

Implementing Patient-Centered CER: Elements for Success

The comparative effectiveness research (CER) provisions of the Patient Protection and Affordable Care Act (PPACA) provide a detailed blueprint for implementing CER that is patient-centered. While some details will not be defined until the independent research Institute created under PPACA is established, many important elements of patient-centeredness are defined in the statute. Through the Patient-Centered Outcomes Research Institute (PCORI), the law provides a unique opportunity to advance a CER program that is sustained, objective and patient-centered, and that has broad buy-in and trust from the patient and provider communities and the public at large. Since its creation, PIPC has been a leading advocate for patient-centered CER, and will work with stakeholders throughout the health care community and the Patient-Centered Outcomes Research Institute to advance research that empowers patients and providers and improves health care quality.

This chart provides an overview of the CER provisions related to patient-centeredness and explains why these are important to patients, physicians and other health care providers.

Elements of Patient Centered CER Included in PPACA	Legislative Summary	Why this matters to patients
<p>Define CER as a tool to improve patient care and meet patients’ medical needs</p>	<p>The bill states the purpose of the Institute is to support health care decision-making “by advancing the quality of evidence concerning how health conditions can best be prevented, diagnosed, treated, monitored, and managed through research and evidence synthesis that considers variations in patient subpopulations, and the dissemination of research findings with respect to the relative health outcomes, clinical effectiveness, and appropriateness of medical items and services.”</p>	<p>CER can play a valuable role in supporting good decision-making in health care. The law’s focus on improving the prevention, diagnosis, treatment and management of health conditions helps ensure that the CER research agenda is centered on better patient care, not narrow cost-containment . While comparative clinical effectiveness research can ultimately help make health care more efficient, focusing first on patient care is essential. In this way, it achieves CER’s potential of supporting physicians and patients by providing them relevant, objective information to help ensure each patient gets the care that best meets his or her needs.</p>

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<p>Giving patients and providers a meaningful role in directing the CER Institute and its research agenda.</p>	<p>The Patient-Centered Outcomes Research Institute is an independent, public-private entity and lead by a Board of Governors consisting of the Director of the Agency for Healthcare Research and Quality, the Director of the National Institutes of Health, and 19 other members representing various public and private sector interests, including members representing 3 patients and health care consumers and seven representing physicians, surgeons, nurses and other care providers.</p> <p>In addition, the Institute is authorized to appoint permanent or ad hoc advisory panels to assist in setting research priorities and the research agenda “and for other purposes.” The Institute shall appoint expert advisory panels for carrying out randomized clinical trials to inform study designs, and shall appoint an expert advisory panel for rare diseases to assist in the design of research. Advisory panels will include representatives from clinicians, patients and scientific experts.</p>	<p>To keep a new CER research entity centered on improving patient care, it is important for it to be independent so that it isn't dominated by any one group or interest. This means everyone in the health care community, especially patients and providers, needs to be included. In addition, it is important for patients and providers to have adequate representation so that the Board includes the diversity of perspectives in these areas, including patients, consumers, people with disabilities, minority health representatives, physicians, surgeons, nurses and others.</p> <p>The statute further ensures input from patients and providers through the creation of expert advisory panels that include representatives of practicing and research clinicians, patients, and other scientific experts. It is important to have input at this level to help ensure that the research projects supported by the Institute actually meet the real-world needs of patients and providers and don't overlook important patient groups such as people with rare diseases.</p>
<p>Ensuring full openness and transparency</p>	<p>Under PPACA, the Institute's Board must hold its meetings in public.</p> <p>The Institute is required to establish public comment periods prior to adoption of research priorities, the research project agenda, methodological standards, peer-review process, and after release of draft findings of systematic reviews. The Institute will also periodically host public forums to increase public awareness and better incorporate public feedback.</p> <p>The Institute is also required to make publicly available the process and methods for</p>	<p>The unprecedented level of openness and transparency for government supported CER will help ensure that the research is responsive to the real-world needs of patients and providers. Providing full opportunity for input early on, before decisions about specific research projects are made, and throughout the process as research questions and standards are set will continually reinforce PCORI's accountability to patients. Requiring public comment and stakeholder input on research policies, including how research results are translated and disseminated to patient and provider groups will help advance patient and</p>

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Ensuring full openness and transparency (cont'd)	<p>conducting research, the identity of the entity conducting each research project, and progress reports on its official website. It also must make public the comments received, as well as the proceedings of the Institute.</p> <p>The Institute also must submit an annual report to Congress and the President, and release it to the public. The report will describe Institute activities, research priorities, methods standards, project agenda and budget, and other information.</p>	<p>provider communication activities that will clearly communicate research results in ways that are accurate, useful and timely for patient and providers.</p>
Communicate research results to provide timely, accurate, relevant information to patients and providers to support their health care decisions.	<p>The Institute must make research findings available to patients, clinicians and the general public. Research findings:</p> <ul style="list-style-type: none"> ○ Must be comprehensible and useful to patients and providers ○ Must fully convey findings and discuss considerations for subpopulations, risk factors and co-morbidities ○ Must include limitations of the research and further research needs ○ May not include mandates for practice guidelines or policy recommendations ○ Must not release information that would violate patient privacy or confidentiality agreements. <p>The Institute is not permitted to mandate coverage, reimbursement, or other policies for any public or private payer. None of the research findings disseminated by the Institute may include mandates, guidelines or recommendations for payment, coverage or treatment.</p> <p>The Office of Communication and Knowledge</p>	<p>Every patient is different, so what works best for one patient may not work for someone else. In addition, each patient has different preferences and may make different choices faced with the same comparative effectiveness findings. That's why it's so important for research findings to be communicated in ways that help providers and patients apply the information to the individual patient's needs, rather than obscuring these differences through "one-size-fits-all" mandates. .</p> <p>This means discussing the different factors that can help decide which treatment is optimal for the individual, like the patient's particular medical condition and genetic variations.</p>

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Communicate research results (cont'd)	<p>Transfer at AHRQ, in consult with NIH, shall “broadly disseminate the research findings” of the Institute and other government funded comparative clinical effectiveness research. The office shall create informational tools that disseminate research findings to patients, providers, payers, and policy makers. The office also shall, in consultation with medical and clinical associations, promote timely incorporation of findings into clinical practices (e.g., via clinical decision support tools).</p>	
<p>Conduct studies that meet standards for high quality research and reflect the diversity of patient populations.</p>	<p>Research must be designed, “as appropriate, to take into account the potential for differences in the effectiveness of health care treatments, services and items as used with various subpopulations, such as racial and ethnic minorities, women, age, and groups of individuals with different comorbidities, genetic and molecular subtypes, or quality of life preferences” and include members of such subpopulations as feasible.</p> <p>The statute requires creation of a PCORI Methodology Committee tasked with developing standards for high quality research.</p>	<p>In order for research to be credible, it must meet high standards for quality and scientific integrity. Studies must be appropriately designed to answer the research question being asked, and must be free from bias. CER traditionally has focused on population averages, not differences in individuals. As understanding of differences in patient subgroups increased through advances in fields like genomics and patient-reported outcomes, this is starting to change.</p> <p>These provisions help ensure that CER research reflects the differences in patients based on factors such as genetics, health status, and patient preference. This will help ensure that CER reflects patients’ individual circumstances rather than encouraging one-size fits all solutions based on average study results.</p>

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<p>Establish research priorities that address the wide range of evidence gaps that must be closed to improve patient care.</p>	<p>Comparative clinical effectiveness research (CER) is defined as research evaluating and comparing the clinical effectiveness, risks, and benefits of two or more medical treatments or services. Services are defined as health care interventions, protocols for treatment, care management, and delivery, procedures, medical devices, diagnostic tools, pharmaceuticals (including drugs and biologicals), and any other strategies or items being used in the treatment, management, and diagnosis of, or prevention of illness or injury.</p> <p>The Institute will employ open, transparent processes to identify research priorities based on disease incidence, evidence gaps, practice variations and health disparities, potential for quality improvement, the effect on health expenditures associated with a health condition or the use of a particular treatment, patient needs, outcomes and preferences, and the relevance to assist in decision making, and the priorities established by the National Strategy for Quality Care.</p>	<p>To improve patient care, CER research should examine the range of issues that affect the quality of patient care. This includes the range of medical tests and treatments, and well as questions related to health care delivery and organization, such as benefit designs and care management programs. All of these elements of health care affect patients' quality of care and health outcomes.</p>
<p>Recognize emerging science of personalized medicine and the potential for targeted therapies that benefit specific groups of patients with rare and orphan diseases.</p>	<p>The reform law helps align CER with personalized medicine by requiring consideration of patient differences at the genetic and molecular level in the design of studies and development of research methods.</p> <p>Advisory panels will include patient and clinician representatives and may also include experts in scientific and health services research, health services delivery, and evidence-based medicine. Advisory panels may include a representative of each manufacturer of each medical technology that is included under the relevant research topic.</p>	<p>The emerging science of personalized medicine is changing the way we think about comparative effectiveness research. Advances in genetics and other fields like health information technology are giving physicians powerful new tools to understand which treatments are likely to work best on which patients.</p> <p>These advances hold potential to improve patient care and health care value. By taking steps to align comparative effectiveness research with personalized medicine, the statute helps support advances in personalized medicine.</p>

