Reversals of Established Medical Practices
Evidence to Abandon Ship

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DEEPLY, GOOD MEDICAL PRACTICES ARE REPLACED BY BETTER ONES, based on robust comparative trials in which new interventions outperform older ones and establish new standards of care. Often, however, established standards must be abandoned not because a better replacement has been identified but simply because what was thought to be beneficial was not. In these cases, it becomes apparent that clinicians, encouraged by professional societies and guidelines, have been using medications, procedures, or preventive measures in vain. For example, percutaneous coronary intervention performed for stable coronary artery disease and hormone therapy prescribed for postmenopausal women cost billions of dollars and supported the existence of entire specialties for many years. Stable coronary artery disease accounted for 85% of all stenting in the United States at the time of the Clinical Outcomes Utilizing Revascularization and Aggressive Drug Evaluation (COURAGE) trial.1

Large, well-designed randomized trials that tested whether these practices improved major patient outcomes revealed that patients were not being helped. Defenders of these therapies and interventions wrote rebuttals and editorials and fought for their specialties, but the reality was that the best that could be done was to abandon ship.

How many established standards of medical care are wrong? It is not known. Medical practice has evolved out of centuries of theorizing, personal experiences, bits of evidence, expert consensus, and diverse conflicts and biases. Rigorous questioning of long-established practices is difficult. There are thousands of clinical trials, but most deal with trivialities or efforts to buttress the sales of specific products. Given this conundrum, it is possible that some entire medical subspecialties are based on little evidence. Their disappearance probably would not harm patients and might help salvage derailed health budgets. However, it is unlikely that specialists would support trials testing practices that constitute their main source of income. Instead, the research community performs studies of modest incremental value without even knowing whether the basic standards of care are appropriate.

Rarely, some investigators find the courage to test established “truths” with large, rigorous randomized trials. When this happens, empirical evidence suggests that “medical reversals” may be quite common. In an evaluation of 35 trials that were published in a major clinical journal in 2009 and that tested an established clinical practice, 16 (46%) reported results consistent with current beneficial practice, 16 (46%) reported evidence that contradicted current practice and constituted a reversal, and another 3 (9%) were inconclusive.2 Perhaps high-profile general medical journals are more prone to publish unusual results and less inclined to defend a clinical practice or specialized turf than specialty journals. However, it is unlikely that the selection filter in favor of reversal publications is stronger than the selection filter favoring the validation of standard of care. The mere testing of a standard of care generates interest because many standards of care are never tested. In another evaluation of trials published in 3 major general medical journals or high-impact factor specialty journals,3 of the 39 most-cited randomized trials published in 1990-2003 that found a significant benefit of a clinical intervention, 9 (23%) found effects stronger than those found in subsequent studies and 19 (49%) found results replicated in subsequent studies, but 11 (28%) remained largely unchallenged, with no large trial conducted on the same question.

Many medical reversals involve conditions for which the standard of care has been promoted over the years based primarily on pathophysiological considerations. Often one or more trials exist, but they have not tested clinically relevant outcomes or have been biased. For example, vertebroplasty—the injection of polymethylmethacrylate cement into fractured bone—gained popularity in the early 2000s for the treatment of osteoporotic fractures. Initial studies addressed the pathophysiology of this therapy, delineated the technical skills required to optimally perform the procedure, and furthered the discussion about the benefits of vertebroplasty. Claims of benefit were strongly contradicted in 2 randomized trials4,5 that included a sham pro-
Such an insistence on well-designed, large studies may be tantamount to clinical end points before being widely disseminated. Approval must be strengthened. This means that newly proposed practices, the standards governing drug and device approval, medical reversals also suggest that reality checks should be encouraged for established practices that constitute the core of medical care. Priority should be given to testing practices having limited or no prior randomized evidence for their use, reassessing old evidence that may no longer be relevant for current clinical settings, and evaluating therapies and interventions that are most expensive. If almost half of these practices are wrong, as empirical studies suggest, the principle of equipoise is fully satisfied and randomization is indicated.

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REFERENCES