



Let Us Not Take the Ethics Out of Innovative Practice: A Case Against Institutional Review

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donor volume developed for the lung transplant program at Toronto General Hospital provided the unique field strength that enabled the innovating surgeons to assure their patients that bilateral pneumonectomy and extracorporeal membrane oxygenator support would be followed by a successful transplant (Cypel and Keshavjee 2011). Innovation at the leading edge of surgical practice requires a learning environment and authoritative oversight. The Surgeon-in-Chief, in consultation with a committee of appropriate stakeholders, can provide the standing institutional memory and the authority to ensure that this important source of surgical progress is managed safely and effectively.

CONFLICTS OF INTEREST

Sunit Das declares he is a consultant for Guidedpoint Medical and for Abbvie Corporation. He is on the advisory board of the Subcortical Surgery Group. ■

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Let Us Not Take the Ethics Out of Innovative Practice: A Case Against Institutional Review

Eline M. Bunnik , Erasmus MC

When Thomas E. Starzl undertook the first human liver transplantation in 1963, he took a great risk. With his team, he had practiced the technique of liver transplantation in nearly 200 animals, but never in humans. The 3-year-old patient, whom I will call Tommy Smith,¹ had biliary atresia, which caused bile to accumulate in the liver, leading to irreparable damage and eventually liver failure. Tommy had been on life support with a ventilator, and he would surely have died soon. Theoretically, a

liver transplantation might save Tommy's life. However, Starzl could not be certain about the safety or efficacy of the intervention. Could he expose Tommy to the risks of an untried intervention?

In 1963, research ethics review committees or institutional review boards were not yet widely established. Instead, Starzl consulted a colleague, who was chair of the Department of Pediatrics at the university hospital in Denver, "had no trouble distinguishing right from

1. Although Tommy's real name is used in the book, I am not sure whether he would have wanted his name mentioned. Therefore, I am using a pseudonym instead.

wrong” (Starzl 1992, 98), and supported Starzl in going ahead with the surgery. In his memoirs, Starzl describes the scene immediately after Tommy’s death:

The surgeons stayed in the operating room for a long time after, sitting on the low stools around the periphery, looking at the ground and saying nothing. The orderlies came and began to mop the floor. ... It was not the last time I would see this scene, both in my dreams and in reality. I never heard anyone who was there describe this as “the [Smith] case”, or the first human liver transplantation. If they mentioned it at all, it was always just about [Tommy]. (Starzl 1992, 100)

Tommy’s death caused immense suffering, for the boy himself, for those who loved him, and for those who treated and operated on him. Was it tragic or was it reprehensible? Was it terrible or was it wrong?

One month after Tommy died, Starzl and his team successfully transplanted two other patients. Liver transplantation soon became a viable and established intervention, which saved patients’ lives. This is not typical for innovations in health care: Many newly approved medical treatments may not succeed in saving or significantly prolonging lives (Davis et al. 2017), and cause harm. Liver transplantation, however, was an innovative breakthrough. Starzl had developed it within the context of clinical research—or what passed for it in the 1960s—and presented the results at scientific conferences. He thus acted in accordance with what Earl calls the “research standard” (2019): the (moral) obligation for doctors to collect and share information about the clinical outcomes of innovative treatments to benefit future patients or society at large. Ideally, doctors should set up randomized controlled clinical trials. Less rigorous “learning activities,” Earl argues, may only exacerbate the risks of diffusion of insufficiently tested interventions. Thus, Earl proposes that when clinicians engage in innovative practices, they should justify not only why they diverge from standard care, but also why they fail to set up a scientifically valid clinical trial. Earl further assumes that for all innovative practices, “prospective review by expert peers and institutional officials is crucial” (2019, 14). I disagree with the latter.

Clinicians should not need to seek the approval of a research ethics review committee or any other form of formal institutional review. When deviating from standard care, clinicians must answer first and foremost to themselves. Innovative practice is often meant to benefit an individual patient with an unmet medical need, who may have exhausted standard treatment options. In this situation, the clinician must assess the balance of risks and potential benefits of the innovative treatment and make a difficult clinical judgment, without an expert consensus to fall back on. Medicine is an art, not only a science. Innovative practice is at—or near—the heart of that art. It demands decision making that is—at least in part—moral. Innovative practice falls, or should fall, within the discretion of the treating clinician. Arguably, clinicians may be

at the heights of their potential, as medical professionals, precisely when they make difficult decisions such as these. When doing so, they exercise professional autonomy, in the Kantian sense, as having their own (*auto*) law (*nomos*), as setting a norm for themselves.

It is recommendable, even obligatory, as Starzl did, to ask for advice from colleagues. When engaging in innovative practices, clinicians should consult (a multidisciplinary group of) peers, and especially experts. But this should not be to ensure “support or approval” (Earl 2019), but to improve the process of clinical and moral decision making. Discussions with others may serve as mirrors, support one’s deliberation process, and improve one’s plan. Of course, patients, too, have an important role to play in decision making with regard to innovative treatments, and it is beyond doubt that enhanced informed consent procedures are imperative. Ultimately, however, the responsibility for the innovative treatment should rest and remain with the treating clinician. Institutional review is not necessary, and it may even undermine clinicians’ professional ethics.

Roger Brownsword, a law professor in the United Kingdom, once used a metaphor of London Underground drivers to illustrate this point (Brownsword 2019).² In 1999, at Ladbroke Grove station 31 people died when two metro trains collided after a newly employed driver neglected a stop signal. In response to incidents like these, Transport for London introduced “automatic train protection,” a technology that puts trains to an immediate halt when they miss stop signals. Transport for London did so—rightly—to prevent avoidable harms. But the technology also has a downside: Metro drivers no longer have the opportunity to make wrong or right decisions. There are no assessments, no judgments to be made. In fact, drivers are no longer moral agents. As Transport for London engineered safety into the underground system, it has inadvertently taken ethics out of the practice of metro driving.

If clinicians are required to obtain institutional approval for a planned innovative treatment, they are not granted the opportunity to make ethical decisions. Instead, they are asked to fill out forms and get documents signed. The accumulation, in health care, of rules to follow, forms to fill out, boxes to check, may eventually come to abrogate ethics. It directs attention away from the most important question: “Am I doing the right thing?” Instead, it places focus on questions that are much less important: “Am I following the rules?”; “How can I obtain approval from the committee?”; “Have I received the right documents?”; “Are all documents signed properly by the right officials?” This displacement of focus is not conducive to the development of responsible professionals with strong ethical compasses. It may actually lead to the opposite.

2. Brownsword mentioned this incident in a lecture in the Netherlands around 10 years ago. In his new book *Law, Technology and Society: Re-Imagining the Regulatory Environment* he briefly refers to it.

Good health care requires professionals who have integrity, who are trustworthy and responsible, also in situations when—in a manner of speaking—nobody is looking, or overseeing. In their efforts to prevent harms, institutions tend to introduce more and more rules and regulations. But as full control or constant oversight is simply not possible, these regulatory efforts may be misdirected. Instead, institutions should allow professionals to exercise their discretion for the good, give them the opportunity to practice and cultivate ethical thinking and ethical behavior and learn to regulate themselves, not seek regulation by others. To do so safely, institutions should invest in moral education, have high expectations of professionals, and have very low tolerance for breaches of trust.

Importantly, clinicians should be deserving of the trust given to them by patients, societies, and institutions, and may not exploit it. For instance, doctors must protect desperate patients asking for untested interventions that are considered unsafe or ineffective. Also, they may not expose their patients to risks for self-interested reasons, such as financial or reputational rewards. We expect no less of doctors than that they act in the best interests of their patients.

I agree with Earl that if clinicians have the capabilities, the time, and the means to set up a robust clinical trial, they should do so, in the interests of society and to the advancement of medicine. They should not, however,

be compelled to seek institutional approval when considering innovative treatments for individual patients with unmet medical needs. Ultimately, such “overregulation” will not serve the interests of patients. Patients need clinicians who can both take and deserve responsibility for clinical and moral judgment. ■

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Advancing Medicine Ethically: Important Considerations for Innovative Practice

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Earl (2019) argues that the current uniform restriction of innovative practice limits clinicians’ ability to provide optimal treatment and stunts progress in medicine. We agree that it is important to balance evidence-based regulation and innovation to foster new discoveries in medicine. However, we believe that the risks of encouraging innovative practice, as outlined by the authors, have been underestimated.

Earl argues that any risk would be mediated by the implementation of a governing body that would oversee clinicians’ appropriate use of innovative practice. However, he does not specify how such a regulatory body could be implemented, how rules would be

enforced, and how conflicts of interest would be handled, nor who would be liable if the treatment caused unexpected harm. These questions are not insignificant. However, the most pertinent question is how these governing bodies would manage the risks of innovative practice when the risks are unknown and there is little high-quality evidence to guide them. As it stands, evidence-based treatments produced through the current research standard and the mechanisms through which they are translated, such as practice guidelines and professional body endorsements, are not sufficient to ensure the best practice implementation of interventions in

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