breast self-examination as our most powerful tool for early detection.

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Reference

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[The author responds:]

The debate around the publication of our recommendations[1] regarding the routine teaching of breast self-examination to Canadian women has certainly been lively. Our objectives were to systematically review the published evidence relating to the effectiveness of *routine teaching* of breast self-examination to reduce breast cancer mortality and to provide recommendations for clinicians regarding teaching breast self-examination to women in various age groups. We clearly stated that in cases where women wanted to learn the technique it was important for clinicians to explain the potential benefits and harms but also to provide thorough training to ensure that breast self-examination was properly and consistently performed. Also lost in the hue and cry about the review was the important difference between breast self-examination (a systematic, rigorous and regular examination of the breasts as a screening method) and ad hoc finding of breast lumps by women during the course of normal activities. Although the majority of women do not perform breast self-examination,[2] women do find their own breast cancers and do not wait for routine or chance visits to present their concerns to a physician or nurse. Although self-detection was the most frequent method of detection (58.1%) in a group of women aged 40–49 years who were diagnosed with breast cancer, less than half of the women (20.6%) found the cancer during breast self-examination.[3]

Leo Mahoney raises an interesting point: it may be possible to teach breast self-examination in a fashion that reduces the number of false positives, and research in this area may have some utility. Although decreasing the number of false positives would not increase the benefit of breast self-examination, at least the risks would be reduced. The bottom line is that breast self-examination education does not improve detection rates enough to affect survival, on the basis of currently available evidence.

In their letter, Anthony Miller and colleagues fail to mention the main finding of the nested case–control study by Harvey and colleagues: *no benefit of regular performance of breast self-examination*.[4] The fact that secondary analyses suggested a potential benefit for thorough versus less thorough breast self-examination is a distraction from the main finding and is at best useful for generating hypotheses.

Our systematic review methods required that the data included in the analysis be published in the peer-reviewed literature. Unpublished data that may or may not ever be available for all to scrutinize were excluded. Although information obtained via personal communications may supplement published data, it cannot form the basis of a process meant to be explicit, transparent and replicable. Should the data to which Miller and colleagues refer ever be published, an updated review might be warranted.

Unfortunately, Tammy Clifford and colleagues seem to have misinterpreted several aspects of the review. First, the analysis is of breast self-examination as a screening manoeuvre, not as a diagnostic technique. Breast self-examination cannot be evaluated in the same way as a diagnostic test. The goal of screening is not simply earlier detection, but improvement of relevant outcomes. It is quite possible to detect cancer at an earlier stage and thereby increase the time people must live with the diagnosis without improving outcome: this is clearly not a desirable result. In contrast to Ellen Warner's lack of faith in randomized trials, I believe that the evaluation of screening through the gold standard of randomized controlled trials is well established.[5] Although there may well be methodologic problems in designing trials of breast self-examination education, they can be overcome, as demonstrated by the researchers in the Shanghai trial.[6]

The recent Canadian study cited by Clifford and colleagues was designed to compare mammography plus clinical breast examination to mammography without clinical breast examination; it does not provide evidence regarding the impact of breast self-examination because breast self-examination was taught to all participants.[7]

Although we acknowledge the point made by Clifford and colleagues that double review of evidence is the latest evolution in the science of systematic reviews (and indeed has recently been adopted by the Canadian Task Force on Preventive Health Care), we are unaware of any data that conclusively link singly reviewed evidence to definitive bias, in particular when the evidence has gone through the Canadian Task Force's process, which involves thorough internal and external review and debate, followed by *CMAJ*'s peer review.

Certainly the development of core biopsy techniques for the evaluation of breast lesions reduces the morbidity of diagnosis. However, as a general surgeon I will state that there are many circumstances (i.e., size of breast, location of lesion, inability to image lesion, lack of access to advanced technology, patient preference) in which excisional biopsies for investigation are still necessary. In any case, unnecessary procedures are best avoided, particularly if they are not associated with any benefit.

The strong reaction of the public to our findings should indeed give pause for reflection. Women believe that breast self-examination saves lives because, despite a lack of evidence, they have been *told* that it saves lives: a triumph of hope over knowledge. To paraphrase Barron Lerner, a veteran of the heated and seemingly unending debate over screening mammography, "in the war against breast cancer, the benefits of early detection have been oversold."[8] Indeed, some, including the editors of *CMAJ*, have put forward the notion that "the rhetoric of cancer puts an intolerable burden of responsibility

and self-determination on the patient,"[9] and that the popular discourse of breast self-examination "blames women for not doing their part to reduce high breast cancer mortality statistics, establishes the locus of all reasons for refraining from the activity with the woman, and chastises these women for failing to engage in the activity."[10] In the future, sound evidence should be available before population screening is promoted, particularly when such screening may be associated with harm.

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Assessing the quality of clinical practice guidelines

Assessment of the quality of clinical practice guidelines (CPGs) is essential, and a systematic review of these guidelines is strongly encouraged. To that end, Ian Graham and colleagues have taken an important step in trying to assess the quality of a number of Canadian CPGs.[1]

The authors state that CPGs are "systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances." However, 38 (17.5%) of the 217 "guidelines" reviewed for this article were letters produced by the Therapeutics Initiative. In our opinion, these letters should have been considered as systematically developed reviews of evidence, not CPGs.

Since 1994, 41 Therapeutics Initiative letters have been produced. In general, our objective is to provide clinicians with an assessment and synthesis of published (and, whenever possible, peer-reviewed) evidence from clinical trials. The information is primarily, although not exclusively, a synopsis of the evidence from randomized controlled trials. We occasionally make recommendations in our letters for the "optimal" clinical use of drugs when supported by evidence from randomized controlled trials. We hope that clinicians combine these synopses with clinical judgement when making decisions about drug therapy for individual patients. Evidence from randomized controlled trials should also be the underpinning of all CPGs; however, in order to generate bottom-line recommendations, authors of CPGs often have to resort to less rigorous evidence or clinical opinion or both, owing to the limited availability of high-quality evidence.

For example, the most recent Canadian guidelines for initial management of community-acquired pneumonia furnish an exhaustive review of this condition; however, there is no clear evidence from randomized controlled trials favouring any one antibiotic regime.[2] In fact, the authors urge recognition that "these recommendations [for the selection of antibiotics] are derived by the consensus of experts and not entirely based on evidence from randomized clinical trials."[2]

These important differences between systematically developed recommendations (e.g., CPGs) and systematically developed reviews of the evidence (e.g., Therapeutics Initiative letters, Cochrane Library) render an appraisal instrument for clinical guidelines less appropriate for assessing systematically developed reviews of evidence. Many of the criteria in Table 1 of the article by Graham and colleagues are not relevant to the latter process. Nonetheless, these authors have presented a number of criteria relevant to both guidelines and systematic reviews of the evidence; we will review these to see if there are areas in which we can improve.

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Clinical guidelines have a more fundamental flaw than those discussed recently in *CMAJ*.[1,2] This flaw was expressed by the pioneer Harvard endocrinologist Fuller Albright. In his introduction to a textbook of medicine popular many years ago, he wrote that medicine can be practised by the rules