

Introducing Perspectives on Comparative Effectiveness Research

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This issue of *PharmacoEconomics* is devoted entirely to issues related to comparative effectiveness research (CER). In recent years, there has been a worldwide evolution in evidence-based medicine to focus on real-world comparative measurement. The most recent manifestation of this trend is highlighted in the prominent role that CER is playing in health reform in the US. Perspectives on what CER is, how it should be implemented and what it will affect vary widely across healthcare constituencies.

As long-time observers and participants in many health economics and outcomes research debates, we were struck by the wide-ranging perspectives and implications of this critically important and increasingly relevant conversation. In response to these various perspectives, we sought to gather many of these voices and considerations together into a single volume.

This set of invited articles features perspectives on CER from thought leaders representing key vantage points: the pharmaceutical industry, pharmaceutical benefit managers (PBM), managed care pharmacy and various government and private payers (US, Canada and a cross-section of European and Pacific Rim countries), as well as opinion leaders in the areas of health economics and outcomes research. In some of these articles, the authors describe how their individual constituencies regard potential conflicts and implementation issues related to CER, and how CER may evolve in the US healthcare system as it undergoes reform. As the co-editors of this special issue, we consciously sought perspectives on CER from diverse constituencies that are highly

opinionated and often conflicting. While we sought to include papers with a traditional scientific orientation towards health outcomes research, in this compilation of perspectives we also wanted to invite debate as well as to include some 'white paper'-style position statements, as appropriate. The rich diversity of papers in this special issue includes attention to such issues as the interaction of CER with personalized medicine and its granular focus on individual effectiveness and safety outcomes as opposed to group-wide averages; the impacts of evolving CER requirements on drug development; and a wide range of methodological concerns, including several novel approaches to resolving complex analytical and data issues in connection with CER implementation. Our objective is to present a broad balance of perspectives that readers can use as a reference guide, albeit one that is different from the usual collection of applied papers found in *PharmacoEconomics*.

The articles in the International Perspectives section consider the evolution of comparative effectiveness-related research. Taken together, they suggest that, while there is receptivity worldwide to considering CER as part of the healthcare policy decision-making process, substantial barriers need resolution to incorporate real-world evidence, particularly in the context of treatment costs. The Policy and Implementation section adds further to this discussion by considering alternative societal and private perspectives about economic issues in prioritizing investments in CER, properly measuring costs, the impact on innovation, and the role of the

clinician in applying the knowledge gained from CER. Not surprisingly, the Industry Perspectives section includes articles that grapple with the practical implications of CER and whether these forces are 'catalyzing or colliding' in the context of drug innovation and development, reimbursement, and implications for patient care. Finally, the Methodological Considerations section presents some innovative suggestions to address several of the classic problems confronting researchers seeking to compare treatment outcomes in the context of limited real-world data.

In summary, the contributors to this special issue discuss a host of matters raised by CER considerations. There is movement to consider interventions that, while they have not typically been subjected to real-world observation, do have the potential to lead to improved outcomes

for at least some of the constituencies involved. As is made clear in these articles, stakeholders offer a divergent range of views on CER.

It remains to be seen whether CER will be a catalyst for conflict or a driver of positive change. How will resulting outcomes evidence be used, and what will be its policy impacts? How will various methodological issues get resolved? Will opposing points of view move toward a common ground, and in what areas is this most likely to occur? These are among the key topics that are taken up in this special issue.

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Guest Editors

Special Issue on Comparative
Effectiveness Research