NIH Pragmatic Trials Collaboratory SC Meeting

Building Data Capacity for Patient-Centered Outcomes Research (PCOR) for the Next Decade

April 20-21, 2022
9:45 – 10:30 am
Bethesda, MD

U.S. Department of Health and Human Services

ASPE
ASSISTANT SECRETARY FOR PLANNING AND EVALUATION
OFFICE OF HEALTH POLICY

OS PCOR TF
OFFICE OF THE SECRETARY
PATIENT-CENTERED OUTCOMES RESEARCH TRUST FUND

About ASPE

- The **Assistant Secretary for Planning and Evaluation (ASPE)** is in the Office of the Secretary. We advise the Secretary on policy development.
- We coordinate the Department's evaluation, research, and demonstration activities, and manages cross-Department planning activities such as strategic planning, legislative planning, and review of regulations.
- The Office of Health Policy within ASPE handles a wide array of issues related to health care financing, health insurance coverage and access to care, public health, health quality and outcomes.

Overview of Today's Presentation

- Background on our work
- Examples of our investments
- Planning for the future
- What's next
- Discussion

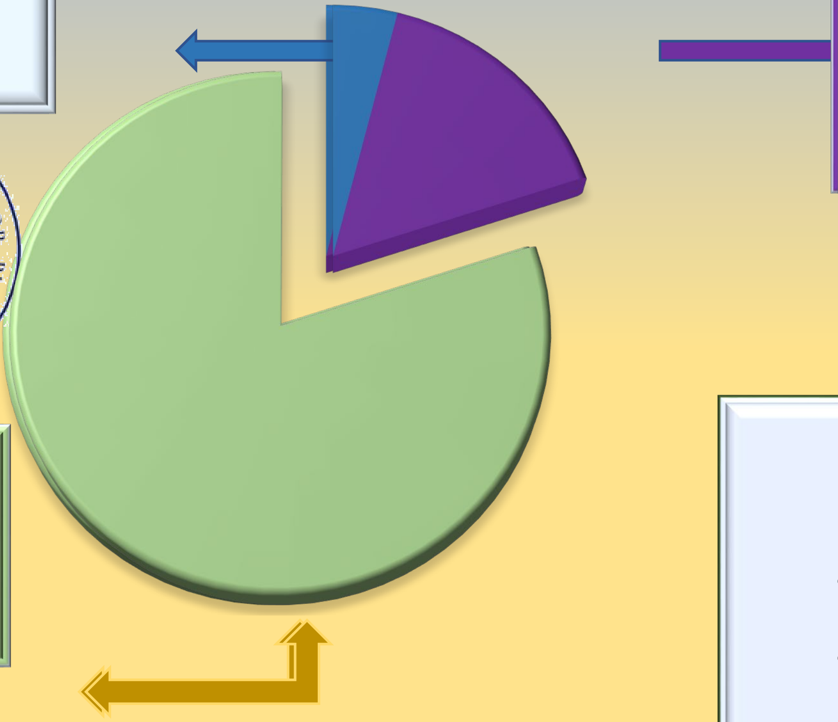
Welcome and Introduction

- For a decade, the Office of the Secretary/ASPE has been working on building data capacity for research.
- Last year we began a series of activities to develop a new strategic plan for the next ten years.
- We reviewed our past efforts, listened to stakeholders, and interviewed experts.
- As we finalize the strategic plan this Spring, we want your feedback and to partner with you in carrying out the plan over the next ten years.

Patient Centered Outcomes Research Trust Fund

ASPE, 4%
Data

AHRQ, 16%
Dissemination, Training, Clin Decision Support



PCORI 80 %
Research

$3.6 Billion (2010 to 2019)

- $2.5 Billion PCORI
- $598 Million HHS (ASPE+AHRQ)
- $128 Million ASPE

Reference: GAO-21-61 Report on Comparative Clinical Effectiveness Research, https://www.gao.gov/assets/gao-21-61.pdf

10-Year Extension of Patient-Centered Outcomes Research Trust Fund

- In 2019, Congress extended PCORTF funding through **Fiscal Year 2029**.
- In total, over that period, we anticipate approximately **$3.3 billion** from the general fund of the Treasury and from the collection of insurance fees.
- About $128 million for ASPE data investments over the 2019-2029 period. About $30-$40 million per year.

What Does the Law Say About Building Data Capacity?

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 Reauthorization of the Trust Fund Broadened Scope:

- **Explicit population group additions**: intellectual/developmental disabilities, maternal mortality
- **Expansion**: “Full Range of Outcomes Data,” including economic outcomes

Who Are Our HHS Collaborators and Partners?

- Administration for Children and Families (ACF)
- Administration for Community Living (ACL)
- Assistant Secretary for Preparedness and Response (ASPR)
- Agency for Healthcare Research and Quality (AHRQ)
- Centers for Disease Control and Prevention (CDC)
- Centers for Medicare and Medicaid Services (CMS)
- Food and Drug Administration (FDA)
- Health Resources and Services Administration (HRSA)
- National Institutes of Health (NIH)
- Office of the Chief Technology Officer (CTO)
- Office of the National Coordinator for Health Information Technology (ONC)
- Substance Abuse and Mental Health Services Administration (SAMHSA)
- Assistant Secretary for Planning and Evaluation (ASPE) Coordinator

How Do We Build Data Capacity for PCOR?

1. Address the **national health priorities** voiced by the Secretary and agency leaders.
2. **Leverage existing resources in HHS** – the people, data, expertise, statutory authorities, intramural and extramural research programs.
3. Collaborate **across agency boundaries** to work on common problems.
4. Strategically fund data projects that will make a **substantial impact**.
5. Produce products that are **needed by the research community** and publicly available.

Data Infrastructure Products

From Our Work With HHS Agencies

Databases

Datasets

Software

HIT Standards

Tools and Guides

Analytic Tools

Data Governance

Data Element & Information Model

Stakeholder Engagements

Examples of Our Projects With Agencies

- **Sync for Science with BlueButton** technology allows claims data donation to All of Us cohort.

- **Harmonization of Common Data Models**: FDA- NIH collaborated to standardize queries and results processed through four existing common data models (CDM) to advance patient-centered outcomes research.

- **Linkage of Medicare claims data** with mortality records from the National Death Index.

- Project to standardize unstructured clinical text data through a **natural language processing (NLP)** web service. The goal of their work is to improve the accuracy, timeliness, and completeness of the data.

- Developing **technical infrastructure to collect patient-reported data** in clinical settings and seamlessly integrate them into electronic health records

FY21 Projects: Better Data and Data Infrastructure during and post COVID pandemic

Use of Clinical Data for Research

- **ONC**: Using Machine Learning Techniques to Enable HIE Data for PCOR

Collection of Participant Provided Information

- **AHRQ-NIH**: 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-CMS-NIH-CDC:** Dataset on Intellectual and Developmental Disabilities (DIDD): Linking Data to Enhance Patient-Centered Outcomes
- **ASPE-NHTSA:** Multistate EMS and Medicaid Dataset (MEMD): A Linked Dataset for Patient-Centered Outcomes

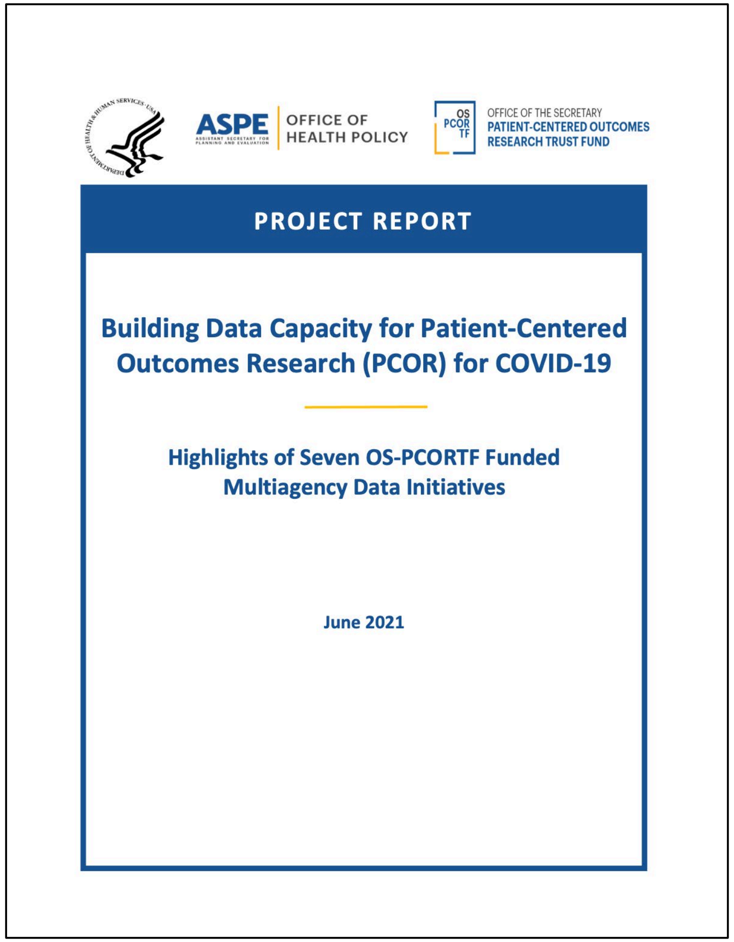
Standardized Collection of Standardized Clinical Data

- **FDA-NIH:** 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

COVID-19 Research Report and Scoping Review on Data Elements for Social Determinants of Health



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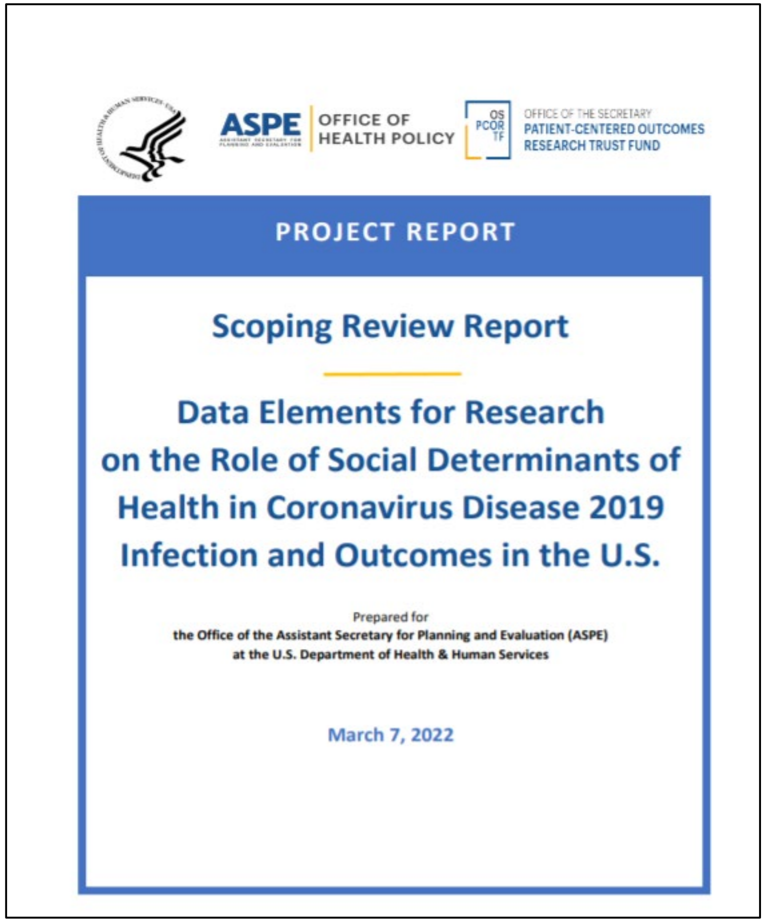
PROJECT REPORT

Building Data Capacity for Patient-Centered Outcomes Research (PCOR) for COVID-19

Highlights of Seven OS-PCORTF Funded Multiagency Data Initiatives

June 2021

https://aspe.hhs.gov/sites/default/files/2021-07/covid-pcor-report.pdf



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PROJECT REPORT

Scoping Review Report

Data Elements for Research on the Role of Social Determinants of Health in Coronavirus Disease 2019 Infection and Outcomes in the U.S.

Prepared for
the Office of the Assistant Secretary for Planning and Evaluation (ASPE)
at the U.S. Department of Health & Human Services

March 7, 2022

https://aspe.hhs.gov/sites/default/files/documents/53fc356858b67f5e9810d107f09ce169/sdoh-covid-19-scoping-review-report.pdf

Overview of Consultations: Who We Listened To

1 Environmental Scan

MITRE

Environmental Scan on Current Legislation and Strategies

Scanned: Legislation, regulations, and strategies.

2 Agency Consultation and Review

Strategic Planning Engagement Council

Comprised of representatives from all HHS agencies

3 HHS Engagements

MITRE

HHS Stakeholder Interviews

HHS Agency stakeholders that produce and use data for PCOR and conduct/participate in PCOR activities.

Clinical Registries and Health Outcomes Research Data Network Stakeholder Interviews

Principal investigators or leads of research data networks.

FY 21 OS-PCORTF COVID 19 Multiagency Data Initiatives

Project leads and project team members

4 Public Engagements

The National Academies of SCIENCES ENGINEERING MEDICINE

Three NASEM Workshops

External to government and non-government organizations and actors involved in producing and using data for PCOR and other health system and healthcare and systems research, policy, and practice purposes.

NORC at the University of Chicago

“Listening Session with AcademyHealth”

Health services researchers, policy analysts, and other PCOR producers and users of PCOR products.

Highlighted Opportunities For Data Infrastructure

- Enhance **research access to federal health data**, expanded to include device and patient-provided information, among other novel sources.
- **Strengthen methods** and tools to promote and sustain authoritative health data linkage.
- Develop and implement **standard approaches** for data quality, consistency, and patient identification.
- Address **source data workflow strategies** for data capture to improve data quality.
- Address **potential for bias against low-resource providers** and their patients.

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PROJECT REPORT

Research Data Networks and Patient-Centered Outcomes Research Trends and Opportunities: Scan and Interviews with Key Informants

An Input to the OS-PCORTF Strategic Plan

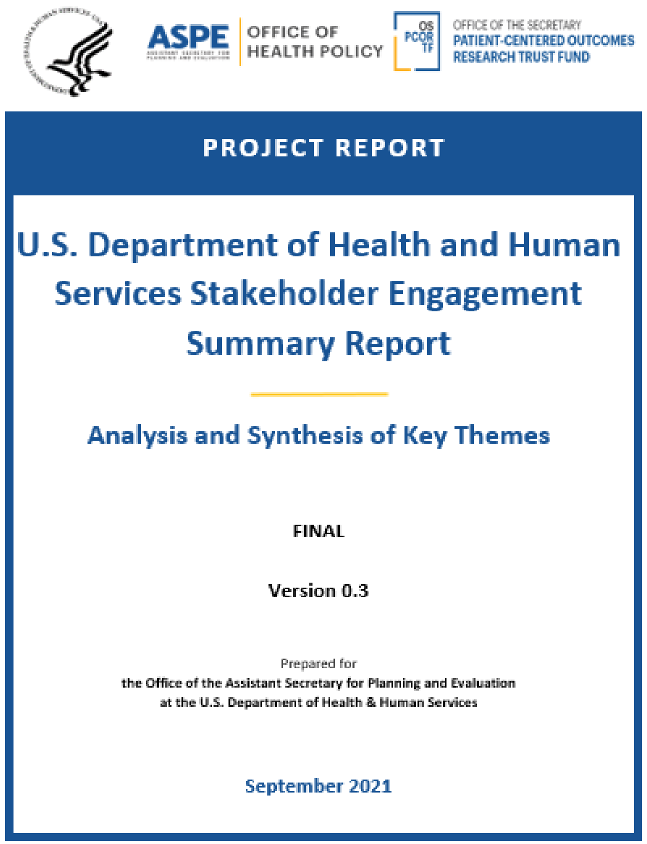
Prepared for the
Office of the Assistant Secretary for Planning and Evaluation (ASPE)
at the U.S. Department of Health & Human Services

July 2021

https://aspe.hhs.gov/reports/pcor-research-networks-report

Highlighted Themes From HHS Interviews

1. **Health Equity and Populations of Focus**
   - Need to apply an equity lens across platforms, projects, & data sources/core data sets.
   - Data for PCOR are insufficient in quantity, quality, and linkages for many populations.
   - Expand focus on linking health and human services data.
2. **Data Infrastructure**
   - Be on leading edge of new technologies and methods
   - Create efficient and reusable data infrastructure.
   - Invest in sustainable, robust data linkages.
   - Develop policy & governance approaches to follow patients over time and across settings that protect privacy and identity.



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PROJECT REPORT

U.S. Department of Health and Human Services Stakeholder Engagement Summary Report

Analysis and Synthesis of Key Themes

FINAL

Version 0.3

Prepared for
the Office of the Assistant Secretary for Planning and Evaluation
at the U.S. Department of Health & Human Services

September 2021

https://aspe.hhs.gov/collaborations-committees-advisory-groups/os-pcortf/about-os-pcortf/os-pcortf-strategic-plan-2021-2029

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VISION 2029

Better Data. Stronger Evidence. Informed Decisions.

VISION

Better data for patient-centered outcomes research to improve evidence generation, decision making, and health outcomes for all Americans.

OUTCOMES

Data, tools, and services to improve patient-centered outcomes research relevant to HHS priorities.

Accessible, timely, interoperable, longitudinal, and linkable data.

Robust RWD across platforms and systems used to generate RWE and expand data usage that informs patient, clinical, and policy decision making.

Accurate, relevant, and representative evidence is accessible to individuals; communities; and state, federal, and tribal programs when making health care decisions.

GOAL 1

Data Capacity for National Health Priorities

GOAL 2

Data Standards and Linkages for Longitudinal Research

GOAL 3

Technology Solutions to Advance Research

GOAL 4

Person-Centeredness, Inclusion, and Equity

COMMUNITIES

- HHS Agencies
- Researchers
- Patients & Families
- Providers & Payers

GUIDING PRINCIPLES

Person-Centeredness | Collaboration | Innovation | Impact

MISSION: Build and strengthen data capacity for patient-centered outcomes research through coordination across agencies and federal programs.

Mission

Build and strengthen data capacity for patient-centered outcomes research through coordination across agencies and federal programs.

Vision

Better data for patient-centered outcomes research to improve evidence generation, decision making, and health outcomes for all Americans.

Guiding Principles

- Person-Centeredness
- Collaboration
- Innovation
- Impact

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VISION 2029

Better Data.
Stronger Evidence.
Informed Decisions.

GOAL 1

Data Capacity for National Health Priorities

Build data capacity for patient-centered outcomes research that informs the needs of federal health programs, providers, and the people served by these programs.

OUTCOME

Data, tools, and services to improve patient-centered outcomes research relevant to HHS priorities.

OBJECTIVES

1.1 Identify the HHS national health priorities that would benefit from expanded data capacity to enable patient-centered outcomes research.

1.2 Address data infrastructure gaps to improve patient-centered outcomes research for the two research priorities – maternal health and intellectual and developmental disabilities – specified in the reauthorization of the PCORTF.

1.3 Develop a collaborative model within the OS-PCORTF community to address high-priority topics and increase expertise and data science workforce capacity.

1.4 Engage end users, including research data networks, PCOR researchers, and other entities within the PCOR ecosystem throughout the OS-PCORTF product development lifecycle.

GOAL 2

Data Standards and Linkages for Longitudinal Research

Expand longitudinal data resources that enable patient-centered outcomes research to advance evidence generation.

OUTCOME

Accessible, timely, interoperable, longitudinal, and linkable data.

OBJECTIVES

2.1 Support the development of pilots and maintain federal linkages for patient-centered outcomes research.

2.2 Support and promote ongoing development and adoption of common data standards for data for patient-centered outcomes research.

2.3 Advance the accessibility and improve the quality of longitudinal and complex data for PCOR users.

2.4 Assess the impact of policies related to privacy, security, and consent specific to patient-centered outcomes research.

GOAL 3

Technology Solutions to Advance Research

Leverage leading technology solutions to improve data capacity for patient-centered outcomes and comparative clinical effectiveness research.

OUTCOME

Robust RWD across platforms and systems used to generate RWE and expand data usage that informs patient, clinical, and policy decision making.

OBJECTIVES

3.1 Support implementation of new technology solutions to advance timely access to data for patient-centered outcomes research.

3.2 Develop and implement a coordinated strategy across OS-PCORTF projects to showcase use of technology solutions expanding comparative effectiveness research methodologies.

3.3 Use AI solutions to enhance accessibility to unstructured data that will further patient-centered outcomes and comparative effectiveness research.

3.4 Explore the use of new technologies to enhance patient-centeredness in patient-centered outcomes research.

GOAL 4

Person-Centeredness, Inclusion, and Equity

Expand the collection and analysis of socioeconomic, environmental, and other data so all people making health care decisions have the evidence they value about the outcomes and effectiveness of health care.

OUTCOME

Accurate, relevant, and representative evidence is accessible to individuals; communities; and state, federal, and tribal programs when making health care decisions.

OBJECTIVES

4.1 Continuously improve data capacity and infrastructure to support people who are medically underserved, underrepresented in biomedical research, and disproportionately affected.

4.2 Strengthen the collection and use of environmental data to support populations that are medically underserved, underrepresented in biomedical research, and disproportionately affected.

4.3 Strengthen the capacity to conduct economic impact analysis within OS-PCORTF funded projects.

Communities

- **HHS Agencies**
- **Researchers**
- **Patients & Families**
- **Providers & Payers**

Discussion Questions

1. What are the most important challenges you think we should address as we implement our new Strategic Plan?

2. What federal data do you wish was linked to EHR data or easily linkable to EHR data (such as housing, environment, labor, etc)?

3. What do you think we in the federal government should do to facilitate PCOR? What do you need from us?

4. How might we collaborate with you as we implement our strategic plan?

5. How might we disseminate and encourage uptake of our work?

See ASPE Website for OS-PCORTF Products

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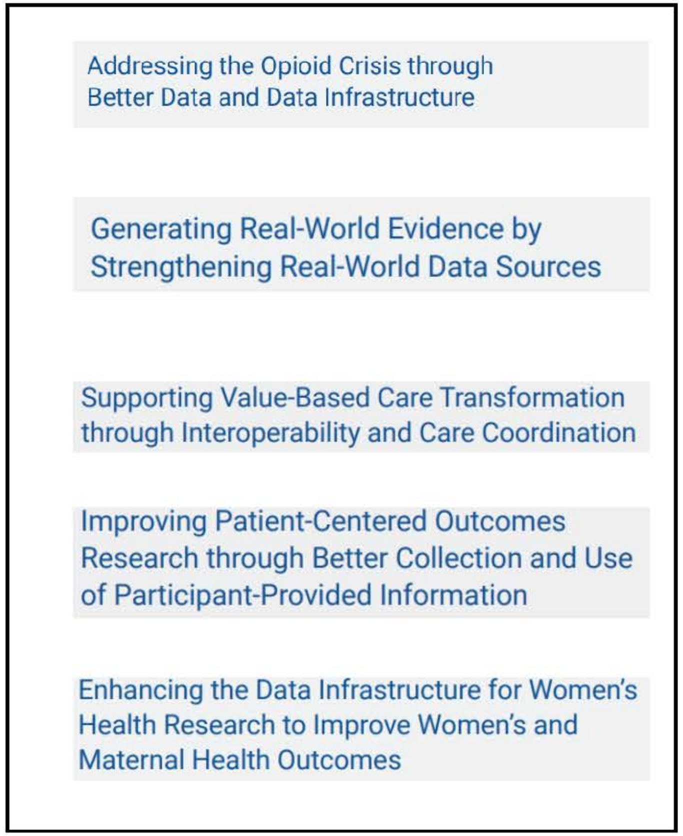
Building the Data Capacity for Patient-Centered Outcomes Research:
The 2020 Annual Report

Office of Health Policy
Assistant Secretary for Planning and Evaluation
U.S. Department of Health and Human Services

April 2021

Annual Reports



Addressing the Opioid Crisis through Better Data and Data Infrastructure

Generating Real-World Evidence by Strengthening Real-World Data Sources

Supporting Value-Based Care Transformation through Interoperability and Care Coordination

Improving Patient-Centered Outcomes Research through Better Collection and Use of Participant-Provided Information

Enhancing the Data Infrastructure for Women's Health Research to Improve Women's and Maternal Health Outcomes

Vignettes

OSPCORTF
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BUILDING DATA CAPACITY FOR PATIENT-CENTERED OUTCOMES RESEARCH
Portfolio Highlights (2016 – 2019)
Impact, Opportunities, and Case Studies

Full Report

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Portfolio Evaluation

https://aspe.hhs.gov/patient-centered-outcomes-research-trust-fund-reports

Thank you!