Office of the Secretary Patient-Centered Outcomes Research Trust Fund (OS-PCORTF)

Building Data Capacity for Patient-Centered Outcomes Research: An Agenda for 2021 to 2030

May 3, 2021

U.S. Department of Health and Human Services

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ASSISTANT SECRETARY FOR PLANNING AND EVALUATION

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PATIENT-CENTERED OUTCOMES
RESEARCH TRUST FUND

Agenda

1. Welcome and Introductions

2. OS-PCORTF Background

3. OS-PCORTF Current Activities

Welcome and Introductions

ASPE Office of Health Policy

- Benjamin Sommers, MD, PhD, Deputy Assistant Secretary for Health Policy, ASPE

- Nancy De Lew, MA, Associate Deputy Assistant Secretary for Health Policy, ASPE

- Scott R. Smith, PhD, Director, Division of Healthcare Quality and Outcomes, ASPE

OS-PCORTF Background

Office of the Secretary PCOR Trust Fund (OS-PCORTF)

- Between 2003 and 2010, three laws were enacted that authorized research and funding to expand research on the **outcomes and effectiveness** of treatments and interventions used in health care
  - MMA 2003, ARRA 2009, ACA 2010

- In 2019, the PCOR Trust Fund was reauthorized for 10 years

3 streams of work and funding:
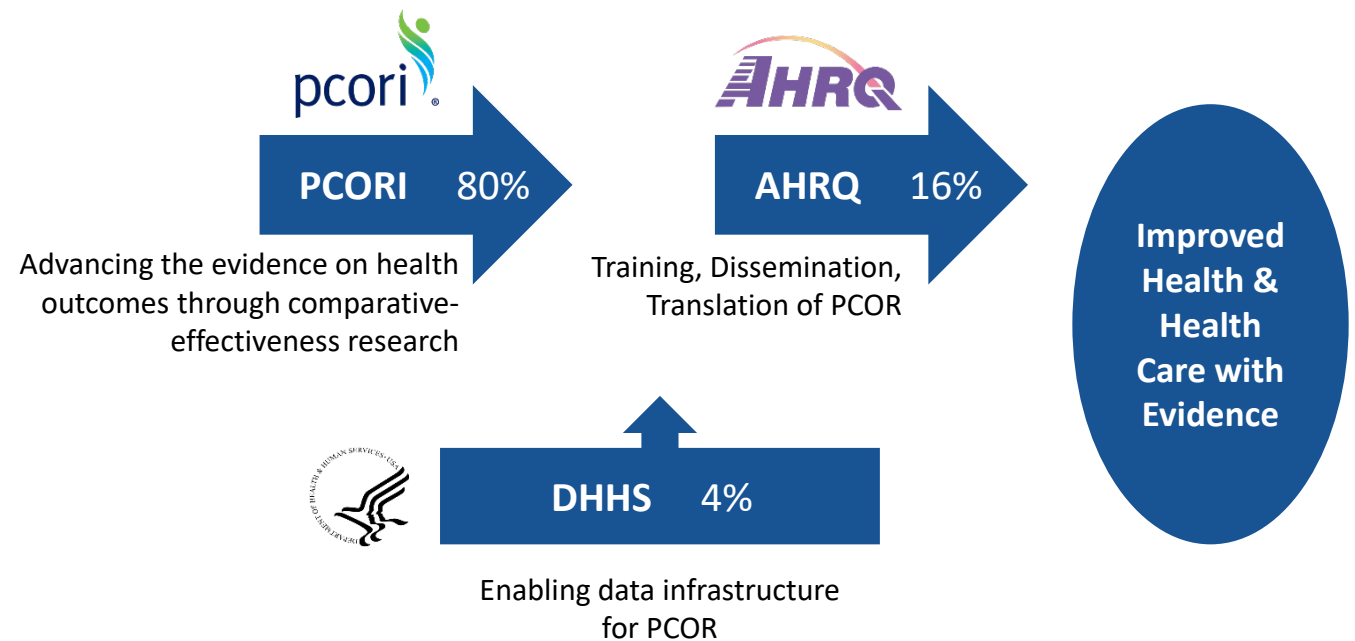
PCORI   80%

Advancing the evidence on health outcomes through comparative-effectiveness research

AHRQ   16%

Training, Dissemination, Translation of PCOR

DHHS   4%

Enabling data infrastructure for PCOR

Improved Health & Health Care with Evidence

PCORTF Reauthorization Through 2029 Invites Reflection, Reconsideration

The Secretary of HHS is to "provide for the coordination of relevant Federal health programs to **build data capacity for comparative clinical effectiveness research**, including the development and use of clinical registries and health outcomes research data networks, in order to **develop and maintain a comprehensive, interoperable data network** to collect, link, and analyze data on outcomes and effectiveness from multiple sources, including electronic health records."

Affordable Care Act, Section 6301

2019 PCORTF Reauthorization Broadened Scope:

- Explicit additions: intellectual/developmental disabilities, maternal mortality
- Expansion: "Full Range of Outcomes Data," including economics

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HHS OS-PCORTF Portfolio Coordination

1. Administration for Children and Families (ACF)
2. Administration for Community Living (ACL)
3. Assistant Secretary for Preparedness and Response (ASPR)
4. Agency for Healthcare Research and Quality (AHRQ)
5. Centers for Disease Control and Prevention (CDC)
6. Centers for Medicare and Medicaid Services (CMS)
7. Food and Drug Administration (FDA)
8. Health Resources and Services Administration (HRSA)
9. Indian Health Service (IHS)
10. National Institutes of Health (NIH)
11. Office of the Chief Technology Officer (CTO)
12. Office of the National Coordinator for Health Information Technology (ONC)
13. Substance Abuse and Mental Health Services Administration (SAMHSA)
14. Assistant Secretary for Planning and Evaluation (ASPE) Coordinator

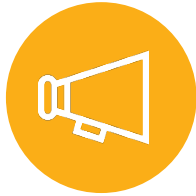ASPE | OFFICE OF HEALTH POLICY
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Key Components of Strategic Planning

Initial Listening Session
Principal Stakeholder Group: "The Field": Including health services researchers, policy analysts and other PCOR producers, users of PCORTF products
Completion: August 2020

NORC at the University of Chicago

External Engagements
Principal Stakeholder Group: External government and non-governmental organizations and actors involved with producing, using data for PCOR and other health care and systems research, policy and practice purposes
Completion: January 2022

The National Academies of SCIENCES ENGINEERING MEDICINE

HHS Internal Engagements
Principal Stakeholder Group: HHS agencies that produce, use PCOR data and conduct/participate in PCOR activities
Completion: March 2022

MITRE

Public Request for Information
Principal Stakeholder Group: Active but not necessarily affiliated organizations and individuals involved with producing, using PCOR data for PCOR and other health care and systems research, policy and practice purposes
Completion: TBD

FEDERAL REGISTER
The Daily Journal of the United States Government

HHS OS-PCORTF Leadership Council Engagement
Principal Stakeholder Group: Decision/advisory entity for ASPE, Secretary
Completion: Ongoing

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OS-PCORTF Current Activities

OS PCORTF Vision -- First Decade

Goal: To build data capacity in HHS that supports research on patient health outcomes.

- PCOR is intended to provide decision makers with objective, scientific evidence on the **effectiveness** of treatments, services, and other interventions used in health care.

- This research is frequently focused on analyzing existing data to study questions and provide objective information for the purposes of **informing real world health care decisions.**

PATIENT-CENTERED OUTCOMES RESEARCH

USERS

Patients Consumers	Researchers Payers and Purchasers Providers & Health Systems	Public Health Federal Agencies

THE "SUPPORT"
Users of the data infrastructure and contributors to PCOR.

FUNCTIONALITIES

Use of Clinical Data for Research	Standardized Collection of Standardized Clinical Data	Linking Clinical and Other Data for Research	Collection of Participant-Provided Information	Use of Publicly-Funded Data Systems for Research

THE "PILLARS"
Core research functions and HHS focus areas for enhancing and improving data infrastructure.

COMPONENTS

Services	Standards	Policies and Governance

THE "BUILDING BLOCKS"
Data sources and components are necessary for ensuring that electronic data is usable for research.

DATA SOURCES

| Primary Data Collected for Clinical Care	Primary Data Collected for Research	Patient Contributed Data Payer-Admin Data Federal Data	Social Determinants of Health [data source]

THE "DATA SOURCE"
These building blocks are used to address collecting, linking, and analyzing of data to support the five core research functionalities.

Addressing the Opioid Crisis through Better Data and Data Infrastructure—An Example of a Use Case
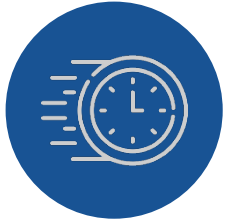
Improving Timeliness and Quality of Outcomes Data

Understanding impact of opioid epidemic on maternal and infant outcomes

CDC (2019): MAT-LINK is a surveillance network that collects data, monitors maternal, child, and infant health outcomes

Building Capacity for Collection of Patient-Reported Outcomes

Collecting patient-reported outcomes not available in the clinical record.

NIH/NIDA (2018): The project is exploring the feasibility of collecting PROs related to opioid use after an ED visit through a patient-friendly app

Building Linkages to Address Co-Morbidities

Linking human services data with health data.

ASPE, ACF (2019): Pilot testing a linkage between state Medicaid records and child welfare records into a single, harmonized dataset

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Addressing COVID through Better Data and Data Infrastructure—An Example of a Use Case

Use of Clinical Data for Research

- **ONC**: Using Machine Learning Techniques to Enable HIE Data Sharing to Support COVID-19 Focused PCOR

Collection of Participant Provided Information

- **NIH-AHRQ**: Understanding COVID-19 Risks, Course, and Outcomes in the Context of MCC (Multiple Chronic Conditions) Through e-Care Plan Development

Linking Clinical Data and Other Data for Research

- **NIH-CMS-ASPE**: A National COVID-19 Longitudinal Research Database Linked to CMS Data

- **ASPE-ACL:** Dataset on Intellectual and Developmental Disabilities (DIDD): Linking Data to Enhance Patient-Centered Outcomes

Standardized Collection of Standardized Clinical Data

- **FDA:** CURE ID: Aggregating and Analyzing COVID-19 Treatments from EHRs and Registries Globally

Use of Federal Data for Research

- **CDC:** Building Infrastructure and Evidence for COVID-19 Related Research, Using Integrated Data from NCHS Data Linkage Program

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Illustrative Examples of OS-PCORTF Products

Datasets

- **CDC-CMS**: Linked NHCS and CMS Medicare Master Beneficiary Summary File (MBSF) data
- **CDC-NHC**S: NDI linked with the National Vital Statistics System mortality files on drug overdose deaths (NVSS-M-DO) file

Data Elements and Information Models

- **NIH:** NIH Common Data Elements Repository
- **AHRQ**: Libraries of Clinical Definitions for Outcome Measures

HIT Standards

- **ONC**: Patient Reported Outcomes FHIR Implementation Guide
- **FDA**: Women's Health Technology CRN FHIR Implementation Guide

Software

- **CMS:** Blue Button 2.0 Application Programming Interface (API) Developer Sandbox
- **FDA:** MyStudies App

Tools and Guides

- **FDA**: Data Quality Metrics (DQM) Tool
- **CMS:** Source Data Capture From EHRS: Using Standardized Clinical Research Data
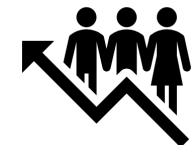
Stakeholder Engagement

- User, TEP, or workgroup engagement documentation
- Training

Questions?