

Comment on “Trends in Published Clinical Trial Phases Among Surgical Specialties, 2007–2017”

Surgical practices are more dynamic than in the past and are advancing at the speed of evidence and translation. Given that randomized controlled trials (RCTs) are the criterion standard source of evidence, it will probably come as no surprise to practicing surgeons that the annual rate of RCT public reporting is on the rise. In this issue, Niforatos et al elegantly confirm that not only has the rate of RCT reporting steadily increased over the last decade, but there has been a trend toward more reporting of phase IV studies.¹ The findings of Niforatos et al are important as they conclusively support that clinical investigators are making remarkable progress towards developing, testing and validating new approaches to surgical care across specialties. Their results indirectly suggest that surgical innovation is alive and well and that surgeons are overcoming barriers to conducting surgical trials. This deserves remark as there was a time when RCTs were thought to be beyond the reach of surgeons, with little expectation that surgery would advance with the benefit of scientific rigor.

Indeed, as the superiority of RCTs and the quality of clinical research was brought into focus at the turn of the century, barriers to surgical randomization were much discussed and detailed. Blinding, technical learning curves, doctor and patient equipoise, funding constraints, quality assurance, and quality control were called out as obvious challenges to the conduct of RCTs in surgery. Fortunately, the solution to achieving high fidelity technical quality, video-recording, was embedded in the technology of laparoscopic surgery, ending the need for costly, in person proctoring. Video-recording surgery immediately raised the quality of surgical RCTs by facilitating the standardization of technical requirements, surgeon credentialing and trial auditing.² The quality of individual trials may still be called into question, as it is all too common for studies to be too

small and underpowered, and yet, existing literature supports that the quality of surgical trials, overall, is improving.³ Clearly, we are heading in the right direction with surgical RCTs improving in both quantity and quality. Surgeons are now more likely to trust data over historic traditions. Without the application of rigorous scientific methods, it is inconceivable that we would have migrated away from the radical mastectomy or questioned the role of emergency surgery for appendicitis and diverticulitis. But what about impact? In an ideal world, life-altering, well-validated new practices would be adopted without hesitation, passing the benefits on to patients expeditiously. This is not, however, the reality. In fact, it is estimated that there is a 17-year delay for translation of research into practice, supporting the notion that there are barriers to translation, much like there were barriers to development of RCTs. This certainly is true for laparoscopic colectomy, which has not yet reached 60% adoption in nearly 2 decades, despite confirmed benefits. We have come to learn that the rate of adoption depends on many factors, including the magnitude of the risks and benefits of the new practice, the degree of certainty of the data and the motivations and degree of difficulty associated with implementation, which can range from managing new perioperative medications, retraining surgeons, or changing life-long dietary, tobacco or exercise habits of patients. Furthermore, most trialists consider publication and presentation of trial results as the culmination and conclusion of their effort, even though we now know there are several additional steps required to deliver the benefits to patients. With so much surgical evidence being generated each year, and so much to gain, it seems that now is the right time to turn our attention toward the emerging field of implementation science which is focused on closing the gap between research and practice.⁴

The trend toward more phase IV trials, as reported by Niforatos et al, is an important step in the right direction. Unlike phase III trials that test efficacy, that is, the performance of an intervention under ideal and controlled circumstances, phase IV trials test effectiveness, that is, the performance of an

intervention under “real-world” conditions. Even when phase IV trials confirm the new intervention is feasible, beneficial and safe when broadly applied, these studies only partially close the translational gap. To reach patients in meaningful numbers, requires either long lapses of time for passive diffusion and gradual adoption or more focused efforts to support scalability. Implementation science is an emerging field intent on accelerating the translation of research into practice to ensure that research return on investment is optimized. A key premise of implementation science is that active promotion of the new intervention, in the form of active dissemination of trial findings and identification and resolution of barriers to practice integration, is required to ensure timely and broad uptake. Although in surgery, it may be reasonable to speculate that barriers to the conduct of trials are also barriers to translation (e.g., technical learning curves, provider and patient resistance to new interventions) it is increasingly clear that to be effective at translation will require new knowledge and skills. If we are going to leverage the increasing volume of trials in surgery for the benefit of our patients, we need to further promote the trend in phase IV trials and start working on identifying and addressing barriers to translation.

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