Clinical Research in Primary Care: A Public Workshop

June 7, 2024
Welcome

Tara A. Schwetz, Ph.D.
NIH Deputy Director for Program Coordination, Planning, and Strategic Initiatives
Director of the Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI) in the NIH Office of the Director
“Clinical trials should reflect the diversity of Americans – because we know that delivers the best results. We are taking a big step towards ensuring communities that are historically underrepresented in clinical research are fully included and have the same access to the best available results and analysis. There has never been more potential for progress than we have today.”

- HHS Secretary, Xavier Becerra
**Agenda**

<table>
<thead>
<tr>
<th>Time</th>
<th>Agenda Item</th>
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<tbody>
<tr>
<td>10:00 AM</td>
<td>Welcome &amp; Our Vision for Communities Advancing Research Equity (CARE) for Health</td>
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<tr>
<td>10:20 AM</td>
<td>Overview of Listening Sessions: <em>What We Heard</em></td>
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<tr>
<td>10:35 AM</td>
<td>Panel Discussion 1: <em>Visions of Success from Providers and Patients</em></td>
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<td>11:15 AM</td>
<td>Panel Discussion 2: <em>Visions of Success from Networks and Feds</em></td>
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<td>11:55 AM</td>
<td>The Path Forward for CARE for Health</td>
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<td>12:10 PM</td>
<td>Open Q&amp;A</td>
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Housekeeping

All participants except the speakers and panelists will be muted.

Questions are welcome using the Q&A function and can be submitted anonymously. Questions will be answered during the panel discussions and the Open Q&A.

The Workshop will be recorded.

The Workshop recording and slides will be posted on the CARE for Health website.
Our Vision for Communities Advancing Research Equity (CARE) for Health™

Clinical Research in Primary Care: A Public Workshop
June 7, 2024

Monica M. Bertagnolli, MD
Director, National Institutes of Health
Our work is not finished when we deliver scientific discoveries, our work is finished when all people are living long and healthy lives.
NIH research encompasses the laboratory, the clinic, and the community.
Progress is accelerated when advanced scientific methods, such as new data analytics, are applied to data that includes everyone, and when new discoveries are rapidly and equitably adopted in clinical care.
Disturbing trends in the health of the U.S. population
U.S. life expectancy ranks low among peers

Concerning U.S. life expectancy trends:
• Declined 2014–2017\(^1\)
• Dropped significantly—2.4 years—between 2019 and 2021\(^2\)
• Increased in 2022 by 1.1 years; gain does not make up for pandemic losses.\(^2\)

(3) Chart data: OECD (2024), Life expectancy at birth (indicator). [DOI: 10.1787/27e0fc9d-en](https://doi.org/10.1787/27e0fc9d-en) (Accessed on 10 January 2024)
What Should NIH Do?
Connect research to primary care
Preparations for Launch

• Listening sessions
  o Patients
  o Community Groups
  o Primary Care Providers
  o Hospital Systems
  o Research Networks
  o Federal Agencies
Communities Advancing Research Equity for Health

**CARE for Health™**

- Integrate research into the clinical care environment
- Engender trust in science by addressing community needs
- Conduct research addressing issues important to diverse communities, particularly those underrepresented in biomedical research
- Achieve longitudinal collection of clinical data to address health across the lifespan
- Reduce burden on providers using innovative data collection methods
- Increase adherence to evidence-based care
- Improve efficiency of care delivery
NIH

Turning Discovery Into Health
Overview of Listening Sessions: What We Heard

Joni Rutter, Ph.D.
Director, National Center for Advancing Translational Sciences (NCATS)
National Institutes of Health (NIH)
We Hosted 4 Listening Sessions in Spring 2024

- **Listening Session 1:** Early, Sustained Engagement of Patients and Community Organizations
- **Listening Session 2:** Clinical Research Network Capabilities
- **Listening Session 3:** Needs of Providers and Healthcare Systems for Research Participation
- **Listening Session 4:** Clinical Research Innovations to Reduce Site and Provider Burden

The listening sessions engaged 78 unique participants with perspectives from:

- Research Networks
- Hospital Systems
- Primary Care Providers and Organizations
- Patient and Community Organizations
- Federal Agencies
What We Heard

Bridging Gaps and Building Connections

Accounting for Provider Needs in Research Integration

Balancing Financial Implications of Research Involvement

For more details on the Listening Sessions, please review the executive summary posted on the CARE for Health website
## Bridging Gaps and Building Connection

### Building Sustainable and Effective Partnerships
- Transition from episodic to continuous engagement
- Build and maintain capacity through mentorship, administrative support, and sustained staffing
- Maintain ongoing relationships (including financially) with local community partners

### Demonstrating Trustworthiness Through Balanced and Bi-directional Partnerships
- Co-develop and shape the research agenda
- Trust and consistency stem from a deep-seated physical community presence
- Active observation to understand and meet community needs

### Understanding the Diverse Needs of Communities
- There is no “one size fits all”; adapt research engagement approaches
- Raise provider and researcher cultural competency and enhance community literacy
- Implement decentralized research studies to increase participation
Accounting for Provider Needs in Research Integration

**Aligning Practice Needs and Research Structures**
- Establish relationships with entire clinical team and stakeholders
- Enhance information access to relevant clinical trials for patients
- Communication and flexible research designs address misalignment between pace of research and pace of care

**Considering the Workload of Health Care Providers**
- Account for the clinical team’s routine operations
- Provide research support and resources for administrative tasks

**Reducing Burden with Innovative Study Design and Technology**
- Novel research allows exploration of questions and interventions relevant to patient care
- Artificial Intelligence, common data models, and data tokenization can simplify research process
- Consultation with providers should inform how technology is integrated into research
Balancing Financial Implications of Research Involvement

<table>
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<th>Addressing Financial Sustainability</th>
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<tr>
<td>Ensure funding is adaptable to meet care and local needs</td>
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<td>Consider revenue impact on providers and explore ways to provide financial remuneration for time spent on research</td>
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<th>Valuing Patient and Community Contributions</th>
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<td>Patient and communities should be included in the decision-making process, to effectively co-create</td>
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<tr>
<td>Existing funding structures pose challenges to compensate community organizations</td>
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<td>Individuals and community organizations deserve equitable compensation</td>
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Panel Discussion: Visions of Success from Providers and Patients

Moderated By: Felicia Qashu, Ph.D.
Program Leader, Office of Strategic Coordination
National Institutes of Health (NIH) Common Fund
Visions of Success from Providers and Patient Organizations

Dr. Sally Hodder
Mountaineer Health Initiative

Dr. Meagan Stabler
Northern New England CO-OP Practice & Community Based Research Network

Mr. Silas Buchanan
Our Healthy Community

Dr. Fornessa Randal
Asian Health Coalition; Pennsylvania State College of Medicine’s Center for Advancing Health Equity in Rural and Underserved Communities
Community-first looks like this.

- Community-vetted materials and campaigns
- Equitable partnerships with the healthcare industry
- Educational content
- Co-developed resources
In OHCEngage, we bring community organizations together to share resources, address health disparities, converse with healthcare stakeholders, and foster dialogue and collaboration.

Connect and collaborate with others, sharing successes along the way

Join regional groups, with events and programming in your own backyard

Connect with organizations for research, collaboration, and innovation
Welcome to Cohort 1

Curious about who's in your cohort?

- Ana Colic, sakasavanaa@gmail.com
- Mercedes Doss, mercedesdoss@yahoo.com
- Erin Marten, emarten@solacehealth.org
- Shrividyam Ramesh, shrividyam10@gmail.com
- Rhondala Jackson-Bizuneh, rbizuneh@birthingbeautiful.org
- Mary Louise Tatum, mtatum1@kent.edu

Faculty Partner: Rachel Dudley, PhD, rachel.dudley@utoledo.edu

BRACE Navigator: Carey Gibbons, gibbons@neoeh.org

Please ensure you've sent your completed vendor form to receive your stipend to Zina Hempstead (zah@case.edu). Need a copy? Please see below.

![Supplier-Form-2021.pdf](Supplier-Form-2021.pdf)
Scan to join us on ENGAGE

Silas Buchanan, Founder & CEO
Our Healthy Community
sbuchanan@ourhealthycommunity.com
Integrating Clinical Research in Primary Care Settings

Dr. Fornessa T Randal, EdD, MCRP
Director, CAHE-RUC
Executive Director, Asian Health Coalition
PI, All of Us Research Program, NCEP
Deliver the Right Care and the Right Time
(New Mexico)

Address issues of a “Whole Person” not a “study participant”
(Illinois)

Provider Cultural Competency to drive Better Health
(Pennsylvania)

Pathways to Research through Multisector Collaboration
(California)


Building Sustainable & Effective Clinical Research Partnerships

EXECUTIVE SUMMARY OF THE FOUNDATION FOR THE NATIONAL INSTITUTES OF HEALTH (FNIH)-NATIONAL INSTITUTES OF HEALTH (NIH) LISTENING SESSIONS ON RESEARCH IN PRIMARY CARE SETTINGS (2024)
Clinical Integration reduces disease burden: Who is most at risk?

Increase in Cancer Incidence by 2030

- White: 31%
- Black: 64%
- American Indian: 76%
- Multirace Hispanic: 101%
- Asian: 132%
- Hispanic: 142%

Panel Discussion: Visions of Success from Networks and Federal Agencies

Moderated By: Tara Schwetz, Ph.D.
Visions of Success from Networks and Federal Agencies

Dr. Adrian Hernandez
Duke Clinical Research Institute

Dr. Melinda Davis
Oregon Rural Practice-based Research Network

Dr. Jannette Dupuy
Health Resources and Services Administration (HRSA)

Dr. Aimee Eden
Agency for Healthcare Research & Quality (AHRQ)
The Problem: Covering Clinical Trial Deserts

Healthcare Deserts, County by County
Counties where most people lack adequate access to pharmacies, primary care providers, hospitals, hospital beds, trauma centers, and/or low-cost health centers.

Population Living in a Hospital Desert
Percent of county’s population living over 30 minutes from the closest hospital.
A Changed World of Possibilities

Pre-COVID-19:
Site based visits & care

The Possibilities:
@Clinic, @Home w/EMR + Digital

https://ctti-clinicaltrials.org
Art of Possible into Reality
Click and Mortar Model for Pragmatic Clinical Trial Platform

N = Millions
across all 50 States

N = Tens of Thousands

N = X,000

Return of Results to Everyone, Everywhere

Tailored Follow-up:
EMR, Digital, Portal, Tele/Video, Clinic
- Healthcare
- Symptoms
- Medications
- Patient reported outcomes
- Health and functional status

Interested Population
Health System Clinics
@Home
Click & Mortar

Enrollment & patient preferences
Baseline data & Randomization
Definition of “primary care research”

Research conducted for the purpose of better understanding or improving primary care (as defined by NASEM 2021). It is research that is

a) conducted in a primary care setting;

b) about primary care patients, clinicians, or teams;

c) on a topic that is integral to, or has direct implications for, the delivery of primary care.
AHRQ defines PBRNs as “groups of primary care clinicians and practices working together to answer community-based health care questions and translate research findings into practice.”
CARE for Health: the Path Forward

Amy Patterson, M.D.
Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI)
Establishing an NIH Network for Research in Primary Care Settings

Coordinated infrastructure that embeds innovative research into routine clinical care in primary care settings, that will...

• Support primary care-based clinical research in mission areas spanning prevention and treatment and with a focus on health equity and whole person health

• Establish a foundation for sustained engagement with communities underrepresented in clinical research

• Implement innovative study designs suitable for primary care settings that address common health issues and inform clinical practice and enhance dissemination and implementation

...thereby facilitating and accelerating research advances for adoption and implementation into everyday clinical care, improving health outcomes, and advancing health equity for all Americans.
Approach

Expand enrollment efforts of existing NIH studies and pilot new studies as the infrastructure is established.

Partner with existing clinical research networks and resources, expanding with new collaborations as the network grows.

Engage primary care sites and community network partners on prioritizing and planning research.

Implement study designs across the landscape of clinical trial innovations to minimize burden on patients and providers.

Network of Research Networks

- Regulatory approvals and support
- Site Contracting
- Data and systems
- Training

Practice-based and Patient-centered
Research prioritization and planning
Clinical study innovations
Sustained community engagement
Potential Synergistic Partnerships

- Patients, Communities

- Federally Qualified Health Centers

- CARE for Health Partners

- Professional Societies

- Practice Based Research Networks

- Federal Agencies

- Community Health Centers

- NIH CEAL

- CTSA Clinical & Translational Science Awards Program

- NIH Collaboratory

- IDEA Clinical and Translational Research

- HRSA Health Resources & Services Administration

- OASH Office of the Assistant Secretary for Health

- FDA U.S. FOOD & DRUG ADMINISTRATION

- INDIAN HEALTH SERVICE

- CMS Centers for Medicare & Medicaid Services

- AHRQ Agency for Healthcare Research and Quality

- PCORI The National Patient-Centered Clinical Research Network

- NIH National Institutes of Health
CARE for Health Leadership

CARE for Health Oversight Committee Co-Chair
Helene Langevin, M.D.
Director, National Center for Complementary and Integrative Health (NCCIH)

CARE for Health Oversight Committee Co-Chair
Joni Rutter, Ph.D.
Director, National Center for Advancing Translational Sciences (NCATS)

CARE for Health Oversight Committee Co-Chair
Debara Tucci, M.D., M.S., M.B.A.
Director, National Institute on Deafness and Other Communication Disorders (NIDCD)

CARE for Health Oversight Committee Ex-Officio
Tara Schwetz, Ph.D.
NIH Deputy Director for Program Coordination, Planning, and Strategic Initiatives
Timeline & Budget

**Spring 2024:** Obtain perspectives from external partners to inform planning for the network
   - Listening sessions and public workshop

**Quick Launch in 2024:** Expand existing NIH-funded studies to increase engagement with underrepresented rural populations and to enhance accrual and collaboration
   - Research Opportunity Announcement published May 6, 2024
   - Common Fund Program with an anticipated budget of $5M in FY24

**Expand in 2025 and Beyond:** Launch new studies across the network and further establish and solidify the network infrastructure and expand to additional populations
   - Anticipated budget: $25M in FY25; anticipate ramp up of $50-100M/year after assessing feasibility and budget requirements
Network Research Hubs: Objectives

- Research in Primary Care Settings in Collaboration with Clinical Sites on Select Existing NIH-Funded Studies and New Studies
- Participant and Community Engagement
- Innovations in Clinical Study Design
- Participation in Coordinated Infrastructure Supporting Research in Primary Care Settings
Infrastructure to Embed Research into Primary Care

Infrastructure components anticipated to be piloted and implemented

Network Research Hubs
Clinical Science Center
Operations Center
Independent Review and Monitoring Boards
Community Engagement
Industry Partnerships
Phased Approach to Launching Studies and Building Infrastructure

This effort is expected to be a two-year pilot

**Year 1**

*Fund Network Research Hubs*
That will participate in selected existing studies. These studies may be interventional or observational and are expected to be suitable for primary care settings

**Year 2**

*Conduct New Research*
In coordination with the other components of the infrastructure

*Perform a Program Evaluation*
Before the end of year two, NIH will evaluate which approaches and efforts are working for broader implementation
CARE for Health: Information Resources

Additional resources can be accessed via the CARE for Health website:

- Research Opportunity Announcement (ROA)
- Technical Assistance Webinar Recording and Slides
- Listening Session Executive Summary

To stay up-to-date on program activities, please sign up for the listserv:

Get Program Updates

The listserv registration button can be found on the left side of the CARE for Health website.
Open Question and Answer

Moderated By: Tara A. Schwetz, Ph.D. and Amy Patterson, M.D.
Stay in Touch!

For program updates, please visit go.nih.gov/CARE-for-Health. You can also sign up to join our listserv.

Reach us at: CAREforHealth@od.nih.gov

Have additional feedback? Share your thoughts via Slido.

Scan the QR code below or visit Slido.com and use code #1222418.
Thank you!

go.nih.gov/CARE-for-Health