In Pursuit of Patient-Centered Innovation: The Role of Professional Organizations

*Ranee Thakar, MB, BS, MD, FRCOG**
and Geoffrey W. Cundiff, MD, FACOG, FRCSC†

As a specialty, urogynecology is really quite young, and we can see this youth in our collective consciousness or the pooled mood of our specialty. At this moment, that collective consciousness is a bit glum. Many of our colleagues in urogynecology share a collective perception that innovation in our specialty is under attack. This sense of loss of control introduces the topic of this commentary, the need to consider a new paradigm of innovation.

For the first time in our short history, we have been restricted by regulatory agencies from Australasia, to the United Kingdom, and to North America. Most recently, on April 16, of this past year, the United States Food and Drug Administration (FDA) published their latest safety action, ordering the remaining manufacturers of transvaginal mesh for prolapse of the anterior vaginal wall to immediately stop selling and distributing surgical mesh products in the United States.[1] This followed the Australian Therapeutic Goods Administration ban on transvaginal mesh in May of 2017,[2] and the surgical pause on transvaginal mesh in the United Kingdom, which included midurethral slings, issued in March of 2018.[3]

The media coverage of the dissension has been particularly polarizing and demoralizing, but more than that, the resulting limits on practice and available products have directly impacted our clinical work and what we can offer our patients. Many surgeons have had to resort to and in some instances retrain in older procedures such as colposuspension and autologous fascia sling insertion—procedures known to be efficacious but with higher complication rates and longer postoperative recovery than midurethral slings. The use of urethral bulking agents with a comparatively lower success rate has increased. Many companies in this space have simply stopped making and marketing their products. Under these conditions, we have heard increasing laments that innovation in urogynecology is dead. But is it? And how does innovation impact our specialty?

Innovation is often regarded as uniformly positive. The paradox is that some innovations diffuse rapidly yet are of unproven value or limited value, or pose risks, whereas other innovations that could potentially deliver benefits to patients remain slow to achieve uptake and may never make it to the bedside.[4] In spite of this duality, there is no doubt that innovation is necessary to improve the care we provide our patients and for the health care systems in which we work. Innovation empowers our patients to select a procedure based on potential risks and benefits.

The ultimate aim of innovation is to find a *new or significantly different* alternative that improves the efficiency, effectiveness, quality, sustainability, safety, and/or affordability of health care. The difficulty, however, is what the patient is told and understands when they are consenting to have a *new* procedure, and this is usually information the surgeon gives to the patient. New is often perceived as improved. But do our patients understand the potential unknown risks and benefits?

So we can accept the notion that innovation is good for our patients, but has it always been an integral part of urogynecology? Well, perhaps for the last 20 years. But before that, during the majority of the 20th century, surgeons' creativity was the main driver of innovation in urogynecology. When we think of recognized surgical innovators in our field, like Drs Marshal, Burch, and Tanago, or Drs McCall, Nichols, and Addison, their insights arose while performing surgery and lead to new solutions that evolved into new surgical techniques. Their revelations reached the rest of us through the surgical literature, most commonly through small case series with what we would describe today as short-term follow-up. These reports dutifully documented the complications that they witnessed but were lacking true evaluations of patient safety. In fact, valid investigations of efficacy using controls or even observational methodologies were surprisingly rare and usually published decades after wide acceptance of the new procedures. It is also worth recognizing that there has never been any regulation of surgical creativity leading to innovation.[5]

This report is being published concurrently in *Female Pelvic Medicine and Reconstructive Surgery* and in *International Urogynecology Journal*. The report is identical except for minor stylistic and spelling differences in keeping with each journal's style. Citations from any of the two journals can be used when citing this article.
From the *Croydon University, London, United Kingdom; and †Department of Obstetrics and Gynaecology, University of British Columbia Vancouver, British Columbia, Canada.
Correspondence: Geoffrey W. Cundiff, MD, FACOG, FRCSC, Department of Obstetrics and Gynaecology, University of British Columbia Vancouver, 1125 Howe St, 9th Floor, Vancouver, Canada BC V6Z 1H2. E-mail: geoff.cundiff@ubc.ca.
The authors have declared they have no conflicts of interest.
R.T. is president and a member of the Board of Directors of the International Urogynecological Association. G.W.C. was president and is a member of the Board of Directors of the American Urogynecologic Society. Neither R.T. nor G.W.C. has financial or other relationships that constitute a conflict of interest.
Presented at the second joint AUGS/IUGA Scientific Meeting, the 40th Annual Scientific Meeting of AUGS and the 44th Annual Meeting of IUGA. This was a co-presentation by both authors on September 25, 2019 at the joint meeting in Nashville, TN.

DOI: 10.1097/SPV.0000000000000842

The standards of scientific evaluation and reporting began to change in the 90s, and this was largely due to Ulf Ulmsten and his introduction of the tension-free vaginal tape (TVT) midurethral sling. Although this innovation was initially surgeon driven, the recruitment of an industry partner to create a product was a departure from just reporting a surgical technique and brought new standards to the process. Corporate responsibility to investors demanded a rigorous assessment of any new product, and the TVT was carefully evaluated for efficacy and safety.[6,7]

In an ideal world, this approach would have been compulsory for all new surgical devices. Unfortunately, the FDA's 510(k) process essentially eliminated the need for new products to demonstrate safety and efficacy. Subsequent manufacturers saw Johnson & Johnson having fabulous success with the TVT, so fiduciary responsibility to investors was also seen as redundant. And in this laissez-faire environment, the new corporate-backed innovation exploded. Although this brought tremendous investment and resources to surgical innovation within urogynecology, the process was not balanced. The missing element was the patient. And when safety concerns did surface, they limited further innovation. As we have now learned, defining safety and efficacy of new products is in the patient's best interest, and as physicians, it is our duty to protect those interests. This is the basis of patient-centered innovation.

PATIENT-CENTERED INNOVATION

What is patient-centered innovation? It shares many qualities with person-centered health care, which is a new way of thinking and doing things wherein patients can work collaboratively to improve the way health care is designed and delivered so that it better meets the needs and priorities of patients.[8] Patient-centered innovation, like person-centered health care, ensures that stakeholders and patients are equal partners in planning, developing, and monitoring innovation to make sure that it meets their needs while balancing efficacy and safety.

So how do we involve patients in the whole process of innovation? We need to review the role of our patients and their provider starting from when an innovative idea is conceived and developed to when it eventually crosses all the hurdles of the regulatory bodies and is available for use in patients. The patient needs to be in the center of the process and be involved, ideally from the beginning. Although a patient cannot be involved when a surgeon develops an innovative approach to a surgical dilemma, the use of that approach in a future patient should include the future patient(s). Do they see the potential benefits as outweighing the potential risk? And the patient perspective remains pertinent because that idea is further developed into a product that needs to be tested and approved. With changing roles, the patient now becomes necessary to the process.

If we are to pursue this ideal of patient-centered innovation, then we need to consider the forces involved in its optimization. There are 4 parties that are responsible for implementing patient-centered innovation: industry, regulatory bodies, physicians, and academics (Fig. 1). Let us consider these individually.

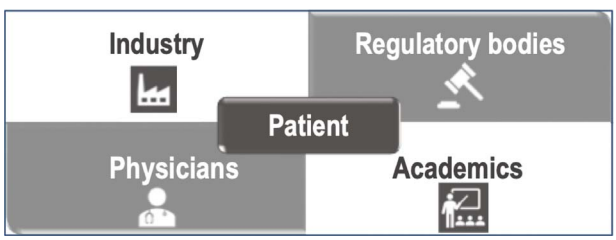

FIGURE 1. Four entities that influence patient-centered innovation.

Industry

When considering the impact of industry on patient-centered innovation, it is important to remember that their fiduciary responsibility is to shareholders. They create value for shareholders through the development of an effective and safe product, which underlines the imperative of research proving efficacy and safety. Of course, industry does not work within a vacuum. It is well to remember that products made of mesh in urogynecology were developed by industry in response to surgeons who were looking for newer techniques because they were dissatisfied with the outcome of available native tissue techniques for prolapse and incontinence.

However, discovery often focuses on the outcomes achieved by the innovator, neglecting the importance of spread and scalability of the innovation. We have recognized for years that adopters frequently do not realize the same results with a new intervention that are reported by the innovator.[9] There are many potential explanations for this phenomenon, from innovator bias, to learning curve, to system or cultural obstacles that vary by environment.[10] The importance of adopters is especially important to the successful implementation of a new product, because the variability in complications and effectiveness is usually what leads to product litigation. Clearly, successful implementation of new products should be a priority for industry, because their duty to shareholders requires companies to avoid litigation. Consequently, it is in the best interests of industry to apply resources not only to discovery but also to successful implementation of innovation. And this translates to ensuring adequate professional development for physicians adopting a new technology and resources devoted to following and reporting results in real-world circumstances.

Regulatory Bodies

Regulatory bodies, which are responsible to the government, are meant to be the gatekeepers for new innovation. Their role is to assess and monitor the safety of new medical products and regulate their sale. This process was compromised in the introduction of transvaginal meshes and tapes because of the 510(k) process that allowed products to be cleared and legally marketed based on similarity to prerequisite devices without full evaluations of efficacy and safety. Later, because issues of safety became apparent, the regulatory bodies had to invoke new regulations on products that were already in use.[11]

Changes are needed and are currently being implemented. Regulators need to ensure that new products are adequately assessed not only for efficacy but also safety in phase 1 studies before introduction into clinical practice. If it is not available, new procedures should be restricted to experimental or research settings until an adequate body of evidence is available for routine use. They also need to ensure that the results are generalizable through continued long-term outcome monitoring, and this is probably best done by developing unbiased registries that include patient-reported outcome measures and complications. Finally, before a new product is introduced to the market, considerations need to be given to support, training, and systems to ensure its optimal implementation.[10]

The complexity of the role of regulatory bodies is compounded by the fact that regulations throughout the world vary greatly. To counter this, a voluntary group of medical device regulators from around the world have come together to build on the strong foundational work of the Global Harmonization Task Force on Medical Devices and to accelerate international medical device regulatory harmonization and convergence.[12]

Physicians

Physicians are the third group that are necessary to accomplish patient-centered innovation. Our fiduciary responsibility is

to the individual patient. Of course, no 2 patients are the same, which is why they benefit from treatment choices. However, for them to compare different treatment options, patients need to understand the benefits and risks of the available treatments.

Within the context of shared decision-making, it is the surgeon's responsibility to ensure that patients comprehend the benefits and risks of alternative treatments. However, this framework is compromised by innovative procedures for which the long-term and even short-term outcomes are unknown. Moreover, a surgeon innovator who is enamored of the new procedure also potentially compromises the informed consent process, through the loss of objectivity. In fact, patients tend to lose objectivity themselves toward innovation, because our society perceives innovation as not just *new* but also *improved*. This can be particularly misleading for patients when innovations are used in marketing campaigns by hospitals and physicians.

If the surgeon providing informed consent is not the innovator but an adopter, then the patient could suffer from poor generalizability of purported outcomes. What is the learning curve for the new procedure, and where is the adopter on that curve? This highlights the challenge of lifelong learning for surgeons and the importance of effective professional development that uses simulation and preceptors to ensure that patient safety is not compromised by the introduction of innovative procedures.

Recognizing the challenges that innovation brings to effective informed consent and shared decision-making highlights the potential harm to patients from imprudent surgical innovation, and yet limiting innovation through excessive regulation also harms patient care in the long run. The answer is not stricter oversight but better training of surgeons to strengthen their understanding of the ethical issues associated with innovation and the primacy of the patient in that ethical framework. Finally, surgeons should perform surgery if they are adequately trained in this subspecialist area, perform such surgery on a regular basis, and are aware of all potential therapeutic options.

Academics

The relationship between academics and industry is a double-edged sword, for it carries with it the potential of an exciting future as much as the possibility of misappropriation. Most clinical research, especially randomized clinical trials, involving new products, are expensive and are mostly funded by industry, yet these investigations are often led by very well qualified academics.

The ties between clinical researchers and industry include not only grant support but also many other arrangements. Researchers serve as consultants to companies whose products they are studying, join advisory boards and speakers' bureaus, enter into patent and royalty arrangements, agree to be the listed authors of articles ghostwritten by interested companies, promote drugs and devices at company sponsored symposiums, and may allow themselves to be plied with expensive gifts and trips to luxurious settings. Many also have equity interest or shares in the companies.[13]

Academic institutes increasingly use conflict of interest declarations to try to manage faculty members with these complex relationships. This is complicated by the fact that some academic institutions enter into partnerships with industry to set up research centers and teaching programs in which students and faculty members essentially carry out research. Although the ultimate goal and mission of the institution and industry are different, both sides benefit in this arrangement. For cash-strapped medical centers, it means financial support. For the companies that make the drugs and devices, it means access to research talent, as well as affiliation with a prestigious institute or key opinion leader from the field and help with technology transfer from the laboratory to the marketplace.[14]

Although there are mutual benefits to both industry and academics, refocusing innovation on the patient requires a paradigm shift in academia and industry interactions. The cooperation should be at arm's length, with both sides maintaining their own standards and ethical norms. Strong conflict of interest policies should be in place. Financial arrangements for writing and presenting need to be reconsidered. What is not well known is that the costs of the industry-sponsored trips, meals, gifts, conferences, and symposiums and the honorariums, consulting fees, and research grants are simply added to the prices of drugs and devices.

We have already considered a number of threats to successful patient-centered innovation that flow from the interactions of industry, academics, physicians, and regulatory bodies, and our recent history as a specialty provides clear tangible examples from which we can learn. The introduction of transvaginal mesh kits for prolapse offers a concrete example of innovation that was not patient centered. The evidence that was used to market these products was largely based on the experience of the innovators, who were usually physicians within our field. These innovators became strong advocates based on their own positive experience. When the products were used in different settings by less experienced surgeons, the results were less beneficial with significant complications. This was a failure of implementation of innovation, as well as a failure of continuing education of practicing surgeons.

As already noted, the absence of a meaningful regulatory system allowed the marketing of products for which there was inadequate evidence of safety and efficacy. Although this was an omission on the part of the regulatory bodies, there is adequate blame to go around, because manufacturers marketed products they knew were inadequately tested and physicians used them. In the absence of adequate evidence of safety and efficacy, how could they provide patients with reasonable benefits and risks?

So all of these entities failed to meet their responsibilities in this case, but how do we prevent this moving forward? Ethical surgeons are the key to balancing the risks of unregulated surgical innovation with the risks of no innovation due to overregulation. This highlights why new innovations should be restricted to research settings until adequate evidence is accumulated.

THE ROLE OF PROFESSIONAL ORGANIZATIONS

Increasingly, we see that the ongoing development and evaluation of innovations necessitate continuous information, education, and training of health care professionals. Who are better placed to assume this role than professional organizations?

Professional organizations are run as nonprofit associations governed by peers. Both at the national and international levels, these associations have access to diverse expertise, have governance structures in place, are transparent in their goals, respected and representative of their constituent bodies, and comprise a network of members that can ensure dissemination of information and accessibility.

The annual meetings are more than formal events where academics share data on efficacy and safety of new products. They offer a venue for physicians, academics, industry, and regulatory bodies to interact. They provide a unique opportunity to network at a personal level, exchange ideas, and learn from each other. These meetings also provide industry a chance to meet physicians and familiarize them with new products. More importantly, the younger generation gets the opportunity to listen and interact with experienced colleagues who can model ethical innovation, thereby empowering them to become future leaders in the field.

The importance of physician education to successful implementation of innovation keeps coming up. For the last few decades, manufacturers of surgical devices have seen training of surgeons on these devises as their responsibility and they have spent millions of dollars to accomplish this. And yet, education is not within the skill set of industry, which generally hire the innovators to provide training in short formats that are not tied to the development of competence or credentialing. In contrast, our societies are experienced purveyors of professional development. They can provide impartial perspectives on new technology, with simulation-enhanced workshops, competence-focused curricula, and a patient-centric approach that highlights benefits, risks, and alternative treatments. In fact, these expertise and equipoise are why education provided by professional organizations can seek continuing medial education accreditation.

The value of "arm's length equipoise" that professional organizations have for education also applies to research. Research funds to evaluate new innovations that are directed through professional organizations or their foundations eliminate the perceived bias associated with direct industry funding. Surgical registries, such as the International Urogynecological Association (IUGA) Surgical Registry (https://www.iuga.org/resources/surgical-database) and the AUGS Urogynecology Quality Registry (https://www.augs.org/aquire/), provide an excellent receptacle of ongoing knowledge on safety and complications and how well the new innovation is implemented in the real world. Professional societies can advocate for funding for research projects, strictly following the code of conduct. Our societies have all the key opinion leaders and thus the knowledge. To make this work effectively, careful guidelines need to be in place so that there is no misappropriation. And when we have data, this can effectively be transferred to our wide membership through our journals and presentations at annual meetings.

As we become more aware of the important role that professional organizations have to play in cultivating patient-centered innovation, it is worthwhile to consider what are the greatest obstacles to realizing it. We have noted the importance of a responsible regulatory process and the need for separation between industry and the academy that provides research to determine safety and efficacy for new technology. What we have neglected is the inclusion of the patient voice. Let us be clear that professional organizations are formed to serve the needs of their members, but a better understanding and inclusion of the needs of our patients are part of this equation. We need to be advocates for our patients.

For those of you who have feared that innovation in urogynecology is dead, be reassured that it is far from dead. Instead, it is reconstituting itself in a new format that will allow patient-centered innovation to flourish. Your professional organizations, IUGA, and American Urogynecologic Society (AUGS) are already cultivating the ground. For example, both IUGA and AUGS are maintaining a balanced approach to assessing new technology while celebrating the very best in science. This year at the joint AUGS/IUGA Scientific meeting, we held and expanded the basic science session and AUGS sponsored the Prolapse Consensus Conference, whereas IUGA held the International Urogynecologic Consultation to develop a consensus document on prolapse. Examples outside the annual meeting include webinars and podcasts that keep members abreast of new innovations.

But we are also ensuring that investigation maintains an appropriate focus on patient safety. The focus on patient safety is seen in AUGS work with FDA to develop a framework for longitudinal collection of real-world data, and both societies work with industry to facilitate 522 studies. In fact, our combined meeting included a session to present late breaking results from the 522 studies along with discussion. We have also dedicated resources toward the management of patient complications, including workshops, research support for new studies focused on surgical complications, and a jointly written Position Statement on the Management of Mesh Complications by Female Pelvic Medicine and Reconstructive Surgery specialists, which will be published shortly.

But perhaps the most important steps toward patient-centered innovation are the recent efforts to engage patients and advocate for their needs. Both organizations have developed websites dedicated to patients with pelvic floor disorders, and IUGA's website includes patient resources available in 19 different languages.

The AUGS has created a new patient advisory panel composed of patients with pelvic floor disorders. The goal for the group is to inform the AUGS Board and Committees on issues of importance to women with pelvic floor disorders, and this will include providing a patient's perspective on new clinical guidance documents, patient information materials, and quality improvement activities. The IUGA is in the process of developing an international patient advisory group.

Our organizations have both sought to cultivate strong industry support of innovation through collegial relationships with industry while ensuring that funding is at arm's length. Examples include the development of the IUGA surgical registry and AUGS Urogynecology Quality Registry. These registries help the companies to meet regulatory requirements while ensuring that implementation of new technology is optimized.

Similarly, the AUGS Foundation and The Foundation for International Urogynecological Assistance (FIUGA) facilitate interactions between academic members and industry through the provision of third-party research grants. And increasingly, our organizations are providing third party education to clinician members around new technologies, for example, through the Fellow's Cadaveric Course. This allows industry to ensure that adopters of new technology are optimally trained without a conflict of interest.

Lastly, AUGS and IUGA are cultivating a culture of transparency that is necessary to truly create patient-centered innovation. For example, AUGS will provide an addendum to their annual report this year that will provide public transparency on industry support. We also want to celebrate the innovators in our specialty, so AUGS is announcing a new lectureship for future meetings, the AUGS Innovation Lectureship that will celebrate innovation in medical devices, surgical technique, education, and patient care. The IUGA is introducing a prize for the abstract based on the most innovative concept—the IUGA innovation abstract.

CONCLUSIONS

The management of all conditions evolves over time, and consequently, mature surgical specialties are not defined by individual procedures. Our patients benefit from this progression because it provides choices of alternative treatments that will fit their specific conditions and personal priorities. Viewed from this perspective, the patient becomes the center of ethical innovation that defines the framework of how innovation will proceed. Moreover, your professional organizations provide the nexus to optimize ethical interactions among parties that will allow patient-centered innovation to flourish.

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