An Advisory Committee for the Regulation of Innovation in Gynaecologic Practice: Development and Implementation

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Abstract

The fundamental precepts that underpin the delivery of all medical care are safety and efficacy. Although these precepts, in theory, are accepted without challenge, in many settings where clinical care is delivered, there is a lack of formal oversight necessary to ensure their implementation in practice. Even though most medical specialties have national bodies that provide guidelines for good medical practice, and hospital accreditation makes reference to dissemination of such guidelines, there is usually not a mechanism to monitor medical uptake and adherence to good practice in the day-to-day delivery of care. Most hospitals require approval by an institutional review board before research protocols can be undertaken, but regional health authorities and hospitals do not usually have formal processes in place to regulate the adoption of new technologies into clinical practice.

Recognizing the lack of a formal process at the hospital level to guide and regulate the introduction of new technologies or procedures, we set out to establish an oversight process to fill this gap. A committee was established to oversee innovation in the Gynaecology Division of our hospital. We describe here the establishment of this committee, the tools the committee used, and the processes used for the committee to do its work. We conclude that formal, local oversight of medical innovation is indispensible for ensuring the high standards of medical practice necessary to optimize patient safety.

Résumé

La sécurité et l'efficacité constituent les préceptes fondamentaux qui sous-tendent la prestation de tous les soins médicaux. En théorie, on accepte ces préceptes sans les remettre en question. Dans nombre de milieux cliniques, cependant, il n'existe aucune supervision formelle pourtant nécessaire à leur mise en pratique. La plupart des spécialités médicales sont dotées d'organismes nationaux qui proposent des lignes directrices relatives aux pratiques médicales exemplaires, et l'agrément des hôpitaux fait référence à leur diffusion. En général, toutefois, il n'existe aucun mécanisme de surveillance de l'adoption et du respect de ces pratiques exemplaires dans le cadre de la prestation quotidienne des soins par le personnel médical. La plupart des établissements hospitaliers doivent obtenir l'autorisation d'un comité de révision avant d'appliquer leurs protocoles de recherche. Cependant, les autorités régionales de la santé et les hôpitaux régionaux n'instaurent généralement aucun processus formel pour réglementer l'intégration des nouvelles technologies à la pratique clinique.

Conscients de l'absence de processus formel visant à orienter et à réglementer l'introduction de technologies ou d'interventions nouvelles en milieu hospitalier, nous avons cherché à établir un processus de supervision afin de combler cette lacune. La création d'un comité a permis à la division de gynécologie de notre hôpital de superviser l'innovation. Dans le présent document, nous décrivons la fondation de ce comité, ainsi que les outils et les processus auxquels il recourt pour accomplir ses travaux. La supervision formelle de l'innovation médicale à l'échelle locale est indispensable, d'après nos conclusions, au respect de normes élevées de pratique médicale, qui sont nécessaires à l'optimisation de la sécurité des patients.

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INTRODUCTION

Medical practice is inherently autonomous. Before beginning to practise medicine, physicians must complete a formal training process at an accredited institution. They must then satisfy the licensing authorities and hospital boards that they are qualified to practise by providing proof of training and successful completion of appropriate examinations. Once a physician has entered medical practice, oversight of that practice falls to the licensing authority of the region and to the administration of the facilities that accepted his or her credentials. Traditionally, these organizations have relied on the public and medical colleagues to monitor the practice of an individual physician and to report malpractice. Physicians only come to the attention of these oversight bodies as a result of an egregious deviation from accepted medical practice or when a serious medical complication occurs. Although this oversight process helps to ensure a measure of safety for patients, it is not designed to detect and follow

more gradual changes to medical practice or to evaluate the resulting effect these changes may have, whether positive or negative, on the delivery of care.

Although most medical specialties have national bodies that provide guidelines for good medical practice,[1,2] and hospital accreditation makes reference to dissemination of such guidelines,[3] there is usually no mechanism to monitor medical uptake and adherence to good practice in the day-to-day delivery of care. The delivery of modern medical care involves the use of an extensive array of "tools" that include medications, medical devices, diagnostic processes, and therapeutic procedures. Many of these "tools" are furnished by the pharmaceutical and medical device industries. The profit motive, by necessity, drives industry behaviour.[4] If this motive leads to the development and availability of products that enhance the delivery of medical care, then the practice of the physician, whose goal is to deliver safe and effective care to patients, is improved. In the clinical environment, however, members of industry are often in competition, offering multiple options and actively courting physicians. Industry touts innovation as the key to the most up-to-date and effective practice. Medical practitioners assume that regulatory authorities have carefully vetted new products before licensing; this assumption is not always valid.[5]

An example of how regulatory oversight of innovation failed is the widespread introduction of mesh kits for the surgical correction of pelvic prolapse in the United States. The Food and Drug Administration in the United States requires a premarket approval application that includes evidence of safety and effectiveness from large clinical trials for all new pharmaceuticals. On the other hand, a class I and II device intended for human use, for which a premarket approval application is not required, demands only a 510(k) application to the FDA. A 510(k) application assumes that new devices are essentially equivalent to those already in the market.[5,6] The mesh kits for pelvic prolapse were cleared for use through a 510(k) process. The use of these kits resulted in unacceptably high rates of complications that often necessitated their surgical removal. The FDA and Health Canada subsequently issued a warning concerning the risks associated with surgical mesh kits used for the treatment of pelvic prolapse and called for withdrawal of the kits.[6,7]

The surgical mesh example highlights the need for an additional layer of oversight for medical innovation at the level of the health professional. Once a medical device has been cleared for manufacture and distribution, government does not regulate use of the product.[8] Self-regulation by surgeons, individually and collectively, remains key to ensuring patient safety. This self-regulation requires the highest levels of professionalism.[9] A surgeon's motivation to introduce a new procedure or technology into his or her practice may include one or more of the following: the desire to provide the best care to patients, the lure of the procedure, the drive to remain competitive among peers, or demand from the patients themselves.[4] Feeling these pressures to innovate, the average busy clinician may be tempted to introduce new procedures or devices into their practice despite not having the expertise and time to adequately evaluate innovative therapies before introducing them to patients. Even though most hospitals require approval by an institutional review board before research protocols can be undertaken, most regional health authorities and hospitals do not have formal processes in place to regulate the adoption of new technologies into clinical practice. The result is a haphazard process whereby individual clinicians adopt new equipment and procedures as they see fit, with only a loose oversight by the medical executives in their facility. This lack of regulation often results in early adoption of therapies that have not been subjected to the rigorous evaluation a clinician or a consumer would expect to have taken place.[10] An ineffective treatment squanders resources and disappoints patients. A treatment with significant unanticipated side effects or complications can result in harm to patients, as was the case with the mesh kits used for pelvic prolapse.

Recognizing the lack of a formal process at the hospital level to guide and regulate the introduction of new technologies or procedures, we set out to establish an oversight process to fill this gap.

Committee Development

A committee was established in 2010 to oversee innovation in the Gynaecology Division of our hospital. The mandate of the committee was to introduce a formal process for the evaluation and approval of medical innovation in clinical gynaecologic practice. The committee was chaired by the Chief of Gynaecology, and its membership included a physician from each discipline in the Gynaecology Division (urogynaecology, reproductive endocrinology and infertility, and general gynaecology), the clinical leader of Operative Services, the Manager of Gynaecology and Breast Health, and a resident representative. The committee was designed to examine any new gynaecologic innovations as they were proposed for use in the hospital. Additionally, the committee also met to develop the

ABBREVIATION

FDA Food and Drug Administration