Cost-effectiveness analysis should be mandatory in clinical-effectiveness research

We read with interest the paper by Krahn and colleagues in the July 2 edition of the journal.[1] We agree with their arguments on the scientific value of cost-effectiveness analysis (CEA) and the broad need to incorporate CEA in clinical guideline development and public health decision making.

We suggest that we need to go a step further by mandating CEA for all clinical trials funded by governmental payers as part of the original study design. Several research funding agencies around the world (e.g., National Institute for Health Research and Medical Research Council in the United Kingdom) already strongly encourage this.[2,3] The Medical Research Council states explicitly that "An economic evaluation should be included if at all possible, as this will make the results far more useful for decision-makers."[3]

In 2005, the International Society of Pharmacoeconomics and Outcomes Research published the "Good research practices for cost-effectiveness analysis alongside clinical trials" report, updated in 2014.[4] It offers several useful directions to researchers on trial design, data management, analysis and reporting from a CEA framework, and we believe this serves as a readily available template for researchers and policy makers.

In our own sphere of expertise (critical care medicine), several examples of such joint economic evaluations exist, including the PRaCTICaL[5] and PAC-Man[6] trials. The PRaCTICAL trial studied the effect of postintensive care clinics on physical and psychological quality of life after discharge from critical care. The trial concluded that these clinics were not cost-effective owing to a lack of clinical effectiveness. The PAC-Man trial also offers some interesting insights on how joint CEAs are critical to the wider health care system and specifically to policy makers. This trial evaluated the clinical effectiveness of pulmonary artery catheters in the management of patients in the intensive care unit. While the trial itself found no difference in the primary outcome of mortality between the patients who received pulmonary artery catheters and those who did not, the economic evaluation that was undertaken in parallel indicated that withdrawal of pulmonary artery catheters from intensive care units would be cost-effective for the National Health Service.[7]

Nevertheless, we acknowledge that there are several challenges to the incorporation of CEA alongside clinical trials, including the use of uncommon or inappropriate comparators, and narrow inclusion and exclusion criteria that may reduce generalizability and pragmatism in trials that enhance compliance with interventions.[8,9] Additionally, in multinational clinical trials, there are challenges with wide variations in health care delivery and payer models. None of these issues, however, are insurmountable and demand only a deeper engagement by researchers at the trial design and analysis stages.

Public resources are finite, and numerous health problems and priorities compete for the same slice of the pie. The mere intent or ability to show clinical effectiveness in trials is inadequate to guide the health care delivery agenda. We believe it is time for policy makers and funders in Canada, including the Canadian Institutes of Health Research, to mandate CEA as part of all clinical-effectiveness research.

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