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## Surgical innovation and ethical dilemmas: Precautions and proximity

*No! I am not Prince Hamlet, nor was meant to be;  
Am an attendant lord, one that will do  
To swell a progress, start a scene or two...*

—T.S. Eliot, *The Love Song of J. Alfred Prufrock*

Let me start by thanking the organizers for their invitation to be here and to start this off. I am not sure if that invitation was an act of kindness or of throwing a fellow bioethicist to the lions, as we will be addressing a complicated set of issues upon which well-intentioned folks disagree and sometimes disagree with a passion.

What I would like to do is to lay out some of the inherent ethical problems related to surgical innovation. I will argue that some of these problems are unique to surgery and that others relate to how we have chosen to define categories like research and practice. Other problems involve how we view the proportionality of risks and benefits in surgical research. I will argue that we have falsely analogized surgical progress to progress made in other areas of biomedical research and misunderstood the highly personal, or proximate, nature of surgical inquiry. Without appreciating the import of what I will call “surgical proximity,” we will be unable to adequately address ethical issues in surgical innovation.

### ■ PROBLEMS OR DILEMMAS?

So let me begin with the title of our session, “Surgical Innovation and Ethical Dilemmas,” and why this juxtaposition is counterproductive. A colleague long ago taught me to distinguish problems from dilemmas—the former being resolvable, the latter intractable, often involving a choice between two equally unfavorable choices.

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**In a surgical trial, the therapeutic impact has to be larger than in a drug trial to warrant ongoing study. This burden of scale increases the probability of reciprocally large adverse effects.**

Although I may be making too much of the semantics, I do think the title betrays a presumption that surgical innovation invariably forces adversarial choices. It tends to dichotomize ethical reflection, pitting those who favor prudence against those who endorse progress, or it creates too stark a difference between ethical issues in surgical practice and those encountered in the conduct of surgical research.

Even therapeutic, validated surgery in many ways has the potential to become innovative, if not outright experimental. Patients may have anatomical differences that require surgical improvisation, or complications may arise during “routine” surgery, creating the need for an imaginative response.<sup>1</sup> At what point do these departures from expected care become novel interventions, innovative or even experimental? A routine case with an unexpected turn can even become a case report opening up a new field of endeavor.

For instance, the field of stereotactic functional neurosurgery was born out of a “routine” case of ablative surgery for Parkinson’s disease in the 1980s, when the French neurosurgeon

Alim Benabid was using electrodes to determine which areas of the brain should be destroyed. As he was mapping the thalamus, he noted that the tremor of his patient abated. This led him to wonder if one could treat drug-resistant Parkinson’s with electrical stimulation instead of destructive lesioning.<sup>2</sup> Benabid’s translational insight during an ordinary case led to the development of the rather extraordinary field of stereotactic functional neurosurgery and neuromodulation.<sup>3,4</sup>

Another example from an earlier era comes from the life work of neurosurgeon Wilder Penfield, who did pioneering work in the surgical treatment of epilepsy. Here, the accumulation of experience from “routine care” led to generalizable knowledge, much like hypotheses are validated in experimental work. In Penfield’s case, his clinical use of electrical stimulation to plan resections of scar tissue causing epilepsy led him to map the human homunculus, a magnifi-

cent achievement of profound importance.<sup>5,6</sup>

So let us avoid simplistic and confounding demarcations. Instead of dichotomizing innovation and prudence—or surgical research and surgical practice—let us try to start our deliberations with an eye toward a more synthetic approach. Like most things in nature and in biology, ethics too is on a continuum with gradations that can fit into an Aristotelian taxonomy. Let us emulate what Aristotle called *phronesis*, or practical wisdom, these next 2 days so that we achieve constructive outcomes, or what the pragmatists would call instrumental goods.<sup>7</sup>

If we are successful in laying out the ethical issues in this clinically pragmatic fashion, we can turn intractable “dilemmas” into problems amenable to resolution through the particularistic invocation of ethical principles as they relate to the surgical context.<sup>8</sup> If we follow this inductive method of moral problem solving, we will avoid sweeping ethical generalizations, or categoricals, that can misrepresent the complexity of innovative research and deprive society of its benefits.<sup>9</sup>

### ■ INNOVATION VS PRUDENCE: A FALSE DICHOTOMY

So let us start by understanding the pre-suppositions that led to the expectation that *dilemmas* will descend upon those who engage in surgical innovation. In my view, this expectation begins with what is called the precautionary principle, a concept with some currency in the realm of environmental ethics.<sup>10</sup>

The precautionary principle urges caution and prudence when facing unknowns and is an antecedent sort of utilitarianism. One makes judgments about the advisability of actions based on a prior assessment of foreseeable risks and benefits. If the risks are excessive or exceed benefits, the precautionary principle urges care, caution, and even avoidance of a given course of action.

When the precautionary principle is implicitly invoked in making judgments about research, the objective is to pursue a degree of safety that is comparable to that of established therapy. But interventions that have progressed to being deemed “therapeutic” have of course achieved a requisite degree of both safety and efficacy—that is what makes them therapeutic, as opposed to investigational, interventions. One cannot know before one has conducted a clinical trial, and completed statistical analysis, whether a new surgical advance or device meets these expecta-

tions. Because of this lack of knowledge, there is an inherent degree of risk in any novel intervention.

The challenge posed by innovation or novelty creates the possibility of untoward events. It leads to invocation of the precautionary principle, which, echoing the admonitions of the philosopher Hans Jonas, urges us to “give greater weight to the prognosis of doom than to that of bliss.”<sup>11,12</sup>

This is not a bad way to go through life, assuming one wants to emulate T.S. Eliot’s J. Alfred Prufrock, who lamentably “measured out my life with coffee spoons.”<sup>13</sup> Unlike the surgeon, who must make decisions in real time, Eliot’s protagonist could not move forward. Despite his desire to avoid the indecision of Prince Hamlet, alluded to in this paper’s epigraph, Prufrock was paralyzed by doubts and fears, with “time yet for a hundred indecisions, and for a hundred visions and revisions.”<sup>13</sup>

Despite Eliot’s invocation of “a patient etherised upon a table,”<sup>13</sup> the poem shares little with the surgical life. It has much more in common with the precautionary principle. Like Prufrock, the precautionary principle favors what is known—the status quo—as what is unknown is invariably more risky than the familiar. Needless to say, this is antithetical to innovation because discovery invariably requires scenarios that involve novelty and unknown risks. When faced with the certain security of stasis or the potential dangers of innovation, the precautionary principle will invariably choose

stasis, leading us, as the legal scholar Cass Sunstein notes, “in no direction at all.”<sup>14</sup>

Seen through the prism of the precautionary principle, then, surgical innovation invariably presents a dilemma. Discovery and innovation are fundamentally at odds with the precautionary principle, because of their potential for risk.<sup>15</sup>

The challenge posed by the precautionary principle—which, to be fair, is seen in all areas of clinical research—becomes even more pronounced in surgical research because of the size and scope of clinical trials. As is well appreciated here, compared with drug trials, surgical trials are small. Sometimes they can involve a single subject, whereas drug trials may include thousands of participants. Because of drug trials’ large volume of subjects, therapeutic effects can be small to justify ongoing research. In a surgical trial or a device trial, the number of subjects is smaller, so the therapeutic impact has to be larger to warrant

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further development and ongoing study. This burden of scale increases the probability of reciprocally large adverse effects. This potential for disaster magnifies the impact of the precautionary principle and may lead to a distortion in ethical judgment along the lines of Hans Jonas' admonition.<sup>12</sup>

By all of this I am not suggesting that we abandon precautions and prudence. Instead, my point is to explicate the additional challenges faced by surgical research and the sway of the precautionary principle over this area of inquiry and innovation. By being explicit about the impact of this principle, we can be cognizant of its potential to distort judgments about risks and benefits. Only then can we hope to balance the pursuit of progress with that of safety.

### ■ SURGICAL RESPONSIBILITY

These distortions also need to be recognized, and made explicit, because surgical research, more so than pharmacologic research, is much more personal and intimate. This point becomes clear if we consider a surgical trial that does not succeed.

In the surgical arena, such failures are taken to heart and personalized. Unlike trials that involve drugs, surgical research is more proximate. It is not just the failure of a drug or of pharmacology; it is also possibly the failure of the operator, the surgeon who did not achieve the desired goal because of poor execution of surgical technique.

This crucial difference in medical versus surgical cultures is captured by Charles Bosk in his magisterial sociological study of surgery, *Forgive and Remember: Managing Medical Failure*. In a discussion of morbidity and mortality rounds, Bosk writes:

The specific nature of surgical treatment links the action of the physician and the response of the patient more intimately than in other areas of medicine....When the patient of an internist dies, the natural question his colleagues ask is, "What happened?" When the patient of a surgeon dies, his colleagues ask, "What did you do?"<sup>16</sup>

As in clinical surgical practice, in surgical research, it is the personal and individualized mediation of the surgeon that is central to the intervention. Here the intermediary is neither a drug nor its bioavailability; rather, it is the operator's technique plus or minus the operative design and the reliability of an instrument or a device. In either case, the contribution is more

proximate and personal, stemming from the actions of individual surgeons and the work of their hands.

History is instructive on this theme of surgical causality and personal culpability if we consider the life of Harvey Cushing, a Cleveland native whose ashes are buried nearby in Lake View Cemetery.<sup>17</sup> Cushing was a gifted and innovative surgeon whose technique handling tissues changed how the brain was approached operatively. He is acknowledged as the father of neurosurgery, having created a professional nexus to institutionalize and carry on his innovative work.<sup>18</sup>

Cushing's greatest innovation was probably in his individual efforts as a working surgeon. Over the course of his lifetime, he made the resection of brain tumors a safe and sometimes effective treatment for an otherwise dread disease. Michael Bliss, Cushing's most recent biographer, reports mortality data from more than 2,400 surgeries done by Cushing during his operative lifetime.<sup>17</sup> Early in his career (from 1896 to 1911), while he was at Johns Hopkins, Cushing's case mortality rate was 24.7%. During his later years at the Brigham Hospital, it was 16.2%. By 1930–1931 it was down to 8.8%.

These were extraordinary statistics: no one matched Cushing's numbers, or his ability to do what he did. Bliss cites mortality data from his surgical contemporaries in the late 1920s as ranging from approximately 35% to 45%. By the numbers Bliss compares Cushing's talent—his truly brilliant outlier performance—to that of his Jazz Age contemporary, Babe Ruth, who also

had outsized talent compared with his peers.<sup>17</sup>

Cushing himself, a collegiate second baseman at Yale, linked sport and statistics in a most telling way. Documenting his ongoing surgical progress was a hedge against failure and lightened the emotional burdens of the surgical suite. Cushing observed: "A neurosurgeon's responsibilities would be insufferable if he did not feel that his knowledge of an intricate subject was constantly growing—that his game was improving."<sup>17</sup>

This quote and Cushing's operative statistics point to his nascent effort to engage in evidence-based research and speaks to the spectacular difference that a surgical innovator can make. The extraordinary results achieved by Cushing in his day also suggest that surgeons are not fungible at the vanguard of discovery. History tells us, as contemporary assessments of current research cannot, that only Harvey Cushing could achieve Cushingoid results.

**Even the great Harvey Cushing perceived the weight of surgical burdens, suggesting that any effort to depersonalize the ethics of surgical innovation would be naïve.**

A second point that stems from Cushing's comment about the burdens of operative work and surgical research is how personally taxing that responsibility can be. Without making progress, he said, the "responsibilities would be insufferable"<sup>17</sup> (my italics).

Even the great Harvey Cushing perceived the weight of these burdens, suggesting that any effort to depersonalize the ethics of surgical innovation would be naïve. The singularity of Cushing's surgical accomplishments (his operative excellence as compared with his peer group) and the felt weight of these achievements suggest that surgical innovation is highly personal and proximate to the surgical researcher in a way that is distinct for surgical innovation. This relationship of operative causality and personal culpability can be subsumed under what I will call *surgical proximity*.

### ■ SURGICAL PROXIMITY

Surgical proximity has several implications for the conduct of research. In this section I will address two issues: conflicts of interest and clinical equipoise.

#### **Surgical proximity and conflicts of interest**

As the Cushing example illustrates, at least at the outset of a clinical trial the surgeon himself is part of the actual design of the trial. The same surgical method in the hands of one of his contemporaries would have led to a dramatically different result. The surgeon who is at the forefront of innovation becomes an experimental variable until the methods can be generalized.

The importance of the operator as an essential ingredient in early surgical research points to a key difference with pharmaceutical trials, where the purity of the drug-based intervention can be maintained. This difference has implications for the "rebuttable presumption" stance promulgated by the Association of American Medical Colleges (AAMC), which looks askance at innovators conducting clinical trials if they have a conflict of interest, such as intellectual property rights for their discoveries.<sup>19,20</sup>

In many cases, the work that surgical innovators do, as in the case of device development, could not be done without collaborations with industry. Taking the surgical talent of the potentially conflicted—but highly talented—innovator out of the equation may be counterproductive.

Time does not allow me to fully address the con-

flikt-of-interest issue in this forum; suffice it to say that the differential knowledge, skill, and talent of early surgical innovators may be the difference between a trial's early success or failure. The role of such innovators should neither be truncated or precluded nor be viewed a priori in a prejudicial fashion. Instead, their talents and vision should be welcomed as instrumental to the potential success of the work, managed of course with the proper degree of transparency and disclosure.

As I have noted previously,<sup>4,21</sup> if the rationale for a conflict of interest is to allow laudable work to continue that otherwise could not occur without the personal intervention, and talents, of a surgical innovator, it seems prejudicial to view the conflict of interest as disqualifying until proven otherwise. This view is consistent with the legal framework of the US Constitution, which explicitly authorizes Congress "to promote the Progress of Science and the useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings

and Discoveries."<sup>22</sup> It is also embedded in the Patent Act of 1790,<sup>23</sup> which balances the patent's period of exclusivity against the inventor's obligation to share and disseminate expertise. This role for the innovator is also consistent with the intent and incentives within the framework of the Bayh-Dole Act of 1980,<sup>24</sup> which was passed with the expectation that industrial partnerships would move ideas from the bench to the bedside.

I hope that others at this conference will be able to return to the issue of conflicts of interest and how the question of surgical proximity may, or may not, alter our ethical judgments about the surgeon's role in research where there may be a conflict of interest.

#### **Surgical proximity and equipoise**

Surgical proximity also has an impact on clinical equipoise, the ethical neutrality about outcomes felt necessary for the conduct of clinical trials.<sup>25</sup> The surgeon's sense of causality and proximity to the operative act makes surgical research different because the equipoise, which exists objectively about the research questions at hand, may not exist in the mind of the surgical researcher. Let me explain.

Taking a patient to surgery is highly consequential. As we have seen from Bosk's work,<sup>16</sup> surgeons feel a sense of responsibility for their operative acts and surgical work. This felt responsibility, inculcated in surgical training and surgical culture, obligates the surgeon to make a

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proportionality judgment about bringing a patient to the operating room, be it for research or for clinical practice. In this way, surgical investigators have determined, at least in their own minds, that net benefits outweigh net risks, thus breaching clinical equipoise.

It is hard for a surgeon to commit to an operative procedure—be it for clinical care or for research—with all its attendant risks if he or she does not believe that the intervention is safe and effective. We can appreciate the importance of the surgeon's perspective on the utility of any proposed operation if we consider the opposing question of futility in clinical practice.<sup>26</sup> Whereas internists or intensivists might be compelled by families to continue aggressive intensive care, surgeons cannot be compelled to take a patient to the operating room when they deem that the risks outweigh the benefits. Because the surgeon is such a proximate moral agent, he or she will be held culpable for the actions that occur in theater. This degree of responsibility is accompanied by a retained degree of discretion—an almost old-world paternalistic discretion<sup>27</sup>—to counter the demands for disproportionate care.

This same sense of culpability and responsibility informs the surgeon's willingness to take any patient to the operating room. In the case of research, this willingness becomes an issue of concern because it means that in the surgeon's mind, favorable operative proportionality has been achieved.

This process of self-regulation<sup>28</sup> can have implications for the informed-consent process because surgeons believe in their work and can exert a strong dynamic transference on subjects who may be desperate for cure.<sup>29</sup> Because of this potential bias, surgical research may become especially prone to a therapeutic misconception. That is, if the surgeon is willing to take the risks of doing an innovative procedure in the operating room, then it has crossed some sort of internal threshold of proportionality in which the risks, whatever they are, have become acceptable given the putative benefits. Given what Bosk has written about surgical failure,<sup>16</sup> a high bar is crossed when a surgeon takes a patient to the operating room

for a novel procedure, even though motivations at that bar may occasionally be mixed.\*

## ■ FROM SURGICAL RESEARCH TO EDUCATION

This leads to my closing observations about transitions in surgical research, when the work of the pioneering surgeon is bequeathed to the broader surgical community to pick up the torch—or scalpel—and expand the work.

This takes me away from research and, fittingly here at a medical school dedicated to research training, brings me to medical education. To transcend the personal dimensions of surgical innovation—and the courage and vision of the founders—and sustain it more broadly, innovators also have to become educators of future surgeons, organizers of talent, and moral exemplars for the next generation. They have to appreciate that the work that they started, if it is important, will not be completed during their tenure but that future generations will carry it forward and expand

upon it. They also have to prepare the next generation with the tools and orientation to appreciate their vision and to embrace what Thomas Kuhn might call new scientific paradigms.<sup>30</sup>

On several occasions Wilder Penfield, who founded the Montreal Neurological Institute, wrote with regret about Victor Horsley, the neurosurgeon at Queens Square in London. Penfield viewed Horsley as the founder of his field, but Horsley left no disciples. In

his autobiography, fittingly entitled *No Man Alone*, Penfield noted that Horsley, “the most distinguished pioneer neurosurgeon, had died in 1916 without having established a school of neurosurgery.”<sup>31</sup> This is in contrast to the discipline-building work of Cushing.

It is not an accident that Dr. Cushing founded a field full of trainees and protégés, of which my copanelists are descendants. It was intentional and part of his ethos of being truly innovative. And it is not an accident that the distinguished surgical innovators at this symposium have also created institutional structures to continue their work for decades to come. Their achievements have transcended the individual innovator and have become systematic. It is said that Dr. Thomas Starzl launched a field.<sup>31</sup> Dr. Denton Cooley founded the Texas Heart Institute.<sup>32</sup> Dr. Thomas Fogarty started the Fogarty Institute for Innovation, whose mission statement explicitly notes that it is “an educational non-profit that mentors, trains and inspires the next generation of medical innovators.”<sup>33</sup>

**Surgical investigators have determined, at least in their own minds, that net benefits outweigh net risks, thus breaching clinical equipoise.**

\*Lest I be misconstrued as too idealistic, this burdens-vs-benefits equation may be fueled by a complex mosaic of motivations and may not always be informed fully by patient-centered benefits. If the surgeon is the innovator and the inventor, these benefits may be for the pursuit of a hypothesis and associated with potential fame or fortune. But even in these cases, judgments about proportionality are informed by surgical proximity. (For more on the ethics of conflicts of interest, see references 4 and 21.)

Each of these pioneers, I believe, appreciates the need for continuity and dissemination.

But even here there is something that we nonsurgeons need to understand: although the work transcends the individual surgeon, the ties remain personal and linked to the impact and legacy of founders. Take, for example, highly prized membership in the Denton A. Cooley Cardiovascular Surgical Society.<sup>34</sup> This too is about the importance of individuals and surgical proximity, but here it is transgenerational.

■ **CONCLUSION**

If we truly want to continue the dialogue begun here today, we need to understand these social and professional networks and the importance of surgical proximity in transmitting both methods and values. The proximate nature of surgical research—and the causality and responsibility that accrues to the surgeon—makes surgical research different than other areas of biomedical inquiry. This difference has implications for risk-benefit analysis, conflicts of interest, and clinical equipoise. I hope that my colleagues return to these themes in the coming days so that the regulation of this important area of research can be informed by a deeper understanding of the ethics of surgical discovery and innovation.<sup>35</sup>

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