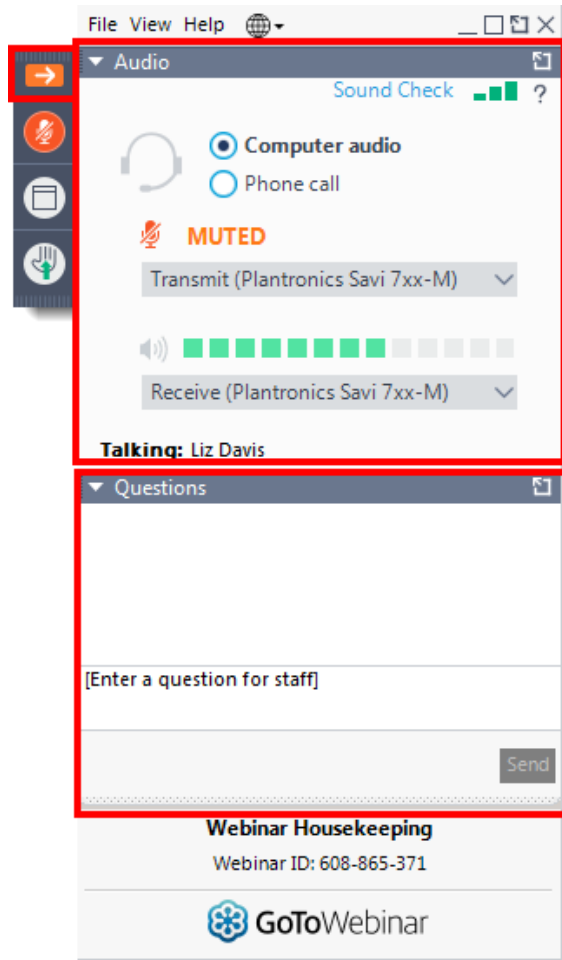


Welcome!

The meeting will begin promptly at
1 pm ET.

Member Participation



Your Participation

Open and close your control panel

Join audio:

- Choose **Computer Audio** to listen through your computer (headset recommended)
- OR-
- Choose **Phone Call** and dial in using the information provided

Clinical Effectiveness and Decision Science

PCORI Advisory Panel Meeting

June 4, 2020 | 1 pm-4 pm

June 5, 2020 | 9 am-noon

Housekeeping

- **Today's webinar is open to the public and is being recorded.**
 - Meeting materials can be found on the PCORI website, www.pcori.org:
 - Meetings & Events → Advisory Panel Meetings → Advisory Panel on Clinical Effectiveness and Decision Science Spring 2020 Meeting
 - Comments may be submitted via chat; no public comment period is scheduled.
- Please remember to **speak loudly** and **clearly into a microphone**.
- State your name and affiliation when you speak.
- Please avoid technical language in your discussion.
- As a reminder, members and staff should mute themselves when they are not speaking.

Conflict of Interest Statement



Disclosures of conflicts of interest of members of this Committee are publicly available on PCORI's website and are required to be updated annually. Members of this Committee are also reminded to update conflict of interest disclosures if the information has changed by contacting your staff representative.

If this Committee will deliberate or take action on a manner that presents a conflict of interest for you, please inform the Chair so we can discuss how to address the issue. If you have questions about conflict of interest disclosures or recusals relating to you or others, please contact your staff representative.

Welcome & Introductions

Bridget Gaglio, PhD, MPH

Senior Program Officer, CEDS



Overview – Previous CEDS Meeting Fall 2019



- Day-long meeting devoted to women's health
- Hosted two guest presenters and two guest reactants
 - Cardiovascular disease
 - Health implications of menopause
- Large group discussion on both topics
 - Perceptions and understanding risk across the lifespan
 - Studying different ways of presenting risk
 - Reporting of study results—needs to be split out by gender
 - SDM tools that are tailored to patient preferences, culture, and literacy level and convey appropriate health messages

CEDS Panel Chair and Co-Chair

Cornell Wright, MPA

Executive Director, NC Office of Minority Health Disparities
NC Department of Health and Human Services
Representation: Policy Makers
CEDS Advisory Panel Chair



Lawrence Goldberg, MD

Psychiatrist Surveyor, The Joint Commission
Representation: Clinicians
CEDS Advisory Panel Co-Chair



CEDS Spring 2020 Panel Members



[Nancy Blake, PhD, RN, NEA-BC, CCRN](#)

[Eric Cannon, PharmD, FAMCP](#)

[Neela Goswami, MD, MPH](#)

[Lawrence Goldberg, MD](#) (Co-Chair)

[Melissa Hicks](#)

[Kate Houghton, MPA](#)

[Robin Karlin, MS](#)

[Helen Osborne, M.Ed., OTR/L](#)

[Ruth M. Parker, MD, MACP](#)

[Andrew Rosenberg, JD, MP](#)

[Sandi W. Smith, PhD](#)

[David Webster, MD, MBA](#)

[Maureen White, MD, MS, MBA](#)

[Cornell Wright, MPA](#) (Chair)

Overview of Agenda & Activities

Cornell Wright, MPA

Lawrence Goldberg, MD



Agenda Day 1

Time	Duration	Activity
1 pm	(45 min)	Introduction to Nakela Cook, MD, MPH, FACC
2:15 pm	(30 min)	Overview of Reauthorization
2:45 pm	(15 min)	BREAK
3 pm	(60 min)	National Priorities and Research Agenda
4 pm	-----	Adjourn

Agenda Day 2

Time	Duration	Activity
9:15 am	(60 min)	Cost Data Provision
10:15 am	(10 min)	BREAK
10:25 am	(60 min)	Maternal Mortality, Intellectual and Developmental Disabilities, and Balancing Short- and Long-Term Priorities
11:25 am	(30 min)	Round Robin Conversation
11:55 am	(5 min)	Closing Remarks
Noon	-----	Adjourn

Executive Director Report

Nakela L. Cook, MD, MPH

Advisory Panel Introduction

June 2020

Navigating Our Course Together



- **My First Few Months at PCORI**
 - My Personal Journey
 - Early Onboarding
 - Passionate and Mission-Driven PCORI Staff and Board
- **Envisioning PCORI 2.0**
 - Opportunities for the Future
 - Learning in a Public Health Crisis
- **Our Course Together**
 - Year 1 Priorities

My Journey: Fulfilling a Life's Purpose

**Motivated by CV
Disparities in My
Neighborhood**

University of
Alabama
at Birmingham

**Inspired to
Leadership in
Health**

Harvard
Medical
School

**Defined
Patient-Centered
Healthcare**

Massachusetts
General Hospital

**Pursued
Health Services
Research**

Harvard
School of
Public Health

**Focused on
Research Agenda
& Management**

NHLBI Office of
the Director

**Privileged
to Serve;
Destined to Be**

Patient-Centered
Outcomes Research
Institute

Outstanding, Passionate, and Mission-Driven Staff, Panels, and Committees at the Heart of PCORI



- **Dedicated and Mission Driven**

- Communication and Dissemination Research framework (CDR panel)
- Topic Prioritization/Ranking (APDTO panel)
- Identifying areas of scientific inquiry and direction for CER questions (CEDS)
 - Peripheral Artery Disease (RAI 19C3 and 20C1)
 - Women's Health topics for CER

A true testament to your efforts



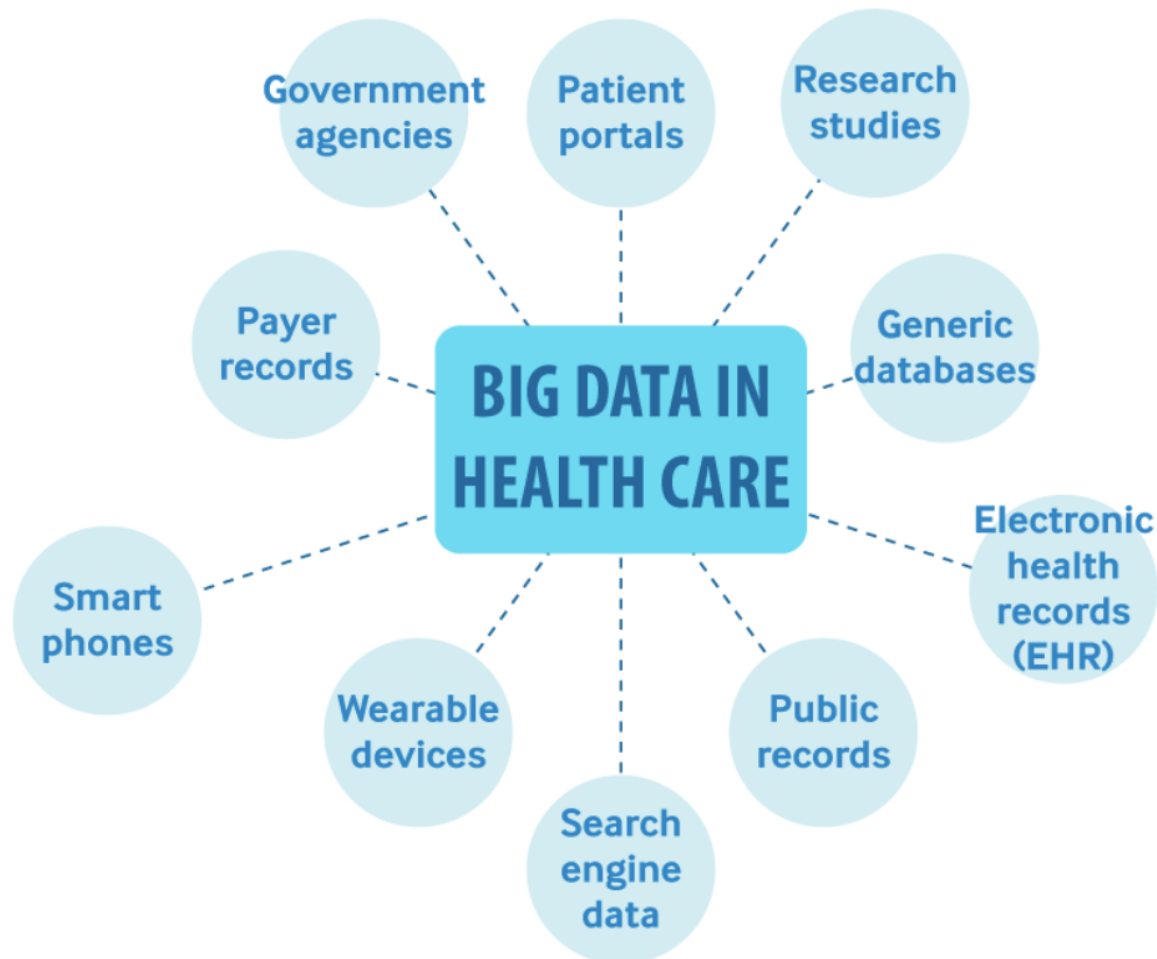
Navigating Our Course Together



- **My First Few Months at PCORI**
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- **Envisioning PCORI 2.0**
 - Opportunities for the Future
 - Learning in a Public Health Crisis
- **Our Course Together**
 - Year 1 Priorities

Evolving Healthcare and Research Landscape in a Big Data Era

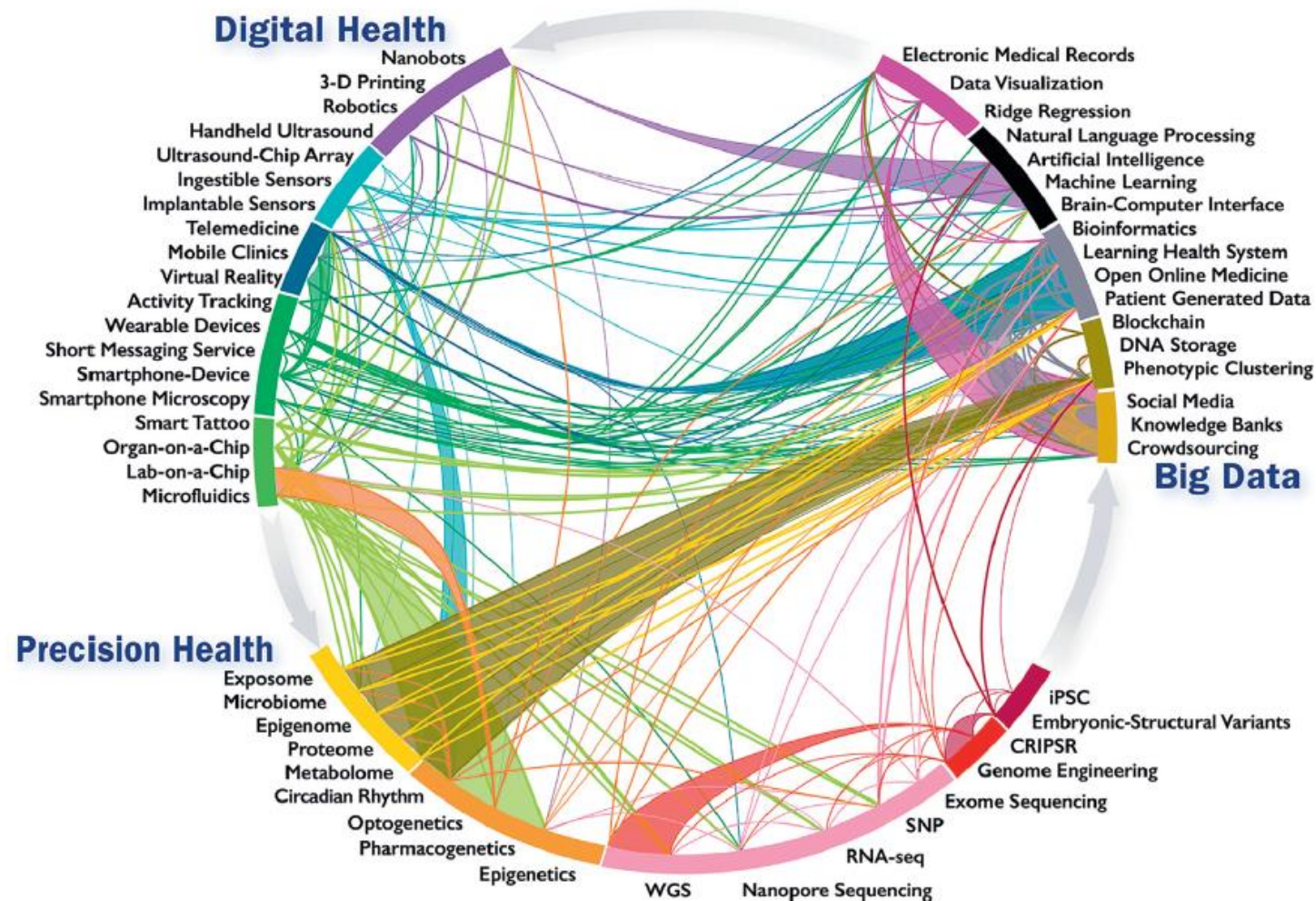
Sources of Big Data in Healthcare



Applications for Big Data in Health Care

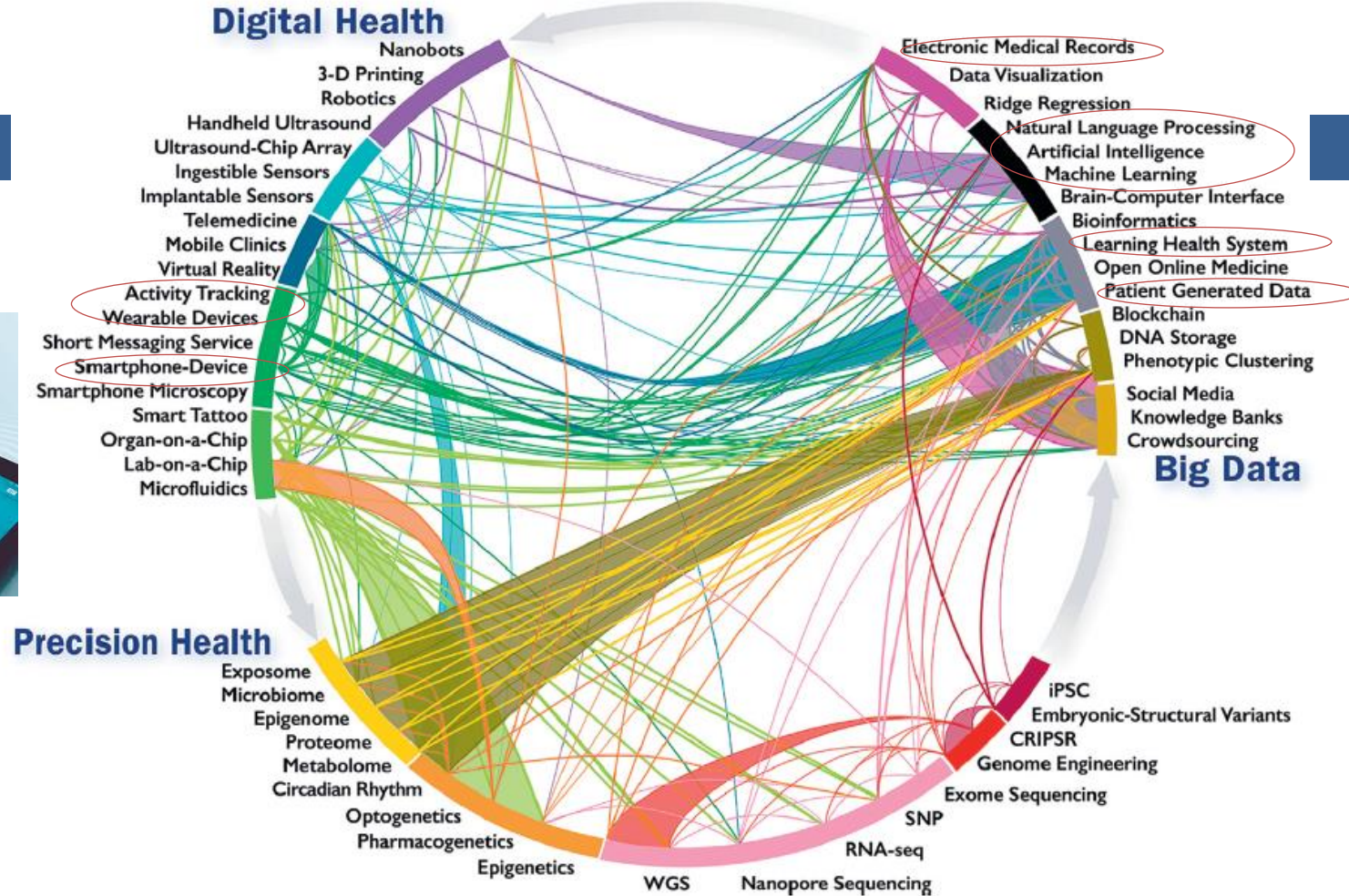


Leveraging Innovations in Health Care to Promote the Science of Delivery for Improved Outcomes



Leveraging Innovations in Health Care to Promote the Science of Delivery for Improved Outcomes

Patient Centered



Community Centered



Despite Marked Improvements in Health, Disparities and Variation in Care Still Remain

This Issue Views **90,724** | Citations **22** | Altmetric **4322**

Special Communication

November 26, 2019

Life Expectancy and Mortality Rates in the United States, 1959-2017

Steven H. Woolf, MD, MPH¹; Heidi Schoomaker, MAEd^{2,3}

» Author Affiliations

JAMA. 2019;322(20):1996-2016. doi:10.1001/jama.2019.16932

<https://jamanetwork.com/journals/jama/article-abstract/2756187>

Black curve indicates age-adjusted mortality for all US adults aged 25 to 64 years; bolded data points indicate joinpoint years, when the linear trend (slope) changed significantly based on joinpoint analysis. The lowest mortality rates per 100 000 (and the years they were achieved) are listed first in parentheses; mortality rates for 2017 listed second. Source: CDC WONDER. Copyright 2019 American Medical Association. All Rights Reserved. Date of download: 4/28/20

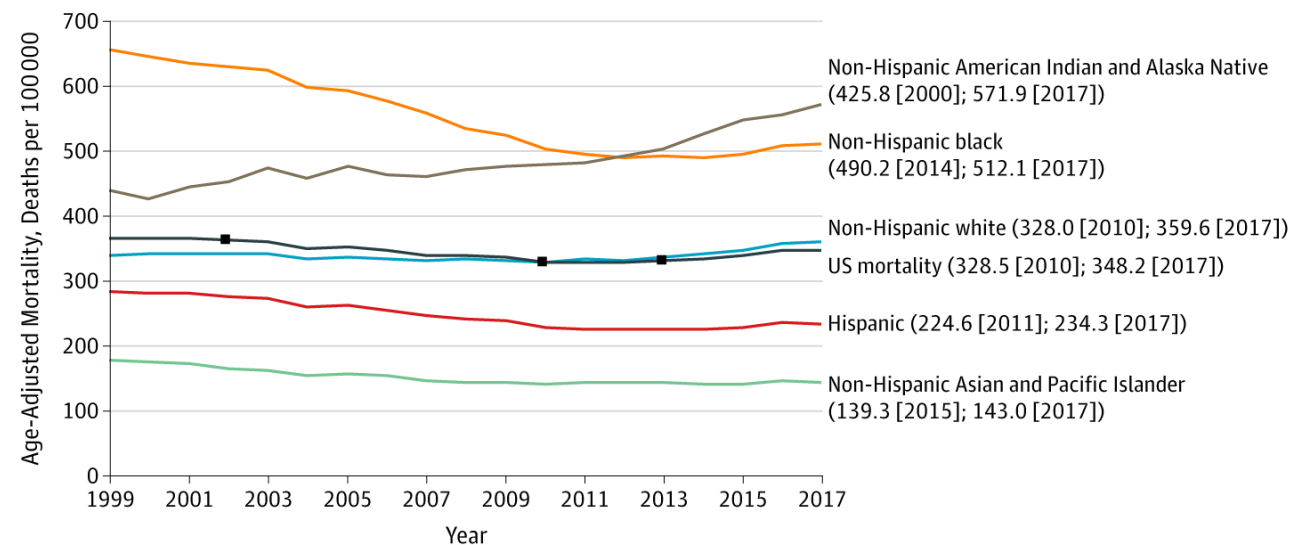


The analysis documents a host of health disparities by geography, sex, and race... The authors also consider how poverty, income inequality, unstable employment, psychological distress, and divergent state policy choices could explain these outcomes, especially for vulnerable populations.

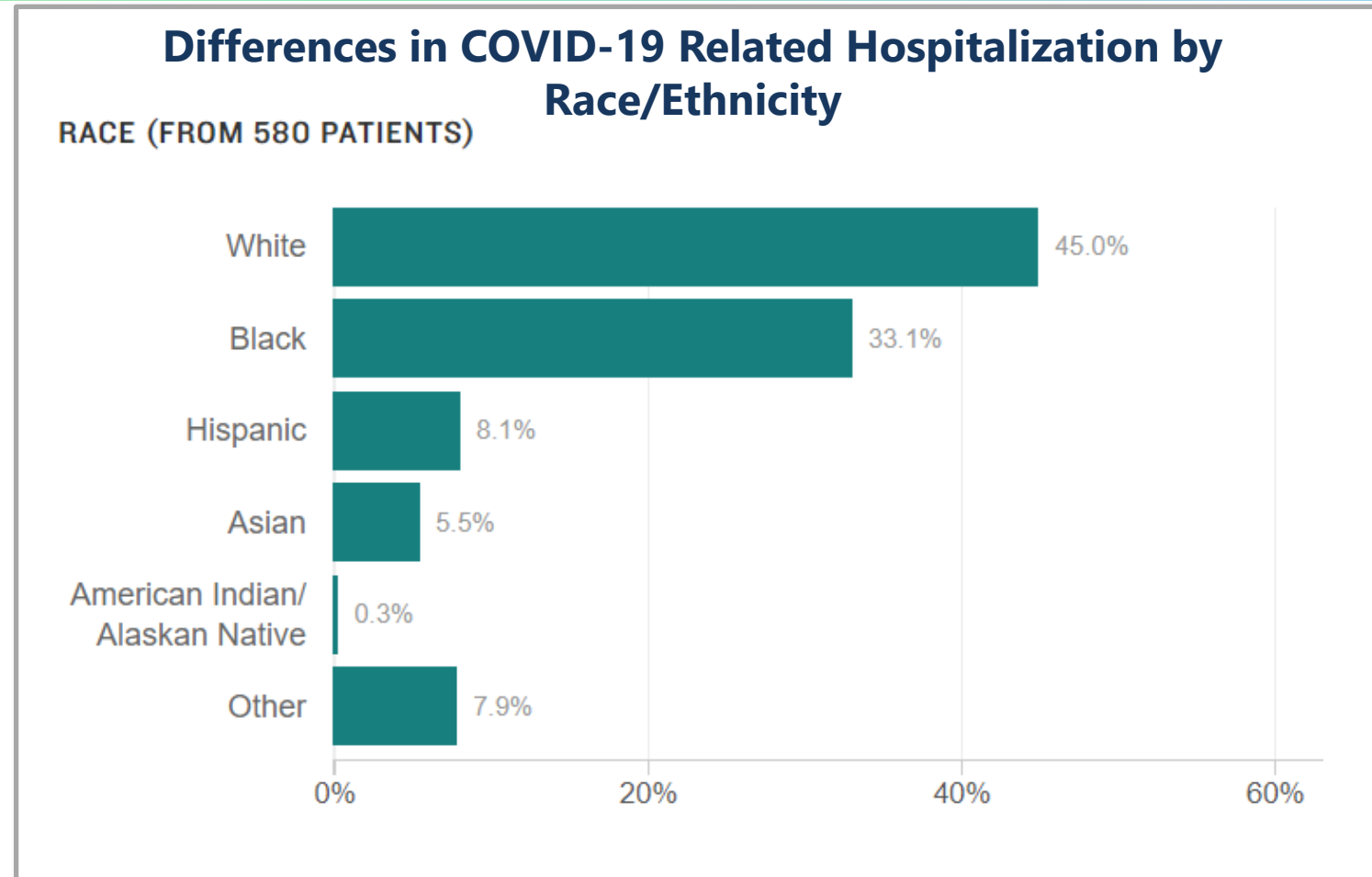
Quote from Associated Editorial

Koh HK, et al. Confronting the Rise and Fall of US Life Expectancy. JAMA. Nov 2019. <https://jamanetwork.com/journals/jama/fullarticle/2756159>

Age-Adjusted Mortality Rates, US Adults Aged 25-64 Years, by Race/Ethnicity, 1999-2017

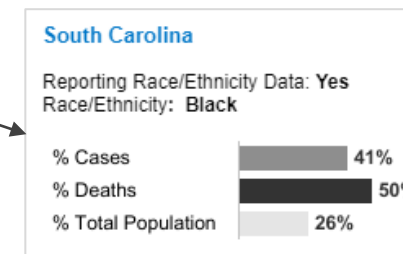
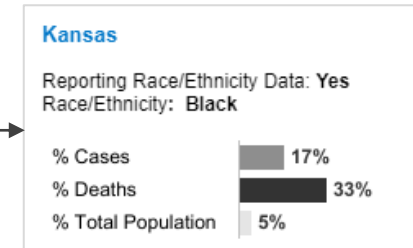
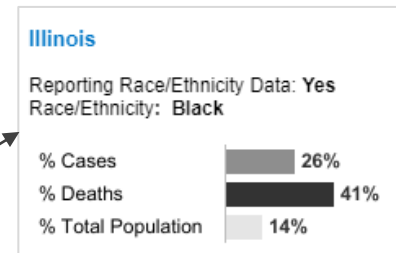
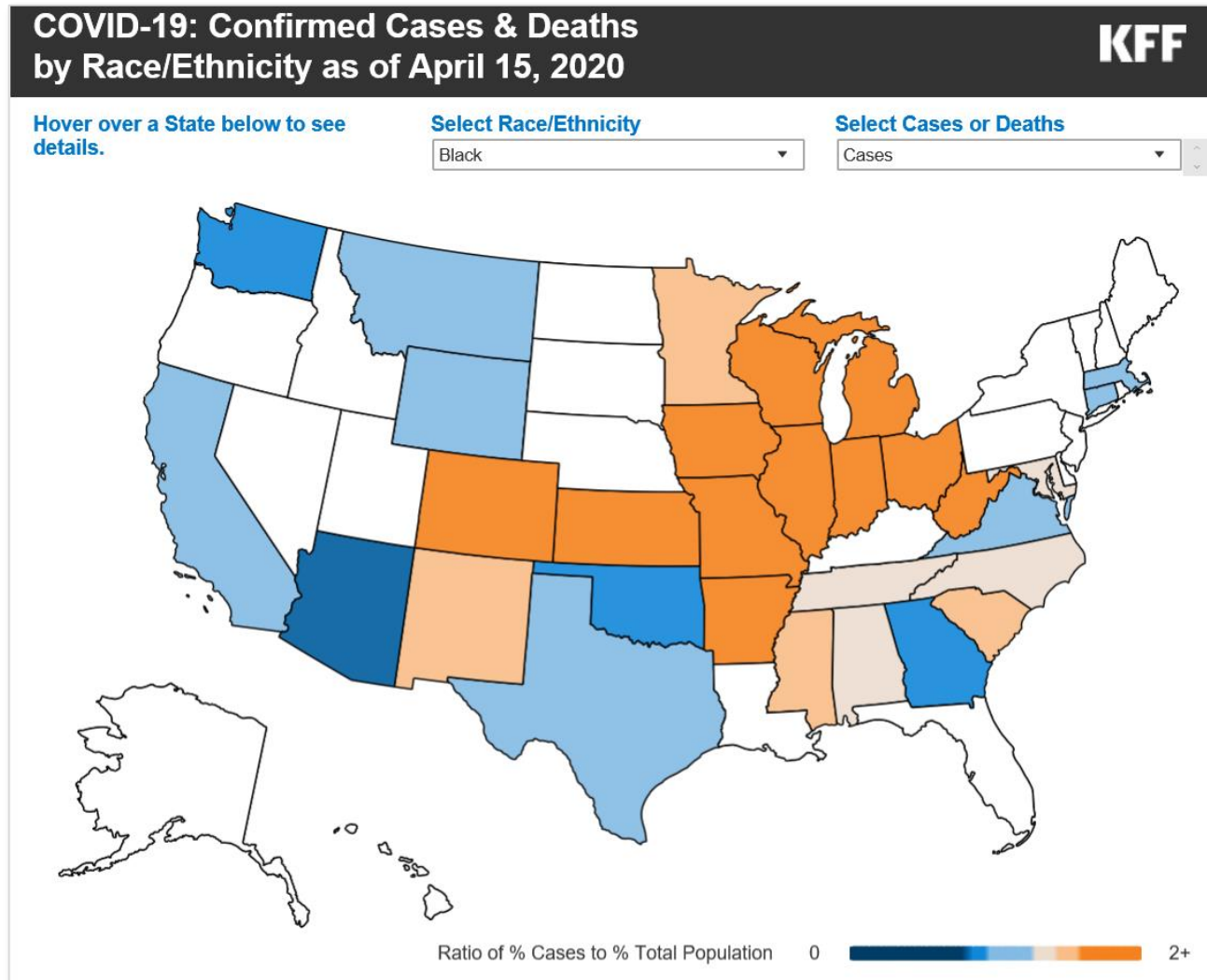


COVID-19 Outcomes Clearly Elucidate the Challenge of Health Disparities



Source: Aubrey A, Neel J. CDC Hospital Data Point To Racial Disparity In COVID-19 Cases. April 8, 2020. ([link](#))
Data from Centers for Disease Control and Prevention ([link](#)); Figure credit: Stephanie Adeline/NPR

Emerging Data: Unmasking the Interplay Between Race/Ethnicity and COVID-19

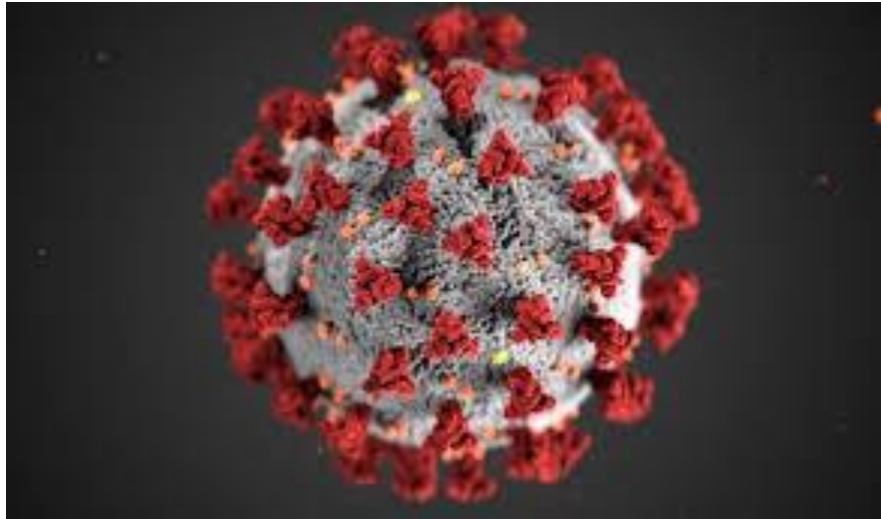


Source: Kaiser Family Foundation. [COVID-19: Confirmed Cases & Deaths by Race/Ethnicity as of April 15, 2020](#). Distribution of Cases/Deaths by Race/Ethnicity based on KFF analysis of publicly available state websites. Total State Population Distribution by Race/Ethnicity based on KFF analysis of 2018 American Community Survey. Accessed 4/28/20

A Pandemic of Unprecedented Scale and Consequences

Cumulative Confirmed Cases of COVID-19:

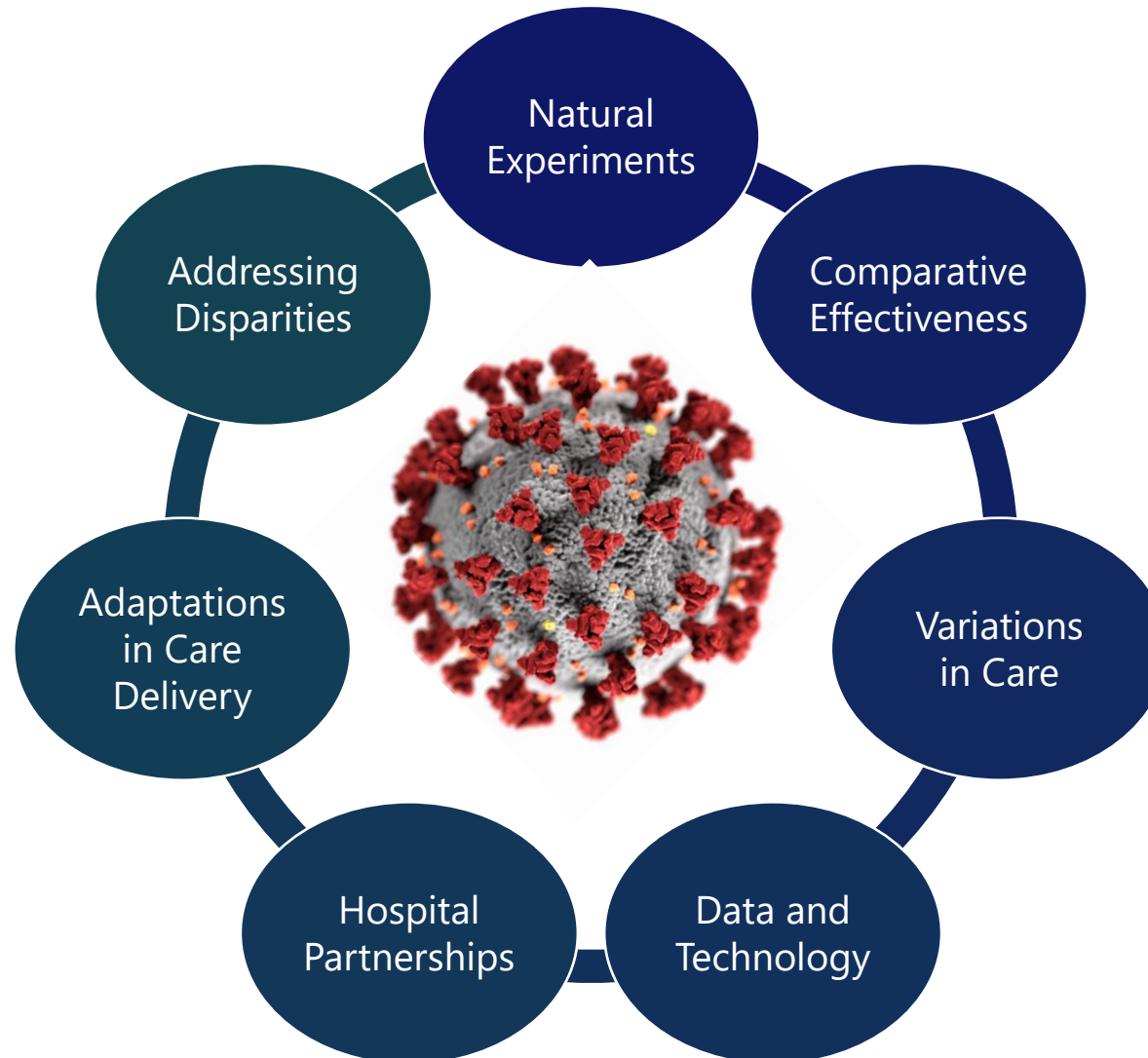
>6 million worldwide



Source: COVID-19 Dashboard by the Center for Systems Science and Engineering (CSSE) at Johns Hopkins University (JHU). <https://coronavirus.jhu.edu/map.html> Accessed 4/28/20.

COVID-19 Pandemic – Not Only a Stress Test, but also Learning Opportunity

Advancing PCORI 2.0
A Learning Organization
Nimbly Embracing
Opportunities in a Crisis for
Short- and Long-Term Impact



A Multipronged Approach in Response to the COVID-19 Health Crisis

In our efforts to inform the current pandemic and learn for the future, PCORI has identified **three priority areas**:

Healthcare Delivery

Vulnerable Populations

Healthcare Workers

Many approaches to supporting critical work in these three areas and more:

Awards

- Enhancements of existing awards
- Solicitation of new awards, e.g., natural experiments
- Healthcare worker registry and trial

Information Sharing

- Webinars
- Collaboration with other funders

Adapting for Awardees and Applicants

- Adaptations to existing projects
- Extending application timelines

Open Opportunities

Applicant and Awardee FAQs Related to COVID-19: PCORI is working to assist applicants and awardees in finding solutions that may help address issues related to disruptions associated with COVID-19, including general guidance and information about funding application deadline extensions.



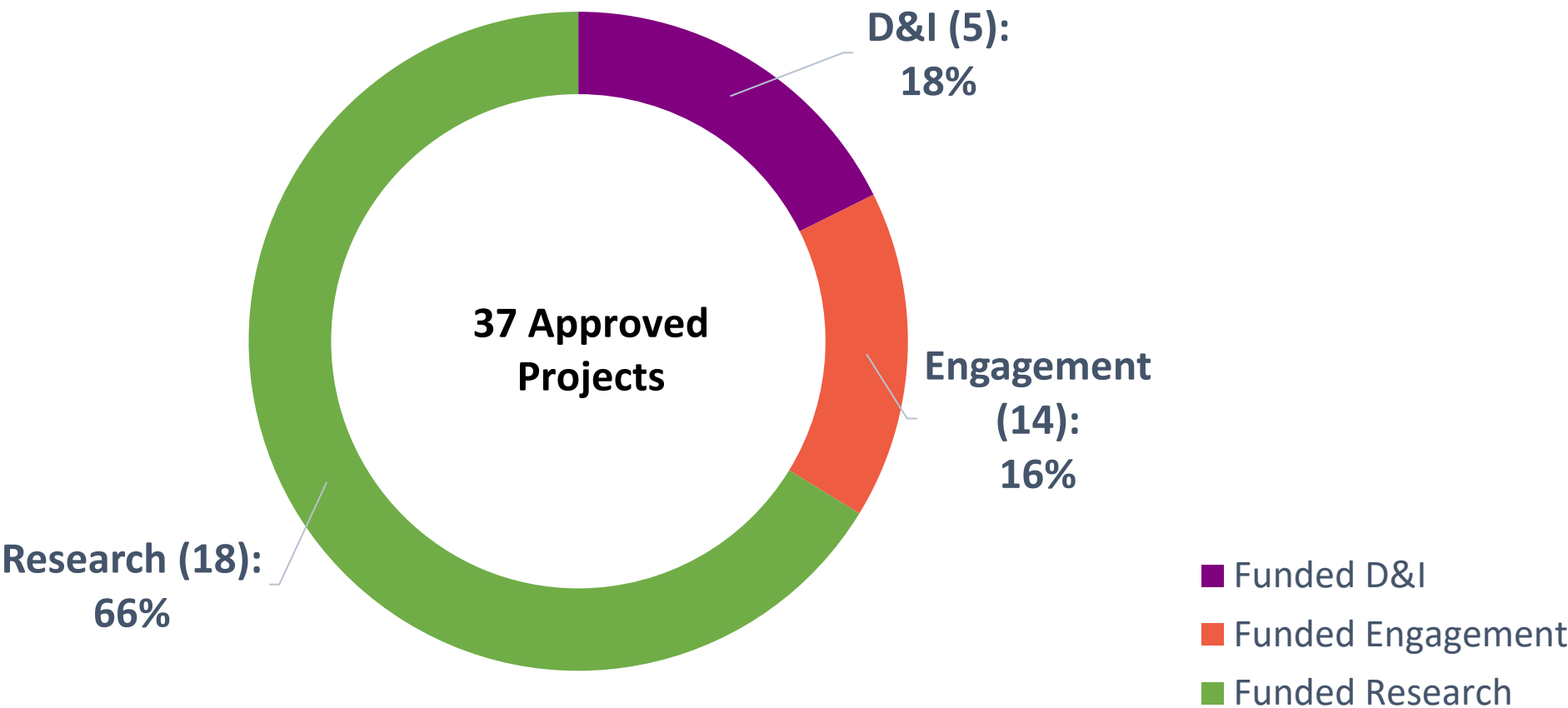
Confronting COVID-19: Finding Hospital Capacity and Improving Patient Flow

A Webinar Series Hosted by PCORI for Hospitals and Health Systems

COVID-19 Enhancements – Current Funding

Funded Enhancements Data

Last updated: June 2, 2020



COVID-19 Enhancements – Current Funding

Health Condition	Research Awards & Intervention Strategy						Dissemination & Implementation Awards	Engagement Awards
	<i>Drug</i>	<i>Other Clinical</i>	<i>Health Services</i>	<i>Telemedicine</i>	<i>Training and Education</i>	<i>N/A*</i>		
<i>Cardiovascular Diseases</i>								
<i>Cancer</i>								
<i>Gastrointestinal Disorders</i>								
<i>Genetic Disorders</i>								
<i>Infectious Diseases</i>								
<i>Mental/Behavioral Health</i>								
<i>Muscular and Skeletal Disorders</i>								
<i>Neurological Disorders</i>								
<i>Nutritional and Metabolic Disorders</i>								
<i>Reproductive and Perinatal Health</i>								
<i>Respiratory Diseases</i>								
<i>Other or Non-Disease Specific</i>								

PCORI – Always Relevant

Meaningful research questions in healthcare delivery



Does pre-exposure prophylaxis with HCQ reduce rates of COVID-19 among healthcare workers?

What are the most effective practices for telehealth? Can this natural experiment shed light on whether telehealth can deliver similar outcomes for patient care and management?

What are the predictors of poor outcomes in COVID-19 infection and can we systematize predictive algorithms to determine who is likely to need intensive care?

What approaches are effective in eliminating health and health care disparities in COVID outcomes and how are they generalizable to disparities more broadly?

PCORI 2.0: Opportunities to Accelerate Impact on Care Delivery and Patient Health Outcomes



Engagement

- New and sustained partnerships
- Diverse stakeholder inclusion
- Bipartisan congressional support

Impact:

- *Patients, payers, systems as partners for dissemination & uptake*
- *Evidence to implementation*
- *PCORI integral in research ecosystem*

Innovation

- Patient-centered learning health care
- Rapid cycle of evidence to implementation
- Pragmatic approaches to ↓ disparities

Impact:

- *“Real-time” implementation of findings*
- *Uptake into guidelines & care*
- *Reduced variation in care & disparities in conditions/pops*

Operations

- Creative funding approaches
- Efficient and effective processes

Impact:

- *Nimble and adaptable methods to speed innovation to results to patients*
- *Robust pool of outstanding research (built capacity)*

PCORI 2.0: Opportunities to Accelerate Impact on Care Delivery and Patient Health Outcomes



Engagement

- New and sustained partnerships
- Diverse stakeholder inclusion
- Bipartisan congressional support

Impact in Post-COVID-19 Era:

- *Hospitals and healthcare systems working together*
- *Gaps in evidence for decision making driving research*
- *PCORI essential*

Innovation

- Patient-centered learning health care
- Rapid cycle of evidence to implementation
- Pragmatic approaches to ↓ disparities

Impact in Post-COVID-19 Era:

- *"Real-time" queries, output, and implementation*
- *Accelerated uptake*
- *Acute focus on variation in care & disparities*

Operations

- Creative funding approaches
- Efficient and effective processes

Impact in Post-COVID-19 Era:

- *Nimble and adaptable processes, research*
- *Clearer approach to leveraging data, technology, infrastructure*
- *Expanded research pool*

Envisioning PCORI 2.0



Advance Patient-Centered Learning Health Care

Reduce Health Disparities

Disseminate & Implement Scientific Findings

Engage Stakeholders

Crowdsource

Reflect, Discuss

Comment

**Generate Evidence:
Patient Centered & Relevant to Patients**

Envisioning PCORI 2.0



Advance Patient-Centered Learning Health Care

Reduce Health Disparities

Disseminate & Implement Scientific Findings

Engage Stakeholders

Crowdsource

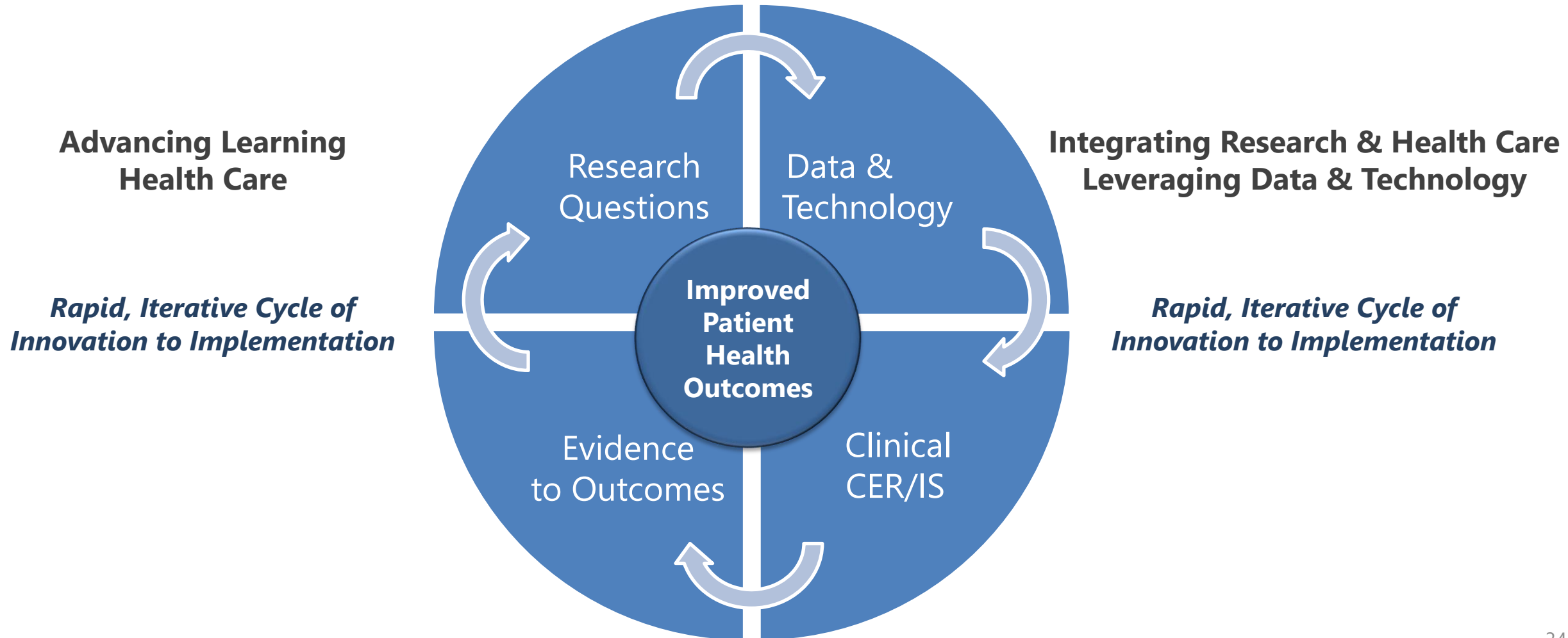
Reflect, Discuss

Comment

**Generate Evidence:
Patient Centered & Relevant to Patients**

Pillars Underscored by Current Pandemic

PCORI 2.0: A Virtuous Cycle of Evidence to Implementation



Navigating Our Course Together



- **My First Few Months at PCORI**
 - My Personal Journey
 - Early Onboarding
 - Passionate and Mission-Driven PCORI Staff and Board
- **Envisioning PCORI 2.0**
 - Opportunities for the Future
 - Learning in a Public Health Crisis
- **Our Course Together**
 - Year 1 Priorities
- **PCORI's Response to the COVID-19 Pandemic**

Navigating Our Course Together

First-Year Focus

- Onboarding and Virtual Listening Tour
- PCORI's Response to the COVID-19 Pandemic
- National Priority Setting and Development of Research Agenda and Strategic Plan
- Other Priorities Stemming from Legislation (e.g., Maternal Mortality, Intellectual and Developmental Disabilities, Cost Outcomes, and Methodology Committee)



Collaborative Strategy to Advance a Vision for PCORI 2.0

Refreshing National Priorities, Research Agenda, and Strategic Plan

Garner diverse input to guide scientific directions

*Patients, Clinicians, Researchers, Purchasers, Payers, Industry,
Hospitals & Health Systems, Policy Makers, Training Institutions*

Listening Tour
Board & Staff

Conduct portfolio analyses & evaluate research programs

Refine priority research areas

Develop implementation plans

Align resources with research priorities

CEDS Advisory Panel

National Priority Setting and Research Agenda



What are the driving questions to fulfill PCORI's comparative clinical effectiveness research agenda?

How do we accelerate evidence generation to implementation and impact? What are the implications for the conduct of clinical CER?

How do we advance communication, implementation, and dissemination research for seamless integration into all PCORI efforts?

What are the critical resource and workforce issues to implement these considerations for the next phase for PCORI?

Questions?

PCORI Reauthorization Briefing

Jean Slutsky, PA, MSPH

Congressional Leaders

House Champions



Diana DeGette (D-CO)
Energy & Commerce



Don Beyer (D-VA)
Ways & Means

Senate Champions



Mark Warner (D-VA)



Bill Cassidy (R-LA)

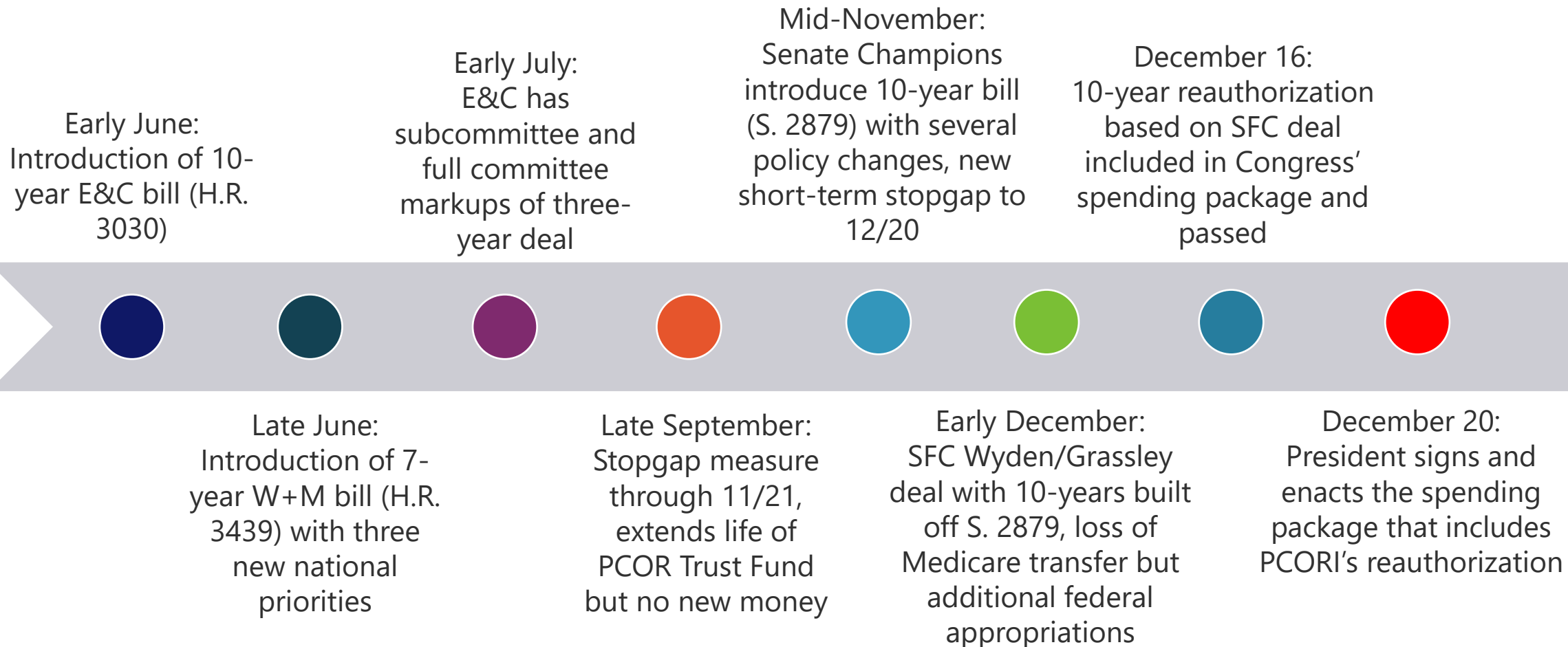


Chris Van Hollen (D-MD)



Shelly Moore Capito (R-WV)

Legislative Activity



PCORI's Reauthorization Language

Overview of What the Final Reauthorization Language Looks Like



- Extends funding for **10 years**
- Replaces funding from the **Medicare Trust Fund** by increasing **mandatory federal appropriations** to the PCOR Trust Fund
- Adds **intellectual and developmental disabilities** and **maternal mortality** as research priorities
- Requires PCORI to **balance long- and short-term priorities** when identifying research priorities
- Permits PCORI-funded studies to **collect certain economic data**, where appropriate
- Increases **private payers' representatives** on the Board by up to two slots
- Shifts **Methodology Committee members** appointments to the **PCORI Board**
- Strengthens and formalizes PCORI's **dissemination and implementation** mandate
- Directs GAO to review certain **barriers** to conducting research
- GAO to **analyze PCORI's dissemination program**

Reauthorization for 10 Years



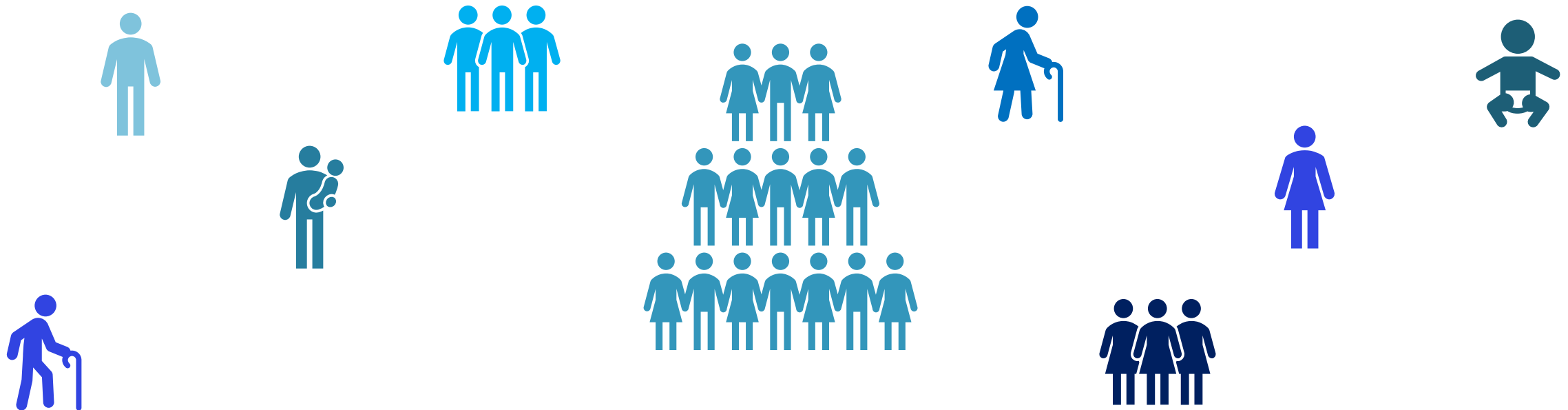
PCORI authorized through
September 30, 2029

.....

**Funding will remain approximately consistent
with previous 10 years**

Health Insurance Policies and Self-Insured Health Plans

Continues the per-life covered fee on private health insurances, self-insured, and employer-sponsored health plans funding to the PCOR Trust Fund.



Identification of Research Priorities

Adds two new research priorities:

1. **Maternal mortality**
2. **Intellectual and developmental disabilities**

PCORI must reflect a **balance of short- and long-term priorities** and **be responsive to changes** in medical evidence and treatments

Consideration of Full Range of Outcomes Data



Where appropriate, PCORI-funded studies may capture data on the **potential burdens and economic impacts** of the utilization of medical treatments, items, and services for all stakeholders. This data includes:

- Medical out-of-pocket costs, including:
 - Health plan benefit
 - Formulary design
- Healthcare utilization
- Nonmedical costs to patients and family, including:
 - Caregiving
 - Effects on future costs of care
 - Workplace productivity
 - Absenteeism

This compromise language **does not** remove statutory prohibitions on PCORI establishing cost-per quality adjusted life year (QALY) thresholds or allow PCORI to conduct cost-effectiveness analyses.

Board Composition

Raises the number of PCORI Board members appointed by the GAO to at least 19, but not more than 21

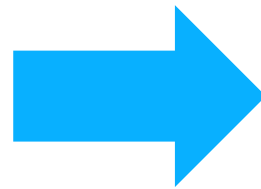
Adds up to two more payer/purchaser representatives to the Board, for a total of up to five slots

- The Directors of the NIH and AHRQ continue to serve on the Board.
- Additionally, Board members who are appointed to fill a vacancy are eligible for a full-term reappointment following the completion of the remainder of their predecessor's term.

Methodology Committee Appointments

Switches responsibility for appointing
Methodology Committee members

**From the
GAO**



**PCORI Board of
Governors**

Directs the GAO to review and report to Congress about:

- PCORI's **dissemination, training, and capacity-building activities**
- **PCORI's dissemination program**
- **Any barriers researchers encounter** during studies, including challenges covering the cost of treatments, services, or items

Thank you!



BREAK

2:45 pm – 3 pm ET

Looking Forward: Refreshing PCORI's National Priorities

Spring 2020 Advisory Panels



Agenda

1. Statutory Mandates
2. Current National Priorities
3. Looking Forward: Panelists' Perspectives on a Refresh

1.

Statutory Mandate



National Priorities



- Required under PCORI's authorizing law
- Identification is a core duty—the first enumerated duty—of the Institute
- Intended to guide PCORI and provide transparency to the public on the Institute's investment strategy in patient-centered comparative clinical effectiveness research

Subtitle D—Patient-Centered Outcomes Research

SEC. 6301. PATIENT-CENTERED OUTCOMES RESEARCH.

(a) IN GENERAL.—Title XI of the Social Security Act (42 U.S.C. 1301 et seq.) is amended by adding at the end the following new part:

“PART D—COMPARATIVE CLINICAL EFFECTIVENESS RESEARCH

“COMPARATIVE CLINICAL EFFECTIVENESS RESEARCH

“SEC. 1181 [42 U.S.C. 1320e]. (a) DEFINITIONS.—In this section:

“(1) BOARD.—The term ‘Board’ means the Board of Governors established under subsection (f).

“(2) COMPARATIVE CLINICAL EFFECTIVENESS RESEARCH; RESEARCH.—

“(A) IN GENERAL.—The terms ‘comparative clinical effectiveness research’ and ‘research’ mean research evaluating and comparing health outcomes and the clinical effectiveness, risks, and benefits of 2 or more medical treatments, services, and items described in subparagraph (B).

“(B) MEDICAL TREATMENTS, SERVICES, AND ITEMS DESCRIBED.—The medical treatments, services, and items described in this subparagraph are health care interventions, protocols for treatment, care management, and delivery, procedures, medical devices, diagnostic tools, pharmaceuticals (including drugs and biologicals), integrative health practices, and any other strategies or items being used in the treatment, management, and diagnosis of, or prevention of illness or injury in, individuals.

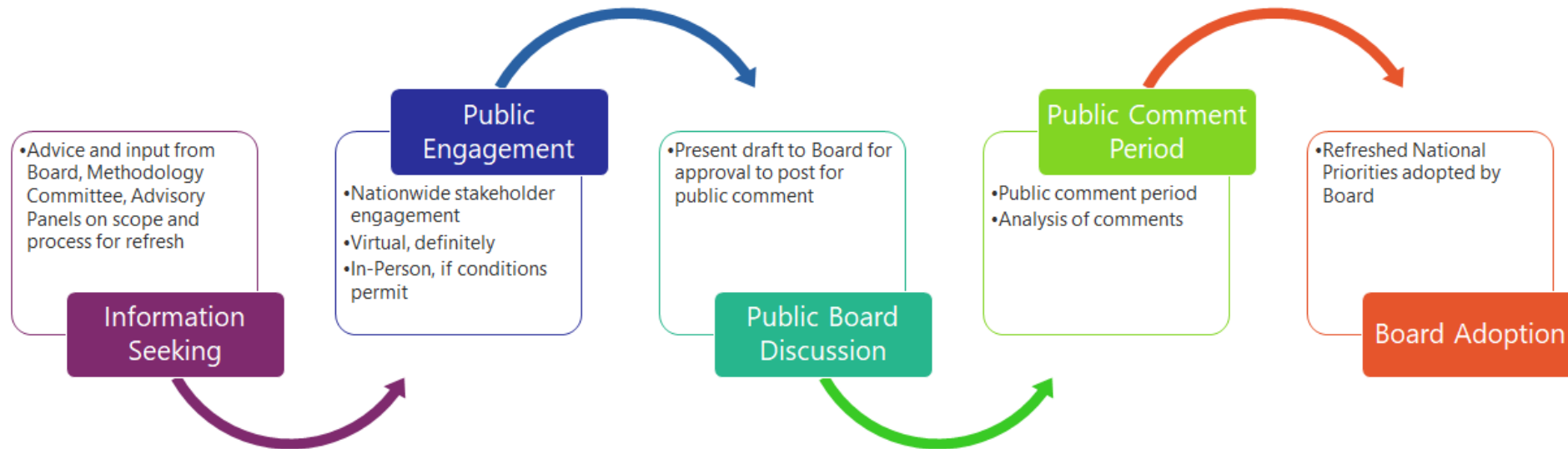
National Priorities

- The Institute shall identify national priorities for research, taking into account **factors of disease** incidence, prevalence, and burden in the United States (with emphasis on chronic conditions), **gaps in evidence** in terms of clinical outcomes, **practice variations** and **health disparities** in terms of delivery and outcomes of care, the **potential for new evidence** to improve patient health, well-being, and the quality of care, the effect on national expenditures associated with a health care treatment, strategy, or health conditions, as well as patient needs, outcomes, and preferences, the relevance to patients and clinicians in making informed health decisions...

**emphasis added*

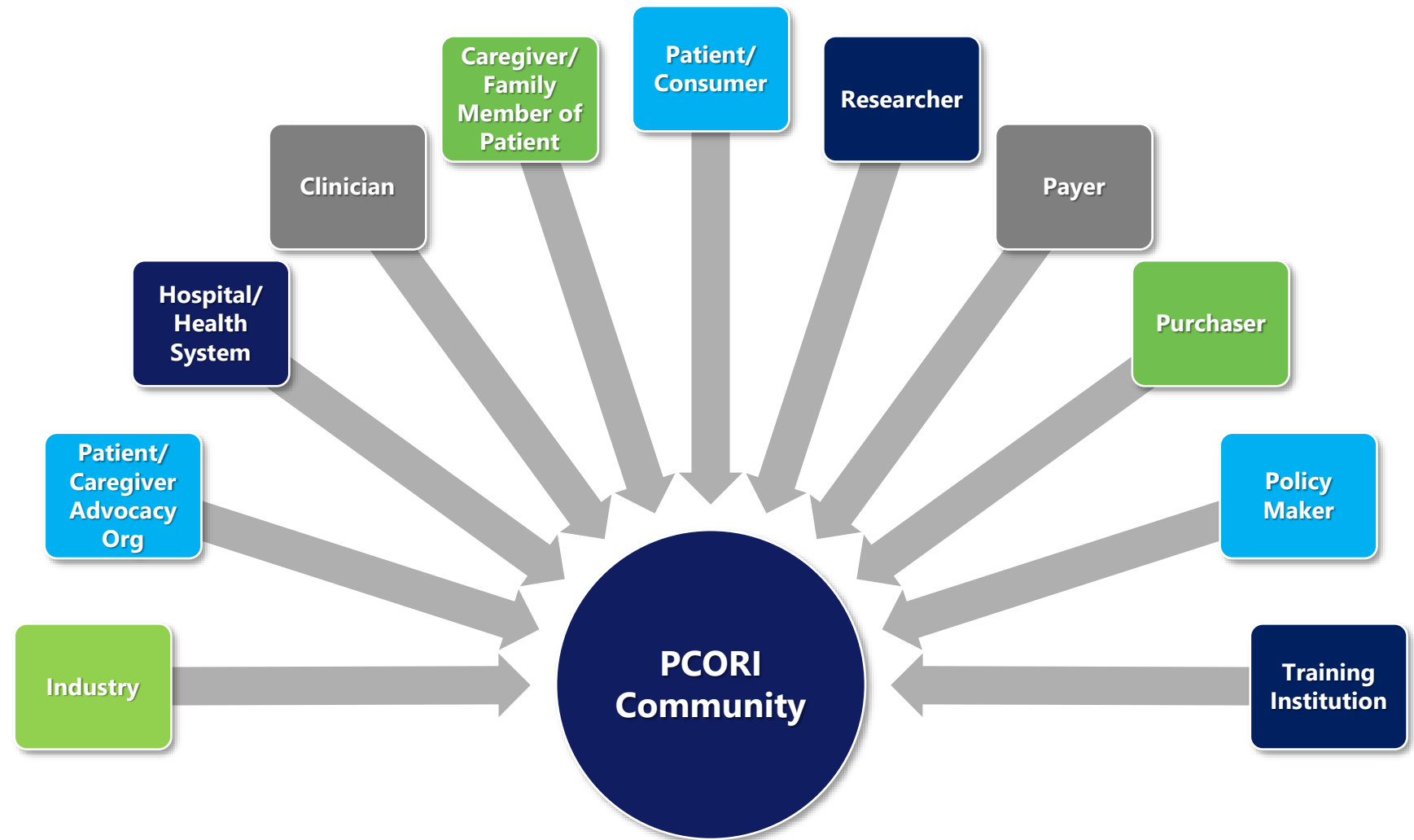
Mandated Process

- Formal Public Comment is required
 - Minimum: 45 days
 - Maximum: 60 days
- Final approval/adoption rests with PCORI Board of Governors



Who We Will Engage

- PCORI
 - Board of Governors
 - Methodology Committee
 - Advisory Panels
- Our Stakeholders across the Nation



2.

Current
National Priorities



Our Current National Priorities



Our prior approach

- Broad national priorities
- Articulation of criteria to inform the *process* for establishing a research agenda

Assessment of Prevention, Diagnosis, and Treatment Options

- Comparing the effectiveness and safety of alternative prevention, diagnosis, and treatment options to see which ones work best for different people with a particular health problem.

Improving Healthcare Systems

- Comparing health system-level approaches to improving access, supporting patient self-care, innovative use of health information technology, coordinating care for complex conditions, and deploying workforce effectively.

Communication and Dissemination Research

- Comparing approaches to providing comparative effectiveness research information, empowering people to ask for and use the information, and supporting shared decision-making between patients and their providers.

Addressing Disparities

- Identifying potential differences in prevention, diagnosis or treatment effectiveness, or preferred clinical outcomes across patient populations and the healthcare required to achieve best outcomes in each population.

Accelerating Patient-Centered Outcomes Research and Methodological Research

- Improving the nation's capacity to conduct patient-centered outcomes research, by building data infrastructure, improving analytic methods, and training researchers, patients and other stakeholders to participate in this research.

3.

Looking Forward:
Perspectives
on a Refresh



We Want to Hear from You



- Questions and Discussion

Wrap Up/Closing Day 1

Cornell Wright, MPA
Lawrence Goldberg, MD



Welcome back!

The meeting will begin promptly at
9 am ET.

Welcome Back and Recap

Cornell Wright
Larry Goldberg

Agenda Day 2

Time	Duration	Activity
9:15 am	(60 min)	Cost Data Provision
10:15 am	(10 min)	BREAK
10:25 am	(60 min)	Maternal Mortality, Intellectual and Developmental Disabilities, and Balancing Short- and Long-Term Priorities
11:25 am	(30 min)	Round Robin Conversation
11:55 am	(5 min)	Closing Remarks
Noon	-----	Adjourn

Consideration of Full Range of Outcomes Data

Jean Slutsky
Andrew Hu
Joanna Siegel
Bill Lawrence
Penny Mohr



Consideration of Full Range of Outcomes Data



Where appropriate, PCORI-funded studies may capture data on the **potential burdens and economic impacts** of the utilization of medical treatments, items, and services for all stakeholders. This data includes:

- Medical out-of-pocket costs, including:
 - Health plan benefit
 - Formulary design
- Healthcare utilization
- Nonmedical costs to patients and family, including:
 - Caregiving
 - Effects on future costs of care
 - Workplace productivity
 - Absenteeism

This compromise language **does not** remove statutory prohibitions on PCORI establishing cost-per quality adjusted life year (QALY) thresholds or allow PCORI to conduct cost-effectiveness analyses.

Consideration of Full Range of Outcomes

Congressional and Stakeholder Intent



- Congressional leaders and stakeholders across the healthcare community weighed in on whether to include provisions directing PCORI to capture additional economic/cost-related data.
- The goal of this provision is to direct PCORI-funded research to better inform healthcare decisions based on the clinical effectiveness, impact on patient-reported outcomes, **and** potential economic and cost burden.
- The provision is a compromise between stakeholders to ensure PCORI-funded research captures both population-level (i.e., utilization, ROI, etc.) and patient-centric (i.e., caregiver burden, impact on medical out-of-pocket costs, etc.) data.
- This compromise language **does not** remove statutory prohibitions on PCORI establishing cost-per quality adjusted life year (QALY) thresholds or allow PCORI to conduct cost-effectiveness analyses.

Consideration of Full Range of Outcomes Early Stakeholder Input on Implementation



Summary of the key take-aways for implementation include:

- Ensure **transparency**, notably patient engagement, throughout implementation
- Identify the **long-term goals** of capturing this data to inform implementation efforts
- Consider the **full range of treatment options** and the **investment costs** for payers and health systems to implement practice change
- Need to **develop standards** around identifying and capturing patient-centric cost data
- **Concerns around the use/misuse** of cost data that could lead to cost-effectiveness or inappropriate value assessment
- Hope to **expand beyond traditional health economic perspectives** on cost/value

Considerations of Full Range of Outcomes

Tentative Implementation Proposal

Phase 1

- Providing guidance to PIs in future PFAs on how they should interpret this policy and incorporate it into their research proposals.
- **Timeline:** Complete Phase 1 by January 5, 2021

Phase 2

- Establishing standards and methods to inform the field on how to capture relevant data.
- **Timeline:** 12 months from the initiation of this process

Phase 3

- Convening discussions on how this information can/should be used.
- **Timeline:** Ongoing Discussion

BREAK

10:15 am–10:25 am ET

Maternal Mortality and Intellectual & Developmental Disabilities Balancing Short- and Long-Term Priorities

Jean Slutsky
Michele Orza
Greg Martin



Round Robin Conversation



Wrap Up/Closing Day 2

Cornell Wright, MPA
Lawrence Goldberg, MD



Adjourn

Thank you!

