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Equity under the knife: Justice and evidence in surgery

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Abstract

Surgery is an increasingly common and expensive mode of medical intervention. The ethical dimensions of the surgeon-patient relationship including respect for personal autonomy and informed consent are much discussed, but broader equity issues have not received the same attention. This paper extends the understanding of surgical ethics by considering the nature of evidence in surgery and its relationship to a just provision of healthcare for individuals and their populations.

Keywords: Surgery; Equity; Justice; Evidence; Health technology assessments; Public health ethics

Justice and evidence in surgery

The aim of this paper is to show that, like other forms of healthcare, surgery can and should be responsive to the requirements of justice. It is perhaps uncontroversial that to meet the requirements of justice, surgeons should provide effective treatments in an equitable manner. We argue that this involves a broader set of considerations and responsibilities than are customarily associated with surgical practice. To defend this claim, we critically examine the use of evidence in surgery, present examples that show the importance of effectiveness studies, consider barriers to a justice orientation in surgery.

1. Surgery and justice

Many diseases are treated surgically. People living in industrialised societies will likely undergo at least five operations in their lifetime.¹ Surgeons are trained to tailor their

¹ P.H.U. Lee & A.A. Gawande. The number of surgical procedures in an American lifetime in 3 states. *Journal of the American College of Surgeons* 2008; 207: S75, A. Elixhauser & R.M. Andrews. Profile of Inpatient Operating Room Procedures in US Hospitals in 2007. *Arch Surg* 2010; 145: 1201-1208.

interventions to the individual needs of patients, but the effects of surgery are not limited to the treatment of patients one-by-one. Surgical services must also meet the needs of populations and serve the public good. They should be accessible to people on the basis of clinical need, and they must be as safe and effective as possible. Patients, providers and payers all need information on how, when and where it is best to seek and deliver surgical care.

While surgical interventions themselves are not the kinds of things that can be just or unjust, the provision of surgical services can be unjust, insofar as actions on the part of surgeons and health service providers can generate, exacerbate or ameliorate health inequities.² Such health inequities may arise from uneven distribution of surgical services, a more general lack of access to effective surgical interventions, or from other causes such as skewing of service provision secondary to commercial interests. In order to identify and avoid such injustices, we require comprehensive evidence about surgical interventions, including patient outcomes, access to services and patterns of distribution.

The claim that decisions about evidence have ethical implications is not new.³ Choices about the collection of and reliance on evidence can clearly affect ethical issues such as how practice should be organized, how resources should be distributed, and who should be the beneficiaries of research.⁴ However, the issue of what constitutes good evidence in surgery remains contested, and the relevance of these debates for justice has not been explored. Claims about surgical evidence can concern efficacy or effectiveness.⁵ Each provides different types of knowledge about the usefulness, safety and effects of surgical interventions on individuals and populations.⁶ The difference between evidence of efficacy and evidence of effectiveness is directly relevant to justice in surgery.

Efficacy refers to a measurable difference made by the intervention in an experimental population. Effectiveness refers to the difference it makes in real patients' lives. By far the majority of surgical research concerns efficacy, not effectiveness. We argue that for both ethical and pragmatic reasons, effectiveness matters. Without the generation and collection of effectiveness data, we risk being oblivious to inequities in access, and in outcomes, and therefore liable to exacerbating them.⁷ To achieve justice in surgical practice, the best

² We use the term "health inequities" to refer to avoidable differences (disparities) in health status and health outcomes that occur between more and less-advantaged social groups and which reflect the social determinants of health. For further discussion see: P. Braveman & S. Gruskin. Defining equity in health. *Journal of Epidemiology and Community Health* 2003; 57: 254-258.; W. Rogers. 2007. Health Inequities and the Social Determinants of Health. In *Principles of Health Care Ethics*. John Wiley & Sons, Ltd: 585-591.

³ J. Worrall. Evidence and Ethics in Medicine. *Perspectives in Biology and Medicine* 2008; 51: 418-431.

⁴ W. Rogers & A. Ballantyne. Justice in Health Research: What is the Role of Evidence-Based Medicine? *Ibid.* 2009; 52: 188-202

⁵ B. Flay, et al. Standards of Evidence: Criteria for Efficacy, Effectiveness and Dissemination. *Prevention Science* 2005; 6: 151-175.

⁶ U. Guller. Surgical Outcomes Research Based on Administrative Data: Inferior or Complementary to Prospective Randomized Clinical Trials? *World Journal of Surgery* 2006; 30: 255-266.

⁷ D.R. Urbach & A.M. Morris. Health Care Reform and Comparative Effectiveness: Implications for Surgeons. *Arch Surg* 2010; 145: 120-122.

evidence must be available to clinicians, who need to understand, interpret and act on it.⁸ The best evidence includes effectiveness, which should play a greater role in the way surgeons choose to generate evidence and use it to guide their practices.

2. Ethical evidence: effectiveness not efficacy

In this section we argue that while studies of efficacy are needed to assess the utility of a surgical intervention, such studies do not provide all the evidence necessary for just provision of surgical services. Interventions are efficacious if the treatment produces the anticipated outcome under ideal conditions. In efficacy studies, (sometimes called 'explanatory' trials) surgeons typically test the novel device and/or technique in small relatively uniform groups of patients who meet specific eligibility criteria, to ensure that the results are not confounded by uncontrolled variables. For example, patients with common co-morbidities are generally excluded from these trials. Trials in which patients are randomised to receive either the study intervention or the comparator (randomised controlled trials - RCTs) are considered to yield the strongest evidence of efficacy. Efficacy studies follow basic research, animal trials, or both and are usually conducted in specialist referral centres by one or two surgeons who might well have been involved in developing the technology or technique.

Claims about the efficacy of an intervention are almost always based on measurements of specific outcomes such as symptom scores, laboratory data, time-to-disease-recurrence, and mortality. These endpoints are immediate and intermediate measures of the effects of the intervention - surrogates rather than measures of overall health outcomes. Notably, the outcome measures used in efficacy trials do not typically include standardised 'quality of life' assessments, or even measurements of functional capacity and patient satisfaction. These are described as soft endpoints.⁹ Although evidence of efficacy from RCTs is generally regarded as the 'gold standard' for medical evidence, it does not exhaust the knowledge required for an evidence-based surgery, precisely because the excluded 'soft endpoints' matter to recipients of treatment.¹⁰

The conditions for efficacy studies differ considerably from the conditions under which ordinary patients will likely encounter the intervention. Typical patients in the wider community might well present the co-morbidities that were excluded from the study population. Trial participants must have the capacities to comply with research protocols, there may be age-related criteria and socially-based exclusions, such as fluency in English language, or having a fixed home address, but there are no such restrictions on ordinary patients.¹¹ The trial surgeons and their colleagues in the community may differ in their enthusiasm for and expertise in the intervention. The environment may differ, as a specialist or research centre will likely involve high staffing ratios, close attention to the protocols for

⁸ P.F. Ridgway & U. Guller. Interpreting Study Designs in Surgical Research: A Practical Guide for Surgeons and Surgical Residents. *Journal of the American College of Surgeons* 2009; 208: 635-645.

⁹ R.H. Brook & K.N. Lohr. Efficacy, Effectiveness, Variations, and Quality: Boundary-Crossing Research. *Medical Care* 1985; 23: 710-722, Flay, et al.

¹⁰ J.B. Semmens, et al. The Quality of Surgical Care Project: A model to evaluate surgical outcomes in Western Australia using population-based record linkage *ANZ Journal of Surgery* 1998; 68: 397-403, Guller.

¹¹ W. Rogers. Evidence based medicine and justice: a framework for looking at the impact of EBM upon vulnerable or disadvantaged groups. *Journal of Medical Ethics* 2004; 30: 141-145.

the trial, and so forth. For these reasons, efficacy studies demonstrate what a new procedure or technology can achieve in closely specified circumstances, and suggest by inference what the intervention *could* possibly do when delivered to patients under different conditions.

Investigations into efficacy may be considered unjust with respect to selection for research trials;¹² however their effect upon wider inequities depends upon how efficacy results are applied to the provision of surgical services more broadly. For such services to be provided equitably, information about efficacy is not sufficient; information about effectiveness is also needed.

Effective interventions are those that result in a favourable outcome for patients with the index condition, in relation to variations in their capacities, preferences and context.¹³ The focus of an inquiry about effectiveness is to determine the *average* outcomes for patients, in uncontrolled or 'real world' conditions. Evidence of effectiveness indicates how well a procedure produces the desired result (a beneficial effect) in ordinary practice, rather than in research. Effectiveness studies should be conducted in primary care environments where patients who have the targeted condition are usually seen and treated.¹⁴ Studies of effectiveness are (or should be) conducted on the general population of surgical patients in all its diversity. They typically require widespread long term observation and collection of data; and for the results to be meaningful, data should pertain to 'everyday' surgeons practicing in general surgical units, rather than to results achieved by their colleagues who work in referral or research centres.

Studies of effectiveness typically focus on general health outcomes, rather than relying upon the symptom scores or laboratory data used to demonstrate efficacy. Therefore the sample size in effectiveness studies must be sufficiently large to detect small but important differences in people's health and quality of life. Data collected about the effectiveness of a specific procedure can also provide information about how much it will cost, and the influence of provider factors on outcomes.

Trials of efficacy and trials of effectiveness both provide relevant evidence for the just provision of surgical care. We may think of this as a stepwise process – climbing the evidence mountain. Evidence of efficacy is the first step – if the view is overwhelmingly negative, then the research intervention should be abandoned. If the view is promising, the next stage is to collect evidence of effectiveness in a pilot program, which will give us a view from higher up.¹⁵ Here we can see whether the sunlit slopes predicted by efficacy studies are on the other side of an impenetrable chasm, or whether they are easily attainable. Ongoing monitoring and data collection can strengthen the knowledge base, leading to clearer views from ever higher evidentiary vantage points.

Because of its limitations, ethical and justice problems can arise when evidence of efficacy is

¹² Ibid.

¹³ R. Ashcroft. What is clinical effectiveness? *Studies in History and Philosophy of Science Part C: Studies in History and Philosophy of Biological and Biomedical Sciences* 2002; 33: 219-233.

¹⁴ Brook & Lohr, Flay, et al.

¹⁵ K. Spilsbury. Variations in procedure rates: A need for 'population-based' surgical research *ANZ Journal of Surgery* 2004; 74: 404-405

taken to justify the introduction and broad dissemination of new surgical interventions for the general surgical population. If we are lucky, evidence about effectiveness and evidence about efficacy are consistent: the intermediate outcome measures of efficacy studies accurately predict the longer term measures of effectiveness. This happy congruence exists for some interventions: emergency appendectomy and penicillin for the treatment of pneumococcal pneumonia are examples. But the results of efficacy studies do not necessarily translate to improvements in health outcomes for patient populations.¹⁶ Effectiveness studies are needed to take the step from knowledge that an intervention works “somewhere”, to knowledge that “it will work for us”.¹⁷

Unfortunately however, the surgical literature displays a strong bias towards evidence of efficacy, typified by surgical RCTs. As a result, knowledge that a procedure or implant works “somewhere” is still presumed sufficient to justify its broad dissemination to other surgeons and other patients. These low evidentiary standards do not meet the needs of patients and the general public, although they may reflect the interests of stakeholders such as surgeons and device manufacturers. On this point, a comparison of two orthopaedic procedures shows the value of effectiveness data. The efficacy of the Birmingham Hip Resurfacing procedure (BHR) was established clinically in several small cohort trials. After a pilot study that included monitoring patients for six years, the BHR was made available to surgeons treating the general patient population in 1997. In contrast, De Puy’s ASR[®] implant was released onto the general market in 2003, without any comparable longitudinal clinical trials in patients. The efficacy of the ASR[®] was presumed on the basis of mechanical simulations and its similarity to other approved devices. The De Puy product was promoted aggressively to surgeons as a less invasive alternative treatment for osteoarthritis, specifically designed to meet the needs of younger patients who wanted to maintain a highly active lifestyle.

While the BHR has performed well since its market release with relatively few complications¹⁸, a significant number of patients with ASR[®] hips experienced ‘catastrophic’ problems within 2-5 years after implantation.¹⁹ Complications included debilitating inflammation around the implant and heavy metal poisoning. With 93,000 units sold worldwide the ASR[®] was recalled in 2010; the ongoing consequences of its failure described by regulators as “a public health nightmare”.²⁰ A number of medical opinion leaders have since argued that mandatory clinical trials for medical devices and a formal system of

¹⁶ T.R. Fleming & D.L. DeMets. Surrogate End Points in Clinical Trials: Are We Being Misled? *Annals of Internal Medicine* 1996; 125: 605-613.

¹⁷ N. Cartwright. A philosopher's view of the long road from RCTs to effectiveness. *The Lancet* 2011; 377: 1400-1401., 1401

¹⁸ A.D. Carrothers, et al. Birmingham hip resurfacing: The Prevalence of Failure. *J Bone Joint Surg Br* 2010; 92-B: 1344-1350

¹⁹ D.J. Langton, et al. Blood metal ion concentrations after hip resurfacing arthroplasty: A Comparative Study of Articular Surface Replacement and Birmingham Hip Resurfacing Arthroplasties. *J Bone Joint Surg Br* 2009; 91-B: 1287-1295; D. Cohen. Out of joint: The story of the ASR. *BMJ* 2011; 342.

²⁰ Other issues raised by the dramatic failure of ASR[®] hips include: adverse events reporting, the relationship between surgeons and device manufacturers, and indeed the role of advertising in the rapid dissemination of the product. For further analysis see J. Meek. The Privatisation of the NHS. *London Review of Books* 2011; 33: 3-10.

longitudinal data collection will limit the risks of similar events in the future.^{21 22 23} Clearly the ASR[®] should have undergone some form of longitudinal clinical testing before its general release, but this case reveals a larger ethical problem. Given the availability of a well established and extensively tested treatment why should the benchmark for dissemination of a new procedure or device be set at the low standard of evidence of efficacy? Surely we would first wish to know that any replacement was as effective as the old one. As this knowledge can only be obtained in general surgical practice (rather than in specialist RCTs) new surgical treatments should be introduced in stages to minimize both the risk of harms to patients, and the risk of unproductive expenditure. As it stands the evidentiary and regulatory framework that permitted the general use of the ASR[®] hip served the needs of device manufacturers and surgeons, and not those of patients. Aside from allowing unacceptable and avoidable adverse outcomes, the provision of these surgical services meant that resources were directed away from an effective treatment. If the ASR[®] had been subjected to a study of effectiveness comparable to that undertaken in the BHR case, these unjust outcomes would have been averted.

Taking evidence of efficacy to be sufficient grounds for disseminating a new treatment will also fail to identify any potential problems with service delivery. A highly efficacious procedure “in the hands” of one surgical team, can be an ineffective and even harmful response to the same condition elsewhere due to inevitable variations in case complexity in the general population, diverse hospital and surgeon experience, and differences in the quality of equipment. In health services research and clinical epidemiology, knowledge of the efficacy of an intervention is only an obligatory passage point in the process of acquiring knowledge of its effectiveness.²⁴ Yet in surgery, rather than being recognised as the acme of surgical evidence, effectiveness studies are generally seen as an optional complement to the dissemination of new techniques and technologies to every-day surgical practice.²⁵ Rather than being a mandatory component of surgical research, evaluation of the effectiveness of specific practices and procedures is uncommon.

There are a number of reasons why this might be so. First, the concurrent and continuous evaluation of the effectiveness of surgical procedures is time consuming and resource intensive. When effectiveness data confirms efficacy data, collection of the former can appear to be wasted effort. Second, effectiveness data is messy; there are problems in accounting for and meaningfully analysing the effects of patient variation and co-morbidities on the results of complex treatment. It is difficult to use the results of population-based observational studies in decisions about individual patients; and it is not always clear how patient preferences should be incorporated and assessed. These points reflect some of the

²¹ G.D. Curfman & R.F. Redberg. Medical Devices - Balancing Regulation and Innovation. *New England Journal of Medicine* 2011; 365: 975-977.

²² D.R. Challoner & W.W. Vodra. Medical Devices and Health - Creating a New Regulatory Framework for Moderate-Risk Devices. *New England Journal of Medicine* 2011; 365: 977-979.

²³ S.E. Graves. What is happening with hip replacement? *Medical Journal of Australia* 2011; 194: 620-621.

²⁴ N. Freemantle & T. Strack. Real-world effectiveness of new medicines should be evaluated by appropriately designed clinical trials. *Journal of Clinical Epidemiology* 2010; 63: 1053-1058, Flay, et al.

²⁵ Urbach & Morris, R.S. McLeod, et al. 2008. Evidence-Based Surgery. In *Surgery*. Springer New York: 21-35.

criticisms of EBM levelled by members of the surgical community.²⁶

Despite these concerns, effectiveness studies have contributed and continue to contribute to the equitable provision of surgical care. Publications from the Western Australian *Quality in Surgical Care Project* reveal the epistemic and normative value of population-based studies of surgical effectiveness. Early work focussed on the effectiveness of surgical interventions for abdominal aortic aneurysm (AAA) in Western Australia between 1985-94. At the time, AAA surgery was performed reluctantly in patients over 80 years, because of concerns about procedural risk and the marginal benefits for patients who may be nearing the end of their lives. Findings from the population study indicated that octogenarians should not automatically be excluded from surgical management, and that with careful case selection older patients with AAA may go on to enjoy many more years of life.²⁷ The study also highlighted a gender disparity in outcomes that needed immediate research attention. Later work found that aneurysms tend to rupture at a significantly smaller diameter in women than men, and that the current recommendations for AAA operation left women more exposed to catastrophic ruptures, and worse overall outcomes.²⁸

Soon afterwards the West Australian Health Service adopted a model for care for AAA that aimed to ensure that all patients with this condition “receive the right care, at the right time, by the right team and in the right place”.²⁹ The key features of this program were the education of family doctors and the public to promote early detection and the elimination of gaps in service provision for high risk populations, managed through an integrated surveillance and intervention system. People are now more likely to receive the appropriate form of surgical care, rather than being denied access to treatment on the basis of presumptions about particular patient characteristics such as age or gender. This example shows some of the gaps that result from the uncritical application of the results of efficacy studies to the wider population, gaps that are invisible without comprehensive long term studies of effectiveness. Achieving justice for women and for octogenarians in access to appropriate treatment for AAA required effectiveness evidence.

Effectiveness studies can also contribute to just health care by identifying differences in outcomes across regions because of a lack of access to efficacious care. In this example, the known efficacious interventions for breast cancer were found to be of variable effectiveness, resulting in substantial inequities in outcomes for the treatment for breast cancer in Western Australia.³⁰ Women who were initially treated in non-metropolitan hospitals between 1982-2000 had a 50% greater chance of dying from breast cancer than women treated in metropolitan hospitals. When controlled for other factors, analysis indicated that this disparity arose because the efficacious protocol of care was not always delivered. The causes of this failure were multifactorial but likely included differential access to

²⁶ N. Black. Evidence-based Surgery: A Passing Fad? *World Journal of Surgery* 1999; 23: 789-793.

²⁷ P.E. Norman, et al. Long term relative survival after surgery for abdominal aortic aneurysm in Western Australia: population based study. *BMJ* 1998; 317: 852-856.

²⁸ P.E. Norman & J. Powell. Abdominal Aneurysm: The Prognosis is Worse in Women than in Men *Circulation* 2007; 115: 2865-2869.

²⁹ Department of Health Western Australia. 2008. Abdominal Aortic Aneurysm Model of Care. Perth: Health Networks Branch.

³⁰ K. Spilsbury, et al. Subsequent Surgery after Initial Breast Conserving Surgery: A Population Based Study. *ANZ Journal of Surgery* 2005; 75: 260-264.

intraoperative imaging technologies and appropriate adjuvant therapies (radio- and chemotherapy) for patients outside metropolitan areas, and, potentially, differences in the experience, level and approaches to treatment between rural and urban surgeons.³¹ In this case, effectiveness tracked efficacy; the treatment protocol was good, but the problem was that women outside metropolitan regions did not receive the efficacious treatment. However, this inequity would have remained invisible, and/or the protocol may have been abandoned as ineffective, without the evidence generated by a longitudinal population-based study of effectiveness. Thus achieving equity in breast cancer outcomes relied upon a study of effectiveness, which identified shortcomings in service delivery.^{32 33}

As well as investigating the transferability of efficacious treatments into the community setting, long term studies of effectiveness can help to identify barriers to providing effective care. Given that regulators and policymakers are increasingly reluctant to take action without first seeing 'good quality evidence', such measures are essential to ensure the just provision of surgical care. As the examples above illustrate, effectiveness data can be collected despite the challenges, and when such data are obtained, they can reveal issues of justice and fairness in healthcare. Other studies by the *Quality in Surgical Care Project* have drawn attention to the superiority of specific types of surgical intervention for obesity³⁴ and lower back pain³⁵, thus providing further support for our claim that the just provision of surgical services requires such evidence.

3. Barriers to justice in surgery

The previous section discussed the importance of using effectiveness studies in order to supplement evidence gleaned from efficacy studies. To achieve the just provision of surgical care, effectiveness data are essential. However, improving the use of effectiveness data in guiding the provision of surgical care is but one of the steps needed for surgery to meet the requirements of justice. Barriers to justice in surgery may also be found within the surgical community and culture. These include the individualistic nature of surgery with its commitment to look after the patient "on the table"; the general disinclination of doctors to engage with the social determinants of health; and the lack of uptake of evidence in surgery.

In surgery, like much of clinical medicine, there is a commitment to the individual patient currently seeking care. Broader questions of access to care and resource allocation are often seen as managerial or political issues, rather than clinical issues. Despite the widespread acceptance of justice as an important principle of medical ethics, these issues are presumed

³¹ K.J. Mitchell, et al. Rural-urban differences in the presentation, management and survival of breast cancer in Western Australia. *The Breast* 2006; 15: 769-776.

³² K. Spilsbury, et al. Long-term survival outcomes following breast cancer surgery in Western Australia. *ANZ Journal of Surgery* 2005; 75: 625-630.

³³ C. Clayforth, et al. Five-year survival from breast cancer in Western Australia over a decade. *The Breast* 2007; 16: 375-381.

³⁴ F.J. Smith, et al. Incidence of bariatric surgery and postoperative outcomes: a population-based analysis in Western Australia. *The Medical Journal of Australia* 2008; 189: 198-202.

³⁵ R.E. Moorin & C.D.A.J. Holman. The impact of the evolution of invasive surgical procedures for low back pain: a population based study of patient outcomes and hospital utilization. *ANZ Journal of Surgery* 2009; 79: 610-618.

beyond the responsibility of clinicians.³⁶ Accounts of surgical ethics seem to pay little attention to justice. Aside from periodic discussions about the ethical implications of cost constraints and rationing of services, concern for justice in surgery are typically focussed on protecting the individual from unequal treatment regardless of age, race or sex, rather than preventing health inequities across populations and communities.³⁷ Miles Little describes this focus on individual patients in surgical ethics, and the accompanying hesitancy of health care workers to consider resources or the effects of resource disparities - as “a defining element in ethical relationships”.³⁸ Yet the examples provided in section 2 demonstrate that the ethical aspects of surgical practice go beyond doctor-patient relationships. Surgeons have responsibilities to individual patients, but they also have a collective responsibility to the general community.

Miles Little’s observation points to the second barrier to justice in surgery: the reluctance of doctors to engage with broader issues concerning the nature and distribution of morbidity and mortality. It is widely recognised that the health of individuals and populations is largely determined by social factors, such as location, education, employment and so forth. However, there is evidence (from general practice rather than from surgical practice) that doctors have a limited range of responses in relation to obvious social inequities affecting their patients’ health. These are:

1. Blaming the victim for their disadvantage;
2. Feeling sympathy but excluding social problems from their scope of practice;
3. Feeling powerless about social forces affecting the lives of patients; and
4. Attempting to address social disadvantage in a piece meal way, as best they can.³⁹

Furler and Palmer, commenting on these findings, conclude that together these responses foster collective silence as to how physicians should respond to socially-mediated health problems. This silence is not benign. First, refusal to acknowledge that social inequities cause observable health inequalities allows doctors to assume a level playing field in which the demands of equity are met by providing equal health care to all who access their services. This approach assumes that justice is achieved by treating all patients equally, as if their capacities, access to resources, supports and social capital were all equal. It neglects to notice that patients are not all equal in these respects, and that justice requires us to take such inequalities seriously. Second, silence suppresses evidence that doctors themselves contribute to socially mediated health inequities through differential treatment of patients based upon age, gender, education, ethnicity and so forth.⁴⁰ There is no comparable

³⁶ T. Beauchamp & J. Childress. 1996. *Principles of biomedical ethics*. 4 edn: New York: Oxford University press.

³⁷ M. Little. The Fivefold Root of an Ethics of Surgery. *Bioethics* 2002; 16: 183-201; N. Daniels. 2008. *Just health: meeting health needs fairly*: Cambridge University Press.

³⁸ M. Little. Ethnomics: The Ethics of the Unaffordable. *Arch Surg* 2000; 135: 17-21.,18

³⁹ Harris M, Knowlden S. 1999. Clinical perspective: a general practitioner response to health differentials Sydney: Australian Centre for Health Promotion; Furler J and Palmer V. 2010. The ethics of everyday practice in primary medical care: responding to social health inequities. *Philosophy, Ethics, and Humanities in Medicine* 2010, 5:6.

⁴⁰ van Ryn M, Burke J. 2000. The effect of patient race and socio-economic status on physicians' perceptions of patients. *Soc Sci Med*, 50:813-828; van Ryn M, Fu SS. 2003. Paved with good

evidence concerning surgeons' responses to obvious social inequities affecting the health of their patients; but it seems plausible that their responses would resemble those of their medical colleagues. Indeed, as surgery is very much an action-based practice, feelings of powerlessness in the face of social factors may be exacerbated in surgeons, with a concomitant tendency to ignore them or consider them excluded from the scope of surgical practice. To the extent that surgeons, like other doctors, are reluctant to engage with social factors, inequities may remain invisible and unaddressed.

A third barrier to justice in surgery relates to the role of, and perceptions about research in surgery. As we have argued, effectiveness data is essential to inform safe and equitable practice; however collecting, analysing and disseminating effectiveness data is painstaking work which must involve the whole of the profession, rather than a few research surgeons. There are several reasons why achieving a shift towards this kind of research culture may be difficult. First, there is no strong tradition of research in surgery; surgical practice has been widely criticised for being unscientific, and for the lack of research evidence proving surgical interventions to be safe and effective.⁴¹ This is demonstrated by wide variations in procedures across comparable populations, indicating that surgeons have quite individualistic responses to similar conditions in their patients.⁴² Second, there is little agreement within the profession as to what constitutes appropriate research methods. While there is serious and ongoing debate on the issue⁴³, the focus has tended to be on the need for more RCTs in surgery, and the challenges of performing such RCTs. This focus has directed attention away from the serious and prior question about what kinds of research will best serve the needs of patients. Third, collecting effectiveness data lacks the prestige and excitement of partaking in an RCT investigating a novel therapy. Effectiveness research does not require the imagination and creativity sometimes considered integral to the researcher role, and may thereby be less appealing to researchers and practitioners alike. Next, effectiveness research potentially involves many in the profession, rather than a few dedicated pioneers, creating challenges in motivating and organising large numbers of individual surgeons working across a range of settings. Finally, funding is scarce for surgical research, yet collecting the large data sets necessary for assessing effectiveness is costly. While device manufacturers may fund research into a novel device, they are less likely to want to fund longitudinal studies, such that accessing the resources to perform the research may be difficult.

For all of these reasons, we are a long way from a culture in surgery in which research is the norm; the 'right' research is performed; and the results reliably used to inform practice.⁴⁴

intentions: do public health and human service providers contribute to racial/ethnic disparities in health? *American Journal of Public Health*, 93:248-255.

⁴¹ Lilford R, Braunholtz D, Harris J, et al. 2004. Trials in surgery. *British Journal of Surgery*. 91(1):6-16; Ergina P, Cook J, Blazeby J, et al. 2009. Challenges in evaluating surgical innovation. *Lancet*. 374(9695):1097-104.

⁴² J. Birkmeyer, et al. Variation profiles of common surgical procedures. *Surgery* 1998; 124: 917-923.

⁴³ Barkun J, Aronson J, Feldman L et al. 2009. Evaluation and stages of surgical innovations. *Lancet*. 374(9695):1089-96.; McCulloch P, Altman D, Campbell W, et al. 2009. No surgical innovation without evaluation: the IDEAL recommendations. *Lancet*. 374(9695):1105-12; Cook J. 2009. The design, conduct and analysis of surgical randomised trials. *Trials*. 10:9.

⁴⁴ K. Slim, et al. Half of the current practice of gastrointestinal surgery is against the evidence: A survey of the French Society of Digestive Surgery. *J Gastroint Surg* 2004; 8: 1079-1082.

Yet we need studies of effectiveness, as without these, we are left with inappropriate interventions in use, wide variations in practice, and inequitable outcomes.

Conclusion

To avoid creating or exacerbating health inequities, effective surgical interventions must be provided in an equitable manner across patient populations. Failure to do so risks abandoning patients to ineffective treatments, expensive care or unjust patterns of care. There are compelling reasons to track surgical interventions, and to insist that effectiveness research complements all promising efficacy research. While studies of effectiveness like those of efficacy, have their limitations in directing individual treatments,⁴⁵ the information they provide is essential for ethical and just practice. Provision of a high quality and equitable service requires that procedures be systematically appraised for effectiveness throughout their clinical use.⁴⁶ However, achieving a culture in which effectiveness data is collected and acted upon requires a major shift within the culture and research practices of surgery, and current models of surgical training and education. It is beyond our scope here to do more than gesture at the changes necessary to achieve such a shift, which at a minimum would require: action at the level of individual surgeons in collecting data and using evidence; acceptance by the surgical fraternity of the need for evidence to justify practice; institutional support for collecting data and implementing effective treatments; government support for the costs incurred in collecting data and making results available; and education and support for patients and the general population better to understand why effectiveness matters. In particular, surgical practitioners have a responsibility to contribute where they can towards generating evidence as to the effectiveness of their preferred interventions; justice requires more than the application of technical skills for the benefit of individual patients.

Of course, collecting evidence of effectiveness alone is no guarantee of equity; nevertheless it is an essential step. Further decisions about rationing would remain. However, irrespective of the method of rationing used, information about effectiveness is critical to the decision.⁴⁷ Only with widespread generation and use of effectiveness data can the best and the most just surgical care be provided.

⁴⁵ B.C. Reeves. Limitations of analyses of effectiveness using observational data. *European Heart Journal* 2006; 27: 1642-1643, U. Guller. Caveats in the interpretation of the surgical literature. *British Journal of Surgery* 2008; 95: 541-546.

⁴⁶ Guller. Surgical Outcomes Research Based on Administrative Data: Inferior or Complementary to Prospective Randomized Clinical Trials, P. McCulloch, et al. No surgical innovation without evaluation: the IDEAL recommendations. *The Lancet* 2009; 374: 1105-1112.

⁴⁷ Buyx et al, Ethics and effectiveness: rationing healthcare by thresholds of minimum effectiveness. *BMJ* 2011; 342:d54