

Editorial**Comparative Effectiveness Research (CER)... the Emperor's New Clothes?**

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The Ministerial Summit on Health Research in Mexico City in 2004, convened by the WHO, called for action by national governments to, “promote access to reliable, relevant, and up-to-date evidence on the effects of interventions based on systematic reviews of the totality of available research findings”¹.

Moreover, the concluding statement reinforced that these forms of research should be aligned with countries' priority needs and aimed at achieving internationally agreed-upon health-related development goals, including those contained in the United Nations Millennium Declaration. Priorities for future health research should in any event be based on the most important gaps in current knowledge and this should be integrated into both local and regional planning².

In order to optimize health outcome within the constraints of inevitably limited healthcare resources, low and high-income countries alike require unbiased means of assessing health care interventions for their relative effectiveness.

Systematic reviews allow one to examine what research has been done, where, and to what effect. They can underpin decision-making about healthcare interventions and research because they summarize vast information, identify benefits, harms or unproven interventions, and highlight gaps in research.

So What Is Comparative Effectiveness Research (CER) and Is It a Matter of Terminology?

CER has been defined by the Institute of Medicine as “The generation and synthesis of evidence that compares the benefits and harms of alternative methods to prevent, diagnose, treat, and monitor a clinical condition, or to improve the delivery of care”. Furthermore, its purpose is “to assist consumers, clinicians, purchasers, and policy makers to make informed decisions that will improve health care at both the individual and population levels.”

How Does CER Differ from Other Forms of Research Synthesis i.e. Systematic Reviews?

CER with its broader reach involves not only the assessment of randomized controlled trials but also a more heterogeneous body of evidence which may include pragmatic trials and other

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forms of study design i.e. observational research using data obtained in the course of general clinical practice.

The principal goal of CER is to allow decision makers (patients, clinicians, health care purchasers and policy makers) to make informed decisions on specific health care practices.

Its objective is to provide information at both individual and population level about benefits and harms, as well as costs and logistics of a range of policies or treatments. Therefore, it can be seen to encompass a broader range of interventions and tests to include strategies for prevention and health care delivery as well as those tailored to improvement in the quality of care.

This can best be summed up by the definition of CER by the Agency for Healthcare Research and Quality “*Comparative effectiveness reviews expand the scope of a typical systematic review, which focuses on the effectiveness of a single intervention, by comparing the relative benefits and harms among a range of available treatments or interventions for a given condition. In doing so, [they] more closely parallel the decisions facing clinicians, patients and policymakers, who must choose among a variety of alternatives in making diagnostic, treatment, and health care delivery decisions.*”

What Are the Key Features of CER and What Added Value Will This Provide to Clinicians and Purchasers of Care?

- Direct comparisons of tests or active treatments, i.e. head-to-head comparisons of viable clinical alternatives within current standards of practice.
- A deeper focus on patient-relevant outcome, which would enable patient and physician to make evidence-informed choices between effective treatments for specific health problems. It would include the identification of patient characteristics that are associated with meaningful differences in outcome and the examination of comparison of the economic implication of different approaches to prevention and care.

Therefore, the scope of CER includes new data, old data newly analyzed, and systematic reviews of existing research.

What Will This Mean for Journal Editors?

The editors from a number of medical journals outlined the principles of reporting CER studies³.

Standards for the Conduct and Reporting of CER

- CER studies should follow the highest scientific standards for design, analysis, and interpretation and should adhere to reporting guidelines that build upon initiatives to improve the quality and transparency of clinical science.

- Every CER study should have a research protocol, written in advance and addressing the key research question(s), methods, and planned analyses. Researchers should record all changes in the protocol. These protocols should be publicly accessible.
- Patients and other decision-makers should be involved in selecting and refining topics for CER.
- The study population for CER should be representative of clinical practice or the relevant public health practice.
- To increase transparency about selective publication, researchers should register CER studies before initiation, in a publicly available registry.
- To increase transparency about the practice of presenting post-hoc analyses as conclusive results, study registration should include a clear statement of study hypotheses, outcomes, and analysis plan.
- CER studies must undergo rigorous peer review by independent topical, methodological, and statistical experts.
- To ensure accessibility to the affected public and other researchers, journals (or other sites of publication) should make all CER studies freely available and archive them in a public repository, such as PubMed Central.
- Reports of CER must include a frank discussion of each study's limitations, including biases, confounding and scope of applicability.
- Given the potential impact of CER on the profitability of the interventions being evaluated, researchers performing CER studies must commit to stringent and enforceable competing interest policies.
- Researchers, funders, and other contributors to a CER study must clearly state all relevant competing interests at the time of peer review, and publicly upon publication in any forum.

Medical journals are the primary evaluators and disseminators of peer-reviewed health research. As such, they must ready themselves to play a crucial role in advocating CER, advancing CER methods and facilitating the translation of CER results into practice. Most importantly, journals and peer reviewers must do their part to ensure that CER, like all research with relevance to health, meets the highest scientific and ethical standards. They must therefore develop the methodological and statistical expertise to evaluate new or unfamiliar methods of health care research properly.

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