpl.healthit.gov/#/collections/apiDocumentation

Medicare EHR Incentive Program Attestation Data:
https://dashboard.healthit.gov/datadashboard/documentation/ehrproducts-mu-attestation-data-documentation.php

**Discussion**

**Arien Malec** commented that this is fantastic data and thanked ONC for providing the survey information.  He shared that this has been the fastest development of standards due to the mechanism used to get FHIR spread throughout the country.  He noted that he will retweet this on his Twitter thread.  He provided a bit of history on the Argonaut Project development which brought provider and developer organizations together and was led by Micky Tripathi who helped drive standards based FHIR application protocol interfaces (APIs).  ONC enabled this approach by putting together functional certification criteria, rather than naming standards. This was a well-formed consortium that drove voluntary adoption, and it provided a thoughtful means of standards development.  This is leading to a secondary revolution such as other Health Apps providing the ability to import data into people's records. This is what a successful policy framework looks like and is a model for good standards-based evolution which has led to the most rapid evolution of standards availability in the country.  He applauded ONC on getting to this point.

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### National Committee on Vital and Health Statistics (NCVHS) Update
*Bill Stead, NCVHS Chair*
*Rich Landen, NCVHS & Member of Subcommittee on Standards*
*Rebecca Hines, NCVHS Executive Secretary/DFO*

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**Bill Stead, NCVHS Chair,** thanked the HITAC for the opportunity to discuss collaboration between HITAC and NCVHS.  He began by sharing NCVHS' mandate:

- Assist and advise the HHS Secretary on health data, statistics, privacy, national health information policy, and the Department's strategy to best address those issues.
- Assist and advise the Department in the implementation of the Administrative Simplification provisions of the Health Insurance Portability and Accountability Act (HIPAA).
- Inform decision-making about data policy by HHS, states, local governments, and the private sector. The NCVHS Charter was approved in January 2018.

He noted that 21st Century Cures calls for HITAC to coordinate with NCVHS.
- To avoid conflict in the items being recommended these committees should work to converge on activities and deliverables.  The better the coordination, the better the committees will be at serving the industry.

He shared a key point from public comment: "It's important to consider the opportunity, as technologies advance, to move away from the currently dominant model of 'billing-system-with-clinical-bolted-on' and towards integrated systems that use one set of underlying standards (or, better yet, a single harmonized standard) that reflect the reality that this is all supposed to be about one goal: patient care. Providers, public health, and billing/payors ultimately really need the same data—what care was given for what patient

characteristics—abstracted at different levels. Reflecting that in base standards would do a lot to advance the technology field towards integrated/seamless systems."

**Bill Stead** then reviewed NCVHS' work plan for 2018 which included:
- Predictability Roadmap (Standards)
- Health Terminologies and Vocabularies (Standards)
- Health Information Privacy and Security Beyond HIPAA (Privacy, Confidentiality, Security)
- Next Generation Vital Statistics (Population Health)
- Small Area Population Health Data (Population Health)
- 21st Century Cures Collaboration with ONC and HITAC

Predictability Roadmap
- Standards development, adoption and implementation are not predictable and are not keeping pace with business and technology innovations.
- The Predictability Roadmap is an initiative to evaluate barriers to the update, adoption and implementation of standards and operating rules under the authorities of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and the Patient Protection and Affordable Care Act of 2010 (ACA).
- For the past 18 months, NCVHS has been collaborating with industry stakeholders to understand the challenges and develop actionable recommendations for the Secretary of HHS, covered entities, standards development organizations and operating rule authoring entities.

Emphasis of Recommendations
- Improvements for the federal processes
    - More visible enforcement of existing regulations
    - More frequent guidance and outreach to industry
    - Improve responsiveness to NCVHS recommendations and timeliness of regulatory activities
- Improvements for standard development organization (SDO) processes
    - Increase diversity of industry participation in standards and operating rule workgroups
    - Improve timeliness of standards development to support innovation and evolving business and technology changes
    - Improve workgroup processes for productivity
- Governance and Oversight (Stewardship)
    - Transparency of processes (Federal and SDO)
    - Advancing industry needs and garnering value from standards

Roadmap Outcome Goals

1. Improved education, outreach, and enforcement will promote efficient planning and use of the adopted HIPAA standards and operating rules. This goal supports the themes of regulatory processes and third parties as covered entities.
2. Policy levers will successfully support industry process improvement changes. This goal supports the themes of governance and updates to standards.
3. Regulatory levers will enable timely adoption, testing, and implementation of updated or new standards and operating rules. This goal supports updates to standards and regulatory processes.

Input on Recommendations
- Submit public comment to the committee to NCVHSmail@cdc.gov
  - Would these recommendations improve the predictability of the adoption of administrative standards and operating rules?
  - What additional recommendations are critical to achieving predictability?
- Specific questions:
  - What is the value proposition of each recommendation and what improvements to the current state do you believe will arise from each recommendation or group of similar recommendations?
  - Are there potential unintended consequences from any of the recommendations? What are those and how can they be mitigated with modifications to the recommendations?

Near-Term Opportunities
1. Update principles to guide adoption of health terminologies and vocabularies
2. Develop principles for updates to health terminologies and vocabularies
3. Scope a project to evaluate ICD-11

**Bill Stead** noted that most of the work is built around managing compliance risk.  How to protect consumers from misuse, does not currently exist and may be handled with regulatory compliance or new data protections (e.g., GDPR and California).

He noted that an essential question on the road to harmonization is whether it is in the best interest of patients, the U.S. health care business community, and health statistics and research to maintain an health level seven (HL7) clinical document architecture (CDA)/ fast healthcare interoperability resources (FHIR)/ extensible markup language (XML) system for clinical and an X12/ National Council for Prescription Drug Programs (NCPDP)  electronic data interchange (EDI) system for administration and payment.

**Bill Stead** also noted that a scoping document was developed and shared with the HITAC prior to the meeting to help the committees collaborate.

**Elise Sweeney Anthony** thanked Bill and NCVHS and noted that she looks forward to the collaboration between ONC's HITAC and NCVHS.

## Discussion

**Steven Lane** commented that as a practicing clinician there is a challenge with all the different standards and the various ways to support and implement standards. At a high-level, simplification and harmonization makes a lot of sense. The key question is, what is the best path forward? The challenge is looking for opportunities to collaborate going forward, and there even may be an opportunity with the ISPTF which will be presenting next.

**Arien Malec** thanked Bill and NCVHS for the presentation. He also agreed that the administration inefficiency of split systems is a drag on the industry. As an example, accountable care organizations (ACOs) and Medicare Advantage (MA) plans that receive risk adjusted funds often require reconciliation to clinical records and claims because the risk adjustment is based on administrative data. A more efficient process would allow for better methods for risk adjustment. He questioned what it would take for CMS to change its risk adjustment and clinical quality measurement systems, as an example? A way to frame this problem is to think about the timeframe, as it will be a long journey, but one that can't be completed if it isn't started.

- **Rebecca Hines, NCVHS,** commented that the recommendations are laid out in three phases to reflect Arien's comment.

**Clem McDonald** added a few additional comments:
- One of the strong points made during the summer discussions was that there was only one code for usage.
- NCPDP was not listed in the standards.
- Coding systems are the same thing and shouldn't be forgotten.

**Christina Caraballo** commented that this looks like an area that a deeper look is needed for harmonization. She noted that a section can be added in the annual report to bring up the topic. Based on the public comment shared, there seems to be a widespread desire to move away from having different approaches for billing and clinical systems.

**Lauren Richie** then turned the meeting over to the Interoperability Standards Priorities Task Force chairs.

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### Interoperability Standards Priorities Task Force (ISPTF)
*Steven Lane and Ken Kawamoto, ISPTF co chairs*
*Dan Vreemen, Regenstrief/LOINC*

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**Steven Lane, ISPTF co-chair,** presented draft recommendations to the HITAC.

- The ISPTF held three meetings on orders and results.
- The ISPTF reviewed the relevant sections of the Interoperability Standards Advisory (ISA) pertaining to orders and results.
- The ISPTF received presentations from Ken McCaslin (Accenture), Virginia Turmel (Quest Diagnostics), Swapna Abhyankar & Dan Vreeman (Regenstrief Institute/LOINC) on the standards associated with orders and results.
- The ISPTF, in subsequent discussions, identified two priorities associated with orders and results

## Orders and Results Priorities and Draft Recommendations

- Priority 1: Results Ordering
  - Priority 1A: Consistent encoding of lab and other test results
  - Priority 1B: Results need to be sent to clinicians in codified format
  - Priority 1C: Results need to be available for patients/proxies to effectively view, receive, and utilize
  - Priority 1D: Orderable tests need to be standardized between systems and with mapping to standard terminologies
- Priority 2: Standardization
  - Priority 2A: Need standard methodology to integrate external decision support for all stakeholders into orders workflow
  - Priority 2B: Need standards to support Prior Authorization workflows

## Priority 1: Results Ordering

- Priority 1A: Consistent encoding of lab and other test results
  - Standardized Logical Observation Identifiers Names and Codes (LOINC) and Systematized Nomenclature of Medicine - Clinical Terms (SNOMED-CT) coding must be provided by resulting agencies as a Clinical Laboratory Improvement Amendments (CLIA) requirement.
    - Identify and prioritize the most common/important results of each order type.
    - Require and enforce the use of information models and terminology standards for all test orders and results.
    - Mapped codes must be included with results as they are maintained in and exchanged between health information technology systems.
    - Resulting systems (e.g. electronic health records (EHRs) & laboratory information systems (LISs)) should provide a mechanism that allows clients to map internal result codes to standard vocabularies.
    - Implement mechanisms to support and ensure proper LOINC encoding by resulting agencies, such as auditing or certification by CLIA.
  - Potential Policy Actions Addressing Priority 1A

- o ONC
  - Use available EHR data sources to assess current compliance with Laboratory Results Interface (LRI) specifications & LOINC and SNOMED encoding to identify areas for additional focus.
  - Work with Health Level 7 (HL7) & industry stakeholders to create an LRI companion guide for HL7 Medical Document Management (MDM) and associated content and terminology standards to allow standards-based exchange of textual reports.
  - Continue work with Center for Medicare & Medicaid Services (CMS), Centers for Disease Control & Prevention (CDC) and associated industry stakeholders, e.g., the American Medical Association (AMA) Integrated Health Model Initiative, to harmonize information models and terminology standards to electronic clinical quality measures (eCQM) definitions and reportable disease requirements.
  - Continue coordination with Food and Drug Administration (FDA), CLIA and the National Library of Medicine (NLM) to establish mapping between the output of analysis devices and LOINC terms.
- o FDA
  - Continue to promote use of LOINC in diagnostic device approval and oversight.
- o CMS
  - Establish safe harbors or fast lanes for fulfilling CLIA quality obligations through delivery of HHS-endorsed standards-based results (e.g., LRI with LOINC encoding) electronically to certified EHRs.
  - Require certification under CLIA to HHS-endorsed standards-based results (e.g., LRI with LOINC encoding).
  - Work with the National Institute of Standards & Technology (NIST) to develop and provide testing program to assure compliance with coding standards.
  - Should above steps be insufficient to promoting standards-based interoperability, require certification as a condition of payment.

- Priority 1B: Results need to be sent to clinicians in codified format
  - o Utilize US Core Data for Interoperability (USCDI) to assure that prioritized results are interoperable via HL7 v2 messages (where applicable), C-CDA, Fast Health Information Resources (FHIR), and future transport standards.
  - o Prioritize complete and accurate coding at the data source (e.g., LIS, RIS) rather than trying to code or correct externally sourced data downstream.
  - o Require that resulting agencies provide standardized metadata, (e.g., methodology, units, normal ranges) to ordering and copy to providers as well as patients.

- o Standard metadata must be maintained as result data is transmitted between systems (e.g., LISs, Imaging systems, EHRs, PHRs, HIEs, Payers, and Public Health).

- o Priority 1B: Potential Policy Actions
- o ONC
  - Work with HL7 and industry stakeholders to map and harmonize USCDI to LRI, Laboratory Order Interface (LOI) & associated implementation guidance, and Argonaut-profiled FHIR, and support end-to-end stakeholder testing of discrete lab result and report transmission to providers and patients.
- o CMS
  - Establish guidance promoting use of standards (LRI, LOINC and others) with certified HIT to address laboratory requirements for accurate reporting.
  - Include laboratory and other result transmittal requirements in Advanced Alternative Payment Model (APM) program requirements (e.g., require Medicare Shared Savings Program [MSSP] applicants to specify how provider participants will receive standards-based electronic results).
  - Reconsider "topped out" nature of electronic laboratory receipt in the Merit-based Incentive Payment System (MIPS) program. Previous requirements addressed receipt or entry of electronic laboratory information but not the structure, content and terminology associated with such receipt which should be re-introduced with these additional requirements.
  - Work with NIST to develop and provide testing program to assure compliance. Other Federal Agencies » Require use of standards-based laboratory receipt in VHA, DoD MHS, IHS, and other applicable Federal provider organizations (e.g., DOJ, DHS).

- Priority 1C: Results need to be available for patients/proxies to effectively view, receive, and use
  - o Require that ordering providers make results available to patients/proxies within a reasonable timeframe, as allowed by state laws, assuring that, where appropriate, providers have an adequate opportunity to review and comment on results to facilitate patient interpretation.
  - o Make all results in the EHR available to patients via APIs, whether results are LOINC/SNOMED-CT encoded.
  - o Develop and require the use of standardized "patient friendly" result display names to patients based on LOINC and SNOMED-CT standards (in process).
  - o In the future consider requiring resulting agencies to make results available directly to patients. This could initially be required via CLIA regulations. As

necessary, this could be required as a condition of payment for resulting agencies.

- o Alignment of state and federal policies to assure consistent and predictable patient data accessibility and interoperability. This should begin with a clear articulation of varying state requirements, followed by specification of national standards to promote maximal sharing of data with patients/proxies in both human and machine-readable formats.

- o Potential Policy Actions Addressing Priority 1C
- o CMS
  - Make patient access to data via APIs a required measure for all relevant programs.
  - Augment program requirements to include receipt of information in other standardized structured formats (e.g., C-CDA) like API requirements.
  - Continue to promote patient access and API requirements using certified HIT.
- o ONC
  - Facilitate completion and maturation (with relevant stakeholder feedback) of ongoing LOINC work to define patient friendly result display names.
  - Encourage and facilitate use of patient-friendly terms for patient-facing purposes.

- Priority 1D: Orderable tests need to be standardized between systems and with mapping to standard terminologies
  - o Develop and eventually require the use of standards-based catalogs of orderable tests with consistent mapping to associated code sets (e.g., LOINC) for all order types.
  - o Utilize consensus development process to develop standard orderables for the most common/important tests of each order type, including the orders that link to prioritized results.
  - o Standardize commonly used order panels, building on the ~2,000 order panels currently cataloged by LOINC.

**Ken Kawamoto, ISPTF co-chair,** reviewed the second priority area.

**Priority 2: Standardization**
- Priority 2A: Need standard methodology to integrate external decision support for all stakeholders into orders workflow
  - o Leverage and advance CDS Hooks standard.

- o Develop and support the use of standards to determine and expose net pricing information to relevant stakeholders including providers, payers, and patients.
- Priority 2B: Need standards to support Prior Authorization workflows
  - o Several prior authorization standardization efforts are underway, including Da Vinci, NCPDP, and CMS AUC requirements. These efforts should be harmonized into a consistent approach.

**Next Domain Area for ISPTF Review**

- Closed loop referrals and care coordination
- Meetings scheduled 10/23/18, 11/13/18 and 11/27/18

**Dan Vreeman**, **Regenstrief Institute/ LOINC** made a few additional comments. He applauded the task force for this great work and noted that it is signaling an important direction. Tying back to the NCVHS update, LOINC is focused on creating specific identifiers for tests, observations, and documents. Consistent orders and results facilitate the development of other priorities mentioned and it is a facilitator of the other goals recommended.

Dan then highlighted a few items:

- The general recommendations of CLIA is a good start, but as the TF outlined, encouragement of additional requirements will help move the ball forward.
- Prioritizations of tests and results can be helpful. On the lab side they have looked at the patterns of orders and results.
  - o The results side is a little dated, but a small number of tests account for the large portion of the volume. The downside is that across institutions, the core common set does vary. You can achieve significant benefit even if not everything is done and 99% of patients had all their data in the common set. There may be some things that don't get coded immediately, but broad-based benefit can be achieved with prioritization.
  - o On the order side, LOINC worked with the S&I Framework in 2015 to come up with a common order set and ended up with a consensus-based list of orders. That work was important, but it does need to be refreshed.
- Strong implementation guide standards from HL7, thinking about the semantic standards and the relation to syntax standards is important in thinking about the path of exchange. He noted that there is a need to make sure the semantic representation works across all models.
- FDA encourages standardized coding of test results. That activity is ongoing, and momentum seems to be building.

- In October, LOINC entered into a cooperative agreement with ONC to work on LOINC development around the data classes described in the USCDI.  In addition, they will continue to monitor the policy vision around order panels.
  - Additional flexibility may be needed for reuse in certain context and input from the community will be considered.
- The American Clinical Lab Association did a study that demonstrated cost savings for implementing an electronic directory of services.

**Steven Lane** commented that these are interim recommendations that are being presented and the taskforce anticipates briefing final recommendations back to the HITAC for approval in the September 2019 timeframe.  Until then, findings will be refined in alignment with the other priority use areas.  As the priorities are worked through, the taskforce will leverage the work done on each priority area to inform the next.

## Discussion

**Clem McDonald** commented regarding getting the information to the patient; if there isn't a code on the name of the test, it will not be possible to get the names to line up to share with the patient. The test result versus what it measured is different.

- **Steven Lane** noted that the desire is to have both items standardized and codified.  Noting that the taskforce believes that all items should be standardized and required by all agencies.  There was additional feedback from the taskforce that there are no standards for the timing of the release of results to patients.  Standards of when results are released will need to be harmonized.  These additional comments will be incorporated into the final recommendations.

**Cynthia Fisher** commended the work and highlighted the importance of releasing the information to the patient when it is digitally available.  She also noted that billing and pricing information is becoming more important for the standardization of the codes.

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### Health IT Advisory Committee Annual Report Workgroup (ARWG) Update
*Carolyn Petersen and Aaron Miri, ARWG co-chairs*

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**Carolyn Petersen, ARWG co-chair,** reviewed the Annual Report Workgroup's schedule, noting that the workgroup has met four times already with the next meeting on October 18, 2018.  She went on to review the proposed annual report structure.

## Proposed Annual Report Structure

   i.    Executive Summary
  ii.    Overview

iii.    HITAC Progress in FY18
iv.    Health IT Infrastructure Landscape Analysis
v.    Health IT Infrastructure Gap Analysis
vi.    Recommendations for Addressing Health IT Infrastructure Gaps
vii.    Suggestions for Additional HITAC Initiatives VIII. Conclusion
viii.    Appendices

## Proposed Annual Report Structure

- Overview
  - Legislative Requirements
  - Current ONC and HITAC Priorities
- For Each Priority Target Area:
  - Background
  - Current State
    - Describe Recent Advancements for Various Topics
    - Provide Examples from Stakeholder Groups

## Landscape Analysis: Interoperability

- Current State Topics and Advancements
- Existing exchange efforts including Direct Trust, Health information Exchanges (HIEs), vendor networks, Consolidated Clinical Document Architecture (C-CDA)
- ONC's proposed regulation covering open APIs, information blocking, and other health IT topics
- Draft Trusted Exchange Framework
- Standards and implementation specifications to support priority uses of health IT
  - U.S. Core Data for Interoperability (USCDI)
  - Interoperability Standards Priorities
  - HL7's Fast Healthcare Interoperability Resources (FHIR) standard for transferring electronic medical records

## Landscape Analysis: Privacy and Security

- Current State Topics and Advancements
  - OAuth 2.0 security profiles for authentication
  - Privacy and security protections for patient-generated health data, remote monitoring data, and other telehealth data
  - User-controlled mental health and behavioral health information sharing – Interoperability frameworks such as CareQuality
    - Health IT activities that address opioid epidemic and social determinants of health

- - HHS Office for Civil Rights (OCR) consumer and provider guidance for mental health and behavioral health
  - Substance Abuse and Mental Health Services Administration (SAMHSA) guidance for 42 CFR part 2
  - Privacy and security concerns arising from increased health information sharing for research purposes
    - For example, Apple ResearchKit, PatientsLikeMe, 23andMe, and the NIH All of Us Research Program
  - Improved patient matching and verification
    - HHS PCOR Patient Matching, Aggregating and Linking (PMAL) Project and many other efforts
  - Disaster planning for health IT – HHS HIPAA Security Risk Assessment tool

## Landscape Analysis: Patient Access to Information

- Current State Topics and Advancements
- Blue Button initiatives
  - MyHealthEData at CMS
- Data collection using mobile/wearable devices
  - FDA pre-certification program
- Use and sharing of patient-generated health data
  - ONC PCOR PGHD Policy White Paper, Practical Guide and Patient Engagement Playbook
  - Changes to Current Procedural Terminology (CPT®) code set to support telehealth
- Use and sharing of social determinants of health data
  - Efforts to standardize data capture using Logical Observation Identifiers Names and Codes (LOINC)
  - Efforts to address health inequities
- Emerging platforms for data sharing by patients and caregivers
  - For example, Apple HealthKit and OpenNotes

## Gap Analysis

## Proposed Gap Analysis Structure

- For each priority target area:
  - Gaps Identified
  - Opportunities Identified

## Gap Analysis: Interoperability

Interoperability Gaps Identified by Workgroup

- Ongoing efforts regarding open APIs, information blocking, Trusted Exchange Framework, and standards and implementation specifications

- Lack of knowledge about user experience of health information exchange
- Unmet needs of additional care settings and stakeholder groups
- Delay in timeliness between issuance of guidelines and development of technology
- Need to increase level of interoperability
- Need to improve data quality, provenance, and usefulness
- Infrastructure needs of stakeholder groups, especially broadband access

Interoperability Opportunities Identified by Workgroup
- Establish usability metrics for health information exchange
- Expansion of priority use cases to meet needs of additional care settings and stakeholder groups
- Address alignment of timeliness of guidelines and development of technology
- Incentives for change across stakeholder groups to improve level of interoperability and data quality
- Support for increased broadband access across stakeholder groups, especially underserved populations
- Continue to improve patient matching when sharing data
- Address "reality gap" between perception of what certification requires and its operationalization
  - For example, continued mapping of Common Clinical Data Set via C-CDA and FHIR standards required when integrating networks and sharing data among smaller providers who may lack resources

## Gap Analysis: Privacy and Security

Privacy and Security Gaps Identified by Workgroup
- Variability of information sharing policies across states
- Lack of knowledge about HIPAA and Confidentiality of Substance Use Disorder Patient Records (a.k.a. 42 CFR Part 2) regulation implications
- Lack of user control to share and disclose information
- Implications of European Union's General Data Protection Regulation (GDPR) and Privacy Shield
- Implications of the California Consumer Privacy Act of 2018
- Widespread adoption of cybersecurity framework(s)
- Lack of user awareness and education about privacy and security settings
- Implications of emergence of the Internet of Things (IoT)

Privacy and Security Opportunities Identified by Workgroup
- Increased uniformity of information sharing policies across states
- Education about HIPAA and Confidentiality of Substance Use Disorder Patient Records (a.k.a. 42 CFR Part 2) regulation implications
- Granular levels of consent to share and disclose information

- Address implications of European Union's General Data Protection Regulation (GDPR) and Privacy Shield
- Address implications of the California Consumer Privacy Act of 2018
- Support for widespread adoption of cybersecurity framework(s)
- Education of technology users about privacy and security settings, especially for social media
- Consider what to regulate about the Internet of Things (IoT)
- Continue to improve patient matching when sharing data

## Gap Analysis: Patient Access

Patient Access Gaps Identified by Workgroup
- Lack of patient and caregiver access to patient data
- Use and sharing of patient-generated health data (PGHD) and other data from mobile devices
- Need to improve alignment of timing of planning activities with operational impact of technology development
- Potential for lack of net neutrality due to market forces
- Unmet infrastructure needs for underserved populations
- Accessibility and usability of patient portals continue to need improvement
- Patient awareness and education about health IT resources

Patient Access Opportunities Identified by Workgroup
- Support use of APIs to improve access to patient data
- Consider workflow and technology improvements to increase use and sharing of PGHD and other data from mobile devices
  - For example, impact of clinical grade data collected by patients on testing costs
- Better align timing of planning activities with operational impact
- Consider implications of varying experiences with net neutrality at national, state, and local levels
- Support infrastructure needs for underserved populations, including exchange costs, prevalence of electronic equipment, internet access, availability of pharmacy services, and use of telehealth services
- Patient and caregiver education about health IT resources
- Consider improvements to accessibility and usability of patient portals and other patient-facing technology
- Encourage patient and caregiver education about health IT resources
- Address "reality gap" between perception of what has been certified for a system and what is truly interoperable in the field

**Carolyn Petersen** then turned the presentation over to her co-chair, **Aaron Miri,** to present the initial recommendations ideas.

**Aaron Miri** stressed that these are initial recommendations and ideas. He commented that it is important that the committee help inform items that might be missing and there will be time at the end of the presentation to help identify those items.

## Initial Recommendation Ideas

### Recommendations Ideas: Interoperability

Potential Interoperability Activities Identified by Workgroup to Date
- Opportunity: Address "reality gap" between perception of what has been certified for a system and what is truly interoperable in the field
  - For example, continued mapping of Common Clinical Data Set via CCD-A and FHIR standards required when integrating networks and sharing data among smaller providers who may lack resources to upgrade their systems
  - HITAC Activity Idea: Further measure whether systems are truly interoperable at both content and transport levels after implementation, especially among smaller providers

Other Opportunities for Further Consideration
- Establish usability metrics for health information exchange
- Expansion of priority use cases to meet needs of additional care settings and stakeholder groups
- Address alignment of timeliness of guidelines and development of technology
- Incentives for change across stakeholder groups to improve level of interoperability and data quality
- Support for increased broadband access across stakeholder groups, especially underserved populations
- Continue to improve patient matching when sharing data

### Recommendations Ideas: Privacy and Security

Potential Activities Identified by Workgroup to Date
- Opportunity: Increased uniformity of information sharing policies across states
  - Address implications of the California Consumer Privacy Act of 2018 – HITAC Activity Idea: Consider federal role in setting guidelines for exchange of data across states
- Opportunity: Support for widespread adoption of cybersecurity framework(s)
  - HITAC Activity Idea: Consider whether a nationwide cybersecurity framework should be adopted
  - HITAC Activity Idea: Delineate cybersecurity accountability for data by role

Other Opportunities for Further Consideration
- Education about HIPAA and Confidentiality of Substance Use Disorder Patient Records (a.k.a. 42 CFR Part 2) regulation implications
- Granular levels of consent to share and disclose information
- Address implications of European Union's General Data Protection Regulation (GDPR) and Privacy Shield
- Education of technology users about privacy and security settings, especially for social media
- Consider what to regulate about the Internet of Things (IoT)
- Continue to improve patient matching when sharing data

## Recommendations Ideas: Patient Access to Information

Potential Activities Identified by Workgroup to Date
- Opportunity: Support use of APIs to improve access to patient data
  - ONC and CMS already raising awareness of value of use of APIs
- Opportunity: Support infrastructure needs for underserved populations, including exchange costs, prevalence of electronic equipment, internet access, pharmacy services, and use of telehealth services
  - HITAC Activity Idea: Measure impact of monetization of exchange of data
- Opportunity: Consider improvements to accessibility and usability of patient portals and other patient-facing technology
  - HITAC Activity Idea: Measure amount/length of time a portal has been online and working properly, patient engagement and/or patient understanding of data
- Opportunity: Encourage patient and caregiver education about health IT resources
  - HITAC Activity Idea: Identify use cases demonstrating value of patient's data to the patient

Other Opportunities for Further Consideration
- Consider workflow and technology improvements to increase use and sharing of PGHD and other data from mobile devices
  - For example, impact of clinical grade data collected by patients on testing costs
  - Better align timing of planning activities with operational impact
  - Consider implications of varying experiences with net neutrality at national, state, and local levels

## Discussion Questions
- Do you have any suggestions for the current state topics and advancements listed in the landscape analysis?

- Do you have any suggestions for the gaps and opportunities listed in the gap analysis?
- What recommendations would you suggest for HITAC activities that would address the gaps and opportunities?
- It was noted that the workgroup will continue their discussion about recommendation ideas at their meeting on October 18.

**Aaron Miri** noted this is a work in progress and there are more meetings scheduled to continue to refine the report.

## Discussion

**Terry O'Malley** commented that alternate service providers and provider sites, is an excellent place to be looking for areas that overlap with NCVHS and the HITAC.  Home and community-based providers are central to some of the more complicated patients, yet these entities are not covered under HIPAA.  This would be a great use case to flag and flesh out as it has policy and health IT standards relevance.

**Sasha TerMaat** questioned how this would work from a logistical perspective.  She wondered if the ARWG is proposing new task forces for the future and does this work detail the work already done by the HITAC?

- **Carolyn Petersen** commented that the work of this workgroup and HITAC is defined in 21st Century Cures.  The workgroup will highlight the work done by the HITAC and then identify items that the HITAC should be covering in the coming year.  There is some freedom to work with ONC to decide how that work should get done.
- **Elise Sweeney Anthony** commented that the report would cover where things are currently and identified additional charges that could be reviewed and considered in the future by the HITAC.
- **Sasha TerMaat** added that the HITAC's current work should be monitored and progress should be noted and considered when identifying any future work.
- **Aaron Miri** commented that there should be a means to monitor how the HITAC is doing on the items it is working on.
- **Seth Pazinski**, **ONC** agreed with Sasha's point to keep the current work on the list in addition to new topic areas that are being proposed.

**Steven Lane** commented that NCVHS provided a good presentation about collaboration and asked how that work can be combined with HITAC's work.

- He noted that there is an opportunity to align the ISPTF work with NCVHS and an additional meeting may be helpful to discuss opportunities for collaboration.
- **Carolyn Petersen** added that the NCVHS work will be considered during the next ARWG meeting on October 18, 2018.

**Denise Webb** commented that she was getting a little confused between current work and future work. As an outsider looking in, she found the outline of the report to be a little confusing. She agreed with Sasha's recommendation to be a little bit clearer regarding current and future work.

**Carolyn Petersen** commented that there is a lot of information to organize.

**Denise Webb** commented that the HITAC doesn't want to lose sight of the work that has already been done and there is more work to do.

**Aaron Miri** reiterated his point that it would be helpful to hear from members regarding any feedback.

**Christina Caraballo** commented that the workgroup has not yet discussed the work that has been done. She referred the HITAC back to the initial outline and noted that it will be added.

**Carolyn Petersen** commented that it was too early to define the work that had been done by the HITAC when the ARWG initially began its work. As the workgroup approaches the end of the year, it will be easier to summarize the HITAC's work and it will be important to add that into the report.

With no additional comments regarding the annual report, that concluded the presentations for the meeting. **Carolyn Petersen** transitioned to public comment.


## Public Comment

There was no public comment.

*The following public comments were received in the chat feature of the webinar during the meeting:*

**Thompson Boyd (Philadelphia):** On slide 19 of the NCVHS presentation, I would add construct of APIs (Privacy and Security of APIs) and Mobile Health.

**Thompson Boyd (Philadelphia):** For the Interoperability presentation, you should consider adding the notion of IHE Profiles.

**Susan Clark:** I agree with Thompson Boyd regarding IHE profiles.

**Thompson Boyd (Philadelphia):** If Radiology Orders are in scope for this meeting, one would want to discuss the AUC (Appropriate Use Criteria) requirement, as of January 1,

2020 for Radiology Orders.  Requiring this "consultation" will affect Provider workflows.  "Starting Jan. 1, 2020 - the Protecting Access to Medicare Act (PAMA) requires referring providers to consult appropriate use criteria (AUC) prior to ordering advanced diagnostic imaging services (ADIS) — CT, MR, Nuclear Medicine and PET — for Medicare patients."

- https://www.acr.org/-/media/ACR/NOINDEX/Advocacy/Advocacy-News/2018-PR-AUC-Detailed-Summary-Final.pdf?la=en
- https://www.acr.org/Clinical-Resources/Clinical-Decision-Support

**Mike:** I would suggest reaching out to the American College of Radiology at mpeters@acr.org.  There needs to be more imaging representation in the task force's recommendation development efforts.

**Mike:** The AUC policy is a CDS requirement, not a prior authorization requirement.

**Thompson Boyd (Philadelphia):** Annual Report Presentation, Slide 12. OAuth 2.0 is or Authorization. https://oauth.net/2/. OpenID Connect 2.0 is for Authentication https://openid.net/connect/.

## Closing Comments

**Steven Lane** suggested setting up a follow-up meeting with NCVHS to continue discussing collaboration.

**Terry O'Malley** asked if there was a matrix from ONC that could help identify the areas where HITAC and NCVHS can best collaborate.
- **Elise Sweeney Anthony** commented that Cures identifies areas that the HITAC should consider.  She noted that Lauren Richie, ONC's DFO, will collaborate with Rebecca Hines, NCVHS' DFO, to identify areas for collaboration.

**Lauren Richie** closed out the meeting noting that the next meeting will be on November 14, 2018 and all materials from today's meeting and all future meetings can be found on Healthit.gov.

The meeting was adjourned at 11:22 am ET.