10 Making Sense of Vaginal Mesh

ARIEL DUCEY WITH BARRY HOFFMASTER, MAGALI ROBERT, AND SUE ROSS

Vaginal mesh is now the subject of the largest mass-tort litigation in United States history, involving an estimated 100,000 plaintiffs in state and federal courts. Lawsuits against the manufacturers of these devices are also underway in Canada. From the early 2000s to about 2015, transvaginally placed synthetic mesh implants were widely used around the world to surgically treat some types of prolapse (descent of the pelvic organs) and urinary incontinence in women. Litigants in the court cases report debilitating complications, including irreversible chronic pain, and usually that they were not informed such complications were possible. Many women benefited from the less invasive surgical approach and more durable repair the new procedures entailed, but neither the numerator nor denominator are known: how many devices were implanted and how many resulted in complications.

My research, with colleagues in health services research, bioethics, and surgery – Sue Ross, Barry Hoffmaster, and Magali Robert, respectively – has focused on the surgeons who treat these disorders in women: their ways of thinking about their work and responsibilities, and when and how they should adopt new procedures or devices. In recent years, we have interviewed dozens of surgeons and stakeholders in pelvic floor surgery, observed consultations between patients and surgeons in one specialized treatment clinic, observed international and major European and North American medical conferences for physicians and allied health care professionals who treat pelvic floor disorders, and assembled and analysed documentary evidence such as print advertisements for mesh devices, commentaries and op-eds by clinicians concerning mesh kits, and the development of textbook descriptions of when and how to treat pelvic floor disorders.

This chapter draws upon interviews with clinicians who perform pelvic floor surgery. There are differences among these clinicians (for instance

in terms of experience, training, surgical repertoire, and practice type), which are important to a more extended analysis of pelvic floor surgery. For reasons of confidentiality, here clinicians are identified by the initials of the pseudonyms our research team assigned them, and I have refrained from mentioning gender – also a difference that matters, but which needs to be handled with care because of how small this community of Canadian clinicians is and how readily some readers could use gender markers in combination with other details about practice preferences to identify particular respondents.

As a result of the collaborative nature of this research, some of the explanations for the widespread use of transvaginal mesh that would have once been sufficient to me are now less so. The purpose of this chapter is to illustrate how working with colleagues in other disciplines altered my way of approaching this research and understanding this case. I wish to describe a certain stance, which is simultaneously scholarly, emotional, and moral, in the sociological study of health care and medicine. It is a position from which I think there is no escaping the question of how to intervene. What might be done to change things? Transvaginal mesh should not have been so widely used. Yet many of the accepted ideas about what good medicine is entail explanations of medicine's failings that are arguably too removed from the messiness of practice to be the basis of effective intervention. Health care services research today is often oriented around good medicine as evidence based; much of bioethics still makes recourse to principles for practice, such as "first do no harm"; and critical medical sociology calls for medicine that is independent from the influence of corporate interests as well as social categories such as gender, class, and race that have been used to render some lives and bodies less valuable than others. Our research approach has not been to assess medical professionals on these terms, but to document the processes through which medical practitioners make sense of things and seek to demonstrate responsibility on the basis of actions and interactions that are always particular to a patient and case, but also always affected by extra-individual forces that make some ways of acting more possible. In the case of transvaginal mesh, action was not always taken with sufficient evidence for safety and effectiveness; medical professionals did not appear to adhere to ethical principles; and decisions were influenced by bias and self-interest – but even together, these factors do not fully illuminate the transvaginal mesh debacle. As a result, many typical ways of trying to prevent such debacles in the future are likely to fall short. The question that therefore shadows the following account of how transvaginal mesh came to be so widely used is: might this more ethnographic account produce better interventions?

Cowboys and Dinosaurs

The case of transvaginal mesh illustrates problems that have long been recognized by researchers in the traditions of critical medical sociology and health services research. Pelvic floor surgery was dramatically altered in the late 1990s by the development of the tension-free vaginal tape (TVT), a less-invasive surgical treatment for stress urinary incontinence (leakage of urine from coughing or jumping). It entails placing a strip of synthetic mesh under the urethra via an incision in the vagina, then pulling the tape into place through two small incisions in the lower abdomen. For many, it was a procedure *that made sense*:

> It was 1999 ... and I was at a conference in Cape Town. And I, it was an international conference and I walked down the hall and there's all these stations where the companies always show their wares, and their new stuff. And I remember stopping at a booth and looking at a video ... and I basically couldn't leave. I was watching this thing and I was thinking, my god, this makes so much sense. If this works it's going to change the world of what we do. And it did. It was the first TVT. (EE)

When the definitive paper introducing the TVT appeared in 1996 (Ulmsten et al. 1996), the device had already been sold to Johnson & Johnson as a kit bundling the procedure with the mesh tape and a set of customized tools, and it was rapidly and widely adopted.The advantages of the transvaginal rather than abdominal surgical approach and apparent physical tolerability of synthetic mesh then became the basis for the use of larger mesh pieces that wrapped around or above the vagina and the uterus to varying degrees, supporting pelvic floor organs. Many surgeons began to experiment with the transvaginal placement of mesh of varying shapes, sizes, and materials, the most entrepreneurial of whom developed viable commercial products – sold to or developed with device companies. Dozens of kit-devices made by competing companies were brought to the market in the 2000s, all of which were approved by regulators in Canada and the United States without requiring device-specific evidence of safety or effectiveness, because of their classification as moderate risk (until 2016) and as substantially equivalent to other devices on the market (see Hines et al. 2010; on similar regulatory issues in Europe see Kent and Faulkner 2002).

The TVT has now been extensively studied and is regarded by most (but not all) surgeons as at least as safe and effective as previous surgical treatments while resulting in more durable repairs with a less-invasive surgical approach. The more general group of "midurethral slings," based on the TVT, are considered the gold standard for surgically treating stress urinary incontinence. On the other hand, the use of transvaginal mesh kits to repair pelvic organ prolapse was always more contested.

> As soon as TVT came on the market, what it did is exploded the ability of companies to make money ... Before, there was nothing for them, a bunch of sutures. I mean, I'm sorry, that's not going to drive any market per se, or competition in any way. And so it allowed – kind of opened up the ability to use all this stuff, and bringing everything together, people became more – what's the word? I was going to say "cowboy," but that's not really the word – more inventive, let's say, and less traditional in how they were looking at things, and trying new things. (AK)

Extensive research and commentary have identified the shortcomings in the system of regulating medical drugs and devices in Canada and elsewhere. Health services researchers often emphasize the need for greater government funding of regulatory agencies, rather than systems that rely upon fees paid by manufacturers, to assure impartiality; or the creation of more transparent decision-making processes allowing for input from more stakeholders, including patients; or the creation of more rigorous standards for evidence at both the pre- and post-market stages. In the transvaginal mesh case, manufacturers and not regulators defined whether their devices were substantially equivalent to other devices on the market. Critical medical sociologists often raise larger issues usually taken to be external or a matter of context, but which in fact shape the production of "evidence" through and through. Such research shows how profit-making imperatives can contradict those of public health and patient well-being so that medical and scientific knowledge itself is arranged to reflect the aims and interests of drug and device manufacturers (Abraham and Ballinger 2012; Lexchin 2016). Medical devices do not have patent protections such as those granted to new pharmaceuticals, nor are the development costs as high, which encouraged the rapid proliferation of "me-too" device-procedures – variations on licenced devices sufficient to establish marketable differences but not so great as to draw extra scrutiny by regulators. The creation of these devices as "kits" additionally had the potential to create surgeon-customers bound to bundles of a manufacturer's products, and these kits were marketed, and apparently perceived, as making surgery for prolapse and urinary incontinence simpler and therefore possible for a wider range of clinicians and patients.

Did surgeons become "cowboys" or more "inventive" in this context? "Cowboys" – a term used several times by our respondents – seemed to

be another way of referring to those clinicians usually called, in scales of innovativeness (Rogers 2003), innovators and early adopters – those physicians who try new approaches and products earlier than others. But "cowboy" connotes something irresponsible – a willingness to buck the rules, perhaps those of evidence and prudence. AK's shift to the adjective "inventive" captures the ambivalence with which some physicians may view colleagues farther along on a spectrum ending in "cowboys." Cowboys are understood to be necessary to surgical or medical advancement, daring what others will not. At the other end of the spectrum from a cowboy is a "dinosaur," which is what one surgeon, who to this day does not use the TVT, felt perceived as by colleagues:

> I have to say, in retrospect, I would not have had the guts to develop the TVT ... I wouldn't have been brave enough. I would have been – there's just too much potential for something to go wrong, I don't know if I could live with myself if it did. (CH)

Yet the adoption of transvaginal mesh is not only a matter of surgical dispositions or surgical decision-making styles – the descriptors "dinosaur" and "cowboy" both implausibly connote isolatable and immutable surgical types. The adoption of transvaginal mesh is just as much about a market-driven context that encouraged more clinicians to use devices for which they were inadequately trained or skilled, and to use them in patients for whom the risks could have been anticipated to outweigh the benefits.

> You know those kits are just cruel and unusual punishment, they're horrible. They were developed by equipment manufacturers who said it's easy, anybody could do it. They would take you to a weekend course in Miami and send you back with some free kits, and horrible things began to happen. (OG)

The kits were developed by companies often in collaboration with specific surgeons – between "cowboys" and companies – but they were rapidly absorbed into everyday practice. The adoption of transvaginal mesh might be characterized as the internationally synchronous and extensive, largely untracked and unmonitored beta-testing of device-procedures on patients. Analyses that focus on regulatory weakness and the dangers of mixing profit making with medical care are invaluable as diagnoses of problems in the current configuration of markets and innovation in health care, problems that made a situation like transvaginal mesh likely. However, they also gloss over what did and did not make sense

and the possible permutations of responsible action to the people who implant(ed) synthetic mesh in women's pelvic floors. Making sense is not a matter of surgeons' dispositions interacting with context. The effects of the market context were mediated by communities of practice and by situated clinical activities. The mesh kits that were suddenly available to try and purchase, and the training gained on those trips to Miami, would only be widely used in practice if they also accorded with many physicians' learned judgment (Gordon 1988) about what makes sense.

Judgment

Sue Ross first approached me to contribute to the qualitative methods of a study of when and how stakeholders in pelvic floor surgery consider the ethical and economic dimensions of new devices and procedures. Dr. Ross, a health services researcher, was responsible for organizing clinical studies and trials of new device-procedures in an obstetrics and gynaecology department at an academic medical centre. In her role she had, for instance, led an industry-funded clinical trial comparing two mesh slings for the treatment of incontinence and then encountered difficulty getting the results published because of the "negative" finding – there was no statistically significant difference in outcomes between the slings. There is documented publication bias against studies with such findings (e.g., Easterbrook et al. 1991). Surgeons she worked with had also been among the first to adopt an early, significant variation of the TVT procedure as part of a clinical trial she led, and the trial was stopped early when they noticed an increase in post-operative complications. Soon it became known through their, and other, early studies and formal and informal reports at scientific meetings that the specific type of polypropylene material used to make the sling did not allow it to be incorporated into surrounding tissues, resulting in extrusions into the vagina. The device, ObTape, was removed from the market by its manufacturer, Mentor. It had been on the market in the United States for just three years (2003–6), during which time the *New York Times* estimated sixteen thousand American women had the tape implanted. Once another device-kit for the procedure using the emerging industry-standard for polypropylene was available, the surgical approach ObTape introduced was widely adopted. Such experiences led Dr. Ross and her colleagues to publish a commentary in the *Journal of Obstetrics and Gynecology Canada* titled "Ethical Issues Associated with Introduction of New Surgical Devices, or Just Because We Can, Doesn't Mean We Should" (Ross et al. 2008), and to undertake qualitative research to explore how surgical devices come to be used.

I brought to the research project the long-standing tradition of critical medical sociology that has documented non-clinical influences on medical and surgical decision making (e.g., Becker et al. 1967; Bloor 1976; Eisenberg 1979; McKinlay, Potter, and Feldman 1996; Silverman 1981; Waitzkin 1993), such as economic interests and bias and stereotypes. But through the experience of interviewing surgeons, regulators, administrators, and those involved in assessing new medical technologies, Dr. Ross and I developed a similar kind of unease with dominant strains in our respective disciplinary traditions: a tendency to see the world in technocratic terms, as awaiting better systems of organization and control to produce better outcomes. Better regulations, better guidelines, better information systems, better clinical trials – these are what James Scott (1998) called "seeing like a state": dreams of rationality and planning and objectivity and universality, a modernist way of seeing the world. Evidence-based medicine is arguably the most recent form of this way of seeing.

Dr. Ross persuaded a surgeon colleague, Dr. Magali Robert, to become involved with our burgeoning qualitative research, and we wrote a paper describing how the most recent elaboration of the TVT concept, a so-called mini-sling comprised of a shorter mesh strip with "self-affixing anchors" on each end and requiring only a single vaginal incision for placement, came and went from the market in the absence of good evidence. In this case clinical trials only appeared midway through the device's eight-year life on the market, and lacked meaning because the "standard" comparator treatment was being continually displaced, such that devices about which little is known by the criteria of evidence-based medicine were often compared to one another (Ross, Robert, and Ducey 2015). This trend in "evidence" for mesh kits more broadly made it difficult for the traditional purveyors of evidence-based medicine, who assess health technologies or compile meta-analyses of evidence (i.e., health technology assessment agencies or synthesizers of evidence such as the Cochrane review), to reach definite conclusions about when and how to use transvaginal mesh.

The point of our paper was not, however, to argue that only devices and procedures demonstrated as an improvement in high-quality clinical trials should be approved by regulators and adopted by hospitals and surgeons. The market for vaginal mesh products intensified the challenges to evidence-based surgery, but did not create them. Surgical procedures are not as readily studied and compared as pharmaceuticals or other types of medical interventions. No two patients are exactly alike in their clinical history or anatomy, as are no two surgeons in their training and experience. In assessing any new surgical device, the variability of

surgeons and patients cannot be entirely eliminated or controlled for. In the situation of vaginal mesh, distinct components of the procedure – the device as such, the surgical approach or technique used with the device, and the skills and decisions of surgeons – are often impossible to separate for the purposes of forensic investigation or research. Together they are also the basis for continual and often subtle but consequential variation in surgical work. The culture of surgery has long supported continual tinkering with operations and instruments to improve results (Wilde 2004), such that the line between everyday adjustments in practice and innovations is often blurred (Riskin et al. 2006; Rogers et al. 2014). These observations do not mean, alternatively, that personal experience is the only viable basis of decision making in surgery, often positioned as the rival of evidence in the battle over principles of good doctoring (Armstrong 1977; Lambert 2006; Pope 2003).

I once suggested in a team meeting that it was irrational for surgeons to have ever used the mini-sling, which available evidence quickly suggested was less effective than previous versions. Dr. Robert responded by describing a case in which it made sense to use the device: the patient's life was disrupted by her incontinence but her clinical situation made more invasive forms of surgery, including the TVT, riskier, so Dr. Robert put in a mini-sling. As she told the story, it seemed Dr. Robert was and remained dubious about the clinical improvements promised by the makers of mini-slings; nevertheless, in this case the patient's incontinence was resolved. This decision was situated in practice, and was shaped by intersecting layers having to do with the patient, the surgeon, the health care system, and the market for surgical devices. And Dr. Robert's judgment was also grounded in painstakingly acquired experience and skill (Dreyfus 2004; Dreyfus & Dreyfus 2004). Exposure to the work of surgeons, through collaboration and qualitative interviews and observations, raised doubts about the value of idealized and abstracted depictions of medical practice, such as "art" and "science" – which are in addition themselves continually redefined and mobilized as part of various projects to improve medical practice (Berg 1995; Berkwits 1998; Gordon 1988; Lawrence 1985; Mykhalovskiy and Weir 2004; Schlich 2007; Whelan 2009). The more promising path appeared to be to document the processes and outcomes of situated judgments in conditions of contingency and uncertainty (Lutfey and Freese 2007; Pope 2002; Tanenbaum 1994). Mitigation of the dangers of the profit-driven, unregulated market for surgical implants and devices will come from medicine neither as a perfect science nor as a perfect art.

The tradition of critical medical sociology had prepared me to question, not to understand, clinical judgment, because the history of the

medical profession's sanctioned and unsanctioned abuses of trust and authority warrants interrogation (e.g., described in Dixon-Woods, Yeung, and Bosk 2011; Rothman 1991). Understandably, critical medical sociology tends to treat actors in medicine and health care, especially those with power, as deficient: deficient in ethical principles, deficient in the production and use of clinical evidence, deficient in the capacity to see how their practice is subject to bias or conflicts of interest, deficient in their willingness to standardize their practices and to account for them. This image did not readily fit the physicians and researchers in pelvic floor surgery with whom I was engaged, as I intellectually processed their ways of working and talking about their work, but also came to gain a more emotional and personal sense of their feelings of responsibility. In an increasingly chaotic context of continual device changes, Drs. Ross and Robert, along with numerous colleagues, were working to make surgical procedures comparable and to measure their outcomes and report and publish their results. Such physicians and allied researchers were not mere relays in others' agendas, interests, or imperatives.

In another respect, I was well prepared for this encounter with the situated, complex work of surgeons by research from science and technology studies and the history of medicine that shows practices in medicine, and surgery, to necessarily intertwine elements of context, social categories, and clinical considerations (Berg 1992; Mol 2002; Moreira 2001; Pope 2002; Schubert 2007). The production of evidence itself is subject to this negotiation of scientific, social, and political considerations (Berg, van der Grinten, and Klazinga 2004; May 2006; Molewijk et al. 2003; Richards 1988). This does not mean medical decisions are arbitrary, only that routines for how to practise are created to manage multiple, and changing, considerations. What this type of research tends not to do, however, is attend to the moral and normative aspects of how physicians navigate this complexity – that their routines and actions are also bound up with their understanding of what it means to practice medicine responsibly (Ducey and Nikoo 2018; Halpern 2004; Kaufman 1997). Surgeons must not only determine what to do with given varied factors, but their determinations must coincide with their understanding of what is the right thing to do for their patients. This is the dimension of "making sense" that needs to be highlighted. Making sense is not a matter of straightforward evaluation, of asking and answering apparently unambiguous questions: Is there evidence to support this change of practice? Does the use of this device accord with ethical principles? Must this innovation be dismissed because it has been produced and pushed by people

who stand to personally gain from its adoption? Such questions are not unambiguous, and answers to them will flex based upon moral and emotional considerations.

"Making Sense"

Synthetic mesh "made sense" in the particular path of pelvic floor surgery – as a concept in relation to physiology and anatomy – but also as a morally and emotionally responsible shift in practice. In the absence of mesh, the surgical techniques for supporting the urethra or pelvic floor organs rely on the patient's "native tissues" – creating supports out of fascia, ligaments, and muscles using incisions and sutures. If a woman has a pelvic floor disorder, it is already a sign that something about these tissues or structures is no longer functioning optimally. Therefore, surgeons had long been experimenting with graft materials from other parts of the body or animal donors to reinforce their repairs, and various synthetic grafts had been experimentally used for prolapse since the 1960s (Dwyer 2006). Synthetic mesh had also been widely and successfully used to repair abdominal hernias, an analogous "prolapse" in another part of the body:

> I think that the theory upon which the decision to proceed with mesh was founded was sound. We had placed mesh under the urethra, so transvaginal placement of mesh had been around for years. It was working well. Those slings stayed where you put them, ok? And then when I was researching this and deciding whether or not I would do this, most of the supporting data came from general surgery for the treatment of hernias. They have a huge literature on, mesh treatment of hernias is great ... They just put the mesh in primarily [as the first approach to treatment] – that's how good it is. So the expectation that the mesh would behave well was, I believe, quite well founded. (GS)

In addition, surgeons felt the high rate of "failure" of native tissue procedures was unacceptable. According to one surgeon, the failure rates were "up to fifty per cent ... which is the flip of a coin":

> If you have a procedure that has such a high failure rate, like a native tissue anterior repair, then the question is, what don't we understand that is leading to this? Because clearly we keep doing this procedure that we know doesn't work. It's like the definition of insanity ... You can easily see why people wanted to put mesh in, because it's almost unethical to offer them a native tissue repair. (EH)

So too, when surgeons did use synthetic mesh their experience was not only or primarily of complications from these new device-procedures, but of successes:

> The thing that they don't understand, I really don't think they understand, is that whatever percentage numbers you want to put on for a complication – let's just use the number 3 per cent, 5 per cent – whatever number you want to use. So 5 per cent as the complication, but they're ignoring the other 95 per cent, the thousands and thousands of women who have really, their quality of life has been remarkably improved, and having patient after patient coming into your office and thanking you for improving and changing their lives, they feel like a new woman and so forth – that's the fact they don't fully comprehend. (JH)

The experience of talking to women for whom the implantation of synthetic mesh "changed their lives" doubtless carried weight. The rationale for synthetic mesh was therefore comprised of elements of scientific reasoning, prior clinical experience with mesh and native tissue repairs, and the moral and emotional dimensions of interacting with and seeking to help patients.

On the other hand, surgeons' feelings about the failure of native tissue repair, and their ways of interpreting the research on failures, were not independent of the availability of a new surgical option. The new surgical option may have changed perceptions of what was a failure. Not all surgeons saw the mesh kits in the same way.

> I think that there were a group of people who felt that the rate of failure of our more traditional prolapse surgeries was too high and for that reason, we must have something that's going to reduce that failure rate and the mesh was likely to be that thing. So there was a lot of argument there about "we need to do something more about these failures, what we should be aiming for is 100 per cent success," which is crazy because that never happens no matter what you're doing or using. (BL)

Were surgeons who adopted mesh kits for prolapse aiming for 100 per cent success, or something better than the 50 per cent failure rate associated with native tissue repairs? Were the measures used to establish a 50 per cent failure rate scientifically and clinically valid? It depends on whom you talk to, and how they seek to present themselves and remember.

In addition, some surgeons did not experience success with the kits, or any success was overshadowed by complications or unexpected results.

> My big beef with it was it never stayed where I left it, and so I think that the conclusion is for me, is that the anchoring points weren't adequate. Like, you know, when the general surgeon is fixing a ventral hernia, they do it laparoscopically, they lay the mesh in there, and then they put multiple tacking points, ka-ching, ka-ching, ka-ching, ka-ching [the sound of a surgical stapler]. Whereas when we were doing these mesh vaginal repairs, we were anchoring them at the sacrospinous ligament and the obturator internus membrane, and underneath the pubourethral ligament, so they would ... the expectation was that it would granulate in just like the slings do. But the problem is, is that I found, and that's why I quit so quickly, I betcha I only did at the most ten, is that I'd come back and say, "Well, that's not where I left this bloody thing." (GS)

The appeal of the mesh kits must also be understood in the broader trajectory of surgical innovation and division of surgical labour (Zetka 2001). Some interview respondents said or suggested that because of the advent of laparoscopic surgery for incontinence and prolapse in the mid-1990s, surgeons may have felt they needed to be able to offer seemingly similar "minimally invasive" surgical options. Laparoscopy is not easy to learn and is often described as a time-consuming, complex technique. The transvaginal mesh kits therefore could have appealed to some surgeons, perhaps to generalist gynecologists and urologists more than subspecialists in pelvic floor disorders, because they could offer a "minimally invasive" procedure without needing to learn laparoscopy.

Though a full discussion of these issues is beyond the scope of this chapter, they make clear that considering what makes sense to surgeons does not thereby mean neglecting incompatibilities in their views, the possible influence of wanting to appear responsible on what they say as distinct from what they might do in practice, or the organizational, professional, and institutional trajectories that shaped what could and could not make sense.

From Wrong to Fallible

Such differences among surgeons in experiences, reasoning, emotions, arguments, and clinical decisions suggest that perhaps distinctions can and must be made between ways of "making sense" that allowed for better or worse treatment. Surely not all of these surgeons can be said to be right? Surely to intervene we must know who is right and who is wrong?

At one point, I circulated to the team Joan Cassell's (1991) ethnographic study of surgical work, in which she felt compelled to include in

her analysis a provisional, nuanced, and careful categorization of "surgical sins." One chapter focused on the decision by an "old-time" and "prima donna" surgeon, known for his volatility, confidence, and technical facility – a cowboy? – to undertake a then still uncommon approach to colon surgery on a patient who died from infection a week later. The surgeon was criticized by his colleagues. He argued there were no mistakes in the surgery itself and it was not the source of the infection, but his colleagues pointed to aspects of the patient's clinical situation that elevated the risks of infection and which the standard procedure would have reduced. How does a researcher, particularly a non-surgeon, tease apart the elements of a surgeon's decision in order to evaluate it? "After almost three years of observing surgeons," writes Cassell (1991, 22), "I was still unable to evaluate judgment. I could observe *results* ... but I had to rely on [other surgeons] for evaluations of clinical skills." Results are not necessarily a measure of whether a surgeon was right or wrong, responsible or irresponsible. The procedure used by the prima donna surgeon has since become the standard approach to resection of the left colon. Is this also to be the course of the transvaginal use of synthetic mesh to treat prolapse – that once it is more apparent when and how to use it, and who should use it, it will be standard? Even today there are regional and national cultures around the procedure, such that it is widely used as a primary repair in France but largely as a secondary repair (only after a patient's first native tissue repair has failed) in Canada and England. How does one judge judgment?

This would seem to be the domain of clinical ethics, and early on in our work Dr. Ross suggested we needed a bioethicist on our team as an obvious complement to our expertise in health services research, surgery, and critical sociology. Yet a search of the literature showed the case of vaginal mesh had not registered with bioethicists, perhaps because devices for pelvic floor surgery do not raise typical bioethical concerns – those having to do with who shall live and who shall die, or breakthrough technologies that challenge widely and deeply held beliefs. Nor had ethics boards in hospitals or universities noticeably served to limit or control the adoption of transvaginal mesh kits. Bioethics has long been criticized by social scientists for failing to be relevant to specific, everyday moral decisions (DeVries and Subedi 1998; Fox and Swazey 1984; Zussman 1992) – but also by some ethicists, including Dr. Barry Hoffmaster (1994, 2001). In recent work (Hoffmaster 2011; Hoffmaster and Hooker 2009a, 2009b, 2018), he has used empirical research to identify four specific resources of rationality people use in morally complex situations – observation, creative construction, formal and non-formal reasoning methods, and systematic critical appraisal – to improve the capacity for

moral judgment, while recognizing that both the resources and those using them are fallible as well as capable of development. The approach is related to that of ethics as design (Whitbeck 1996) – an agent-based perspective in which ethics is seen to be a practice of developing morally reasonable solutions in conditions where there are real constraints on resources and possible actions, as well as no perfect solutions. In this view, surgeons have to make rational judgments, and a judgment is rational if it emanates from a process of deliberation that is rational. And a process of deliberation is rational when it utilizes the four resources (Hoffmaster 2018).

This perspective recognizes that what is deemed moral and responsible practice can vary by situation, context, and moment, and is therefore quite compatible with social scientific understandings of the construction or negotiation of medical practice and knowledge. This work rejects forms of philosophy or bioethics that emphasize universal, decontextualized notions of morality, but it nevertheless retains an anticonstructionist quality in the notion of coherent, fundamental resources that can improve the process of judgment. Rather than resolve or ignore these epistemological tensions with some social science, I see this project as a way to explore what can happen in the space of these tensions (Mykhalovskiy et al. 2019).

For instance, attending to the processes and tools for improved rationality is a means of assessing some ways of defining and responding to clinical-moral issues as better than others on the basis of the processes through which such definitions and responses were arrived at. This allows for critique that is also oriented towards improving medical practice. Additionally, this shifts the focus away from individual decisions or practitioners as bad apples and individualized responsibility (see Goodwin 2014), towards a focus on whether and how systems and contexts foster or constrain the development of moral capacity. Rather than judge physicians' decisions as right or wrong, or gauge their behaviour by whether they apply abstract ethical principles and criteria, we might examine the processes by which physicians come to make decisions, and work to improve them. Generating and using better clinical evidence has become the primary means of identifying and weeding out bad practices or bad apples in medicine, but it can effectively suggest the only practices that are good and responsible are those known through evidence to be so (see Gordon 1988). Types of "intelligence" in addition to formal metrics and evidence (Martin, McKee, and Dixon-Woods 2015; Shojania and Dixon-Woods 2013) are needed to identify worse *and* better practices, enhancing the critical facility of those who provide and study health care services.

The challenge raised by the case of the adoption of transvaginal mesh was to engage in critique because there is a need for improvement – but without making recourse to an (impossible) objective, evidence-determined medicine governed by regulators, ethics review boards, and surveillance systems, and without making recourse to a (at best partial) depiction of those responsible for allocating and delivering medical care as deficient. In the effort to change medical practice it is essential to learn and collaborate with health care professionals on the project of making care better, a goal they share – in this case, reducing the likelihood of a repeat of the transvaginal mesh mess. Health care improvement is arguably more likely when it works from within the specificities of values and practices of a given setting (Zuiderent-Jerak 2007; Zuiderent-Jerak et al. 2009), rather than from a position of imposing values on practitioners who are assumed to lack them. Therefore, a better intervention would be to facilitate surgical judgment – to assist surgeons, and design conditions that assist surgeons, in recognizing and critically, reflexively navigating the trajectories and contexts in which they are situated: the trajectory of the profession in terms of how surgical skills and privileges are distributed and controlled; their personal history of training and experience and awareness of what works in their hands; the effects of collective norms on what they know and see as responsible; the context of a market and regulatory regime that does not and almost always cannot make determinations of whether and when to use any particular device; the nature of everyday decisions as inherently clinical and moral; and the emotional and personal ramifications of patients' expectations and surgical outcomes.

Extended, interdisciplinary engagement with the case of vaginal mesh shows the extent to which it escapes the typical ways of knowing and intervening in health services research, formal ethical review, bioethical analyses, and health technology assessment. In critical medical sociology, favoured explanations for medicine's wrongs – the undue influence of for-profit interests, the failures of government regulation for device safety, the long-standing problems of professional self-governance, the irresponsibility of surgeons who acted in the absence of good evidence – do not explain "what makes sense." That these devices could come to market with little to no data on their safety and effectiveness, and could additionally be sold and adopted at unprecedented speed and scale, requires interventions at the level of systems and regulations. But many apparent remedies to situations such as the transvaginal mesh case cannot affect important aspects of surgical practice, organization, and values. Most importantly, they do not affect surgical judgment, in which we must still place our trust and our bodies.

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