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Understanding Corporate Responsibility: Culture and Complicity[1]

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Kipnis's fictional account of the televised treatment of Elaine Robbins clearly shows the surgeon's negligence (Kipnis 2011). The problems with Anodyne's support for the telesurgery breakfast are harder to discern, but show up clearly when we take into consideration how surgical evidence is generated, evaluated, and used by surgeons. Current evidentiary practices in surgery have two major weaknesses, related to the epistemic culture of surgery and to practices of knowledge transmission. We argue that this is a systemic problem, which companies such as Anodyne both contribute to and benefit from. Thus, while we agree with Kipnis's claim that Anodyne is complicit in creating "conditions of danger," we believe that Anodyne's contributory roles extend beyond creating moral hazards for susceptible surgeons and harms for individual patients.

The Epistemic Culture of Surgery

By the epistemic culture of surgery, we mean the traditions and practices surrounding the generation, transmission, and uptake of new knowledge in surgery. The traditional research-to-treatment pathway starts with a series of clinical trials to test the safety and efficacy of a new drug or device. Such research results are communicated to practitioners via publications in reputable peer-reviewed journals, and used by regulatory bodies such as the U.S. Food and Drug Administration in decisions about whether to approve use of the novel treatment. For several reasons this ideal pathway does not function well in surgery.

First, surgery lacks a strong foundation in the kind of evidence that characterizes evidence-based medicine (EBM). The best evidence requires results generated by rigorous research such as randomized controlled trials (RCTs), or syntheses of such trials in systematic reviews. Mounting RCTs in surgery is more difficult than RCTs involving drugs. Not only do surgeons provide interventions that are inherently more open to variation than a relatively straightforward prescribing regime, but outcomes may be affected by a range of factors including operating theatres, team composition, postoperative care, and so forth. There are further reasons for surgery's weak evidence base arising from methodological and ethical issues unique to surgical research: difficulties with control groups or blinding; justifying the harms intrinsic to sham surgery in surgical RCTs; and problems of equipoise. Equipoise requires that the investigator be genuinely uncertain as to the merits of two candidate treatments, but is difficult to achieve because the typical orientation of surgeons "characterized by confidence and decisiveness" fits poorly with admitting uncertainty about treatment options (Miller and Brody 2003, 554). The literature reflects these difficulties: Only 3.4%

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of published research in leading surgical journals reports RCTs (Wente et al. 2003), and these RCTs are of variable and often poor quality (Scholler et al. 2009).

Crucially, the surgical community disagrees over what counts as evidence in surgery and how such evidence should be used to direct practice. Some surgeons recommend increased reliance on randomized controlled trials, some advocate for a more systematized approach to innovation, and others promote the use of audits and population-based data (Semmens et al. 1998). Behind these disagreements lie rarely raised but fundamental questions about how we can best obtain knowledge within a practice such as surgery, and corresponding ethical questions about which research methods we ought to use. Such questions indicate that the interactions between evidence and ethics in medicine are far more complex than previously thought (Worrall 2008).

Irrespective of what kind of evidence should count in surgery, a second epistemic problem relates to weak adherence to whatever evidence is available. Surgeons often fail to use evidence from research to guide their practice: One study showed that little more than 50% of practitioners adhered to what was considered strong research evidence (Slim, Panis, and Chipponi 2004). Wide variations in rates of surgical interventions (Birkmeyer et al. 1998) may be explained in part by surgeons' individualistic responses to similar conditions across patient populations. For example, rates of caesarean section vary widely; at least some of this variation is thought to be due to clinician preferences relating to timing and convenience, rather than being driven by evidence about maternal and/or fetal safety. Examples such as these suggest that the lack of research evidence and failure to rely on such evidence are mutually reinforcing: Surgeons cannot depend on research that is of poor quality and/or unavailable, and therefore become accustomed to proceeding without it, and discount its importance for practice.

Knowledge Transmission

Knowledge transmission in surgery raises a second set of concerns. Surgery is characterized by a strong apprenticeship model. Surgeons learn from each other, and surgical "styles" of treatment are often passed down from senior practitioners to registrars (Gawande 2002). That is, colleagues, peers, and mentors are seen as credible and valuable sources of knowledge; demonstration of a new technique is a widely accepted way of inducting a surgeon into that technique. The apprenticeship model of learning has been co-opted by marketing practices, such as the "educational broadcast" used by Anodnyne in Kipnis's example.

The weak evidence base and the strong apprenticeship model may be seen as systemic problems in the practice of surgical research and knowledge transmission. To whom should we attribute responsibility for these problems? This issue is difficult to resolve; nonetheless, some potential candidates who bear some systemic responsibility can be identified. One responsible party is surely the surgical profession itself. That surgery lacks a systematic evidence base and that much surgical research is of poor quality reflects upon the interests and priorities of surgeons to a greater or lesser extent. While surgeons cannot mandate a well-funded surgical research scheme, they are a powerful group with the capacity to influence health policy in this area. In addition, surgeons, like their medical colleagues, consistently deny conflicts of interest secondary to commercial funding of professional education, despite credible evidence to the contrary, and willingly perform (for reward) in roles such as opinion leaders with the aim of changing their colleagues' practice for commercial

rather than evidence-based reasons. The surgical community's laissez-faire approach to these practices amounts to tacit endorsement of a degraded epistemic environment.

Governments or their national health funding bodies also bear substantial responsibility for the impoverished state of surgical research. Surgical research is expensive to perform, and to perennially cash-strapped research funders, the option of manufacturer-funded research must be sometimes irresistible. This strategy is nevertheless one that undermines the purpose of research, as we know that the source of funding influences research outcomes (Collier and Iheanacho 2002). Consequently, health policy, purchasing decisions, and patient care are driven by the over-positive results of industry-funded research. In the case of device registers and other collections of long-term data of the kind that are essential to obtain a full picture of the safety and efficacy of surgical interventions, governments are the only plausible funders.

Finally, and most relevantly for the case of Anodyne, surgical device manufacturers must bear some responsibility for the current state of affairs. It is in their interests to exploit the lack of rigorous evidence available in surgery and to substitute infomercials that promote their products under the guise of education. Although reliable data are difficult to obtain, budgets for marketing (including "professional education") usually far exceed research budgets (Collier and Iheanacho 2002). In the evidence vacuum surrounding many new surgical devices, telesurgery broadcasts involving well-remunerated opinion leaders look like credible evidence; indeed, they may be the only available (and by default the best) evidence about a particular procedure or device. Creating and presenting such material as evidence is wrong on at least two counts. First, it directs resources (time, money) away for creating and accessing credible evidence; and second, it evades peer scrutiny.

In summary, we agree with Kipnis's claim that parties are responsible for injuries caused by the hazardous conditions that they create. While device manufacturers are not solely responsible for the lamentable evidentiary state of much surgical practice, they are directly responsible for systematically and intentionally attempting to fill that space with marketing material presented as credible, authoritative, and educational. Even if Robbins had been a perfect candidate for a surgical intervention that went well for her, to which her informed consent was fully obtained, problems with Anodyne's role in a system of surgical knowledge transmission remain.

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