

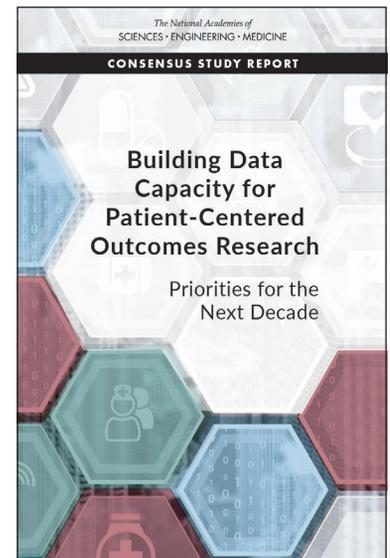


Building Data Capacity for Patient-Centered Outcomes Research

Priorities for the Next Decade

The Office of the Assistant Secretary for Planning and Evaluation (ASPE), in partnership with other agencies and divisions of the U.S. Department of Health and Human Services (HHS), coordinates a portfolio of projects that build data capacity for conducting patient-centered outcomes research (PCOR). PCOR focuses on producing scientific evidence on the effectiveness of prevention and treatment options to inform the health care decisions of patients, families, and health care providers, while taking into consideration the preferences, values, and questions patients face when making health care choices. The data infrastructure includes data sources and functionalities that support the research.

At the request of ASPE, the National Academies appointed a consensus study committee to identify issues critical to the continued development of the data infrastructure for PCOR and provide input for the development of a strategic plan that will guide the work in this area over the next decade. *Building Data Capacity for Patient-Centered Outcomes Research: Priorities for the Next Decade* summarizes the committee's findings and conclusions in the areas that could benefit from being prioritized as part of ASPE's work over the next decade. The report also offers input on how to enhance the overall framework for building the data infrastructure over the coming years.



OVERARCHING CONCLUSIONS

FOCUSING ON THE PERSON AS A WHOLE

Taking a holistic view of an individual's health, and broadening the focus of the PCOR data infrastructure from *patient*-centered to *person*-centered, could be transformative for both research and health care.

CONCLUSION: Broadening the focus from the patient to the person more generally and from populations to communities would enable a more comprehensive approach to the data infrastructure and a better understanding of the outcomes that matter to people.

ASSESSING THE IMPACT OF INVESTMENTS IN DATA INFRASTRUCTURE

Greater attention to how the uses of the PCOR data infrastructure are shaping knowledge, practice, and policy can meaningfully inform future investments in the data infrastructure.

CONCLUSION: A tighter feedback loop with the external end-users and developers of evidence would enhance the value of data infrastructure investments. Examining what evidence was generated due to ASPE interventions and identifying what impact it had on policy and knowledge would also help close the gaps observed in realizing the potential of the PCOR data infrastructure.

INCLUDING HIGH-PRIORITY TYPES OF DATA IN THE DATA INFRASTRUCTURE

The committee identified several emerging data needs and stakeholder priorities that are not well met by the current data infrastructure.

CONCLUSION: A variety of data types were identified that are less likely to be available or easily accessible in the PCOR data infrastructure, including data on mortality, cost of care, social determinants of health, and disability status, as well as other characteristics of people associated with disparities in health outcomes. Increased attention to filling gaps in the availability of these data will enhance the utility of the infrastructure for answering questions that matter to people and will enable research on potential intervention targets.

Data limitations make it difficult to answer many questions important for PCOR, and a reason for this is that most of the data available for research are collected for payment or treatment purposes, rather than for research. While ongoing work to increase the usefulness and availability of these data for research is crucial, there are also opportunities to incorporate additional and newer data sources into the data platforms used for research.

CONCLUSION: An area with opportunities for additional expansion is the collection of patient- and person-generated data and the routine integration of these data into data platforms that can be used both for research and for other purposes, including regulatory decision making and to inform shared decision making.

CONCLUSION: Patient-directed disease registries can be a source of in-depth, longitudinal, prospective clinical and patient-reported data that are not available from other data sources.

Adopting a longitudinal perspective on a person's journey through the health care system and through life events that are relevant to health more broadly could enhance the usefulness of the data and the data infrastructure.

CONCLUSION: Assembling a comprehensive longitudinal record of individuals' health journeys, which also includes the social context of their lives to the extent possible, would facilitate more far-reaching outcomes research.

ADDRESSING FRAGMENTATION

Data silos are a major barrier to research as well as to increasing the usefulness of the information available for decision making more broadly.

CONCLUSION: The data available for PCOR are fragmented across a variety of databases. Expanding data linkages could greatly increase the usefulness of these data for research.

CONCLUSION: Collaboration among federal agencies and between federal agencies and other partners to address barriers that hinder data linkages, such as the limitations associated with the lack of unique health identifiers and patient or person matching, will improve the PCOR data infrastructure. The usefulness of data available for PCOR could further be increased by sharing and adopting best practices among the states concerning the collection of data, data quality, and ease of access.

DATA NOT DESIGNED TO ADVANCE KNOWLEDGE

Developing standards for clinical data and enhancing the interoperability of data systems would facilitate the use of data for research, and ASPE has an important role to play in this area.

CONCLUSION: Standards are most useful when their development is driven by their potential uses and a clear concept of the value they can contribute.

CONCLUSION: Taking an international perspective is important for the development of a PCOR data infrastructure; in particular, the infrastructure focused on standards would benefit from building on work that happens internationally.

CONCLUSION: ASPE, in collaboration with other partners and stakeholders, could add significant value in the area of standards for PCOR by

- continuing to promote the development of a data infrastructure and an implementation strategy that facilitate the use of standards and access to the data;
- convening stakeholder meetings to enhance communication and work toward developing a common language for standards;
- facilitating access to the data and collaborations with existing organizations working in this area;
- leading efforts to catalogue and exemplify data standards and analytic standards for a holistic view of individuals' health; and
- increasing consistency in the use of standards for data interoperability and element definitions.

CONCLUSION: Prioritizing projects that address fidelity or use of standards may convey greater value for the PCOR infrastructure than developing new standards.

GOVERNING DATA ACCESS

Data access and privacy considerations are a recurring theme discussed by stakeholders, yet relatively few projects have been funded in this area.

CONCLUSION: This is an opportune time to revisit and update the legislation and rules governing data privacy and the sharing of data for research.

CONCLUSION: Governance challenges that create barriers to developing the PCOR infrastructure can be found at all levels of the system. Data availability could be increased by exploring challenges at the local level, including variable interpretations of federal laws and regulations, and by identifying approaches to address those challenges.

DATA ACCESS OPTIONS

While a variety of mechanisms exist for accessing PCOR-relevant data, these processes could benefit from additional streamlining to facilitate data use.

CONCLUSION: Investments in identifying mechanisms for facilitating the ability of researchers, patients, and other people to access data will contribute to increased use of the PCOR infrastructure.

CONCLUSION: Building and maintaining trust among the people and communities whose data are being sought for research is essential for producing high-quality data, and patient groups can be helpful partners in these efforts. Including representatives of patients and other people in the research process to understand how to measure health impacts that matter to individuals is an important component in building trust. Providing value back to data donors, such as through the sharing of research results, could help underscore the importance and benefits of the information to stakeholders, including individuals, families, clinicians, and communities, in addition to enabling them to use the information in ways they find relevant. These uses could play a particularly important role in reducing health disparities, complementing research efforts in this area.

CONCLUSION: Successful data-sharing partnerships across health care systems and government agencies require participant trust, clear evidence of mutual benefit, and the ability to control risk.

ADVANCING RESEARCH PRACTICES AND ANALYTIC METHODS

Advances in PCOR methods have led to renewed interest in aspects of how the research is carried out. Some areas in particular could benefit from additional attention in the coming years.

CONCLUSION: PCOR products would be enhanced by investing in methods that are essential for the conduct of PCOR, such as including persons throughout the research continuum, addressing problems of missing data, improving study designs, ensuring appropriate inference from methods utilizing observational data, and addressing structural bias in data systems and studies.

CONCLUSION: Applying best practices to the analytic methods used in PCOR is important to facilitate the reliability and reproducibility of study results.

CONCLUSION: The results of PCOR are only replicable and most useful when the underlying data and comprehensive research documentation (such as analytic code) are made available for use by others.

PROJECT SELECTION TO SUPPORT THE DATA INFRASTRUCTURE FRAMEWORK

The selection of projects to fund as part of the work on the PCOR data infrastructure merits careful attention, and some categories of projects may be particularly worthwhile to pursue because of a high expected return on the investment.

CONCLUSION: The development of the data infrastructure might be enhanced and critical gaps could be filled by proactively identifying necessary projects in areas that examine the overall framework for the PCOR data infrastructure, particularly in the context of broader issues such as the balance between privacy and increased data use.

CONCLUSION: Investments in areas unlikely to be funded or developed by other entities may have a particularly high value.

CONCLUSION: Investments in projects that have potential use and application beyond the condition or disease for which they are proposed will accelerate the use of the infrastructure.

DISSEMINATION OF RESULTS AND USE OF THE DATA INFRASTRUCTURE

Over the years, there have been increasing efforts to disseminate information about the PCOR data infrastructure and PCOR studies, but additional attention to dissemination could further increase awareness of the work.

CONCLUSION: There is a need to increase awareness among all stakeholders about new data infrastructure developments funded by the Office of the Secretary PCOR Trust Fund. Increased awareness will enhance the efficiency and effectiveness of research, which in turn will increase the impact of the investments made in infrastructure development.

CONCLUSION: Investments in implementing and disseminating infrastructure tools and products will accelerate the achievement of overall PCOR infrastructure goals.

CONCLUSION: Dissemination and translation of the research findings could be greatly enhanced by using forms of communication that are relevant to those outside the research community.

UPDATING THE DATA INFRASTRUCTURE FRAMEWORK

The PCOR data infrastructure has not yet reached its full potential to provide data that can answer the questions that matter to people and enable them to make informed decisions. Thinking of improved health as the North Star that guides decisions related to the data infrastructure (see figure) can further enhance the data infrastructure.

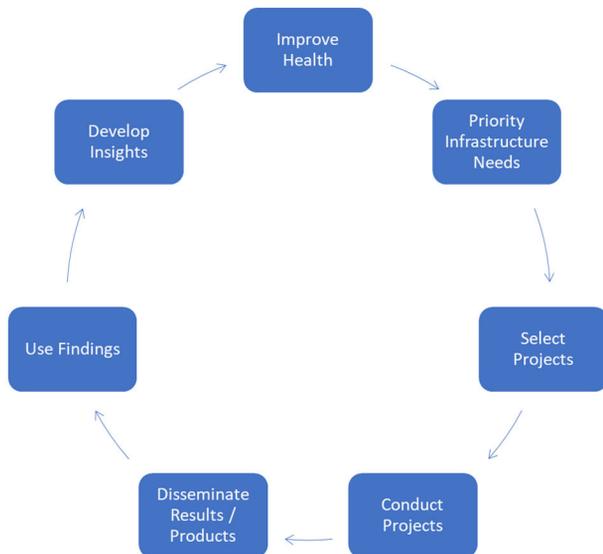


FIGURE A framework for the role of enhanced data infrastructure and effective project management in improving health.

CONCLUSION: Explicitly focusing on improved health as the goal of the PCOR infrastructure may be a useful way to prioritize projects and target infrastructure investments.

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

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For More Information... This Consensus Study was a collaboration of three units of the National Academies of Sciences, Engineering, and Medicine: the Committee on National Statistics, the Board on Health Care Services, and the Computer Science and Telecommunications Board. The Report Highlights was prepared based on the Consensus Study Report *Building Data Capacity for Patient-Centered Outcomes Research: Priorities for the Next Decade* (2022). Copies of the Consensus Study Report are available from the National Academies Press at www.nap.edu. Recordings of the workshops organized by the committee are available on the National Academies website at www.nationalacademies.org/PCORData. The study was sponsored by the U.S. Department of Health and Human Services. Any opinions, findings, conclusions, or recommendations expressed in this publication do not necessarily reflect the views of any organization or agency that provided support for the project.

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