



Pharmacy Interoperability and Emerging Therapeutics Task Force 2023 Meeting #3

Shelly Spiro, Co-Chair

Hans Buitendijk, Co-Chair

July 12, 2023





Call to Order/Roll Call

Mike Berry, Designated Federal Officer, ONC

Pharmacy Interoperability and Emerging Therapeutics Task Force 2023 Roster



Name	Organization	Name	Organization
Hans Buitendijk* (Co-Chair)	Oracle Health	Shelly Spiro (Co-Chair)	Pharmacy HIT Collaborative
Pooja Babbrah	Point-of-Care Partners	Deven McGraw*	Invitae Corporation
Chris Blackley	Prescriptive North Dakota Health Information Network	Ketan Mehta	Micro Merchant Systems
Shila Blend*		Justin Neal	Noble Health Services Dell Medical School, University of Texas at Austin
David Butler	Curatro, LLC Texas Department of State Health Services	Eliei Oliveira*	
Steven Eichner*	MCG Health, part of the Hearst Health network	Naresh Sundar Rajan*	CyncHealth
Rajesh Godavarthi*	Centers for Disease Control and Prevention	Scott Robertson	Bear Health Tech Consulting
Adi V. Gundlapalli**		Alexis Snyder*	Individual
Jim Jirjis*	HCA Healthcare	Fillipe Southerland*	Yardi Systems, Inc.
Summerpal Kahlon	Rocket Health Care	Christian Tadrus	Community Pharmacy Owner
Steven Lane*	Health Gorilla Department of Veterans Health Affairs	Sheryl Turney*	Elevance Health
Meg Marshall**		Afton Wagner	Walgreens
Anna McCollister*	Individual		

Agenda

10:30 AM

Call to Order/Roll Call

- Mike Berry, Designated Federal Officer, ONC

10:35 AM

Opening Remarks

- Shelly Spiro, Co-Chair
- Hans Buitendijk, Co-Chair

10:40 AM

Task 1 Short Term Recommendation for Public Health, Emergency Use Authorizations, and Prescribing Authorities

- Shelly Spiro, Co-Chair
- Hans Buitendijk, Co-Chair

11:10 AM

Guest Presentation and Question and Answer

- Tegan K Boehmer, PhD, MPH, CDR, US Public Health Service Acting Chief, Actionable Data Branch (proposed), Inform and Disseminate Division (proposed), Office of Public Health Data, Surveillance, and Technology

11:30 AM

Task 1 Long Term Recommendation for Public Health, Emergency Use Authorizations, and Prescribing Authorities

- Shelly Spiro, Co-Chair
- Hans Buitendijk, Co-Chair

11:50 AM

Public Comment

- Mike Berry, Designated Federal Officer, ONC

11:55 AM

Task Force Work Planning

- Shelly Spiro, Co-Chair
- Hans Buitendijk, Co-Chair

12:00 PM

Adjourn



Opening Remarks

Shelly Spiro, Co-Chair

Hans Buitendijk, Co-Chair

Pharmacy Interoperability and Emerging Therapeutics Task Force 2023 Charge

Overarching charge: Identify recommendations to support interoperability between pharmacy constituents, and the exchange of information necessary for medication management, patient safety and consumer engagement.

Recommendations Due: November 9, 2023

Specific charge:

1. Public Health, Emergency Use Authorizations, and Prescribing Authorities
2. Identify opportunities and recommendations to improve interoperability between pharmacy constituents (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.
3. Identify standards needs to support prescribing and management of emerging therapies including, but not limited to specialty medications, digital therapeutics, and gene therapies.
4. Identify policy and technology needs and considerations for direct-to-consumer medication services.



Pharmacy Interoperability and Emerging Therapeutics Task Force 2023 Discussion

TOPIC 1 (for discussion July 12 and July 19):

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


Short-term

- a. *Identify critical standards and data needs for pharmacists and interested parties to participate in emergency use interventions.*
- b. *Are there actions ONC can take to enable data exchange in support of public health emergency use cases? For example, Test to Treat and COVID-19 treatment prescribing?*

Long-term

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





Task 1 Short Term Recommendation for Public Health, Emergency Use Authorizations, and Prescribing Authorities

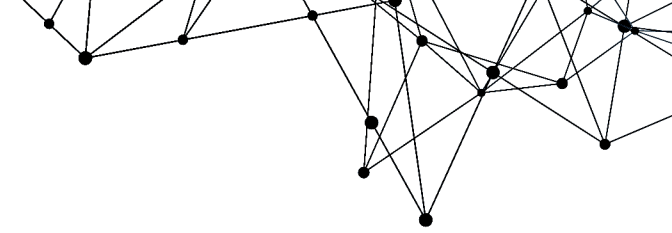
Shelly Spiro, Co-Chair

Hans Buitendijk, Co-Chair



Guest Presentation

Tegan K Boehmer, PhD, MPH, CDR, US Public Health Service
Acting Chief, Actionable Data Branch (proposed), Inform and
Disseminate Division (proposed), Office of Public Health Data,
Surveillance, and Technology



Public Health Surveillance and Insights from Therapeutics Data: The COVID-19 Experience

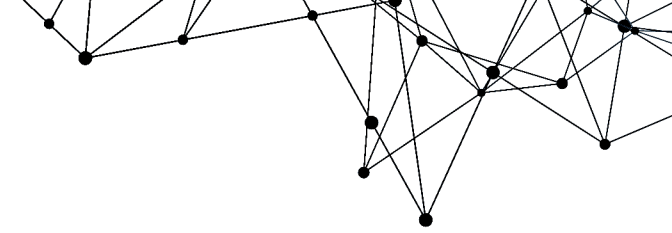
ONC HITAC Task Force on
Pharmacy Interoperability and Emerging Therapeutics.

July 12, 2023

Tegan Boehmer, PhD, MPH
CDR, U.S. Public Health Service
Acting Chief, Actionable Data Branch (proposed)
Inform and Disseminate Division (proposed)
Office of Public Health Data, Surveillance, and Technology
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Disclaimer



- No financial disclosures or conflicts of interest
- The findings and conclusions in this presentation are those of the author and do not necessarily represent the official position of the Centers for Disease Control and Prevention

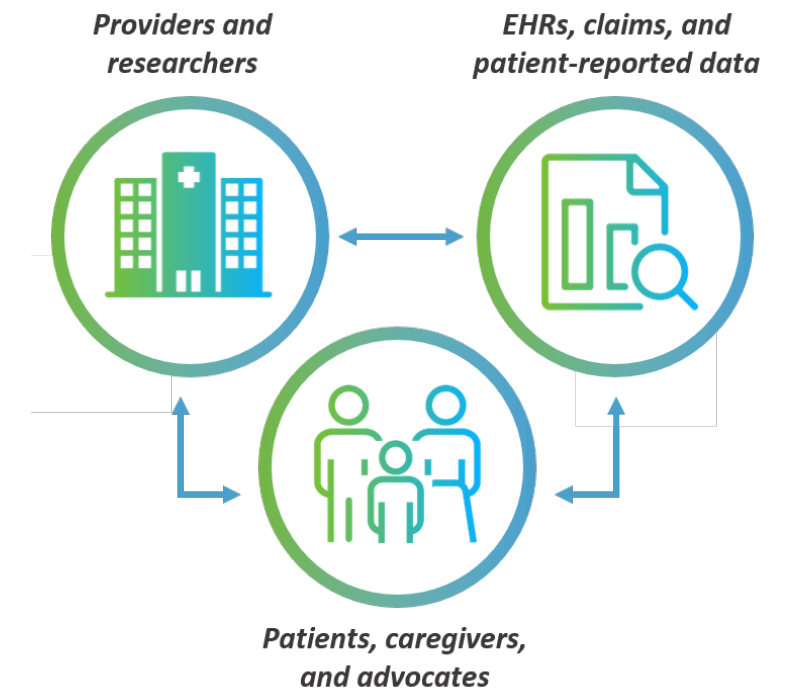
COVID-19 Therapeutics: Who, When, Where?



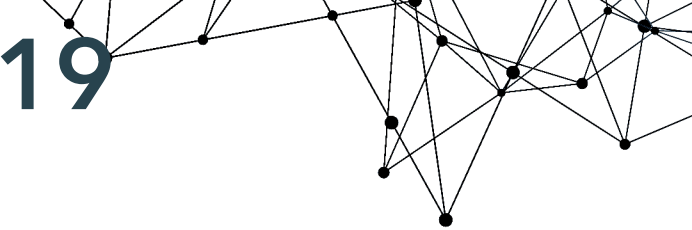
- Emergency Use Authorizations (EUA) were issued for outpatient treatments of COVID-19 in patients at high risk for progressing to severe disease
- Key questions:
 - Who is receiving these medications?
 - When and where are people receiving these medications?
 - Are there inequities in receipt of these medications?
- Data were needed to promote prevention and mitigation strategies for severe COVID-19 and decrease inequities
- CDC examined multiple healthcare data sources available to the agency to garner insights

Source 1: PCORnet[®] EHR data

- In 2020, CDC began partnering with the Public Health Informatics Institute and PCORnet[®] on a COVID-19 surveillance project
- PCORnet[®]
 - National resource for real-world evidence and comparative effectiveness research
 - Network-of-Networks; ~65 participating entities or US healthcare systems
 - Outpatient and inpatient settings
 - Data for ~30 million individuals annually
 - Not geographically representative
 - PCORnet common data model
 - Distributed approach to querying data



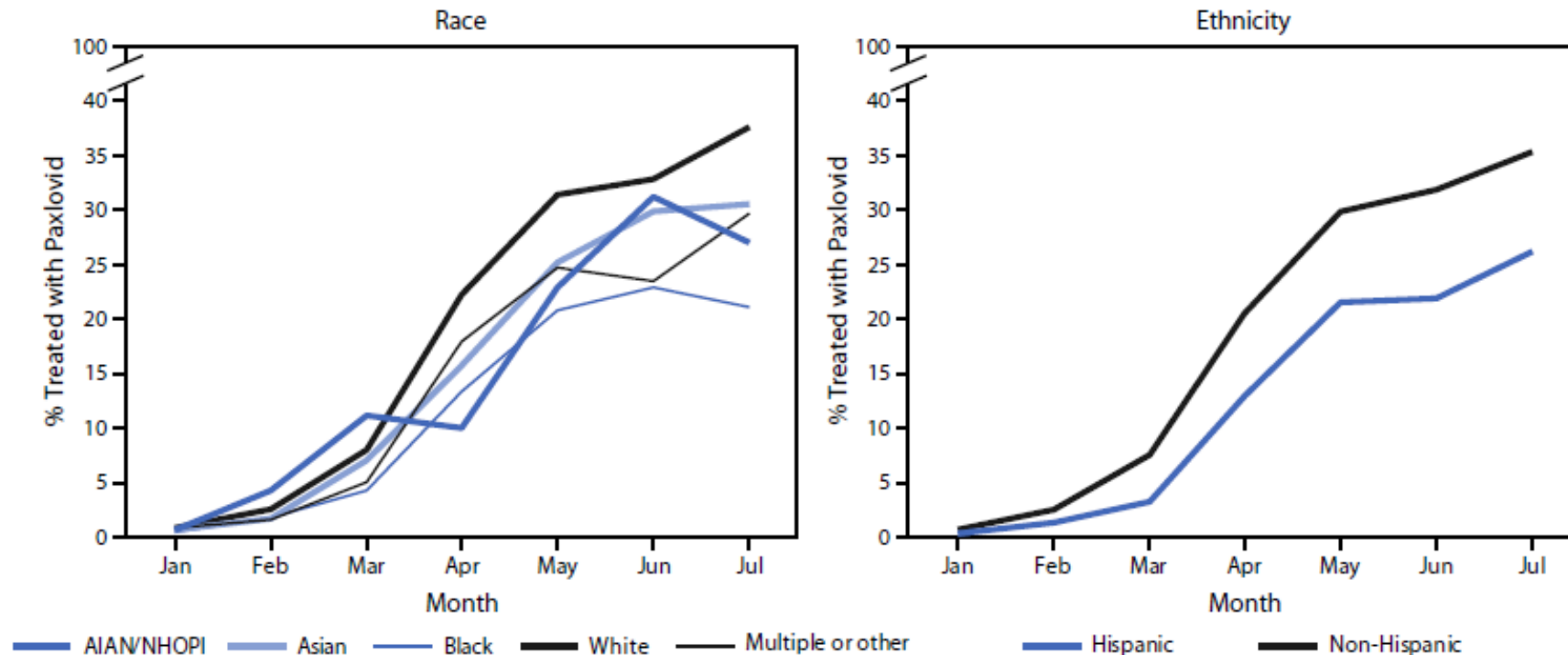
Source 1: Capture of Outpatient COVID-19 Therapeutics and Demographics



- Administered parenteral drugs: *monoclonal antibodies, remdesivir*
 - Identified using National Drug Codes (NDC); Medication Administration table
 - Capture if administered within same healthcare system (ED, infusion center)
- Prescribed oral antivirals: *Paxlovid, Lagevrio*
 - Identified using RxNorm codes; Prescription table
 - Unknown if patient fills prescription; Does not capture pharmacist prescribing
- Race and ethnicity
 - Data fields fairly complete (<10% missing race; ~20% missing ethnicity)
 - Retain detailed race categories because of large sample and aggregate data
- Social determinants of health (new development)
 - Use patient residential address to assign Area Deprivation Index and urban/rural status

Source 1: Insights from EHR Data

- >690,000 COVID-19 patients aged ≥ 20 years during Jan-Jul 2022
- Calculated percentage of COVID-19 patients treated with each medication
 - Overall and for risk groups defined by age and immunocompromise status
- Assessed disparities in treatment by race and ethnicity (Paxlovid example)



Source 1: EHR Data Validity and Opportunities

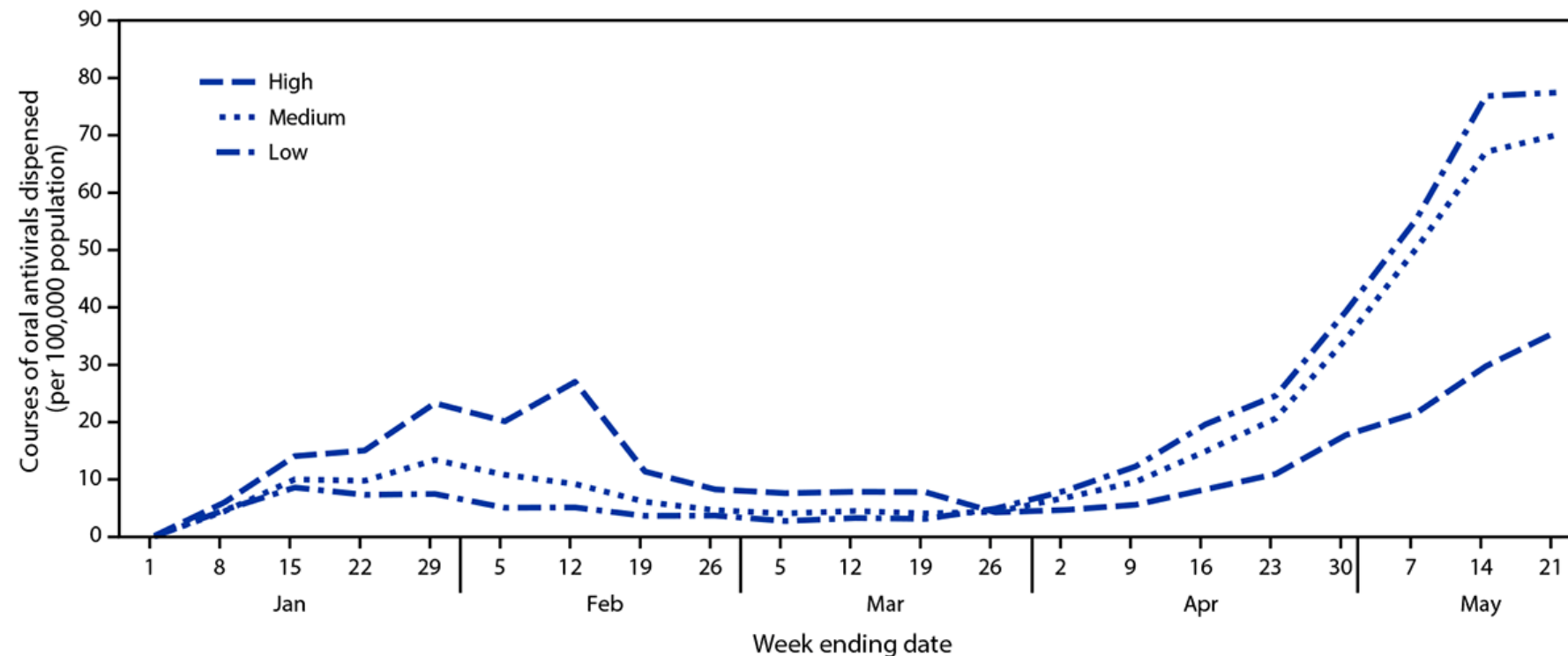


- External validity:
 - Only capture patients seeking care in participating healthcare system
 - Do not capture medication prescriptions, administration, or dispensing from non-affiliated settings (e.g., pharmacies, independent urgent care)
 - Estimates similar to those from other studies (Epic EHR, VA claims)
- Face validity: data show “expected” prescribing patterns over time and by patient characteristics (age, immunocompromise status)
- Opportunities and Future Directions
 - Quicker mapping of new medications, especially those under EUA, to RxNorm and common data model (at healthcare system level)
 - Linkage of EHR data with claims, pharmacy dispensing, and state vaccination registries

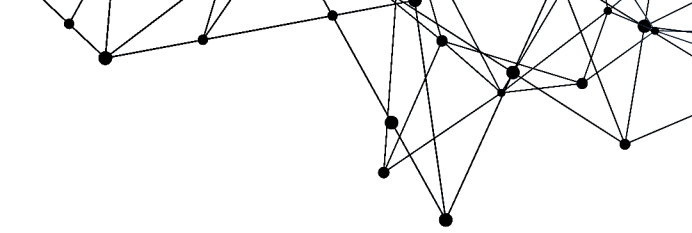
Source 2: HHS Ordering & Dispensing Data

- Oral antiviral dispensing sites reported data to HHS daily
- Zip codes of sites were mapped to population size and social vulnerability
- Assessed differences in dispensing by zip code social vulnerability

FIGURE 3. Courses of oral COVID-19 antiviral therapy dispensed per 100,000 persons, by week and zip code social vulnerability level — United States, December 26, 2021–May 21, 2022*



Source 3: Pharmacy Claims Data



- Community and retail pharmacies included
- Requires pharmacy to submit claim to insurance provider
 - Claims submission may have been lower during the pandemic, since medication costs were covered by federal government
- Generalizability limited to patients with pharmacy benefits
 - Depending on data source, may not include all insurance types
- Race and ethnicity generally not available
- Longer time lag for adjudicated claims
- Not able to differentiate Test-to-Treat participants from others

Conclusions and Potential Opportunities



- Need accurate, comprehensive, and timely data on therapeutics to inform public health actions
- No gold standard
 - Available data sources cover limited populations or components of pharmacy-related continuum of care (e.g., outpatient care only)
 - CDC relied on multiple data sources for corroborating evidence
- Potential future directions:
 - Inclusion of demographic variables with pharmacy claims (directly or link)
 - Direct reporting from pharmacies to public health for high priority therapeutics (precedent: Federal Retail Pharmacy Program vaccination data)
 - Systematic integration of pharmacy dispensing data with EHR data
 - Measuring Test-to-Treat: Custom fields/codes; novel methods to link testing and prescribing related claims by place and time


Thank you!

References

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3. Gold JA, Kelleher J, Magid J, et al. **Dispensing of Oral Antiviral Drugs for Treatment of COVID-19 by Zip Code-Level Social Vulnerability – United States, December 23, 2021–May 21, 2022**. MMWR Morb Mortal Wkly Rep 2022;71:825–829. DOI: <http://dx.doi.org/10.15585/mmwr.mm7125e1>.
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Task 1 Long Term Recommendation for Public Health, Emergency Use Authorizations, and Prescribing Authorities

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Public Comment

To make a comment please
Use the Hand Raise Function

If you are on the phone only, press “*9” to raise your hand

*(Once called upon, press “*6” to mute/unmute your line)*

All public comments will be limited to three minutes

You may also email your public comment to onc-hitac@accelsolutionsllc.com

*Written comments will not be read at this time,
but they will be delivered to members of the task force and made part of the public record*




Task Force Work Planning

Shelly Spiro, Co-Chair

Hans Buitendijk, Co-Chair

Upcoming Meetings



Month	Task Force Meeting Dates	HITAC Meeting Date
July	19, 26	
August	9, 16, 23, 30	August 17 (TF Update)
September	13, 20, 27	September 14 (TF Update)
October	4, 11, 18, 25	October 19 (TF Update)
November	1	November 9 (Final Recommendation and Vote)



Adjourn