Registries as Tools for Clinical Excellence and the Development of the Pelvic Floor Disorders Registry

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KEYWORDS

• Pelvic floor disorders • Registry • Urogynecology • Pelvic reconstructive surgery
• Postmarket device surveillance • Surgical device innovation

KEY POINTS

- Historically, surgical device innovation has been less regulated than drug development, although the Food and Drug Administration (FDA) has recently initiated efforts to strengthen the national postmarket surveillance system through registry development.
- Device registries gather information about how patients respond after medical or surgical devices are used or implanted and can provide postmarket surveillance of new technologies and allow comparison with currently established treatments or devices.
- The Pelvic Floor Disorders Registry was developed in collaboration with the FDA, device manufacturers, and other stakeholders to serve as a platform for industry-sponsored postmarket device surveillance, investigator-initiated research, and quality and effectiveness benchmarking, all designed to improve the care of women with pelvic floor disorders.

INTRODUCTION

Innovation without analysis is perilous, and *convention* without analysis is stagnant.

The goals of healing are what drive our commitment to medical and surgical progress. However, advancements in pelvic reconstructive surgery are plagued by the same catch–22 that envelops all surgeons in turmoil. How do we expand therapeutic options without accepting risk? How do we predict outcomes without performing the experiment? How do we care for the individual who has entrusted her health to us with the confidence that we are providing her our very best? The answer lies in a universal commitment to perpetual, honest, and critical performance analysis.

The author has no financial or other disclosures.
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Obstet Gynecol Clin N Am 43 (2016) 121–130
http://dx.doi.org/10.1016/j.ogc.2015.10.006 **obgyn.theclinics.com**
0889-8545/16/$ – see front matter

HISTORY OF SURGICAL INNOVATION

Randomized controlled trials (RCTs) have gained status and stronghold as the gold standard for evaluating the safety and efficacy of surgical interventions.[1] Yet, most surgical advancements have been accepted from nonrandomized trials and even single case reports.[1] The reason for this internal conflict is time. In modern history, the development of endoscopic surgery for the removal of the diseased gall bladder was first performed in 1985, using a surgeon-designed instrument. However, it was not until 2006 that the Cochrane Collaboration provided a meta-analysis of 38 RCTs with 2338 patients that allowed the investigators to confirm the benefits of laparoscopic over open cholecystectomy.[2] In those 20 years, laparoscopic cholecystectomy had already been accepted as the preferred surgical approach worldwide. When it comes to RCTs, time is not on our side. Patients and surgeons alike have become accustomed to the ever-changing landscape of treatment options, driven largely by in-the-moment device and technique modifications that stealthily creep into standard practice.

Unlike new medical treatments that have followed a formalized development process from bench to bedside, surgical innovation has largely been unregulated because of immeasurable factors, including operator, team, setting, learning curves, and variations in quality metrics.[3] In 1976, the US Congress passed an amendment designed to provide some type of premarket review for medical devices, now monitored by the Center for Devices and Radiologic Health at the Food and Drug Administration (FDA). Novel devices are submitted for premarket approval (PMA) similar to a new drug, whereas design updates (even those from new manufacturers) request a simpler premarket notification (also called 510[k]), which is basically an expedited review based on reports of "equivalence to legally marketed predicate devices."[4,5] The PMA and 510(k) reviews provide clearance for marketing and sales of new medical devices and specifically do *not* indicate FDA clinical approval, *per se*. These premarket submissions are required to provide performance testing to demonstrate any deviations from the predicate device and may include engineering, bench, design verification, and, if requested by the FDA, clinical trials.[5] Once a device has cleared the 510(k) process, it may serve as a predicate device for subsequent 510(k) submissions; however, problems with effectiveness and safety are not readily apparent because postmarket trials are rare.[6]

Although innovations in medical device technologies have translated into significant health advances, the standard review process for medical/surgical devices is less stringent, less expensive, and faster than for drugs.[7] The role of surgical innovation in pelvic floor disorders follows the trajectory of other subspecialties: improving patient outcomes, leading to innovation and, in turn, leading to uncertain risk, a risk that is squarely shouldered by trusting patients. So, how do we responsibly and proactively integrate daily, ever-changing surgical innovation into safe and effective surgical advancement? *The answer lies in the power of the collective*.

REGISTRIES: THE POWER OF POOLING DATA

The emergence of medical and surgical registries to bolster our understanding of treatment outcomes has been evolving over the past 20 years or more with notable success. Patient registries use observational study methods for collecting uniform data to evaluate specific outcomes from a population defined by a particular disease, condition, or exposure.[8] Patient registries can be used to learn about population behavior patterns, develop research hypotheses, collect tissue or blood samples, monitor outcomes, and study best practices. Although the purposes of patient