Career Development Series 2024

# Digital Inclusion and Access to Care by Telemedicine

ITHS





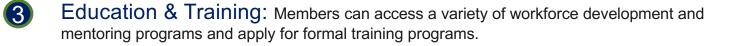
#### What We Offer:

1

Research Support Services: Members gain access to the different research services, resources, and tools offered by ITHS, including the ITHS Research Navigator.



Community Engagement: Members can connect with regional and community based practice networks





**Funding:** Members can apply for local and national pilot grants and other funding opportunities. ITHS also offers letters of support for grant submissions.



#### **Contact ITHS**

#### Director of Research Development



**Project Consultation** 

Strategic Direction

**Resources and Networking** 

Melissa D. Vaught, Ph.D. ithsnav@uw.edu 206.616.3875

#### Scientific Success Committee

- Clinical Trials Consulting
- Guidance on Study Design, Approach and Implementation
- Feedback on Design and Feasibility

https://www.iths.org/investigators/ services/clinical-trials-consulting/ Career Development Series 2024

## Feedback

At the end of the seminar, a link to the feedback survey will be sent to the email address you used to register.



## **Telemedicine 2.0 Series**

Date	Session	Title
	Session 1	Telemedicine 2.0: How Is It Relevant to Me? (Pre-recorded video available)
Sept. 25, 2024	Session 2	Telehealth Then and Now
Oct. 1, 2024	Session 3	Telemedicine Regulatory Issues: Licensing, Standards of Practice, Billing, and Reimbursement
Oct. 8, 2024	Session 4	Protecting Privacy and Maintaining Security in Telemedicine
Oct. 15, 2024	Session 5	The Entrepreneur's Perspective on Telemedicine Technology and Tools Development
Oct. 24, 2024	Session 6	Digital Inclusion and Access to Care by Telemedicine

More details at: <u>https://www.iths.org/event/telemedicine-then-and-now/?instance\_id=1372</u>



#### Telemedicine 2.0 Series – Learning Objectives

#### At the end of the series, participants will be able to:



Identify opportunities to improve remote patient care



Identify security and privacy risks associated with telemedicine technologies



Mitigate introduction of disparities in access to clinical care



Career Development Series 2024

#### Digital Inclusion and Access to Care by Telemedicine

Telemedicine 2.0 Series: Session 6

Presented by:

John Scott, MD, MSc, FIDSA Cindy Jacobs, RN, JD Charlie Gregor, MPH Jason M. Malone, MPA, CIP











Career Development Series 2024

#### **Disclosures**

Today's speakers have no financial relationships with an ineligible company relevant to this presentation to disclose.

None of the planners have relevant financial relationship(s) to disclose with ineligible companies whose primary business is producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients.

\*All relevant financial relationships have been mitigated\*

UW Medicine



## Session 6 Learning Objectives

#### At the end of the session, participants will be able to:

- Describe current barriers and solutions to accessing telemedicine faced by patients
- 2 Identify and describe the main regulatory structure and primary issues regarding DEI in clinical research under federal and state law
- 3
- Understand one approach to implement and coordinate WA legislation, FDA guidance, and NIH policy



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#### **Digital Health Equity**

- Access to digital health has become an independent determinant of health
- Definition: digital determinants of health include access to technological tools, digital literacy, and community infrastructure like broadband Internet. These are likely to "function independently as barriers to and facilitators of health as well as interact with the social determinants of health (SDOH) to impact health outcomes."



Institute of Translational Health Sciences accelerating research. IMPROVING HEALTH. Richardson S, Lawrence K, Schoenthaler AM et al. A framework for digital health equity. Nat Digit Med 2022. 5(119). https://doi.org/10.1038/s1746-022-00663-0)

#### A framework for digital health equity

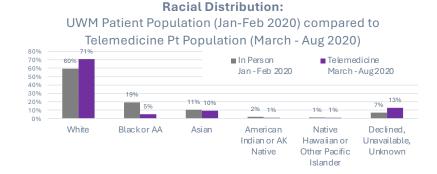
		Levels of Influence*					
		Individual	Interpersonal	Community	Societal		
Domains of Influence (Over the Lifecourse)	Biological	Biological Vulnerability and Mechanisms	Caregiver–Child Interaction Family Microbiome	Community Illness Exposure Herd Immunity	Sanitation Immunization Pathogen Exposure		
	Behavioral	Health Behaviors Coping Strategies	Family Functioning School/Work Functioning	Community Functioning	Policies and Laws		
	Physical/Built Environment	Personal Environment	Household Environment School/Work Environment	Community Environment Community Resources	Societal Structure		
	Digital Environment	Digital Literacy, Digital Self-Efficacy, Technology Access, Attitudes Towards Use	Implicit Tech Bias, Interdependence (e.g. shared devices), Patient-Tech-Clinician Relationship	Community Infrastructure, Healthcare Infrastructure, Community Tech Norms, Community Partners	Tech Policy, Data Standards, Design Standards, Social Norms & Ideologies, Algorithmic Bias		
	Sociocultural Environment	Sociodemographics Limited English Cultural Identity Response to Discrimination	Social Networks Family/Peer Norms Interpersonal Discrimination	Community Norms Local Structural Discrimination	Social Norms Societal Structural Discrimination		
	Health Care System	Insurance Coverage Health Literacy Treatment Preferences	Patient-Clinician Relationship Medical Decision-Making	Availability of Services Safety Net Services	Quality of Care Health Care Policies		
Health Outcomes		A Individual Health	Family/ Organizational Health	合 Community 合合 Health	Health		

#### Challenges faced by patients accessing telemedicine

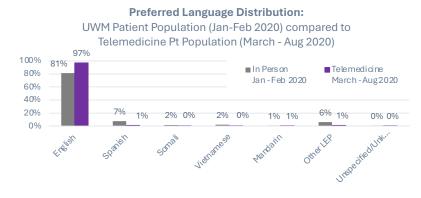
- Language
- Broadband and technology
- Digital literacy
- Visual impairments
- Privacy



#### Limited English Proficiency is a Predictor for Using Telemedicine



While Black/African-American patients accounted for 19.3% of clinic visits in January and February 2020, they comprised only 5.1% of telemedicine visits from March through August 2020.



English speaking patients account for a disproportionate share of telemedicine visits, in comparison to the language distribution of in-person visits at in the preceding months.



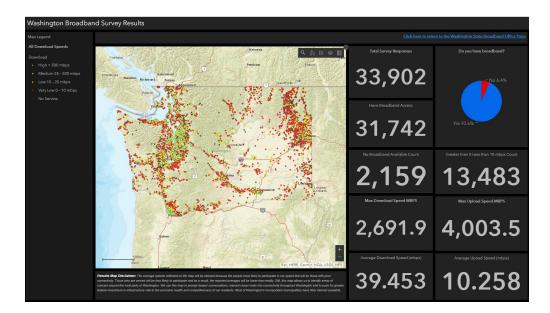
#### Solutions for LEP Patients

- Interpretation of instructions into top languages
- Short videos showing how to join a telemedicine visit in top languages
- Bilingual digital navigators
- Working with family members



#### Broadband and technology limitations

- A large portion of WA state has limited broadband access
- Digital redlining
- Smartphone ownership varies by race (97% in Asians, 91% in white, 84% in black)





#### Solutions for patients with limited technology and broadband

- Telemedicine visits at community centers, libraries or VFW halls
- Low cost Internet plans and devices through WA Medicaid
- Partnerships with schools, job training programs





#### DOJ Final Rule on Web and Mobile Accessibility

- Covered entities must ensure that health programs or activities provided through digital technology are accessible to individuals with a disability
- The following apply:
  - Web content any info on web that is communicated through a web browser, media player and helps user interact with online content. Can include text, images, sounds, videos and animations.
  - Mobile apps software that is downloadable and designed to be used on mobile devices such as smartphones and tablets
- Accessible means that above must meet web content accessibility guidelines (WCAG) 2.1 Level AA standards by Apr 24, 2026



#### Privacy Concerns



## Building in Safeguards

- Measuring telemedicine utilization by SDOH
- · Learning about barriers
- · Designing interventions
- · Assessing impact of interventions
- . Iterating
- Use of equity impact tool for all new digital health programs

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Understand one approach to implement and coordinate WA legislation, FDA guidance, and NIH policy



- NIH policy: Inclusion of Women and Minorities as Participants in Research Involving Human Subjects (Interpretive/"Quasi" Regulatory Law)
  - <u>Statutory authority</u>
    - The NIH Revitalization Act of **1993**, PL 103-43 (Public Health Service Act sec. 492B, 42 U.S.C. sec. 289a-2), which directed the NIH to establish guidelines for inclusion of women and minorities in clinical research. The statute required NIH to ensure that clinical trials are carried out in a manner sufficient to provide for a valid analysis of whether the variables being studied affect women or members of minority groups differently than other trial participants.



The 21st Century Cures Act, PL 114-255 (2016), requires entities conducting applicable clinical trials to submit results of valid analyses by sex/gender, race, and ethnicity in Clinicaltrials.gov. The statute further requires that NIH consider, as appropriate, whether the entity has complied with this reporting requirement when awarding any future grant to that entity; and that NIH encourage the reporting of the results of valid analysis through any additional means determined appropriate.



- NIH policy: Inclusion of Women and Minorities as Participants in Research
  Involving Human Subjects [Latest Update]
  - Additions/changes related to 21<sup>st</sup> Century Cures Act/ClinicalTrials.gov issues
  - FDA connection— "Applicable Clinical Trial"
    - Applicable clinical trial is the term used in Title VIII of the Food and Drug Administration Amendments Act (FDAAA) of 2007 (P.L. 110-85) to designate the scope of clinical trials that may be subject to the registration and results reporting requirements in FDAAA. Clinical trials that are subject to the regulation are, in general, clinical trials of drug, biological, and device products regulated by the Food and Drug Administration (FDA). A pediatric post-market surveillance study of a device product required by the FDA is also subject to the regulation.



- NIH policy: Inclusion of Women and Minorities as Participants in Research Involving Human Subjects [Latest Update]
  - I. Legislative Background
  - II. Policy
    - A. Inclusion of Women and Minorities as Subjects in Clinical Research
      - It is the policy of NIH that women and members of minority groups and their subpopulations must be included in all NIH-funded clinical research, unless a clear and compelling rationale and justification establishes to the satisfaction of the relevant Institute/Center Director that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research.



- NIH policy: Inclusion of Women and Minorities as Participants in Research Involving Human Subjects [Latest Update]
  - Exclusion under other circumstances may be made by the Director, NIH, upon the recommendation of an Institute/Center Director based on a compelling rationale and justification. Cost is not an acceptable reason for exclusion except when the study would duplicate data from other sources. Women of childbearing potential should not be routinely excluded from participation in clinical research. This policy applies to research subjects of all ages in all NIH-supported clinical research studies.



- NIH policy: Inclusion of Women and Minorities as Participants in Research
  Involving Human Subjects [Latest Update]
  - The inclusion of women and members of minority groups and their subpopulations must be addressed in developing a research design or contract proposal appropriate to the scientific objectives of the study/contract. The research plan/proposal should describe the composition of the proposed study population in terms of sex/gender and racial/ethnic group, and provide a rationale for selection of such subjects. Such a plan/proposal should contain a description of the proposed outreach programs for recruiting women and minorities as participants.



- NIH policy: Inclusion of Women and Minorities as Participants in Research
  Involving Human Subjects [Latest Update]
  - B. NIH-defined Phase III Clinical Trials: Planning, Conducting, and Reporting of Analyses for Sex/Gender and Race/Ethnicity Differences.
  - III. Roles and Responsibilities
    - 1. NIH Staff
    - 2. Principal Investigators
    - 3. Institutional Review Boards
    - 4. Peer Review Groups
    - 5. NIH Advisory Councils
    - 6. Institute/Center Directors
    - 7. NIH Director



- NIH policy: Inclusion of Women and Minorities as Participants in Research Involving Human Subjects [Latest Update]
  - IV. Definitions
    - A. Clinical Research
    - B. NIH-defined Clinical Trial For the purpose of these guidelines, an NIH-defined "clinical
    - C. Valid Analysis
    - D. Significant Difference
    - E. Racial and Ethnic Categories
    - F. Outreach Strategies



- FDA—Regulatory, Interpretive, and other guidance with DEI content
  - Limited scope: Only a portion of clinical research technically falls under the <u>FDA's statutory authority (primarily the Food, Drug, and</u> <u>Cosmetic Act, Title 21 of the U.S. Code</u>). In order to be bound by the FDA's standards, the research at issue must involve
    - A "test article" (drug, biologic, or device that requires initial FDA approval/clearance), or
    - A change or update to a "post-market" drug, biologic, or device.



- FDA—Regulatory, Interpretive, and other guidance with DEI content
  - FDA guidances related to DEI in clinical research
    - Diversity Action Plans to Improve Enrollment of Participants from Underrepresented Populations in Clinical Studies
    - Enhancing the Diversity of Clinical Trial Populations Eligibility Criteria, Enrollment Practices, and Trial Designs Guidance for Industry
    - Digital Health Technologies for Remote Data Acquisition in Clinical Investigations



- Washington statutory law: HB 1745 (2023)
  - "An Act relating to improving diversity in clinical trials"
  - Amended the Revised Code of Washington (RCW) in various ways/locations
    - Added a new chapter to Title 69 RCW (Food, Drugs, Cosmetics, and Poisons): "Diversity in Clinical Trials"
      - 69.78.010 Finding—Policy (*Legislative intent*).
      - 69.78.020 Definitions.
      - 69.78.030 Diversity in clinical trials program.



- Washington statutory law: HB 1745 (2023)
  - 69.78.040 Requirements for state entities or hospitals conducting clinical trials.

Any state entity or hospital that receives funding from the national institutes of health to conduct clinical trials of drugs or medical devices shall:

(1) Adopt a policy concerning the identification and recruitment of persons who are members of underrepresented demographic groups to participate in clinical trials. This policy must include requirements that investigators who are conducting clinical trials collaborate with community-based organizations and use methods recognized by the United States food and drug administration to identify and recruit such persons to participate in those clinical trials;



• Washington statutory law: HB 1745 (2023)

(2) Provide information to trial participants in languages other than English;

(3) Provide translation services or bilingual staff for trial screening;

(4) Provide culturally specific recruitment materials alongside general enrollment materials; and

(5) Provide electronic consent when not prohibited by the granting entity or federal regulations



- Washington statutory law: HB 1745 (2023)
  - Added a new section to chapter 43.348 RCW (Andy Hill Cancer Research Endowment)
  - § 43.348.090: Partnership with the University of Washington and Washington State University—Community outreach and engagement to increase participation by underrepresented communities—Grants.
  - (1) Beginning January 1, 2024, the University of Washington and Washington State University may partner with the Andy Hill cancer research endowment, the department of health, community-based organizations, and other entities to increase the participation of persons who are members of underrepresented demographic groups in clinical trials for drugs or medical devices.



- Washington statutory law: HB 1745 (2023)
  - [Example of mandated collaborative activities]
  - The requesting university, the Andy Hill cancer research endowment, and the department of health, in collaboration with community-based organizations and other appropriate entities, <u>shall</u> develop a specific community outreach and engagement plan to increase participation of an underrepresented demographic group or community in the clinical trial.



- Washington statutory law: HB 1745 (2023)
  - Added a new section to chapter 28B.20 RCW (UW)--Title 28B overall is "Higher Education"
  - § 28B.20.540--Diversity in clinical trials.
    - If at any time the University of Washington receives funding from the national institutes of health to conduct clinical trials of drugs or medical devices, the University of Washington shall adopt a policy concerning the identification and recruitment of persons who are members of underrepresented demographic groups to participate in clinical trials of drugs and medical devices.



- Washington statutory law: HB 1745 (2023)
  - This policy must include requirements to:
    - (1) Adopt a policy concerning the identification and recruitment of persons who are members of underrepresented demographic groups to participate in clinical trials. This policy must include requirements that investigators who are conducting clinical trials collaborate with community-based organizations and use methods recognized by the United States food and drug administration to identify and recruit such persons to participate in those clinical trials;



- Washington statutory law: HB 1745 (2023)
  - (2) Provide information to trial participants in languages other than English;
  - (3) Provide translation services or bilingual staff for trial screening;
  - (4) Provide culturally specific recruitment materials alongside general enrollment materials; and
  - (5) Provide electronic consent <u>when not prohibited by the</u> granting entity or federal regulations.



- Washington statutory law: HB 1745 (2023)
  - Added a new section to chapter 28B.30 RCW (WSU)
  - § 28B.30.650--Diversity in clinical trials.
    - Language mirrors the new UW chapter section



- Washington statutory law: HB 1745 (2023)
  - Amended RCW 43.348.040
    - The Andy Hill cancer research endowment program must evaluate requests for grant funding based on factors that include "the ability to offer trial participants information in a language other than English; (j) the ability to provide culturally specific recruitment materials alongside general enrollment materials; (k) the ability to provide electronic consent when not prohibited by other granting entities or federal regulations; and (l) other evidence of outreach and engagement to increase participation of underrepresented communities in clinical trials of drugs and medical devices."



- Washington statutory law: HB 1745 (2023)
  - Does 1745 conflict with existing federal law (NIH and/or FDA)?
    - Federal "pre-emption"
      - Source: Supremacy Clause of US Constitution
      - Power of federal law to trump state law
        - Express Preemption
        - Implied Preemption
          - Field Preemption
          - Conflict Preemption
            - Impossibility (cannot comply with federal AND state schemes)
            - Obstacle



#### **Poll Question: FDA Jurisdiction**

You are planning a completely remote study to monitor rural participants for possible long COVID and to determine whether there is an association between tobacco and/or marijuana use and long COVID. Subjects will be provided with these digital health devices: smart fitness wearable, smart scale, pulse oximeter, BP monitor, spirometer.

What is the FDA's role in this study? Choose any/all options you believe would apply.

- A. No role at all unless the devices are not cleared/approved by the FDA.
- B. No role at all unless *your team (or an industry sponsor funding the study)* is seeking FDA clearance/approval of the devices.
- C. Your team is obligated to comply with the recommendations in FDA's guidances on clinical study diversity covered in the prior slides.
- D. Your team may wish to consider the recommendations in the above guidances.

## Session 6 Learning Objectives

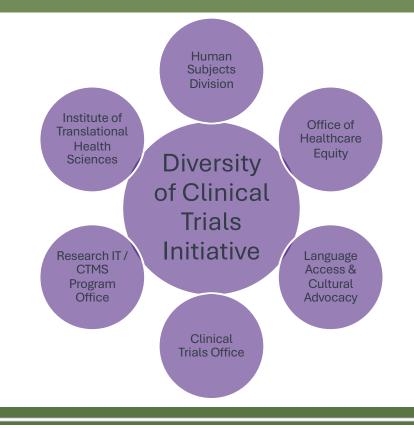
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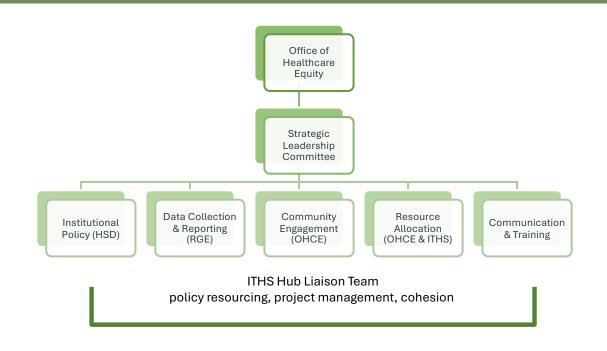
# The UW Approach UNIVERSITY of WASHINGTON

#### Creating an Initiative





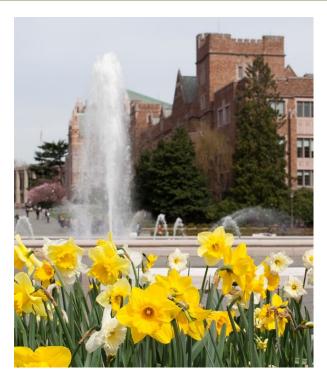
#### Implementation Structure





#### Clinical Trials at UW CY2023

- FDA regulated
  - 65% involve drug/device/biologic with data submitted to FDA
- Trial Location
  - •76% UW/Fred Hutch/SCH
  - •92% Puget Sound region



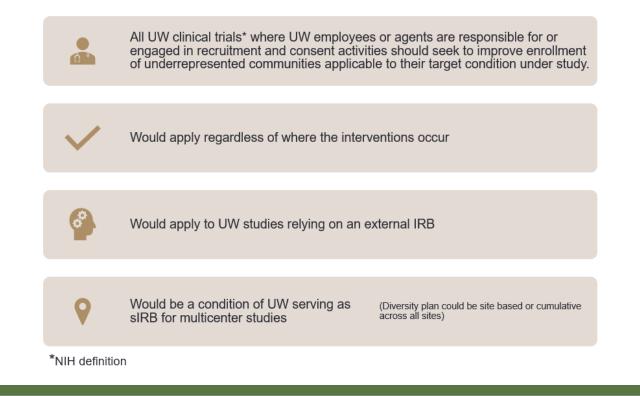


#### RCW 69.78 Definition of Underrepresented Community

"Underrepresented community" or "underrepresented demographic group" means a community or demographic group that is more likely to be historically marginalized and less likely to be included in research and clinical trials represented by race, sex, sexual orientation, socioeconomic status, age, and geographic location.



#### **UW Policy Scope**





#### UW Supplement: Diversity Plan

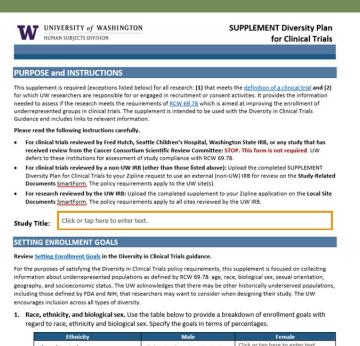
- Modeled off the FDA Diversity Action Plan in the FDA Draft Guidance for Industry: Diversity Action Plans to Improve Enrollment of Participants from Underrepresented Populations in Clinical Studies (June 2024)
- The DCT bill requires use of methods recognized by FDA to identify and recruit members from underrepresented groups





#### DRAFT HSD Diversity Plan – Areas of Focus

- Establishing Enrollment Goals age, race, ethnicity, biologic sex, sexual orientation, geographic location (probably zip codes), social economic status (several variables, TBD)
- Rationale for current enrollment goals and any exclusions
- Strategy for meeting enrollment goals (e.g., study design, recruitment, and retentional plan, reducing barriers to participation
- Description of efforts/resources utilized for community engagement that informs recruitment strategy
- Plan for tracking enrollment data



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Male	Female
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	Click or tap here to enter text. Male Click or tap here to enter text.



#### **Overcoming Barriers to Participation**

- •Absence of technology devices
- •Unreliable, unavailable, and unaffordable broadband and/or phone data
- •Limited digital and health literacy
- •Concerns about quality and personalization
- •Lack of physical accommodations for setting up devices and hearing or vision accommodations
- •Language proficiency barriers
- Privacy concerns



#### Implementation Timeline

- Researchers submitting an initial application to the IRB one year from date new policies/guidance posted would be required to have a diversity plan
  - January 2026
- Existing studies are not subject to the new policy





#### Additional Information

- •UW Diversity in Clinical Trials Initiative Website
  - https://www.iths.org/dcti/
- •HSD newsletter

https://www.washington.edu/research/hsd/subscribe-to-the-hsd-newsletter/



Career Development Series 2024

## **Thank You!**

**Open for Questions** 



#### Career Development Series 2024

#### **Feedback Survey**

A link to the feedback survey has been sent to the email address you used to register.

Please get out your device, find that email, and spend a few moments completing that survey before you leave today.

Tip: If on a mobile device, shift view to landscape view (sideways) for better user experience.

