Facilitating Innovation in the Clinical Setting: A Pathway for Operationalizing Accountability

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Illustrative Case
A pediatric surgeon goes to a national conference and hears a presentation about a new minimally invasive operation for the correction of pectus excavatum (“funnel chest”). The operation involves the placement of a stainless steel bar behind the sternum, using two incisions, one on each side of the chest, and visualizing the bar insertion using a small thoracoscope. He is interested in trying it and subsequently attends a two-day course that is offered by the surgeon who developed the technique.

The surgeon performs the procedure on eight patients with successful results. The ninth patient to undergo the procedure has a routine preoperative evaluation, and the beginning of the operation goes uneventfully. However, when the surgeon is passing the bar behind the sternum, there is sudden onset of severe bleeding that requires the surgeon to do an emergency sternotomy. At that time the surgeon finds a laceration to the heart that he is unable to successfully repair, and the patient ultimately dies on the operating table.

During and after this event, questions arise regarding whether or not it was appropriate for the surgeon to perform this innovative operation.

Introduction
Innovation is essential to ongoing improvements in quality healthcare, yet healthcare institutions continue to struggle with the challenge of how best to operationalize the multiple commit-
ments to risk minimization, accountability, the defensible use of resources and quality innovative practices. Professional conference reports (American College of Obstetricians and Gynecologists 2006; Eaton and Kennedy 2007), peer-reviewed literature (Agich 2001; Eaton and Kennedy 2007; Evans 2002; Fort 1998) and the experiences of families, healthcare professionals and administrators (Al Eyadhy and Razack 2008; Jones et al. 2004; Lantos 1994; McKneally and Daar 2003) highlight the need for innovation pathways that reflect the good practices and lessons learned in the fields of clinical ethics, research ethics, organizational ethics, accountability and risk management. An ideal pathway would be one that adheres to both the ethical values of the institution in which the innovation is being introduced and relevant legal standards in a way that preserves the innovators’ imagination and enthusiasm while ensuring scientific rigour and accountability.

With a commitment to these goals, an interdisciplinary team at The Hospital for Sick Children in Toronto, Ontario, developed a policy-entrenched pathway for managing the introduction of innovative procedures in surgery. This article describes the innovation pathway and the steps taken in its development.

Statement of the Problem: Innovative Procedures without Accountability

Healthcare in research hospitals is generally provided within the context of standard of care or research (e.g., some oncology treatment is delivered through research studies). The delivery of such care is informed by professional ethics and negligence law, as well as statutes, policies and guidelines addressing healthcare and research. In addition, there are healthcare advances, often referred to as “innovations,” that are neither considered standard of care nor the subject of formal research protocols. These “innovations” are entirely new or relatively new procedures generally either made loosely subject to research standards that were not created with such procedures in mind or, more often, not subject to any accountability-driven oversight at all.

The goal for advances in healthcare is to optimally serve the interests of patients, medical practice, society and science (Eaton and Kennedy 2007). Serving this range of interests requires careful appreciation of the potential harms and benefits of specific innovative procedures in relation to the values and goals of each of the above listed interests (Al Eyadhy and Razack 2008). While within a healthcare institution, the primary focus should be on the best interests of the patients, introducing an innovative procedure may have implications beyond the patients. A pathway for introducing innovative procedures is a mechanism for entrenching balance and ensuring that the range of issues that should be reasonably considered before bringing a new procedure to an institution are, in fact, reasonably addressed.

Research ethics theory and practice are currently debated and discussed in most countries around the world, resulting in many well-developed systems for review and control of research by research ethics boards (REBs – the Canadian equivalent to institutional review boards or research ethics committees). Although some of the principles applied in reviewing research are similar to those relevant to guiding the introduction of innovative practices, an REB is not the appropriate forum to review the introduction of an innovative practice when the practice is not itself the subject of a research study. Introducing a new procedure within a hospital is a significant activity with a range of potential physical consequences for patients, training requirements for staff and financial consequences for hospital budgets. A defensible review of innovation warrants an appropriately tailored clinically based mechanism, as opposed to depending on a system designed for the review of research (Agich 2001; Brower 2003; Gunsalus et al. 2006).

Innovation without a clear accountability-driven innovation pathway may do the following:

- Pose risks for patients, physicians and institutions in terms of the quality of care provided and the ability to show due diligence should there be an unexpected harm to the patient
- Result in significant clinical and organizational impacts in terms of cost and training
- Add an inappropriate workload to the research ethics committee

Beginning of a Resolution to the Problem

After a review of the literature on innovation in healthcare, the project distinguished between innovation procedures that were new to the world and procedures that were new to the institution but, in fact, had been researched or used with success elsewhere. The policy that would develop initially was a pathway for introducing the latter – leaving the first category for a future date. Innovations that fell within the responsibility of the REB were excluded. See Table 1 for the definition of innovation requiring internal review.

One of the primary considerations of the policy was the recognition that each person should be accountable for those aspects of the introduction of an innovative practice (i.e., safety,
costs implications, consent etc.) over which he or she has control (Morreim 2001). However, there was no consensus on how to translate this collective moral intention into effective accountable institutional policy. At the outset, there was a commitment to have any new policy framework reflect a system of “shared accountability” by innovators, peers and administrators that characterized the standards that healthcare organizations are increasingly expected to meet (Etchells et al. 2005).

The innovation literature also highlights challenges associated with defining terms and paradigms as well as the potentially complex relationships at play when introducing innovative practices. For example, Eaton and Kennedy (2007) conclude that oversight, disclosure and the duties to learn and educate are important considerations when deploying new medical procedures, but they caution against setting up a system of oversight so complex as to unduly inhibit innovation.

Other important considerations in drafting the policy included the following:

- Innovation is essential to ongoing improvements in the quality care of patients.
- A pathway of review, other than the REB, must be established to protect the interests of patients, healthcare professionals and the institution. (Al Eyadhy and Razack 2008; Evans 2002).
- The pathway should have a focus on how best to achieve the highest-quality healthcare without assigning blame should unintended outcomes ever occur (Morreim 2001).
- The organizational impact arising from an introduction of innovations that may draw resources away from other initiatives should be assessed. This impact should also be justified and approved by the designated parties.
- The process for introducing innovations must be transparent and publically defensible.

As part of policy development originally for the surgical department, discussions took place with surgeons to compile the range of good practices that each surgeon applies as a threshold before trying a procedure for the first time. Table 2 presents the list of “good practices” questions considered by surgeons.

In addition, the innovation pathway needed to adhere to both ethical principles and legal standards. Important ethical values (Table 3) and legal standards (Table 4) were identified for the new innovation pathway.

A draft policy was created with multidisciplinary input from surgeons (at both The Hospital for Sick Children and the University Health Network), bioethicists and risk managers to reflect the ethical principles and legal standards, collected surgical good practices and conceptual issues highlighted in the innovation literature. The draft policy was then circulated among various groups for discussion and input, modified, passed by The Hospital for Sick Children’s Medical Advisory Committee and formalized into hospital policy.

**Innovation**, in this policy, is defined as significant changes in
clinical procedures, techniques, technology, devices and treatment or therapy (involving more than a gradual change) that have not yet been introduced in the particular healthcare institution where they are under consideration but that have been validated elsewhere. The policy requires the review and approval of the innovation through this pathway when the innovation has incremental cost implications or poses sufficient risk that an independent review would be of benefit to the patient, healthcare professional, staff person or hospital, particularly to prevent, and in the event of, an adverse outcome.

**Policy Implementation**

The policy was first implemented in the Department of Surgery. One year following its implementation, a hospital-based evaluation of this process was conducted to consider whether or not the policy was being used as intended and to review the 14 innovation proposals submitted to the surgeon-in-chief. The evaluation included interviews with surgeons, estimations of cost impact and a compliance review by quality and risk management. One of the recommendations that came out of this review recognized that innovation was taking place across the hospital, not just in the Department of Surgery, and suggested that this policy should be expanded to facilitate innovations hospital wide.

Individual departments then developed their own innovation pathways, informed by the good practices of their healthcare professionals, ethical principles and legal standards as well as conceptual issues in the innovation literature.

Approval by the Medical Advisory Committee was given to implement the policy on a hospital-wide basis with innovation pathways for anesthesia, critical care, diagnostic imaging, pediatrics and surgery. While each of the pathways has some characteristics unique to the specific department, there are many similarities.

The components of the policy include submission to the chief, review, monitoring and evaluation.

**Submission to the Chief**

Staff members who would like to introduce an innovative procedure, treatment or therapy or medical device in the clinical setting must first submit a letter or proposal to the chief of the department for approval. The letter or proposal must address the points listed in Table 5.

**Review**

In reviewing a given proposal, the appropriate chief may call out:

- the name of staff member proposing the innovation;
- the anticipated date for the proposed procedure or use of device;
- the description of the innovative procedure or device;
- evidence of effectiveness/rationale for request;
- evidence of collegial endorsement and suggestion of advisers (internal or external) with whom chief may consult;
- potential risks and benefits to the patients;
- special consent considerations;
- a declaration of any conflict of interest;
- the number of patients to be treated during the approval period;
- the expected impact (positive or negative) on resources, including procedure time, device costs, postoperative care and workload implications for others;
- the signature of the financial director as assurance that this proposal has been discussed with him or her and that the appropriate resources are available;
- the assurance of device safety and approval (may include “special” approval) for use in Canada;
- evidence of the necessary skill or training on the part of the staff member proposing the innovation and the interdisciplinary team; and
- plans for collecting and reporting quality assurance and outcome data.

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upon one or more independent advisors to assist in evaluating
the proposal. Any requests deemed “research” by the chief would
not be approved as an innovation under this policy but would
be referred to the REB.

One of the primary considerations of the
policy was the recognition that each person
should be accountable for those aspects
over which he or she has control. (Morreim)

The chief does one of the following: (1) approves the innova-
tive use with or without restrictions; (2) grants clinical evaluation
status for six to 12 months; (3) requests that the innovative use
be continued only through a study protocol approved by the
REB or (4) denies the request as submitted.

Monitoring
Any adverse events resulting from the introduction of an innova-
tion are reported to the appropriate chief and to the appropriate
divisional Mortality and Morbidity Committee.

Evaluation
All innovative procedure outcomes must be reported back to
the appropriate chief in writing within a period of six months
of being first performed. At the end of the clinical evalua-
tion period, the staff member who submitted the innova-
tion proposal must submit a report on quality assurance and
outcome data to the appropriate chief. Based on outcome data
and other considerations (i.e., resources), the chief deems the
procedure (1) appropriate for continued use, (2) not appropriate
for continued use or (3) requiring formal research study.

Ongoing Challenges
While there continues to be strong support for the policy, as
with any change in practice, it is expected that the innovation
policy will be challenged, reviewed and updated. The following
are some of the questions that will need to be considered further
in light of additional experience:

• How can compliance be improved?
• What constitutes sufficient evidence to justify trying an
innovation for the first time in the context of clinical care in
a hospital?
• How different must an innovation be from standard of
care to warrant being introduced through this innovation
pathway?
• Is there a clear point at which institutions and staff members
are held accountable for not offering “innovations” to their
patients?
• What are the distinctions between quality improvement
procedures and innovations?

Management of the Illustrative Case
Prior to doing the procedure on a patient, the surgeon uses
the hospital innovation pathway, which involves answering 14
questions related to the nature of the procedure, his proposed
training, the monitoring of outcomes and required resources.
After the innovation review by the chief of surgery, the surgeon
is approved to do the operation, on a maximum of 12 patients.
He attends a training course. For the first five cases, he is
mentored by a surgeon from a neighbouring city who has done
a large number of these cases and who comes to the operating
room to do the operation with the surgeon.

The surgeon’s attendance at the training course, followed
by his use of the hospital’s innovation pathway, is a respon-
sible process that reflects his accountability to the patients, the
hospital and his professional regulatory body in the adoption of
a new and potentially better surgical technique.

Following the death of a patient, questions are expected from
the patient’s family, the surgeon’s colleagues in the department,
hospital administration and perhaps even from the surgeon’s
professional regulatory body. Respect to the patient and family
is shown by explaining that the innovation pathway was well
thought out and implemented, and that reasonably foreseeable
events were anticipated and planned for.

By developing and following an ethically and legally defen-
sible process, the innovating physician and team, as well as
hospital administration, are in a good position to assure the
patient and family, and others, that the decision to proceed with
the innovation was:

• independently evaluated and reviewed by others knowl-
egable in the field;
• based on considerations of evidence of effectiveness;
• made after all practical precautions were considered
• agreed to by the patient or substitute decision-maker after
informed decision-making; and
• monitored by the chief of the department.

Following an innovation pathway that is clinically, legally,
ethically and organizationally defensible assists in providing the
patient with safe, effective and high-quality innovative care
and is a valuable mechanism for operationalizing accountability.

Acknowledgement
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References
Medical Ethics 27: 295–96.


