Advisory Panel on Clinical Trials
Summer 2020 Meeting
November 6, 2020
12:00 PM – 4:00 PM ET

United States (Toll-free): +1 866 901 6455
Access code: 769-075-707 (muted)

Webinar URL: https://attendee.gotowebinar.com/register/2311419435294597 27
Webinar ID: 808-424-155

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Housekeeping

- Meeting is available to the public and is being recorded.
- Members of the public are invited to listen in and the recording will be made publicly available after the event on PCORI's website.

GoToWebinar Housekeeping

- Remember to mute your microphone if you are not talking.
- Please turn on your video camera.
- If you have poor connection, make sure to dial in through phone (not computer).
- If you are experiencing technical difficulties, contact “PCORI AV” via the chat function.
- To queue to speak, submit your name through the chat to “Organizers Only”.
- If you would like to send a comment to the entire group, select “All Attendees” in the chat function.

COI Statement

Welcome to the CTAP Fall 2020 Virtual Meeting. I want to remind everyone that disclosures of conflicts of interest of members of CTAP are publicly available on PCORI's website and are required to be updated annually. Members of the CTAP are also reminded to update your conflict of interest disclosures if the information has changed. You can do this by contacting your staff representative, Allie Rabinowitz.

If the CTAP will deliberate or take action on a matter 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, Allie Rabinowitz.

Welcome and Goals for the Day

Catherine Crespi, PhD, MS (Chair)
Professor of Biostatistics,
UCLA Fielding School of Public Health

Anne Trontell, MD, MPH
Associate Director,
Clinical Effectiveness and Decision Science, PCORI

Allie Rabinowitz, MPH
Senior Program Associate,
Clinical Effectiveness and Decision Science, PCORI

Today's Agenda

Friday, November 6		
Time	**Agenda Item**	**Discussion Leader**
12:00	Welcome and Goals for the Day	C. Crespi, A. Trontell
12:10	Introductions	A. Rabinowitz
12:50	CTAP Overview	A. Rabinowitz
12:55	Proposed Principles for the Consideration of the Full Range of Outcomes	A. Hu
1:40	Break	
1:50	Strategic Planning: Identifying National Priorities	M. Orza, S. Clauser
2:05	2019 Research Priorities: MMM and IDD	E. Houtsmuller, K. Dunham
2:50	Break	
2:55	COVID-19 Disruptions to Research	J. Gerson
3:45	Closing	C. Crespi, A. Trontell
4:00	Adjourn	

Introductions

First, we will begin with opening remarks from our Chair, Kate Crespi-Chun.

I will next call on our 6 new members to introduce themselves, then move to returning panelists.

In 3 minutes or less, please share a brief introduction, including:

- Your CTAP stakeholder role
- Your institutional or professional organization affiliation
- What experience and perspectives you bring to the CTAP

Advisory Panel on Clinical Trials Overview

Allie Rabinowitz, MPH

Senior Program Associate,
Clinical Effectiveness and Decision Science

Advisory Panel on Clinical Trials (CTAP)
Overview and Legislative Mandate

- One of two advisory panels (along with RDAP) established as part of PCORI's authorization
- Charge: "*The CTAP is changed with advising PCORI, and agencies, instrumentalities, or other entities conducting research through the PCORI MC… The CTAP will not serve in an official decision-making capacity, but its recommendations and advice will be taken into consideration by the Institute's Board of Governors, Methodology Committee, and staff.*"
  - Topics for advice: **selection**, **research design**, **implementation**, and **technical issues** of clinical trials for patient-centered outcomes research.
- Panelist applications are solicited publicly or invited on an annual basis and undergo a multi-tier review process before recommendation and approval by PCORI's Board of Governors
- Traditionally, 2 in-person meetings held annually with occasional webinar
- Members of CTAP or its subcommittee provide ad hoc consultation on methodological and design aspects of PCORI clinical trials

CTAP Activities To Date

- Subcommittee work group provided input to Methodology Standards to address recruitment, accrual, and retention
- Subcommittee advice on ADAPTABLE trial of aspirin dosing for cardioprotection in established CVD
- Discussions and advice to PCORI in its policy development and implementation
  - PCORI's Data Safety and Monitoring Policy Development
  - PCORI Open Science Initiative
  - On pragmatic clinical trial design and conduct (input incorporated into PCORI guidance)
  - Factors predictive of clinical trial success (continuing discussion)
  - PCORI analyses of statistical underpinnings of a subset of its funded cluster-randomized trials
  - Phased funding mechanisms to develop trials and assess feasibility (incorporated into PCORI's initiative for Phased Large Awards in Comparative Effectiveness Research (PLACER)
  - Methodology Standards for Complex Interventions and their relationship to implementation science

Potential Topics for Future CTAP Discussion

- Today:
  - Incorporating PCORI's new national priorities into clinical design and conduct
  - Management of COVID-19 impacts upon clinical trials
- Future:
  - Best practices in development and feasibility testing of large, multicenter trials
  - Input on optimizing clinical trial operations
    - Balancing fidelity and flexibility in trials conducted in real-world research
  - Use of estimands
  - Platform and adaptive clinical trials
- CTAP panelist suggestions

CTAP

Update on PCORI's Proposed Principles for the Consideration of the Full Range of Outcomes

Friday, November 6, 2020

12:55-1:50 pm ET

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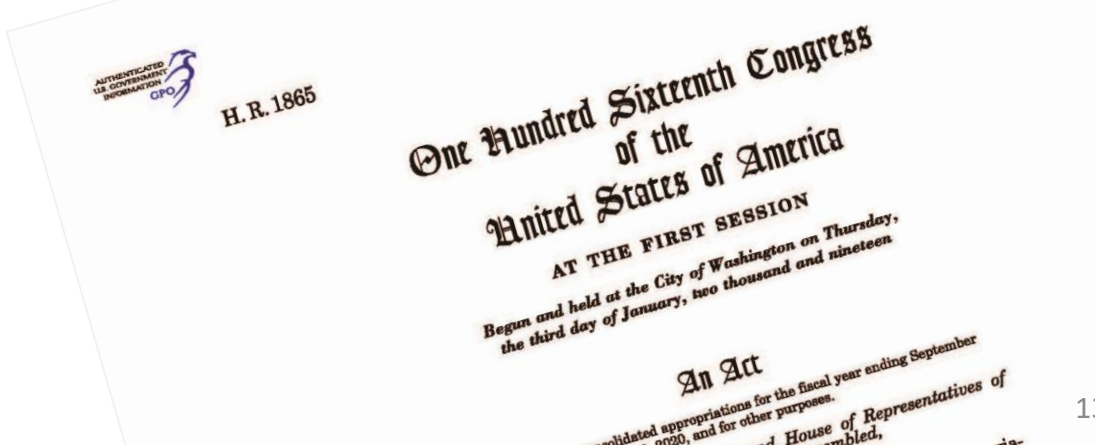
Overview of New Statutory Authority

PCORI's reauthorizing legislation directs PCORI to capture, **as appropriate**, the full range of outcomes data in the course of our research studies.

This includes economic and cost data related to the utilization of health care services, but also outcomes and measures of cost and burden **important to patients**.

Potential Burdens and Economic Impacts Include:

- Medical out-of-pocket costs, including health plan benefit and formulary design
- Non-medical costs to the patient and family, including caregiving
- Effects on future costs of care
- Workplace productivity and absenteeism
- Healthcare utilization


H.R. 1865

One Hundred Sixteenth Congress
of the
United States of America

AT THE FIRST SESSION

Begun and held at the City of Washington on Thursday, the third day of January, two thousand and nineteen

An Act

Social Security Act. Section 1181 [42 U.S.C. 1320e] (d)(2)(F)

Overview of PCORI's Cost Data Implementation Proposal

Pillar 1

- Providing guidance to Principal Investigators in future PFAs on how they should interpret this policy and incorporate it into their research proposals.
- **Timeline:** Final Principles and Guidance for Applicants by **February or March 2021**

Pillar 2

- Establishing methodology standards to further inform how PCORI-funded studies should capture relevant data.
- **Timeline:** Approximately **12 months** from the initiation of this process

Pillar 3

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

Progress Report – Pillar 1

Proposed "Principles"

- PCORI Board of Governors approved the release of the proposed "Principles" for Public Comment on **September 14, 2020**

Seeking Public Input

- 60-Day Public Comment Period
- Webinar Series
- Advisory Panels

Revising Principles & Guidance

- Revise "Principles" based on public input
- Final approval of "Principles" in March 2021
- Guidance to applicants in PCORI funding announcements in Spring 2021

WE ARE HERE

Proposed Principles for the Consideration of the Full Range of Outcomes Data

What are the Principles?

- These principles are a **high-level framework** to describe PCORI's interpretation of the new mandate to collect cost burden and economic impact data

Why do we need them?

- To provide the public and potential applicants with an understanding of how PCORI interprets the mandate

How will they be used?

- These principles will serve as a point of reference for PCORI as a basis for developing guidance to potential applicants and updating PCORI's Methodology Standards
- These principles should not be viewed as standards and methods

Proposed Principles

Identifying Outcomes Important to Patients

- **Principle #1:** PCORI-funded research may consider the full range of outcomes *important to patients and caregivers*, including burdens and economic impacts.

Identifying Outcomes Important to Stakeholders

- **Principle #2:** PCORI-funded research may consider the full range of outcomes *relevant to other stakeholders*, when these outcomes have a near-term or longer-term impact on patients.

Criteria Regarding the Collection of Data

- **Principle #3:** The collection of data on burdens and economic impacts of treatment options must be appropriate and relevant to the clinical aims of the study.

Consideration of Economic Analysis

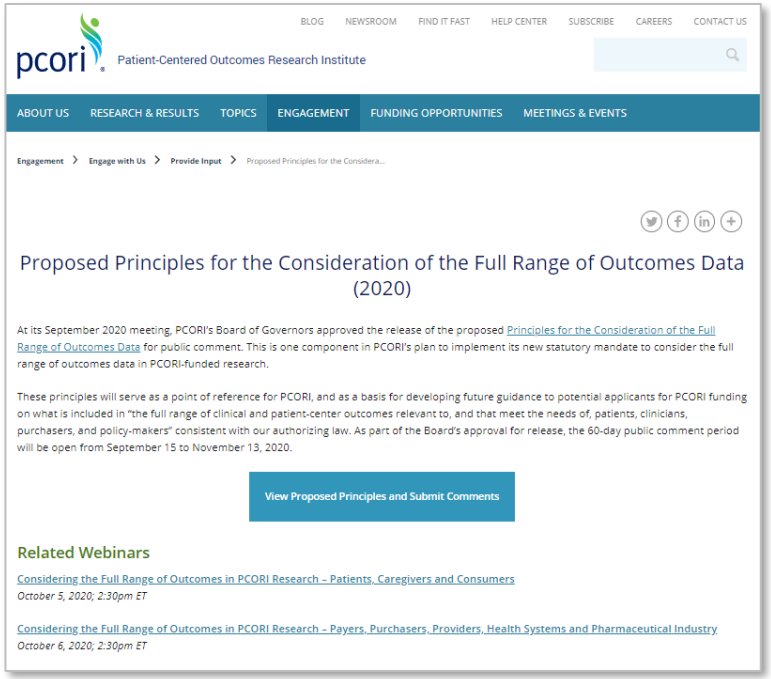
- **Principle #4:** Beyond the collection of burden and economic impact data, PCORI may support the conduct of certain types of economic analyses as part of a funded research study, to enhance the relevance and value of this information to health care decision-makers.

Themes of Input Received

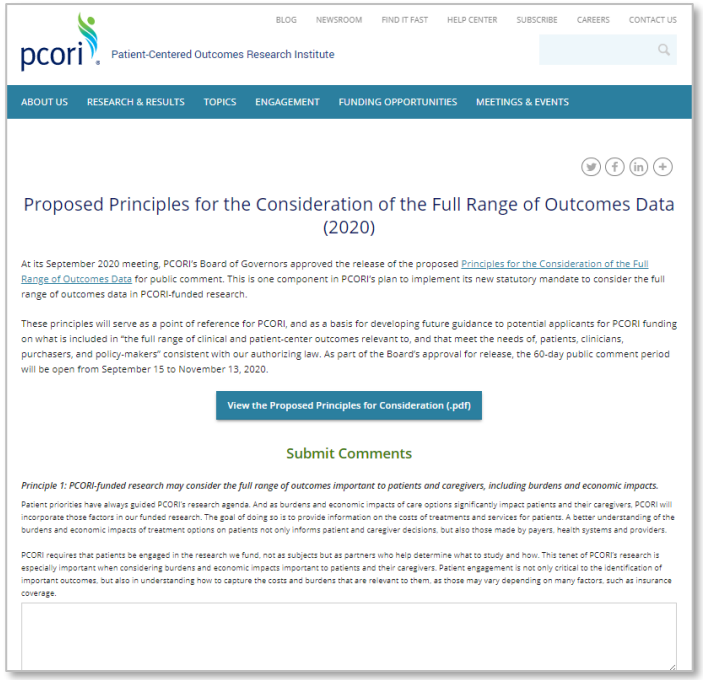
- Broad **support** for the consideration of costs and economic impact data in PCORI research
- Ensure a **patient-centered and holistic** approach to the consideration of costs
- Consider the cost burdens and impacts from a **societal and community** level
- Helpful to capture **implementation or program costs**
- Having patient-centered cost/impact data can help in **value-based payment** models

References & Resources

- Proposed Principles for the Consideration of the Full Range of Outcomes Data ***(Landing Page)***



- Proposed Principles for the Consideration of the Full Range of Outcomes Data ***(Public Comment Webform)***



Strategic Planning: Identifying National Priorities

Michele Orza, ScD

Chief of Staff, Office of the Executive Director

Original Strategic Framework (2013)

NATIONAL PRIORITIES for RESEARCH	STRATEGIC IMPERATIVES	OUTPUTS	GOALS	IMPACT
Priorities that Guide Our Research	How We Create	What We Create	What We Accomplish	Why We Do It

- Addressing Disparities
- Assessment of Prevention, Diagnosis, and Treatment Options
- Communication and Dissemination Research
- Improving Healthcare Systems
- Accelerating PCOR and Methodological Research

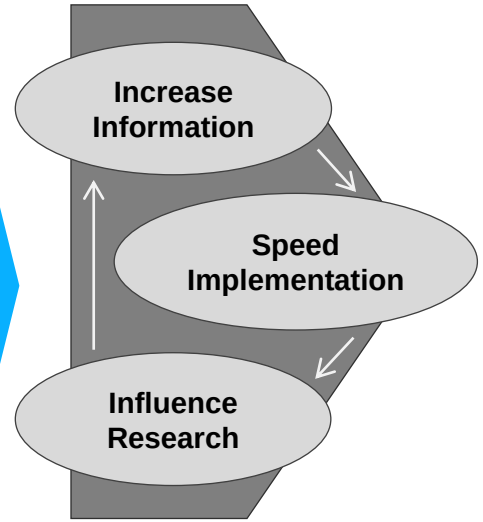
→ Engagement → Skilled Patient-Centered Outcomes Research Community

→ Methods → Patient-Centered Outcomes Research Methods

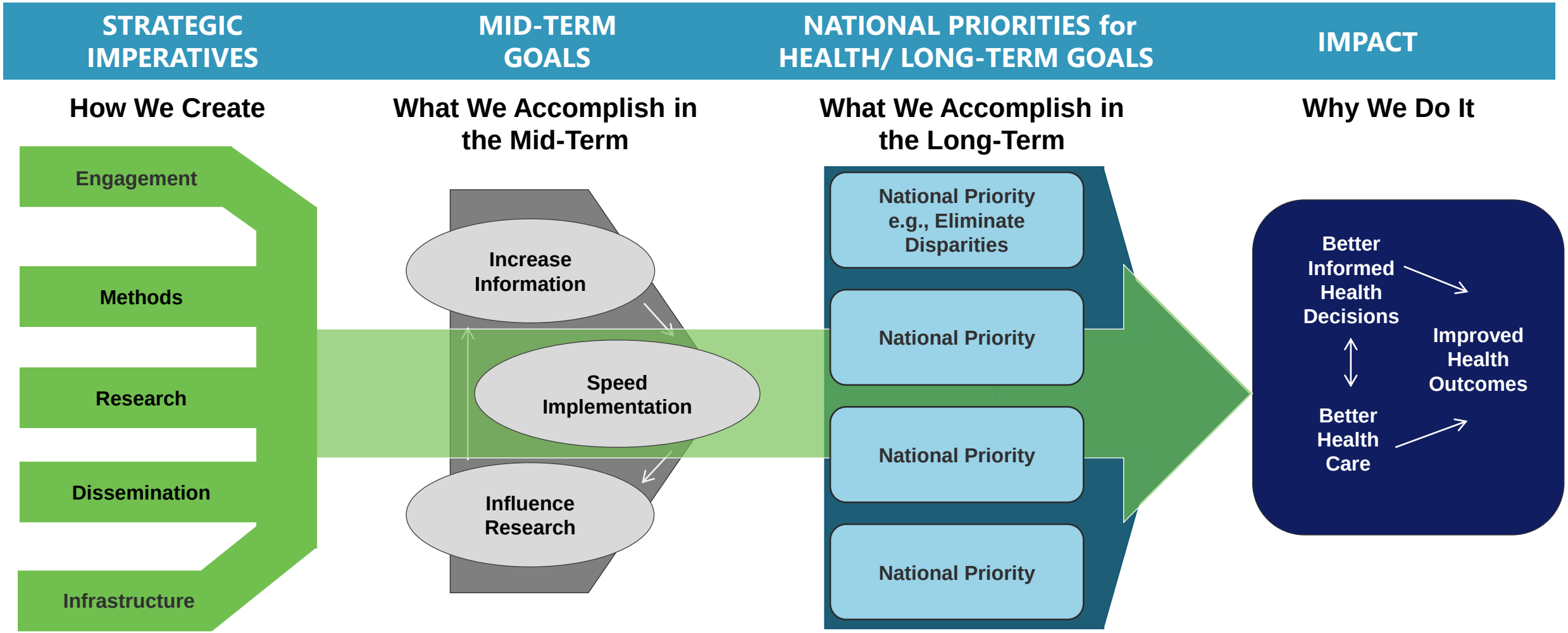
→ Research → Portfolio of Patient-Centered Outcomes Research Studies

→ Dissemination → Communication and Dissemination Activities

→ Infrastructure → Patient-Centered Research Networks



Revised Strategic Framework



Existing National Priorities (Adopted in 2012)

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.

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.

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.

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.

Accelerating PCOR 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.

Legislatively-Mandated Priority Topics Cut Across Our National Priorities

	National Priority TBD	National Priority TBD	National Priority TBD
Intellectual and Developmental Disabilities	A1	B1	C1
Maternal Morbidity and Mortality	A2	B2	C2
Priority Topic TBD			

Intellectual and developmental disabilities and maternal morbidity and mortality:
Priority topics for the next 10 years

Where Do We Go From Here
Addressing Disparities

Description

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.

What we've been hearing about this Priority

- Remains more important than ever
- Needs to be strengthened (e.g., eliminate disparities rather than addressing)

We want to hear from you

- What does the reframing of the National Priorities from categories of research to goals for health mean for the AD priority?
- How can research or clinical trials support a focus on health goals in populations that experience disparities?

Where Do We Go From Here
Assessment of Prevention, Diagnosis, and Treatment Options

Description

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.

What we've been hearing about this Priority

- Importance of prevention and its link to broader public health
- Incorporate the environmental factors and public health efforts with this priority
- Important to maintain focus on comparative trials of drugs, devices, surgical techniques, and other interventions

We want to hear from you

- What does the reframing of the National Priorities from categories of research to goals for health mean for the APDTO priority?
- How can research or clinical trials address what we've been hearing about this priority?

Where Do We Go From Here
Communication and Dissemination Research

Description

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.

What we've been hearing about this Priority

- Importance of doing communication and dissemination, not just the research of it
- Community engagement can facilitate strong dissemination

We want to hear from you

- What does the reframing of the National Priorities from categories of research to goals for health mean for the CDR priority?
- How can clinical trials support a focus on improving communication and dissemination of health outcomes information?

Where Do We Go From Here
Improving Healthcare Systems

Description

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.

What we've been hearing about this Priority

- Reflect intersection of priority with broader public health ecosystem (e.g., social determinants of health)

We want to hear from you

- What does the reframing of the National Priorities from categories of research to goals for health mean for the IHS priority?
- How can clinical trials support evaluations of the public health ecosystem?

Where Do We Go From Here
Accelerating PCOR and Methodological Research

Description

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.

What we've been hearing about this Priority

- Consider infrastructure needed to support the other priorities
- Data infrastructure ecosystem could lead to efforts that complement PCORI's work
- Emphasize human component of infrastructure
  - Capacity building to include diverse participants in research
  - Development of a research pipeline for PCOR

We want to hear from you

- What does the reframing of the National Priorities from categories of research to goals for health mean for the Methods priority?
- How can clinical trials methods support a focus on improved health and outcomes?

Is Anything Missing

Looking at all the existing National Priorities and considering the revised framework,

- Is there an important goal for health that is not reflected in the National Priorities?
- How can the research enterprise, particularly clinical trials, best support a goal-focused strategy on health for our National Priorities?

Thank You!

An Update on PCORI's Mandated Research Priorities

Elisabeth Houtsmuller, PhD

Associate Director, Healthcare Delivery and Disparities Research

Kelly Dunham, MPP

Senior Manager, Office of the Chief Science Officer

Putting our Mandate into Action

- Reauthorization language identified two research priorities:
  - Maternal morbidity and mortality (MMM)
  - Intellectual and/or developmental disabilities (IDD)

- Implementation of mandate will include:
  - Long-term priority areas of investment
  - Ongoing opportunities for engagement

Hear from Dr. Nakela Cook in her recent blog

Formulating Our Approach to New Priority Research Areas

Date: September 8, 2020

Blog Topics: Executive Director's Blogs, Funding Awards, Research

As part of last winter's legislation that reauthorized PCORI's funding for 10 years, Congress included two new research priority areas for PCORI to address: strategies for improving maternal mortality, and improving health for individuals with intellectual and/or developmental disabilities (IDD).

These areas are of critical importance for PCORI given the long-standing health challenges faced by those affected and the opportunities that PCORI's approach to *research done differently* can contribute to meaningful health improvements. We are committed to a multipronged approach to funding research to address a variety of issues related to these two topics over the next decade.

Addressing Maternal Morbidity and Mortality

The United States consistently ranks near the bottom among high-income

Addressing PCORI's New Research Priorities

Stakeholder Engagement: *Landscape review and information gathering (e.g., advisory panels, PCORI Board of Governors, preliminary key informant discussions, stakeholder surveys)*

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- *Broads √*
- *Phased Large Awards √*
- *Pragmatic Clinical Studies*
- *Targeted Funding Announcements*

EVIDENCE SYNTHESIS

- *Systematic reviews*
- *Rapid Reviews*
- *Evidence maps and/or visualizations*

ENGAGEMENT AWARDS

- *Capacity Building √*
- *Stakeholder Convening Support √*
- *Dissemination*

PCORI's Current Special Areas of Emphasis

Up to $30 million set aside for **each** of these topics, with available funding emphasizing:

- Care and care transitions for individuals with intellectual and/or developmental disabilities growing into adulthood
- Person-centered maternal care for populations likely to experience the most significant disparities in care and/or outcomes

Please find additional details on the PCORI website and within the handout provided.

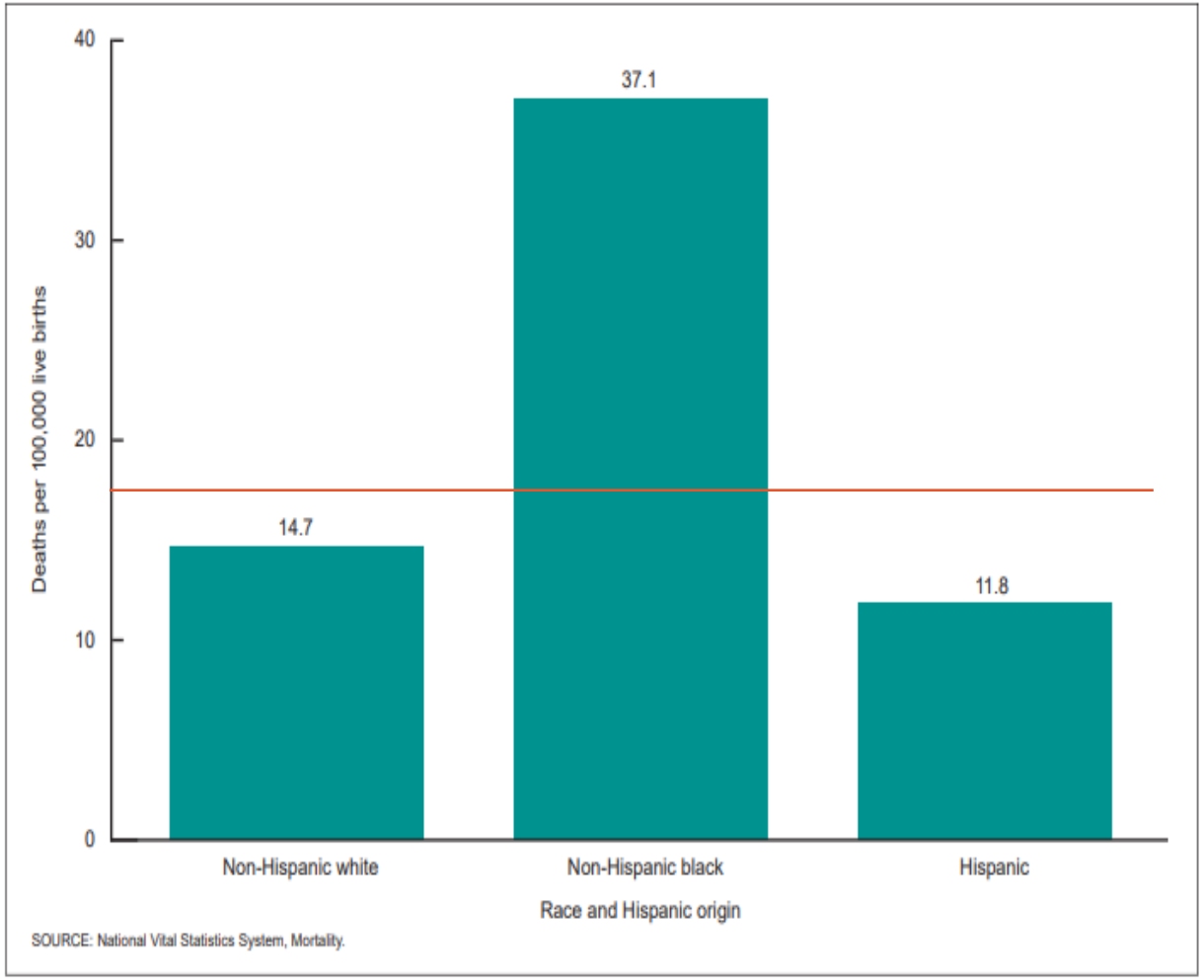
Maternal Mortality and Morbidity

Maternal Mortality: US Rates and Disparities

2017 Maternal Mortality Rates per 100,000 live births by Country

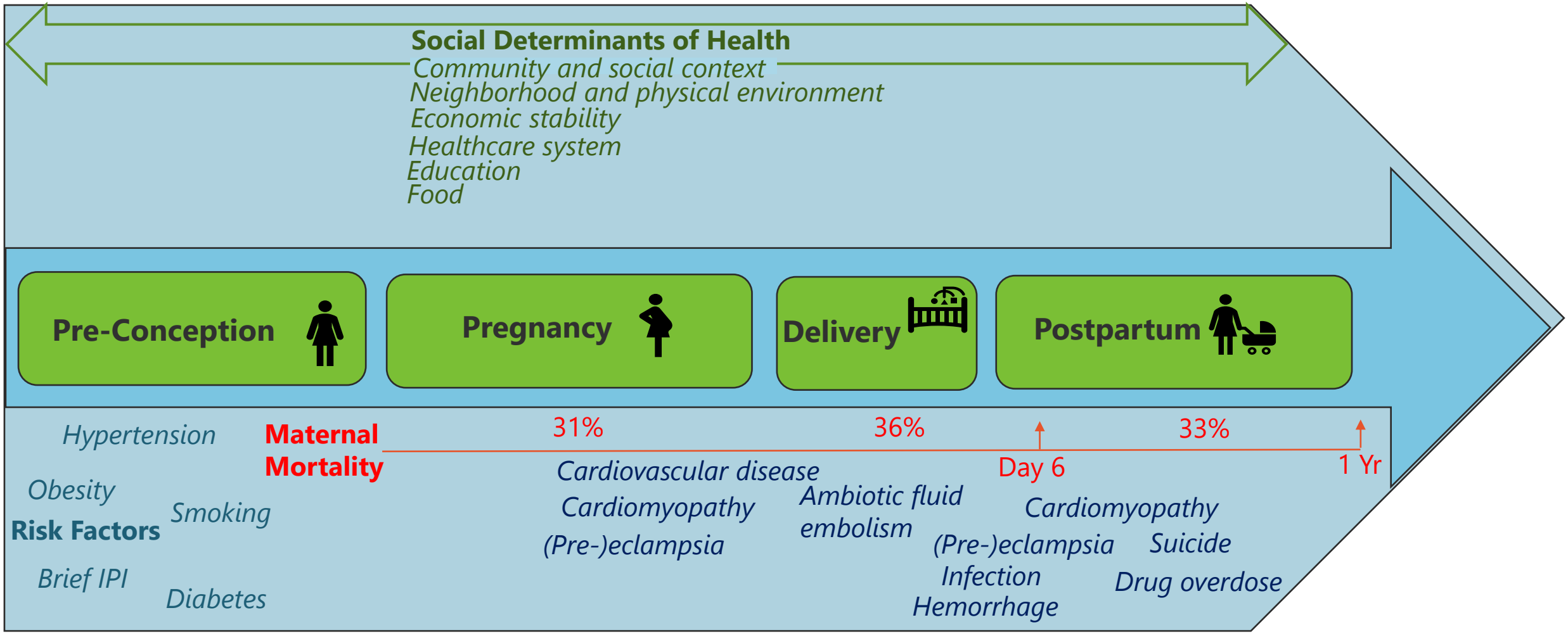
Norway	2
Italy	2
Finland	3
Greece	3
Denmark	4
Spain	4
Sweden	4
Iceland	4
Austria	5
Netherlands	5
Japan	5
Switzerland	5
Germany	7
US	19

The World Factbook, 2020

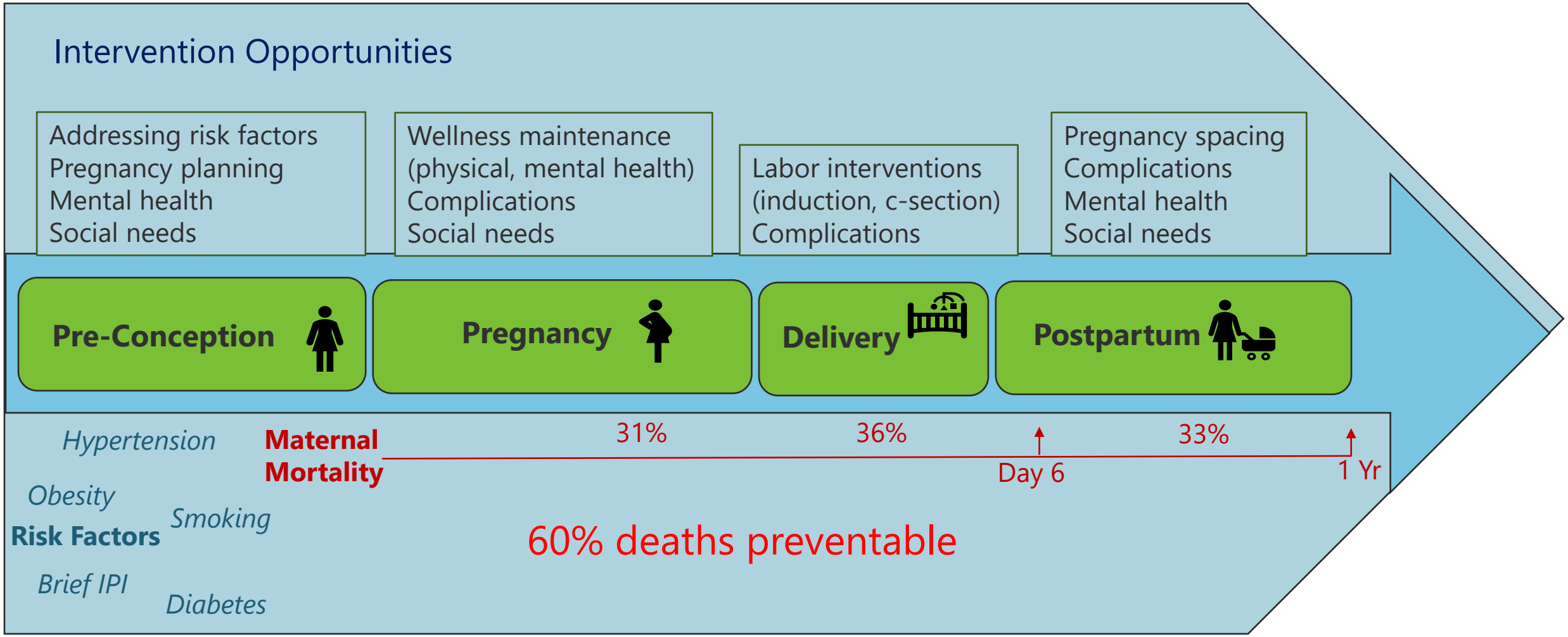


Maternal mortality rates, by single race and Hispanic origin: United States, 2018

Maternal Mortality Framework: More than just pregnancy and delivery



Maternal Mortality Framework: Opportunities for Healthcare Intervention



Maternal Mortality
Stakeholder Engagement to Date: A Sample

- A few organizations that we've engaged with
- Not an exhaustive list

Key Question for Panel

- Are there organizations we should consider?

Patients/Patient Advocates	• National Birth Equity Collaborative • National Partnership for Women and Families • National Rural Health Association
Policymakers	• Black Maternal Health Caucus Advisory Group • Association of State and Territorial Health Officials
Clinicians	• American College of Obstetricians-Gynecologists • American College of Nurse-Midwives • American Academy of Family Physicians
Hospitals/Health Systems	• Colorado Hospital Association • Mamatoto Village
Researchers/Funders	• National Institute of Child Health and Human Development • Individual researchers
Payers	• Centers for Medicare and Medicaid Services • Medicaid Medical Directors Network

Intellectual and/or Developmental Disabilities

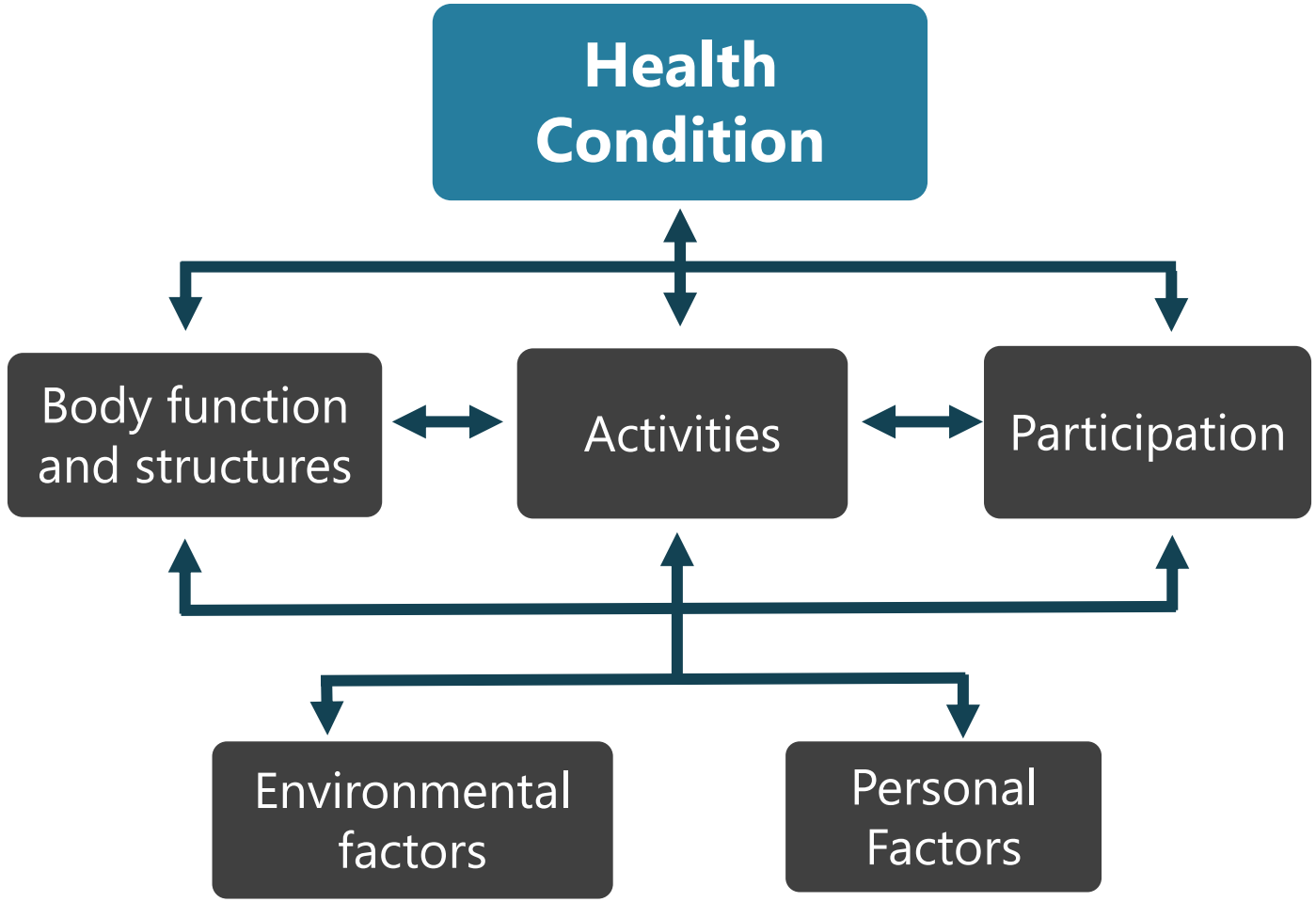
Intellectual and Developmental Disabilities: Context

- Intellectual and developmental disabilities (IDD) are disorders that are usually present at birth and that negatively affect the trajectory of the individual's physical, intellectual, and/or emotional development. [NICHD]
    - **Intellectual disabilities** are characterized by significant limitations in both intellectual functioning and adaptive behavior. [AAIDD]
    - **Developmental disabilities** are chronic and can be cognitive, physical or both. [AAIDD]
- People with IDD comprise a vulnerable population with poorer health status, shorter lifespan, and worse health care outcomes than the general population
    - Additional challenges for populations already at risk for disparities

Levers for improving health outcomes for individuals with IDD: ICF Model

Functioning and Disability

Social determinants of health (Barriers and facilitators)



WHO, 2001

Intellectual and/or Developmental Disabilities
Stakeholder Engagement to Date: A Sample

- A few organizations with whom we've engaged
- Not an exhaustive list

Key Question for Panel

- Are there organizations we should consider?

Patients/Patient Advocates	• National Down Syndrome Society • Autism Speaks • The Arc • American Association on Intellectual and Developmental Disabilities
Policymakers	• National Association of State Directors of Developmental Disabilities Services • US DHHS/Office of Autism Research Coordination
Clinicians	• American Academy of Family Physicians • American Academy of Pediatrics
Researchers/Funders	• Association of University Centers on Disability • National Institute on Disability, Independent Living, and Rehabilitation Research • Teams conducting high-quality IDD-related PCOR (Individuals and UCEDDs)
Payers	• Medicaid Medical Directors Network

PCORI hosted a multi-stakeholder town hall at the 2020 PCORI Annual meeting.

Key Considerations Moving Forward

Challenges of Study Designs in Maternal Morbidity and Mortality Research

- Cluster vs. individual randomization
- Systems of care
- Outcome ascertainments
- Recruitment and operations
- Accessing populations

Challenges of Study Designs in IDD Research

- Heterogeneity of populations
- Good practices
- Examples
- Recruitment and operations
- Accessing populations
- Caregivers as partners in data capture

- **What experience does the CTAP have with research in these populations?**
  - **Good practices?**
  - **Biggest challenges?**
  - **Barriers to research?**
- **What study design features are associated with success?**
- **What other components and key features of research plans are critical to success?**

Thank You!

COVID-19 Disruptions to Research

Jason Gerson, PhD
Senior Program Officer, CEDS

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Background/Context

- The ongoing COVID-19 pandemic is disrupting the conduct of clinical research, impacting almost all PCORI-funded clinical research projects. Disruptions include:
- **Operational**
  - Study suspension at all/some sites
  - Alteration of recruitment mechanisms
  - Alteration of consent approaches
  - IRB review for proposed/necessary changes
  - Maintaining stakeholder engagement
- **Scientific**
  - Altered primary research question or causal model
  - Modified intervention delivery (e.g., in-person to virtual)
  - Non-randomized choice/use of modified intervention by clinicians or patients (e.g., choice of in-person vs. virtual delivery)
  - Remote/nonclinical collection of assessments/outcomes
  - Potential impacts on study precision/power

Questions for Studies Unable to Go Forward as Planned

- ***Research Question:*** Does the adaptation change the nature of the research question? Would the research still address an important evidence gap?
- ***Efficacy of Adaptation:*** Is there sufficient evidence of efficacy for delivering virtual versions of the intervention, if applicable?
- ***Other considerations:***
  - Nature of patient population (e.g. only those with internet?)
  - Effect size
  - Power
  - Analytic approach

Questions for Studies Unable to Go Forward as Planned

- **Feasibility/fidelity assessment:** has an assessment occurred? Is it needed prior to full approval?
  - Track fidelity of adapted intervention delivery
  - Track ability to implement the adapted intervention across multiple sites
  - Training of research/clinical staff + IRB changes
- **Permanence of the change**
  - Is there an intent to return to in-person intervention delivery (if COVID-19 restrictions lessen)?
  - Will in-person/virtual delivery options be determined by the clinic or patient?

Adaptation Scenarios

For Discussion

Scenario 1: Behavioral intervention adapted from in-person --> virtual delivery

- Study compares two in-person behavioral interventions for the treatment of a common outpatient mental health condition; study has already recruited patients for in-person delivery.
- Dilemma: Due to COVID-19 impact, sites are unable to deliver the intervention in-person and are opting for virtual delivery. If a virtual option is not employed, the study must remain "on-pause" until in-person intervention delivery can resume
- Discussion/Considerations:
  - Does virtual delivery change the nature of the patient population, e.g. only those with internet access?
  - Is there an intent to return to in-person delivery once feasible? Is this advisable?
  - Will any/some patients receive a hybrid form of the intervention (i.e. partly in-person, partly remote)? if so, what are the implications?
  - What are the analytical implications to the study design changes? Effect size implications?
  - Is adequate technology infrastructure available?

Scenario 2: Virtual collection of outcome measurements

- Study originally included in-person physical assessments and measurements by a certified assessor.
- Sites can no longer conduct research on-site, due to COVID-19 restrictions.
- Dilemma: PI proposes to employ virtual measurement; patient to collect measurements observed by research staff via virtual platform. This would allow the awardee to move forward with study, but it is unclear whether virtual collection of certain measurements has been validated.
- Discussion/Considerations:
  - Implications re: the study containing measurements collected by both the assessor (pre-COVID) and self-report measurements (during COVID)?
  - Implications to collecting assessment measurements that were not previously validated for virtual collection? Recommend pilot?
  - Temporal nature of request: Permanent? Temporary? As needed?
  - How might remote assessment be compared or validated relative to one done by a certified assessor in-person?

Additional Discussion Questions

Questions: Population Impacts

- What are the consequences and potential solutions (operational and analytical) to address potential changes in the composition and diversity of the study population arising from differences in access to in-person services, technology platforms, and broadband coverage?

- How can in-person recruitment efforts be modified to include individuals who may ignore outreach done by phone, email, or postal mail?

Questions: Intervention Impacts

- Is it possible to determine a priori which kinds of interventions are equivalent when delivered remotely rather than in person?
- Does the manner of remote delivery make a difference, e.g., audio alone, a smartphone sized screen, or a tablet or laptop?
- How might remotely delivered interventions be tested or validated?
  - Examples:
    - Counseling
    - Physical therapy and other forms of guided physical activity (yoga)

Questions: Intervention Impacts

- How can investigators manage and analyze interventions delivered by multiple methods within a population or within a single participant?
- How might sample sizes and analysis be modified without compromising the integrity of the prespecified analytical plan?

Questions: Outcomes

- How can the equivalence or validity of remote outcome ascertainment by clinicians or patients be best determined?
  - Examples:
    - Vital signs such as heart rate, blood pressure, respiratory rate or evidence of distress
    - Weight, height
    - Assessments of disease activity or function normally done by a trained clinician

Acknowledgments

- Thanks to Jess Robb (Program Associate, CEDS) and Soknorntha Prum (Program Associate, HDDR) for their invaluable assistance in preparing this presentation.

Wrap Up and Next Steps

Catherine Crespi, PhD, MS (Chair)
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Associate Director,
Clinical Effectiveness and Decision Science, PCORI

Thank you!