Communities Advancing Research Equity (CARE) for Health™

Advancing Clinical Research *with and for* Primary Care

NCI Council of Research Advocates Meeting

September 18, 2024

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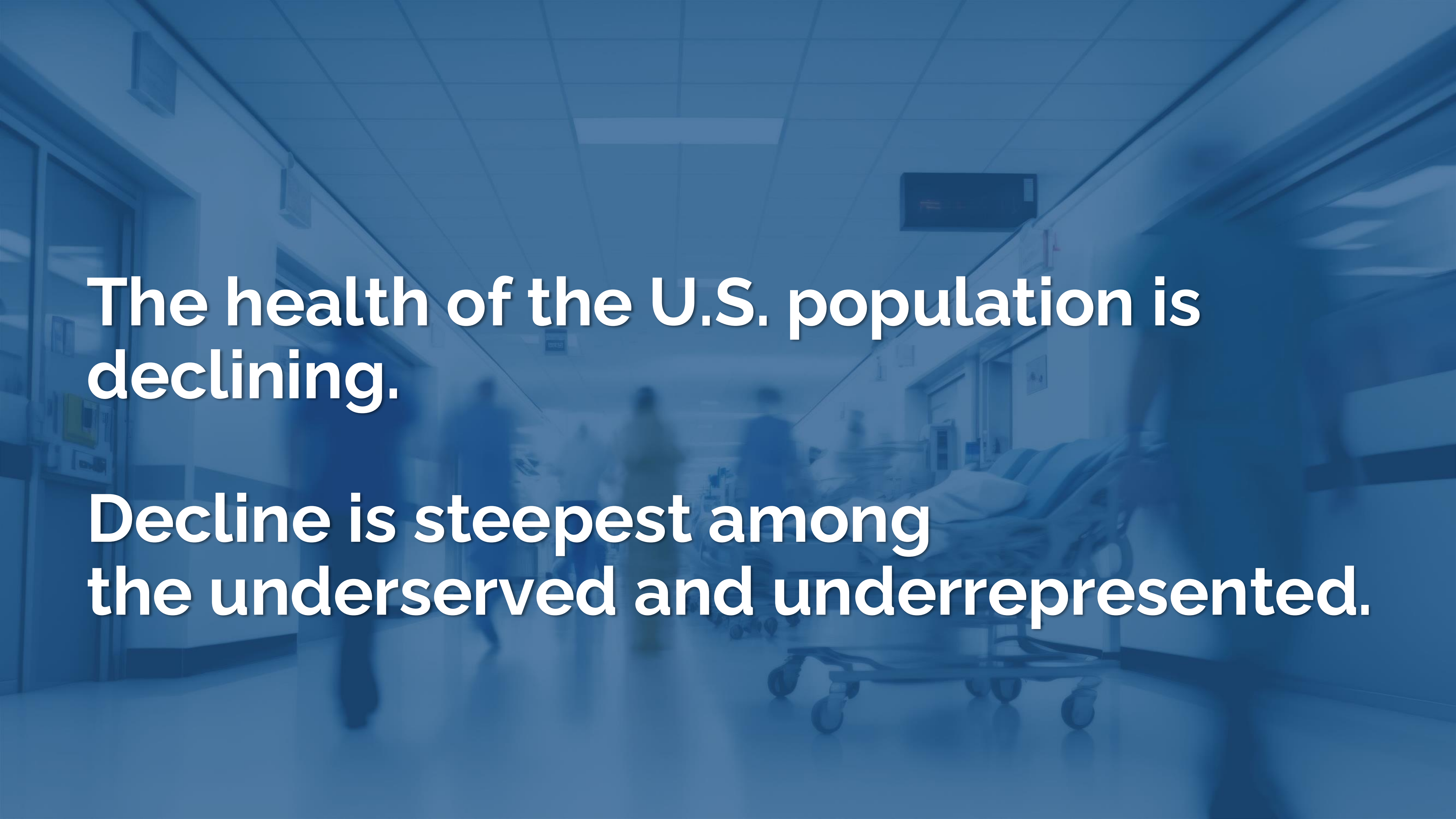
NIH National Institutes of Health

Today's Talk

- Overview of CARE for Health
- Community Engagement Components
- Discussion

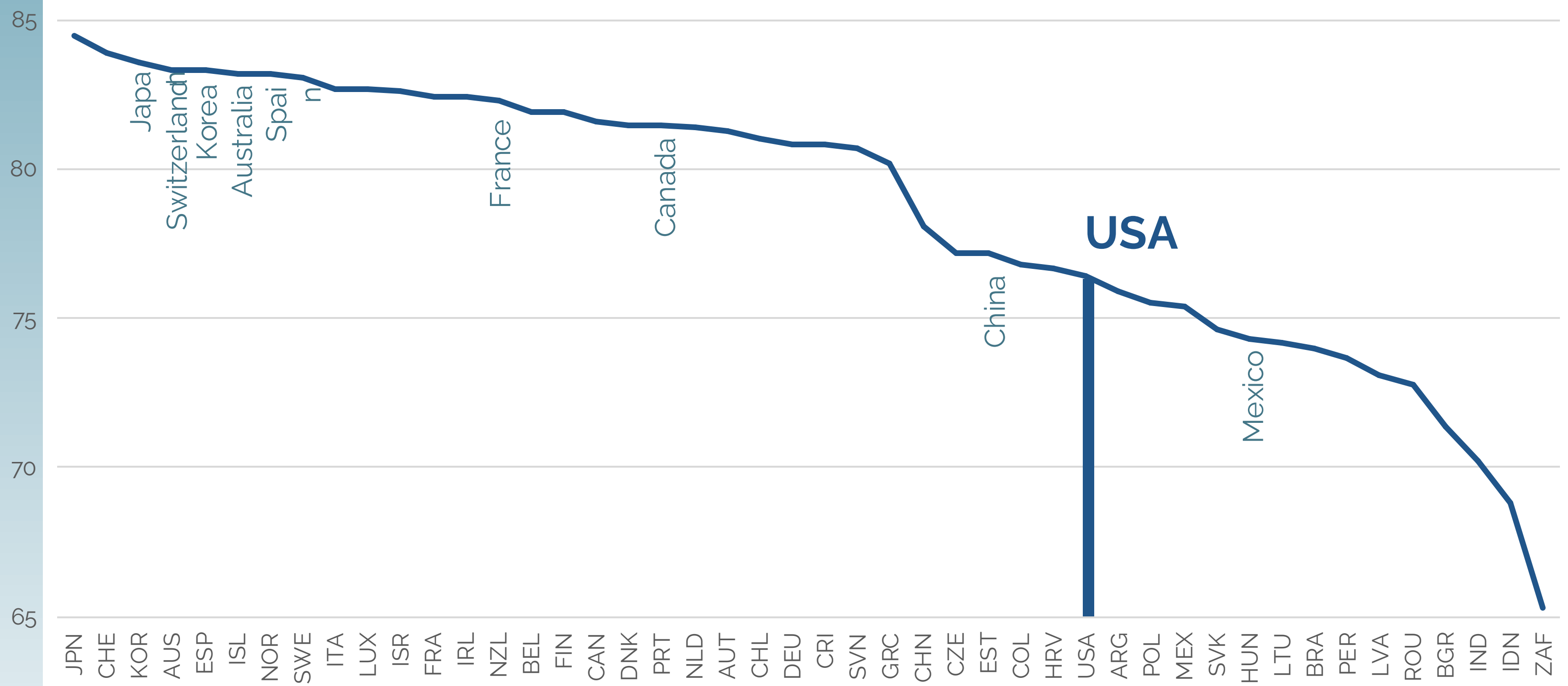


The health of the U.S. population is declining.

Decline is steepest among the underserved and underrepresented.

U.S. life expectancy ranks low among peers

2021 Life Expectancy Throughout World[3]



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]

(1) National Academies of Sciences, Engineering, and Medicine. 2021. *High and Rising Mortality Rates Among Working-Age Adults*. Washington, DC: The National Academies Press.

(2) Arias E, Kochanek KD, Xu JQ, Tejada-Vera B. Provisional life expectancy estimates for 2022. Vital Statistics Rapid Release; no 31. Hyattsville, MD: National Center for Health Statistics. November 2023.

(3) Chart data: OECD (2024), Life expectancy at birth (indicator). (Accessed on 10 January 2024)

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Communities Advancing Research Equity for Health (CARE for Health)

NEWS RELEASES

Thursday, June 6, 2024

NIH launches $30 million pilot to test feasibility of a national primary care research network

Initiative aims to improve health outcomes by integrating research in everyday primary care settings.

The National Institutes of Health (NIH) is investing approximately $30 million in total over fiscal years 2024 and 2025 to pilot a national primary care research network that integrates clinical research with community-based primary care. The new initiative called Communities Advancing Research Equity for Health – or CARE for Health – seeks to improve access to clinical research to inform medical care, particularly for those in communities historically underrepresented in clinical research or underserved in health care. Informed by the health needs of these

Read the announcement

EDITORIAL

Connecting lab, clinic, and community

Despite great progress in biomedical research, the health of the US population appears to be getting worse. The United States spends substantially more per capita on health care than other wealthy countries, yet US life expectancy ranks low among its peers. Mortality rates have been increasing for segments of the US population, including those in rural areas, certain racial and ethnic groups, and individuals with low socioeconomic status. A whole-of-society approach is required to address such negative trends and disparities, and the biomedical research enterprise must play a key role.

To better understand relationships between the genes we inherit and the environmental and societal factors that surround us and to deliver more evidence-driven health care, research must be integrated into clinical care and community settings, reaching patients from all walks of life. Unlike most research settings, primary care is patient- and community-centered and emphasizes health maintenance and preventive care alongside treatment and rehabilitation in a location as convenient as possible for the patient. Communities Advancing Research Equity (CARE) for Health, a new National Institutes of Health (NIH) research network in primary care settings, will expand beyond the existing capacity of clinical researchers to engage patients and communities that are currently not well represented in clinical research. By engaging more primary care providers serving more communities experiencing health disparities, the CARE for Health network will address common health issues, including obesity, mental health, perinatal care, and cancer screening.

> "...the network will offer a wider menu of studies..."

Rather than sticking to a narrow suite of studies determined by researchers centrally, the network will offer a wider menu of studies, allowing more patients and providers more choice to participate in, and influence, those studies most relevant to their needs and the needs of their communities. Studies will place particular emphasis on evaluating new treatment and prevention approaches that are meaningful to underserved populations. The network will focus on research on disease prevention, health care implementation, and information dissemination, as well as trials with multidisease endpoints and those designed to improve the efficiency of care delivery. Primary care providers will receive support to achieve research aims, including funding and study designs that integrate research activities into clinical care workflows and embed data collection in electronic health records.

The CARE for Health network will leverage many existing resources, such as Federally Qualified Health Centers, which offer services for underserved populations, and several existing NIH research initiatives and networks, including the IDeA Clinical & Translational Research Network Award program, which supports biomedical research capacity building in states that have historically low levels of NIH funding.

A second initiative will establish NIH's National Library of Medicine (NLM) as a focal point to accelerate data sharing and use and to advance health-related data science. Rapid growth in biomedical data, together with new artificial intelligence and machine learning (AI/ML) methods, promises to deliver transformative tools and research insights. NIH's Data Management and Sharing Policy requires that all new funding proposals include a data accessibility plan to promote data sharing. But full implementation of this policy requires new approaches and resources that can integrate data from basic and social science research, public health, and clinical care.

NLM will substantially increase its capacity for data hosting, including reaching beyond NIH to incorporate data from agencies across the Department of Health and Human Services. It will employ a federated architecture to allow independent research teams to deliver data in ways that reduce complexity, require minimal cost to access, and foster flexibility and agility in data exchange using open data standards. NLM will promote access to data from diverse populations to facilitate ethical and equitable development of AI/ML, expanding on current NIH programs such as Artificial Intelligence/Machine Learning Consortium to Advance Health Equity and Researcher Diversity, and Bridge to Artificial Intelligence. NLM will also enable access to advanced analytics and computational power by fostering collaboration between computational biology, molecular biology, drug development, and translational, clinical, and social science research. Existing NIH efforts providing data science education and workforce development will expand.

These initiatives will help translate scientific discoveries into effective health care and will require not only support from NIH but commitment from the biomedical research community, other governmental agencies, health care systems, and private citizens who participate in research.

–Monica M. Bertagnolli

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10.1126/science.adq2140

NIH National Institutes of Health

Community-based primary **C**are practices **A**dvancing **R**esearch **E**quity **for Health**

CARE for Health™

Conduct research addressing **issues important to diverse communities**, particularly those **underrepresented** in biomedical research

Reduce burden on providers using innovative data collection methods

Increase adherence to **evidence-based care**

Improve **efficiency of care delivery**

Integrate research into the clinical care environment

Engender trust in science by addressing community needs

Achieve **longitudinal collection of clinical data** to address health across the lifespan

National Institutes of Health

Establishing and NIH Network for Research in Primary Care Settings

Coordinated infrastructure that embeds innovative research into routine clinical care in primary care settings to:

- 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, 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

CARE for Health Engagement: Executive Summary Themes

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

Public Workshop June 6, 2024 engaged **538** participants

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 allow 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

Addressing Financial Sustainability

Ensure funding is adaptable to meet care and local needs

Consider revenue impact on providers and explore ways to provide financial remuneration for time spent on research

Valuing Patient and Community Contributions

Patient and communities should be included in the decision-making process, to effectively co-create

Existing funding structures pose challenges to compensate community organizations

= Individuals and community organizations deserve equitable compensation

Approach to Network Building

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

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

Engage NIH ICOs as well as primary care sites and their 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

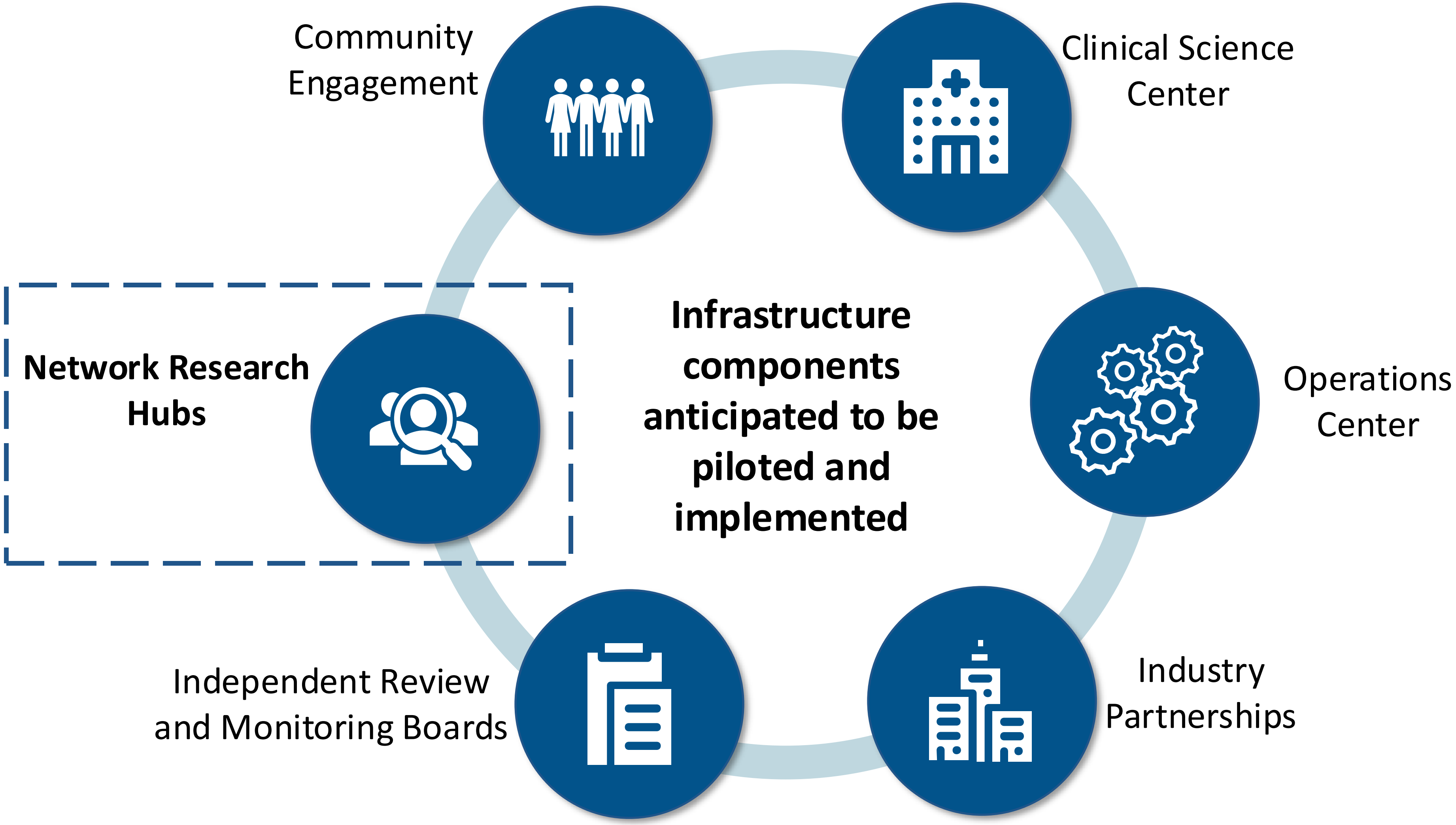
Practice-based and Patient-centered

Research prioritization and planning

Clinical study innovations

Sustained community engagement

Infrastructure to Embed Research into Primary Care



Community Engagement

Clinical Science Center

Network Research Hubs

Infrastructure components anticipated to be piloted and implemented

Operations Center

Independent Review and Monitoring Boards

Industry Partnerships

Potential Synergistic Partnerships

IDeA | Clinical and Translational Research

NIH CEAL
Community Engagement Alliance

NIH PRAGMATIC TRIALS COLLABORATORY
Rethinking Clinical Trials®

CTSA Clinical & Translational Science Awards Program

pcornet®
The National Patient-Centered Clinical Research Network

Patients, Communities

Professional Societies

FQHCs and CHCs

CARE for Health™ Partners

Industry

Federal Agencies

Practice Based Research Networks

COMMUNITY HEALTH CENTER® FQHC QUALITY

HRSA
Health Resources & Services Administration

DEPARTMENT OF HEALTH & HUMAN SERVICES · USA

OASH Office of the Assistant Secretary for Health

FDA U.S. FOOD & DRUG ADMINISTRATION

INDIAN HEALTH SERVICE · PHS · 1955

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

AHRQ Agency for Healthcare Research and Quality

Key Elements of Pilot Launch

- **Leveraging existing clinical research Networks for rapid launch**
- **Focus on populations that are medically under-served and historically under-represented in biomedical research, with emphasis in initial pilot phase on rural populations**

Research Opportunity Announcement (ROA)

Integrating Clinical Research into Primary Care Settings through Network Research Hubs – A Pilot (OT2):

Purpose: Invite applications for organizations to serve as "Network Research Hubs" and establish an infrastructure to conduct clinical research in rural primary care settings as a two-year pilot

Eligibility:

- Located in states with at least 25% of census tracts defined as rural using the Revised 2010 RUCA Codes (codes 4-10)
- Part of or funded by NIH Institutional Development Award Clinical and Translational Research (IDeA-CTR) awards; the NIH Clinical and Translational Science Award (CTSA) Program; or the Patient-Centered Outcomes Research Institute's (PCORI) Network (PCORnet)

Timeline

Spring 2024: Obtain perspectives from external partners to inform planning for the network

- Listening sessions and public workshop

Quick Launch in 2024: Expand existing studies to increase engagement with underrepresented rural populations and to enhance accrual and collaboration

- Administered by NIH Common Fund
- Research Opportunity Announcement (May 6 – June 14, 2024); Anticipate Initial awards in September 2024
- Anticipated initial award budget totaling ~$5.6 M in FY24

Expand in 2025 and Beyond: Launch additional studies across the network, plan new studies, further establish and solidify the network infrastructure

- Anticipated Budget: $25M in FY25; anticipate ramp up of ~$50-100M/year after assessing feasibility and budget requirements

Phased Approach to Launching Studies

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 rural primary care settings.

Year 2

New Research

In coordination with the other components of the infrastructure and partners.

Program Evaluation

Before the end of year two, NIH will evaluate which approaches and efforts are working for broader implementation.

Beyond Year 1: Expanding Focus Populations

Rural Communities

Pediatrics

Tribal Nations

Women

People without Homes

Racial and Ethnic Minorities

Community Engagement Components

Early in Planning	
Network Research Hubs	Local Engagement
Community Engagement Committee	Community Representatives Patient Representatives
CARE for Health™ Community Engagement Coordination	Coordination/Learning Resources/Workshops/Toolkits Collaboration with Advocacy Groups

Discussion

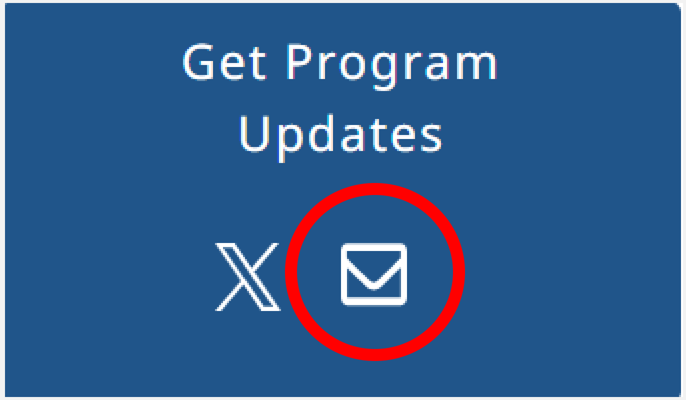
- Questions re: CARE for Health™
- Lessons Learned from NCRA Experience:
  - Effective strategies to communicate CARE for Health™ to the patient community
  - Incorporating research advocacy at research network level
- Other Advice from NCRA

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:



The listserv registration button can be found on the left side of the CARE for Health website