Health Information Technology Advisory Committee
2023 Planning

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HITAC Work Planning Process

- Reviewed transcripts and meeting notes from prior HITAC discussions
- Reviewed HITAC recommendations, including all HITAC Annual Reports to date
- Considered legislative requirements, existing work plans, and emerging issues
- Obtained input from the HITAC co-chairs
- Today: Review planned HITAC topics and timing with full committee
- Discuss opportunities for other HITAC work in 2023 and beyond

Health Information Technology Advisory Committee
Target Areas in the Cures Act

Use of Technologies that Support Public Health:
The facilitation of bidirectional information sharing between the clinical and public health communities

Privacy and Security:
The promotion and protection of privacy and security of health information in health IT

Interoperability:
Achieving a health information technology infrastructure that allows for the electronic access, exchange, and use of health information

Patient Access:
The facilitation of secure access by an individual and their caregiver(s) to such individual's protected health information

In addition to the priority target areas, the HITAC may consider certain additional target areas defined in the 21st Century Cures Act. For example, the HITAC is considering **"Design and Use of Technologies that Advance Health Equity"** as an additional target area.

HITAC Activities in 2022

Complete

- HITAC Annual Report for FY21
- e-Prior Authorization Request for Information Task Force 2022
- FY22 Interoperability Standards Workgroup (USCDI v3 and ISA)
- Adopted Standard Task Force 2022

In Progress

- HITAC Annual Report for FY22
- Public Health Data Systems Task Force 2022

HITAC 2023 Work Plan

	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
HITAC Committee Meeting												
HITAC Annual Report WG	FY22 Report				FY23 Report							
Interoperability Standards WG												
ONC NPRM TF (Timing TBD)												
Health Equity by Design TF (Timing TBD)												
Public Health Task Force or Feedback Sessions (Timing TBD)												
Pharmacy Interoperability TF (Timing TBD)												

Pharmacy Interoperability and Emerging Therapeutics

Supporting Clinical Pharmacy Services and Coordinated Care

1. Identify opportunities and recommendations to improve interoperability between pharmacy stakeholders (prescribers, pharmacists, pharmacy benefit managers, dispensers, payers, intermediaries, PDMPs, public health agencies, HIEs, third party service providers, consumers, etc.) for pharmacy-based clinical services and care coordination?
   - How can ONC help facilitate adoption and use of standards to support data exchange for pharmacy-based clinical services?
   - Which priority pharmacy-based clinical use cases should ONC focus on in the short-term and long-term?
   - What technology gaps exist for pharmacists to participate in value-based care?

Supporting Public Health

2. Public Health, Emergency Use Authorizations, and Prescribing Authorities

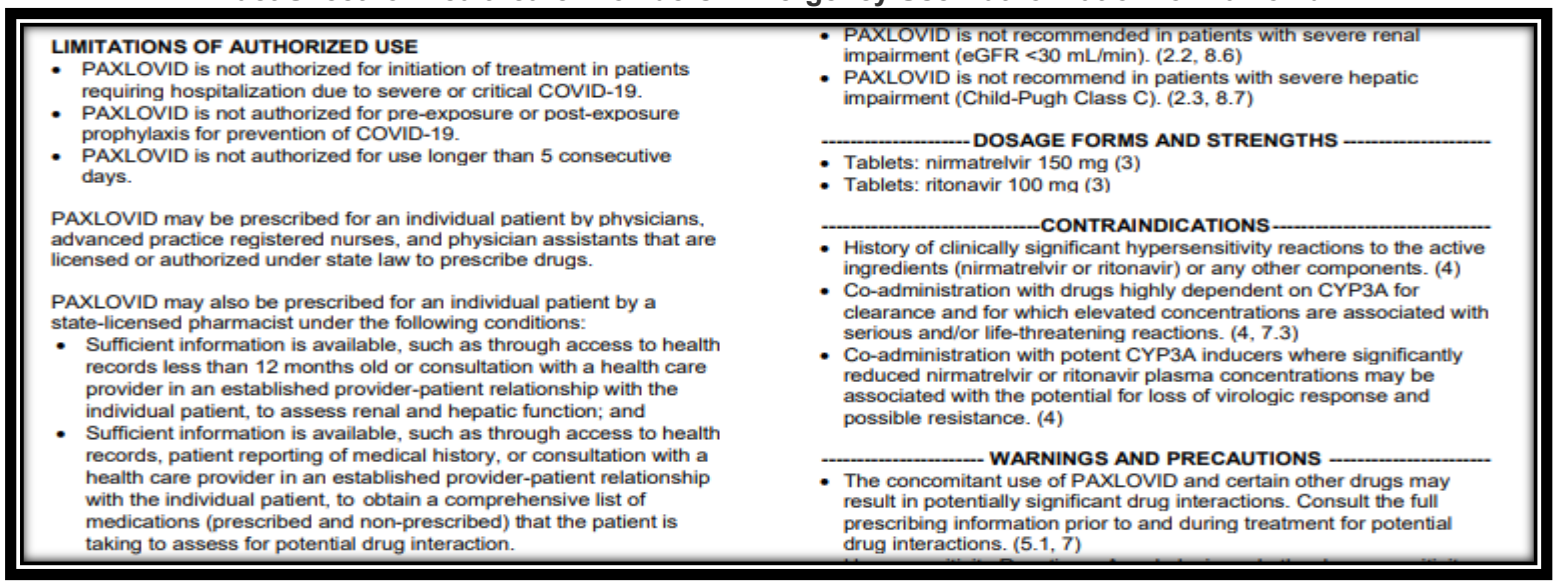
Short-term

- Identify critical standards and data needs for pharmacists and pharmacy stakeholders' participation in emergency use interventions.
- Are there actions ONC can take to enable data exchange in support of public health emergency use cases? For example, Test to Treat and Paxlovid prescribing?

Long-term

- Recommendations to better integrate pharmacy systems and data for public health surveillance, reporting and public health interventions.

Fact Sheet for Healthcare Providers: Emergency Use Authorization for Paxlovid



LIMITATIONS OF AUTHORIZED USE

- PAXLOVID is not authorized for initiation of treatment in patients requiring hospitalization due to severe or critical COVID-19.
- PAXLOVID is not authorized for pre-exposure or post-exposure prophylaxis for prevention of COVID-19.
- PAXLOVID is not authorized for use longer than 5 consecutive days.

PAXLOVID may be prescribed for an individual patient by physicians, advanced practice registered nurses, and physician assistants that are licensed or authorized under state law to prescribe drugs.

PAXLOVID may also be prescribed for an individual patient by a state-licensed pharmacist under the following conditions:

- Sufficient information is available, such as through access to health records less than 12 months old or consultation with a health care provider in an established provider-patient relationship with the individual patient, to assess renal and hepatic function; and
- Sufficient information is available, such as through access to health records, patient reporting of medical history, or consultation with a health care provider in an established provider-patient relationship with the individual patient, to obtain a comprehensive list of medications (prescribed and non-prescribed) that the patient is taking to assess for potential drug interaction.

- PAXLOVID is not recommended in patients with severe renal impairment (eGFR <30 mL/min). (2.2, 8.6)
- PAXLOVID is not recommend in patients with severe hepatic impairment (Child-Pugh Class C). (2.3, 8.7)

DOSAGE FORMS AND STRENGTHS

- Tablets: nirmatrelvir 150 mg (3)
- Tablets: ritonavir 100 mg (3)

CONTRAINDICATIONS

- History of clinically significant hypersensitivity reactions to the active ingredients (nirmatrelvir or ritonavir) or any other components. (4)
- Co-administration with drugs highly dependent on CYP3A for clearance and for which elevated concentrations are associated with serious and/or life-threatening reactions. (4, 7.3)
- Co-administration with potent CYP3A inducers where significantly reduced nirmatrelvir or ritonavir plasma concentrations may be associated with the potential for loss of virologic response and possible resistance. (4)

WARNINGS AND PRECAUTIONS

- The concomitant use of PAXLOVID and certain other drugs may result in potentially significant drug interactions. Consult the full prescribing information prior to and during treatment for potential drug interactions. (5.1, 7)

https://labeling.pfizer.com/ShowLabeling.aspx?id=16474&format=pdf

Emerging Therapeutics

3. Identify standards needs to support prescribing and management of emerging therapies including, but not limited to specialty medications, digital therapeutics, and gene therapies.
   - What standards gaps exist for the prescribing and management of:
     - specialty medications
     - digital therapeutics
     - gene therapies

Specialty prescribing mostly fax, portals, limited electronic routing and limited switch connectivity

No standard definition or terminologies for digital therapeutics, yet increasing in use

Expecting 10-20 FDA approvals of new gene therapies through 2025

Direct to Consumer Medication Services

4. Identify policy and technology needs and considerations for direct-to-consumer medication services (For example, Roman, Hims, Rory, Nurx, etc.). Is there a role for ONC?

Additional Potential Topics for HITAC Discussion in 2023

- Increased Health Equity across Populations, Locations, and Situations
- Interoperability
  - Information Blocking Progress
  - Standards Priorities Use Cases
- Bidirectional Exchange for Public Health: Datasets and Standards, HIEs and HINs
- SDOH Data: Standards Development, Standardized Data Across Agency Programs, Barriers to Exchange
- EHRs and Patient Safety
- Data Standards and Exchange to Support Behavioral Health, Mental Health, and Substance Abuse Disorders
- FHIR Standards Advancements
  - Including for public health data systems
- NCVHS Collaboration: Exchange of Data Across States and HIPAA Revisions
- API Use: Assess Deployment of 2015 Edition Certified Health IT
- International Regulations and Exchange, e.g. international patient summary; global master standards guide
- Workforce Development

Discussion

- Are there additional topics that should be considered?
- What are the key factors/considerations for these topics as we develop the charge?
- Which topics are more suitable for a subcommittee, panel hearing, or full committee discussion?
- Are there topics that should be prioritized or targeted to certain time points in 2023?

Next Steps

- Consider HITAC feedback from today
- ONC will adjust and finalize the work plan
- Present final work plan at the January 2023 HITAC meeting

ONC | HealthIT ADVISORY COMMITTEE

Thank You

Phone: 202-690-7151

Health IT Feedback Form: https://www.healthit.gov/form/healthit-feedback-form

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LinkedIn: Office of the National Coordinator for Health Information Technology

Youtube: https://www.youtube.com/user/HHSONC

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