Commentary

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Controversy

Equipoise, a term whose time (if it ever came) has surely gone

David L. Sackett

ß *Dr. Sackett responds to Drs. Shapiro and Glass.*

I thank Drs. Shapiro and Glass for the spirit, as well as the letter, of their commentary. In the same collegial spirit I reply.

If a term is to do more good than harm in human affairs, it must pass at least the following 3 tests:

• Consistency: it must mean roughly the same thing to everybody who uses it.

• Reality: it must describe something that's real.

• Utility: it must be frequently employed to aid and justify decisions.

The term "equipoise" fails all 3 tests.

Consistency: Published definitions of "equipoise" vary wildly, and new, often-conflicting ones are still being generated that defeat attempts to distinguish any "theoretical" versus "clinical" distinction. Some users define it as a perfect balance of evidence and would "take odds of 1:1 on a bet,"[1] only to be contradicted by others to whom it means "the data suggest but do not prove" efficacy and safety.[2] Some permit its ownership by individual clinicians and patients,[3] but a letter in this issue insists that equipoise, "unlike uncertainty, can never be possessed by individual trialists."[4] Drs. Shapiro and Glass define their brand of equipoise as "uncertainty that rests with the expert clinical community as a whole."[5] By employing my transparent, old-fashioned term ("uncertainty") to define their opaque, newfangled one ("equipoise") they render things wonderfully clear, but leave me wondering why on earth they cling to such an arcane, confusing word. Nonetheless, and despite the general confusion, we appear to be in agreement that, at the community level, *uncertainty* over the efficacy and safety of a treatment provides a proper basis for conducting a randomized controlled trial (RCT).

Reality: A recent report to the Health Technology Assessment Programme of Britain's National Health Service has summarized it best: "There is some ingenuity in the equipoise theory, although its constraints seem bizarre if one tries to apply the theory in practice.[6]"

Utility: The term "equipoise" just hasn't been found useful at the coal face. My PubMed search yielded only 52 hits for "equipoise" (a text word that maps to no MeSH terms or trees at all), and none of them came from the reports of actual trials. On the other hand, a similar search yielded 292 860 hits for "uncertainty," and this word was commonly employed in primary reports of actual RCTs as justification for their execution. Moreover, "uncertainty" maps to the MeSH tree of "probability," the first branch of which is Bayes' theorem (a formula for reassessing uncertainty in the face of new evidence)!

Our remaining area of disagreement, the issue of individual uncertainty, points to a double shame. First, we clinicians who accept the awful responsibility of caring for individual patients with their unique risks, responsiveness, values and expectations have simply failed to communicate key elements of our decision-making to some ethicists and

methodologists who don't diagnose and treat individual patients. Second, and in part as a consequence of the first, the latter group frequently comes across as dismissing the crucial importance of trust in relations between clinicians and patients. Drs. Shapiro and Glass provide 2 glaring examples of the ethicist's failure to grasp the clinical realities. First, their definition of evidence-based health care stops with external evidence and ignores the other 2 of its 3 vital elements: clinical expertise and patients' values.[7] Second, they insist that a clinician who is reasonably certain that one of the treatments that might be allocated to a particular patient would be inappropriate for that patient "set aside his or her opinion, bias or 'certainty' in deference to the reasoned uncertainty that exists within the larger community of experts."[5] This command not only fails the test of reality (substantial proportions of "eligible but not randomized" patients arrive at that state precisely because they and their clinicians are reasonably certain which treatment they want or need). It also is inconsistent with the parallel and vital protection of the patient's autonomy and right to refuse to be randomized on the basis of their opinion, bias or certainty. Even those who use the term "equipoise" agree that it asks clinicians to violate trust in the physician–patient relationship.[8] I can't see the frontline clinicians and patients who actually carry out trials ever agreeing with the proponents of equipoise on this point.
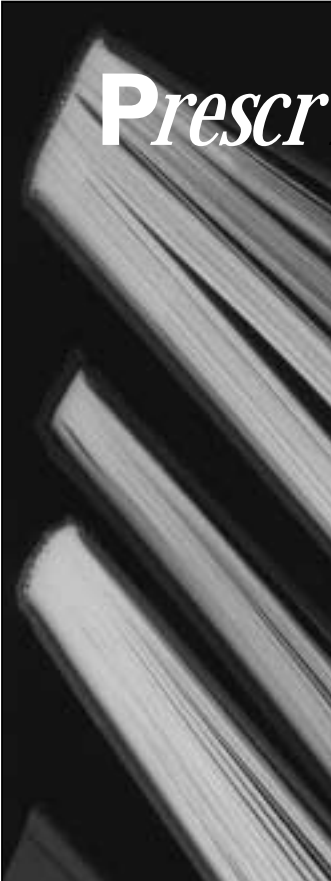
Dr. Sackett is Director of the Trout Research & Education Centre at Irish Lake, Markdale, Ont.

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Correspondence to: *Dr. David L. Sackett, Trout Research & Education Centre at Irish Lake, RR 1, Markdale ON N0C 1H0; sackett@bmts.com*