

Comparative Effectiveness Research and Patient-Centered Outcomes Research

The Academy of Managed Care Pharmacy (AMCP) supports scientifically sound research that compares the effectiveness and value of prescription drugs, as well as research aimed at tailoring treatment options to individual patients' needs. Prescribers and patients value this information to evaluate treatment options and select treatments most likely to achieve a desired therapeutic outcome for a given patient. Entities that pay for prescription drug benefits use this information when designing benefits which ensure that the best value therapies are covered for the resources expended. Such research can support positive patient outcomes by encouraging optimal medication use while also promoting the prudent management of financial resources within the health care system. While there may be differences between the evolving definitions of comparative effectiveness research (CER) and patient-centered outcomes research (PCOR), AMCP believes that the following principles apply to both types of research in the context of managed care: the appropriate role of the federal government and other entities (both public and private) in coordinating, funding and disseminating the results of such research; the characteristics of research design; and the use of research results by patients, providers, and managed care organizations.

The role of the federal government and other entities (both public and private) in coordinating, funding and disseminating research

AMCP has supported efforts by Congress in the past that have advanced the role of the federal government in coordinating, funding and disseminating the results of such research. AMCP was also supportive of the Patient-Centered Outcomes Research Institute (PCORI), which was established by the Patient Protection and Affordable Care Act (P.L. 111-148). The Institute, which operates as a non-governmental, public-private partnership and which will receive dedicated, continuous funding from both the Medicare trust fund as well as fees paid by health insurers, will ideally provide needed leadership in the further development of both comparative effectiveness and patient-centered outcomes research. AMCP is also supportive of research conducted by other entities, such as academic institutions, managed care organizations and other stakeholder partnerships. In instances of privately-funded research, sponsors of the studies and any potential conflicts of interest should be clearly disclosed.

Characteristics of research design

Perhaps most importantly, it is essential that both CER and PCOR adhere to optimal research design and transparency standards. Randomized, controlled trials are preferred over observational studies when practicable. Additionally, research designers should be free to examine the relative values of the treatments studied, including costs, in addition to patient outcomes. In instances where several treatment options lead to similar outcomes of safety and effectiveness, other factors such as cost, convenience, or patient preference serve an important role in informing conclusions regarding the relative value of treatments.

The use of research results by managed care organizations, providers and patients

All research funded by the federal government should rightfully become part of the public domain and should be available to any interested party for use in making personal or patient care decisions. Ideally, sponsors of privately-funded research would make their findings publicly available as well, regardless of results. For years, managed care pharmacy organizations have been using CER and similar research as one of several variables when evaluating treatment options for coverage. Managed care organizations serve varied patient populations and therefore must retain flexibility to use the research results in the manner they deem most appropriate for the benefits designed for the populations that they serve. AMCP does not support any government mandate that would require coverage based solely on the results of any CER or PCOR study. Research results funded by the federal government should also be available to providers and patients to help guide decisions regarding the best course of treatment for each individual patient. To that end, research results should be presented in such a manner that they are understandable to a lay person, with a clear explanation of realistic outcome expectations, as well as any side effects that could be associated with the treatments studied. Similarly, entities that conduct privately-funded research should be encouraged to make research results available to providers and patients to help guide treatment decisions and should be encouraged to present the research in an understandable manner as well.

Conclusion

The results of CER and PCOR have the potential to provide invaluable insight to patients and providers searching for optimal treatment options, as well as managed care organizations and other payers as they design affordable benefits to best suit their patient population. Such projects must be well-designed and should include a comprehensive view of all treatments studied, including relative value and patient satisfaction. However, it is important for managed care organizations to retain the flexibility to use such research as one of several variables in the evaluation and determination of coverage for medications.

Please see AMCP's website for revisions and updates to our *Where We Stand* series:
www.amcp.org/positionstatements.

Revised by the AMCP Board of Directors, February 2012

Revised by the AMCP Board of Directors, April 2008

Approved by the AMCP Board of Directors, March 2004