



Annual Report Workgroup

Carolyn Petersen, Co-Chair Aaron Miri, Co-Chair

September 20, 2018



Agenda

- Call to Order/Roll Call
- Review of Workgroup Scope and Proposed Report Structure
- Workgroup Discussion
 - » Feedback from HITAC Full Committee on 9/5/18
 - » Content for Landscape Analysis
 - » Content for Gap Analysis
- Work Plan and Schedule
- Public Comment
- Next Steps and Adjourn



Annual Report Workgroup Membership

Member Name	Organization	Role
Carolyn Petersen	Individual	Co-Chair
Aaron Miri	Imprivata	Co-Chair
Christina Caraballo	Kizmet Health	HITAC Committee Member
Brett Oliver	Baptist Health	HITAC Committee Member
Chesley Richards	Public Health Scientific Services, CDC	Federal Representative



Workgroup Scope

- **Overarching:** The workgroup will inform, contribute to, and review draft and final versions of the HITAC Annual Report to be submitted to the HHS Secretary and Congress each fiscal year. As part of that report, the workgroup will help track ongoing HITAC progress.
- **Detailed:** Provide specific feedback on the content of the report as required by the 21st Century Cures Act including:
 - » Analysis of HITAC progress related to the priority target areas
 - » Assessment of health IT infrastructure and advancements in the priority target areas
 - » Analysis of existing gaps in policies and resources for the priority target areas
 - » Ideas for potential HITAC activities to address the identified gaps



Proposed FY18 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
- IX. Appendices



Workgroup Discussion:

Feedback from HITAC Full Committee on 9/5/18



Feedback from HITAC Meeting on 9/5/18

- Feedback on Workgroup Update:
 - » Proposed report structure makes sense
 - » Report presents opportunity to describe person-centered future state
 - » Think about measurement
 - Set both realistic and stretch targets
 - Establish empirical measures of achievement of health IT infrastructure
 - Future ONC objectives and benchmarks and recommendations for HITAC activities should help "move the needle" and show how the HITAC is delivering solutions
 - » Make use of existing analysis work from past FACA activities and other organizations
 - » Address multiple definitions of interoperability
 - Consider impact of business models, including provider compensation for effort to share data



Feedback from HITAC Meeting on 9/5/18

- HITAC Discussion on Interoperability:
 - » Relevant themes to consider:
 - Unintended consequences
 - Misaligned business drivers
 - Patient matching
 - Inconsistent use of standards
 - Workflow change management
 - More on USCDI

- Cross-vendor exchange
- Mobile device, telehealth concerns
- Secondary uses of data
- Health IT safety
- Adding insight layer to large datasets
- How HIEs bridge to TEFCA
- » How does the HITAC envision an achieved state of interoperability in one, five, and ten years?



Workgroup Discussion: Content for Landscape Analysis



Proposed Landscape Analysis 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



Landscape Analysis: Privacy and Security

- Current State Topics and Advancements (continued)
 - » 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



Landscape Analysis: Patient Access to Information

- Current State Topics and Advancements (continued)
 - » 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



Workgroup Discussion: Content for Gap Analysis



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Proposed Gap Analysis Structure

- For each priority target area:
 - » Gaps Identified
 - » Opportunities Identified
 - » Recommendations for Addressing Gaps and Opportunities



Gap Analysis: 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



Gap Analysis: 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



Gap Analysis: 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)



Gap Analysis: 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 to Information

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



Gap Analysis: Patient Access to Information

- 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
 - » Consider improvements to accessibility and usability of patient portals
 - » Patient and caregiver education about health IT resources



Recommendations for Addressing Gaps and Opportunities

• TBD



Work Plan and Schedule



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Meeting Schedule for Workgroup

Month	Deliverables to Review
June 20, 2018	Workgroup scope for FY18 Annual Report announced
August 2, 2018	Discuss plans for FY18 Annual Report
August 24, 2018	Landscape Analysis Outline Gap Analysis Outline
September 20, 2018	Landscape Analysis and Gap Analysis Discussion
Mid-Late October 2018	Landscape Analysis and Gap Analysis Discussion Outline of HITAC Progress in FY18
November 1, 2018 (or later if need be)	Description of HITAC Progress in FY18 FY18 Annual Report Outline
December 6, 2018	FY18 Annual Report Draft
Winter/Spring 2019	FY18 Annual Report Completed as Needed
Spring 2019	Work begins on FY19 Annual Report



Review Schedule for Full Committee

Meeting Date	Action Items/Deliverables	
June 20, 2018	Subcommittee Charge Presented	
September 5, 2018	Workgroup Update	
October 17, 2018	Landscape Analysis and Gap Analysis Update	
November 14, 2018	Description of HITAC's Work in FY18 Reviewed	
January 23, 2019	FY18 Annual Report Reviewed	
Winter/Spring 2019	FY18 Annual Report Approved by HITAC FY18 Annual Report Submitted to HHS Secretary FY18 Annual Report Submitted to Congress	



To make a comment please call:

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(once connected, press "*1" to speak)

All public comments will be limited to three minutes.

You may enter a comment in the **"Public Comment"** field below this presentation.

Or, email your public comment to <u>onc-hitac@accelsolutionsllc.com</u>.

Written comments will not be read at this time, but they will be delivered to members of the Workgroup and made part of the Public Record.







Health IT Advisory Committee

Meeting Adjourned



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Additional Slides



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Review of Annual Report Parameters



HITAC Priority Target Areas noted in Section 4003 of the 21st Century Cures Act cover the following areas:

- Interoperability Achieving a health information technology infrastructure that allows for the electronic access, exchange, and use of health information
- Privacy and Security The promotion and protection of privacy and security of health information in health IT
- Patient Access The facilitation of secure access by an individual and their caregiver(s) to such individual's protected health information
- Any other target area related to the above target areas that the HITAC identifies as an appropriate target area to be considered on a temporary basis with adequate notice to Congress



For fiscal year 2018 (FY18), ONC has identified several objectives:

- Publish proposed regulation for implementation of the health IT provisions of the 21st Century Cures Act to drive access to clinical data by:
 - » Advancing proposals related to application programming interfaces (APIs); and
 - » Identifying behaviors not considered information blocking, which will assist the HHS Office of Inspector General (OIG) in their enforcement of the Cures Act provisions that prohibit information blocking.
- 2. Publish the draft **Trusted Exchange Framework (TEF)** to improve data sharing across disparate health information networks.
- 3. Consider standards and implementation specifications to support priority uses of health IT based on HITAC recommendations, encouraging all stakeholders to implement and use as applicable to the specific interoperability needs they seek to address.



ONC Benchmarks

For fiscal year 2018 (FY18), ONC has identified several benchmarks*:

- 1. Proposed Regulation Covering APIs, Info Blocking, and Other Health IT Topics Published
 - » Possibility of HITAC activity by end of FY18 in line with schedule for publication of Certification and Interoperability Enhancements (CIE) Proposed Rule
- 2. Draft Trusted Exchange Framework Published
 - » Draft Trusted Exchange Framework released on January 5, 2018, for public comment
 - » HITAC charged with making recommendations and submitted recommendations to the National Coordinator on draft Trusted Exchange Framework in FY18
- 3. Standards and Specifications to Support Priority Uses Considered
 - » Draft U.S. Core Data for Interoperability (USCDI) and Proposed Expansion Process released on January 5, 2018
 - » HITAC charged with review and feedback and submitted recommendations to the National Coordinator on USCDI structures and process in FY18
 - » HITAC charged with making recommendations on priority uses of health IT and associated standards and implementation specifications in FY18

* For FY18, ONC has defined the HITAC benchmarks as standalone measures rather than comparisons to an established industry standard of excellence.

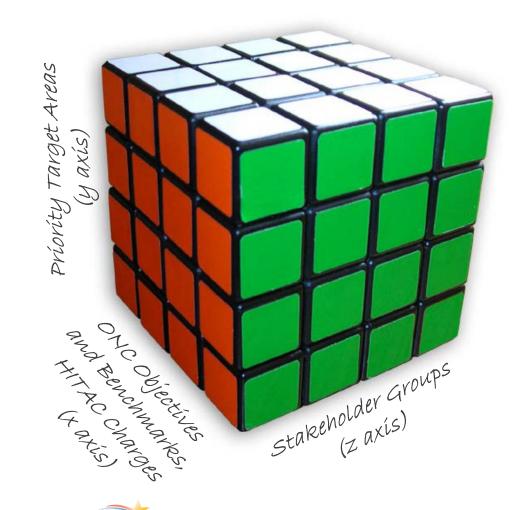


2D Crosswalk of Priority Target Areas for FY18

	Impact on HITAC Priority Target Areas				
	Interoperability	Privacy and Security	Patient Access	Additional Target Area(s) TBD	
ONC Objectives					
Publish Proposed Regulation					
Publish Draft Trusted Exchange Framework					
Consider Standards and Specifications					
ONC Benchmarks					
Proposed Regulation Published					
Draft Trusted Exchange Framework Published					
Standards and Specifications Considered					
HITAC Charges					
Trusted Exchange Framework					
U.S. Core Data for Interoperability (USCDI)					
Interoperability Standards Priorities					
Additional Initiatives TBD					



3D Crosswalk of Priority Target Areas for FY18



The interests of key stakeholder groups add another dimension to consider, including:

- Patients
- Providers
- Researchers
- Public Health Organizations
- Developers
- Payers/Employers
- Policymakers
- Emerging Voices



Stakeholder Groups

- Should the interests of select stakeholder groups be considered?
 - Patients
 - Providers

- Developers
- Payers/Employers

Researchers

- Policymakers

Public Health Organizations

- Emerging Voices
- Should the interests of stakeholder groups become an organizing principle for the report?
- If so, should the content be categorized primarily by priority target areas or by stakeholder groups?
 - » If priority target areas are emphasized, examples from stakeholder groups can illustrate concerns in each area
 - » If stakeholder groups are emphasized, the priority target areas can be handled as cross-cutting themes

