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Abstract

Surgical innovation promises improvements in healthcare, but it also raises ethical issues including risks of harm to patients, conflicts of interest and increased injustice in access to health care. In this paper, we focus on risks of injustice, and use a case study of robotic prostatectomy to identify features of surgical innovation that risk introducing or exacerbating injustices. Interpreting justice as encompassing matters of both efficiency and equity, we first examine questions relating to government decisions about whether to publicly fund access to innovative treatments. Here the case of robotic prostatectomy exemplifies the difficulty of accommodating healthcare priorities such as improving the health of marginalized groups. It also illustrates challenges with estimating the likely long-term costs and benefits of a new intervention, the difficulty of comparing outcomes of an innovative treatment to those of established treatments, and the further complexity associated with patient and surgeon preferences. Once the decision has been made to fund a new procedure, separate issues of justice arise at the level of providing care to individual patients. Here, the case of robotic prostatectomy exemplifies how features of surgical innovation, such as surgeon learning curves and the need for an adequate volume of cases at a treatment centre, can exacerbate injustices associated with treatment cost and the logistics of traveling for treatment. Drawing on our analysis, we conclude by making a number of recommendations for the just introduction of surgical innovations.

Introduction

Surgical innovation can bring improvements in patient survival and quality of life, and sometimes improve the situation of those in marginalized groups.[1] However, it can also pose ethical concerns. For example, patients may be subject to unacceptable risks of harm during the development of new devices or procedures; conflicts of interest can compromise surgical decision making; and innovation may lead to inequities such as a two-tiered treatment pathway, where patients who are already better off have greater access to cutting-edge treatments.[2] To date, work on the ethics of surgical innovation has mainly focused on harms to patients and conflicts of interest. However, there are also important issues of justice to be examined. For example, some features of surgical innovation present *prima facie* risks in terms of introducing or exacerbating unfair inequalities in health outcomes and health care access. For instance, surgical innovations tend to be high-cost and involve surgeon learning curves, which means that they require a sufficient volume of patients to remain cost-effective and safe. A high volume of patients, in turn, may only be possible in densely populated urban areas, where population health and health care access may already tend to be better than in rural and remote areas, as is the case in Australia. In this way, surgical innovations risk exacerbating unfair inequalities in health and health care access. In this paper, we examine such justice-related ethical issues as they arise in relation to surgical innovation. We aim to formulate recommendations to assist policy makers and regulators to avoid introducing or exacerbating injustices when making decisions regarding the development, uptake, funding and distribution of surgical innovations.

We develop these recommendations by analyzing a case study: robotic laparoscopic prostatectomy (henceforth robotic prostatectomy). In this case, a new technology – a surgical robot – offers an alternative to the standard surgical treatments for prostate cancer: either a non-robotic laparoscopic procedure – laparoscopic prostatectomy – or an open prostatectomy. The case study enables us to explore how features of what is clearly an instance of surgical innovation,[3] can exacerbate familiar injustices related to access to healthcare treatments. We find that such injustices can result from financial barriers (e.g. the new treatment is too expensive for some patients), geographical barriers (e.g. the new treatment is only available

[1] A recent non-surgical example is the Indian invention, *Swasthya Slate* (health tablet), a revolutionary device that makes diagnostic tests with same-day results available to patients in remote regions. It was designed to improve antenatal services in rural India, and amongst other benefits it has reduced the mortality from *pre-eclampsia* in this marginalized population. See, Wunker, Stephen "How the swasthya slate is revolutionizing healthcare" *Forbes Magazine* 22nd November 2014. Accessed online at: http://www.forbes.com/sites/stephenwunker/2014/11/22/how-the-swasthya-slate-is-revolutionizing-healthcare-and-why-it-steers-clear-of-the-united-states/.

[2] J. Johnson & W. Rogers. Innovative surgery: the ethical challenges. *J Med Ethics* 2011, DOI:10.1136/jme.2010.042150.

[3] Part of the rationale for choosing to focus on a new technology rather than a new procedure, is that it represents an uncontentious case of surgical innovation. It thereby sidesteps questions of how to define surgical innovation, which are by no means straightforward.

in certain centrally located hospitals) or social barriers (e.g. the new treatment depends upon the availability of social supports such as a carer during the postoperative period).

We begin by outlining how robotic surgery was developed and diffused. Following this, we distinguish justice considerations at the health system level from those at the individual patient level, and explore each in turn. We conclude with a summary of the implications of our analysis for the uptake of innovative surgical treatments, and with recommendations for avoiding or ameliorating the effects of patterns of injustice associated with surgical innovation.

Case study: the history of robotic prostatectomy

In 2000 the Food and Drug Administration (FDA) first approved for use in the United States a robot designed to perform surgery: the *da Vinci*® surgical system commercialized by Intuitive Surgical®.[4] The same device had been given CE mark approval more than a year earlier, in January 1999.[5] An earlier robot, the AESOP (Automated Endoscopic System for Optimal Positioning) System, developed by Computer Motion, had been approved by the FDA to assist with surgery in 1994; it used voice recognition to enable the surgeon to control the camera for laparoscopic procedures, but it did not perform surgical tasks, such as making incisions, dissecting tissue and suturing.[6] In contrast, the *da Vinci*® system undertakes all these tasks, with instruments held by four robotic arms. The system is controlled by a surgeon seated at a console, which can be located remotely from the patient (see Figure 1). Nursing staff and anaesthetists, as well as a surgical assistant, stand at the bedside. By default, references to robotic surgery in this paper refer to the *da Vinci*® surgical system, since this is the only system on the market after Intuitive merged with its only rival in 2003.[7]

[4] US Food and Drug administration (FDA) website, accessed online January 2015. URL: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K990144.
[5] Health Information and Quality Authority (HiQA) website, accessed February 2015. URL: www.hiqa.ie/system/files/HTA-**robot**-assisted-surgery.pdf.
[6] N.G. Hockstein, C.G. Gourin, R. A. Faust,& D. J. Terris. A history of robots: from science fiction to surgical robots. *Journal of Robotic Surgery* 2007; 1: 113-118. DOI: 10.1007/s11701-007-0021-2.
[7] Ibid. 116.

Figure 1: Surgeon positioned at the control console of the original *da Vinci* system© 2015, Intuitive Surgical, Inc.

To ensure that this article's scope is manageable within its prescribed length, we focus on one application of robotic surgery: prostatectomy. This procedure has had the widest uptake of all procedures that have been attempted robotically. As a consequence, the literature and data available on outcomes are more extensive than for other robotic procedures. Since the robot was first approved for use in urological surgery (2001), uptake for prostatectomy has been rapid, particularly in the USA, where features of the predominantly insurance-funded healthcare system seem to have facilitated its uptake to the point that robotic procedures now account for more than 75% of prostatectomies.[8] Reasons for this rapid uptake include the appeal of laparoscopic techniques for patients (e.g. in view of a speedier recovery), and surgeons' preference for robot-assisted laparoscopic prostatectomy rather than standard laparoscopic prostatectomy. From the surgeons' point of view, the robot simplifies what is otherwise a very challenging laparoscopic procedure. Its four arms enable the surgeon to control the camera rather than relying on an assistant and make an extra arm available for other tools. Other advantages over non-robotic laparoscopic surgery include: increased dexterity; resolution of the Fulcrum effect (where the tip of the laparoscopic instrument inside the patient moves in the opposite direction to the surgeon's hand); and incorporation of 3D vision. Prostatectomy is associated with two side-effects that can seriously compromise

[8] M. A. Pilecki, B. B. McGuire, U. Jain, J. Y. S.Kim & R. B. Nadler. National Multi-Institutional Comparison of 30-Day Postoperative Complication and Readmission Rates Between Open Retropubic Radical Prostatectomy and Robot-Assisted Laparoscopic Prostatectomy Using NSQIP. *J Endourol* 2014; 28(4):430-436. Much of the data informing this paper is drawn from studies based in the US, due to its high uptake of robotic prostatectomy.

quality of life for the patient– urinary incontinence and impotence. In the 1980s surgeons developed new 'nerve-sparing' techniques on the basis that damage to a key nerve bundle running alongside the prostate was a contributing factor to both these side-effects. The nerve-sparing procedure is difficult due to the proximity of the nerves, challenges associated with the awkward operative field for prostatectomy, and the importance of removing all cancer. As a result, incidence of urinary incontinence and impotence after prostatectomy remain high. In this context, patients and clinicians are interested in options that improve the chance (however slightly) that these side-effects will be avoided. On this basis, there is *prima facie* support for using the robot, since the robot enables scaled down and therefore extremely controlled, tiny movements of the surgical instruments. In theory, then, there are a range of reasons why robotic surgery appears to represent an improvement over non-robotic prostatectomy.[9]

Justice and innovation

Having described key features of robotic prostatectomy, we now turn to the ethical issues that are the focus of this paper: issues concerning justice. In a recent paper in this journal, David Hunter identified three types of justice-based objections that can be raised against research into radically new technologies: objections based on a lack of procedural justice; objections based on an unjust distribution of outcomes at a particular point in time; and objections based on outcomes that conform to an unjust pattern of distribution over time.[10] Hunter emphasized the third type of objection, arguing that, when considering the introduction of a radically new technology, we should be most concerned when essential features of the new technology are likely to preserve and even exacerbate injustice over time. Given this, we examine whether there are essential features of surgical innovation that tend to preserve or entrench existing patterns of injustice, especially in regard to health outcomes and access to health care.

For our purposes, we do not need to adopt a highly nuanced theory of healthcare justice – something more minimal and inclusive will ensure the applicability of our recommendations to most contexts in which healthcare justice is considered. The concept we are invoking includes concerns for both efficiency and equity. In the terminology of Cookson and Dolan, we invoke a 'combination principle', which combines, loosely speaking, 'maximizing' and 'egalitarian' principles of justice.[11]

Maximizing principles of justice are common in health economics. These are principles like 'allocate resources so as to maximize population health' or, put differently, 'allocate

[9] J. Binder & W. Kramer. Robotically-assisted laparoscopic radical prostatectomy. *BJU International* 2001; 87: 408-410.
[10] D. Hunter. How to object to radically new technologies on the basis of justice: the case of synthetic biology. *Bioethics* 2013; 27(8): 426-34.
[11] R. Cookson & P. Dolan. Principles of justice in health care rationing. *J Med Ethics* 2000; 26: 323-329.

resources so as to maximize the number of Quality Adjusted Life Years (QALYs) gained per dollar spent'.[12] We invoke a concept of justice that includes such a concern for population health and for some degree of efficiency, and which therefore invites some attention to the costs and benefits of different treatments. We do this for three reasons. First, it could be unjust to expose patients to treatments that cost them more but benefit them less. Second, it could be unjust to stifle a beneficial treatment that comes at no loss to others in terms of benefits denied.[13] Finally, it could be unjust to stifle a *greatly* beneficial treatment that comes only at a *small* loss to others in terms of benefits denied.[14]

Maximizing principles may help to ensure that population health is maximized given available resources, but they do not ensure – or aspire to – any degree of equality in the distribution of health across the population. Consequently, theorists may regard maximizing principles as fundamentally unrelated to, or even opposed to, concerns for *justice*. However, Cookson and Dolan,[15] like Beauchamp and Childress before them,[16] do talk of maximizing principles as principles of justice, namely on the understanding that the ethical question of how we ought to allocate resources simply is a question of justice. Turning to the 'egalitarian' dimension of our conception of justice, we note that Parfit has helpfully distinguished 'egalitarian' approaches, according to which equality is a good thing in itself, from 'prioritarian' approaches, according to which the intuitive appeal of equality really lies in a concern about the absolute welfare of individuals, i.e. who is worst off.[17] Notwithstanding their differences, egalitarian and prioritarian approaches both tend to prioritise the people worst off. Another approach, sometimes called 'sufficientism', proposes that the needs of anyone below a certain threshold (of health, wealth, or welfare, for example) should be prioritized over the needs of those who meet the threshold.[18] Proponents of all these approaches share a concern for the equal or better-than-equal treatment of those who are worst off, at least up to a threshold.

For the purposes of this paper, we propose a minimal conception of justice partly based on this common ground: those who are vulnerable, marginalized, or overall worse off should not be systematically excluded or disadvantaged in their access to health care or in terms of their

[12] J. Richardson, K. Sinha, A. Iezzi, & A. Maxwell. Maximising health versus sharing: measuring preferences for the allocation of the health budget. *Soc Sci Med*, 2012. 75(8): p. 1351-61.

[13] In the economist's parlance, this is a concern for Pareto-efficiency.

[14] This equates to a concern to avoid very large opportunity costs. Opportunity costs refer to the benefits that must be foregone when resources are allocated to one use and therefore cannot be allocated to their next most beneficial use.

[15] Cookson & Dolan *op. cit.* note 11.

[16] T.L. Beauchamp & J.F. Childress. 'Justice', in *Principles of Biomedical Ethics*. 2009, Oxford University Press: Oxford.

[17] D. Parfit. Equality and Priority. *Ratio* 1997; 10: 202-221.

[18] See, for example, H. Frankfurt. Equality as a Moral Ideal. *Ethics* 1987. 98: 21-43; R. Crisp. Equality, priority, and compassion. *Ethics* 2003; 113:745-763; C. Brown. Priority or sufficiency …or both? *Econ Philos* 2005; 21:199-220.

health. Thus, we are interested in whether there are any features of surgical innovation that would tend to systematically disadvantage those who are already worst off in terms of, for example, financial status, geographical location or social group membership. Our conception of justice also contains some concern for efficiency, namely whether the costs and benefits associated with a treatment justify its being made available to the public and/or subsidized by the government. In the next two sections, we explore these questions at the health system level and the individual patient level in light of experiences with robotic prostatectomy. Then, in the final section, we make recommendations based on our analysis.

Justice issues at the health system level

At the health system level, justice considerations largely relate to ensuring that available treatments are safe and effective and that public resources are spent wisely, namely on treatments that provide good value for money. Regulatory bodies like the FDA in the US and the Therapeutic Goods Administration (TGA) in Australia are responsible for authorizing the availability, but not the public subsidy, of new health technologies in the national health system. They serve to protect the public from harm and, to the limited extent to which they assess new technologies for efficacy, from financial exploitation subsequent to misleading advertising. In principle, approved products are safe and do what their makers and sellers say they do. The regulatory bodies are an important safeguard insofar as they minimize harm from unsafe treatment or misleading advertising, but the primary function of these bodies is one of market regulation – they authorize marketing and use, leaving questions of value to the market or other bodies.

In addition to federal regulatory bodies, welfare states like Australia, the UK and the social democracies of Western Europe have further government bodies that evaluate health technologies to determine whether they should be publicly subsidized.[19] (For simplicity, we ignore the important role of private health insurers in supporting the development and public availability of new technologies.) These bodies try to strike a balance between maximizing population health and ensuring fairness in the allocation of funds across a range of health conditions that may disproportionately impact different demographic groups. Such bodies may be seen as answering two questions: (1) how should limited resources be allocated across disparate areas of health care; and (2) for any given condition, which treatments should be publicly funded?

[19] We focus on countries with universal health coverage (owing to government subsidies) because we would expect justice issues to be least exaggerated in these countries. Thus, if we can identify likely justice issues here, then we have reasonable grounds for expecting these issues to arise in countries without public subsidy of healthcare, or more limited public supports.

In practice, however, the first of these questions may not arise explicitly, and may be answered solely in answering the second question. Australian funding bodies, for example, primarily focus on whether products are clinically effective, and make their funding decisions on the expectation that products "of similar clinical effectiveness" will have a similar cost (so, conversely, produces of dissimilar effectiveness can have a dissimilar cost).[20] On this basis, the government bodies approve for public funding a wide variety of treatments, increasing the choices available to clinicians and patients. Such an approach avoids unfair allocation of resources among medical conditions by publicly funding a wide range of acceptably effective products for all medical conditions at a dollar rate that compares to already funded products. National research priorities in Australia also avoid naming particular health conditions, but the most recent priorities list 'reducing disparities for disadvantaged and vulnerable groups' and 'better health outcomes for Indigenous people' alongside maximizing principles such as 'increase efficiency and provide greater value for given expenditure'.[21]

This approach is consistent with the principle of justice we are invoking insofar as what matters is not purely the aggregate number of health gains achievable under a given resource constraint (efficiency), but also the distribution of those gains across the population or, in other words, the characteristics of the people to whom the gains accrue (equity).[22] At the health system level, then, a new technology will arguably provide better value for money than suggested by its conventional economic evaluation (being focused only on efficiency) if publicly subsidizing the technology will: help the worst off, even if only by a small margin; help people to reach their potential for health gain, even if this health gain is small in absolute terms (for instance, due to intractable disability or co-morbidity); help to reduce unjust health

[20] This wording comes from the Australian Government Department of Health and Aging. Prostheses List Guide – Part 1, July 2010: 28. Accessed online at http://www.health.gov.au/internet/main/publishing.nsf/Content/EC52EB2B75C19C49CA257BF0002063C5/$File/plguidept1Oct10.pdf.

[21] Australian Government. Science and Research Priorities and Practical Research Challenges factsheet. May 2015:4. Accessed online at http://science.gov.au/scienceGov/ScienceAndResearchPriorities/Documents/15-49912%20Fact%20sheet%20for%20with%20National%20Science%20and%20Research%20Priorities_4.pdf.

[22] See, for example, A. Wagstaff, 1991. QALYs and the equity-efficiency trade-off. *J Health Econ* 10:21-41.; O. F. Norheim, M. Johri, D. Chisholm, E. Nord, R. Baltussen, D.W. Brock, P. Carlsson, R. Cookson, N. Daniels, M. Danis, M. Fleurbaey, K.A. Johansson, L. Kapiriri, P. Littlejohns, T. Mbeeli, K.D. Rao, T. Tan-Torres Edejer, and D. Wikler. Guidance on Priority Setting in Health Care (GPS Health). In PRIORITIES 2012: Partnerships for Improving Health Systems. Vancouver: International Society on Priorities in Health Care; J. McKie & J. Richardson. 2005. Neglected equity issues in cost effectiveness analysis – part 1: severity of pre-treatment condition, realisation of potential for health, concentration and dispersion of health benefits, and age-related social preferences. Monash University, Centre for Health Economics; A. J. Culyer, & A. Wagstaff. 1993. Equity and equality in health and health care. *J Health Econ* 12 (4):431-57; A. J. Culyer, 2001. Equity – some theory and its policy implications. *J Med Ethics* 27 (4):275-83.

inequalities, such as inequalities associated with morally irrelevant characteristics like socio-economic status, gender and area of living; help to protect people's workforce productivity or ability to care for others; or help to protect people from financially catastrophic health expenditures.[23]

In light of the above, it is important to consider health system level questions about who benefits from publicly subsidized prostatectomy. Does prostate cancer disproportionately affect some social groups, and does this raise any questions of justice? There is some evidence that prostate cancer does affect different racial groups differently. For example, African-American men suffer from higher rates of prostate cancer than other racial groups, and these cases of cancer occur in younger individuals and more commonly result in death.[24] It is likely that a number of factors contribute to this phenomenon; these are likely to include both genetic and socio-economic factors, since the disparity persists in groups with equal income and access to healthcare.[25] If evidence of this phenomenon is accepted, then the fact that prostate cancer has a disproportionate impact on members of a marginalized group might be a reason to prioritize its treatment, with particular emphasis on the accessibility of gold-standard treatment to the disproportionately affected group.

Another social dimension arises because prostate cancer is only suffered by men, and as such its treatment may arguably be associated with gender biases. For example, many innovations in prostate cancer care focus on reducing side-effects of treatment, such as impotence; and while male sexual function is an important thing to preserve, there is arguably a risk of valuing this too highly in a patriarchal society and a male-dominated medical establishment. It is important to ensure that gender bias does not lead to the disproportionate public subsidy of a treatment offering marginal or merely perceived improvements in outcomes associated with male sexual function, namely over other candidates for funding that may offer greater benefits, such as breakthroughs in cancer treatment or improved treatments for conditions suffered by a larger patient cohort.

A key component of value for money, especially when resources are limited, concerns how much it costs to achieve the additional health benefits made possible by a new technology over its comparator (e.g. an older, rival technology). New technologies tend to be both more

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[23] O. Norheim, M. Johri, D. Chisholm, E. Nord, R. Baltussen, D. Brock D et al. 2012.Guidance on Priority Setting in Health Care (GPS Health). In *PRIORITIES 2012: Partnerships for Improving Health Systems*. 2012, International Society on Priorities in Health Care: Vancouver: doi:10.1186/1478-7547-12-18

[24] F. T. Odedina, T. O. Akinremi, F. Chinegwundoh, R. Roberts, D. Yu, R. R. Reams, M. L. Freedman, B. Rivers, B. L. Green & N. Kumar. Prostate cancer disparities in Black men of African descent: a comparative literature review of prostate cancer burden among Black men in the United States, Caribbean, United Kingdom, and West Africa. *Infectious Agents and Cancer* 2009; 4 :S2 doi: 10.1186/1750-9378-S1-S2.;

[25] T. S. Wells, A. T. Bukowinski, T. C. Smith, B. Smith, L. K. Dennis, L. K. Chu, G. C. Gray & M. A. K. Ryan Margaret. Racial Differences in Prostate Cancer Risk Remain Among US Servicemen With Equal Access to Care. *The Prostate*, 2010; 70: 727-734.

effective but also more costly, so the question then arises as to whether the additional effects are worth the additional costs. However, this is an oversimplification of the assessment required, because new technologies may be more effective in the future even if they are not initially more effective, and they may be more affordable in the future even if they are not initially more affordable. Government bodies must consider the opportunity cost of publicly subsidizing a new technology by, in effect, asking whether the public will be better off if the new technology is subsidized or if the resources needed for this are instead expended differently, for example, on an older, rival technology. In assessing whether a treatment such as robotic prostatectomy represents value for money, it is important to consider both its costs and outcomes. In what follows, we discuss each of these in turn.

While estimates of the cost of a robotic prostatectomy vary, it seems fair to say that there are cheaper ways of treating prostate cancer. Both of the alternative surgical treatments – open prostatectomy and laparoscopic prostatectomy – are less expensive, even accounting for the cost of the extra days in hospital for the open procedure.[26] The comparison of costs is further complicated by the availability of non-surgical therapies such as Cryoblation (localized freezing) and Brachytherapy (internal radiotherapy),[27] while in some cases of early prostate cancer in older men, watchful waiting appears to be an appropriate management option.[28]

Of course, costs can change over time, altering whether or not a procedure is cost-effective. For instance, one of the reasons robotic surgery is currently expensive is because there is a monopoly. If other companies were to develop and get approval for similar devices, increased competition might lead to lower costs for buyers and users. Increased uptake can also lead to reduced costs, as mass production reduces costs by increasing the efficiency of production and distribution. However, it is difficult to see how the cost of a robotic system plus associated laparoscopic instruments could ever be less than the cost of laparoscopic instruments without the robot, or indeed the scalpel and other simple instruments required for open surgery. The robot replaces neither the tools, nor the surgeon (who is still required to operate the robot), so there is no obvious potential for cost saving in terms of the equipment. Furthermore, while laparoscopic surgery reduces the cost of the hospital stay compared to open surgery (due to reduced surgical wound and blood loss), robotic surgery may not offer

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[26] Y. Lotan. Is robotic surgery cost effective: no. *Curr Opin Urol* 2012; 22:66-69; R. M. Hall, N. Linklater & G. Coughlin. Robotic and open radical prostatectomy in the public health sector: cost comparison. *ANZ Journal of Surgery* 2013; 84:477-480; S. L. Chang, A. S. Kibel, J. D. Brooks & B. I. Chung. The impact of robotic surgery on the surgical management of prostate cancer in the USA. *BJU International* 2014; Online Early View. DOI: 10.1111/bju.12850.

[27] J. B. Malcolm, M. D. Fabrizio, B. B. Barone, R. W. Given, R. S. Lance, D. F. Lynch, J. W. Davis, M. E. Shaves & P. F. Schellhammer. Quality of Life After Open or Robotic Prostatectomy, Cryoblation or Brachytherapy for Localized Prostate Cancer. *J Urol* 2010; 183: 1822-1829.

[28] A. Bill-Axelson, L. Holmberg, M. Ruutu, H. Garmo, J. R. Stark, C. Busch, S. Nordling, M. Häggman, S. – O. Andersson, S. Bratell, A. Spångberg, J. Palmgren, G. Steineck, H.- O. Adami, J. – E. Johansson. Radical Prostatectomy versus Watchful Waiting in Early Prostate Cancer. *New Engl J Med* 2011; 364: 1708-1717.

even these advantages over standard laparoscopic surgery. Nor does robotic surgery currently lead to efficiencies in the operating suite, such as fewer medical staff or shorter operating times.[29]

Alongside costs, another factor central to the value for money offered by a procedure lies in the quality of its outcomes. It is difficult to know whether the robot offers sufficiently better outcomes to represent value for money, due to limitations of the current evidence.

When comparing the outcomes of treatments for prostate cancer, there are three different sets of outcomes to take into account, with different levels of importance: the cancer-related outcomes, the rates of serious or long-term complications, and short-term or less serious complications. Cancer-related outcomes are most important insofar as the motivation for prostatectomy is to cure prostate cancer and thereby prolong life. Cancer-related outcomes include margin clearance rates, prostate-specific antigen (PSA) levels, subsequent cancer treatments required, and mortality from prostate cancer. Most of the published research suggests that robotic surgery is comparable to open and standard laparoscopic surgery in terms of these cancer-related outcomes.[30]

Cancer-related outcomes aside, there are two common and undesirable long-term, potentially permanent side-effects associated with prostatectomy: incontinence and impotence.[31] A 2005

[29] C. Bolenz, S. J. Freedland, B. K. Hollenbeck, Y. Lotan, W. T. Lowrance, J. B. Nelson & J. C. Hu. Costs of Radical Prostatectomy for Prostate Cancer: A Systematic Review. *Europ Urol* 2014 ; 65: 316-324.

[30] W. T. Lowrance, E. B. Elkin, L. M. Jacks, D. S. Yee, T. L. Jang, V. P. Laudone, B. D. Guillonneau, P. T. Scardino & J. A. Eastham. Comparative Effectiveness of Prostate Cancer Surgical Treatments: A Population Based Analysis of Postoperative Outcomes. *J Urol* 2010; 183: 1366-1372.; M. Alemozaffar, M. Sanda, D. Yecies, L. Mucci, M. J. Stampfer & S. A. Kenfield. Benchmarks for Operative Outcomes of Robotic and Open Radical Prostatectomy: Results from the Health Professionals Follow-up Study. *Europ Urol* 2014 (in press, online early). http://dx.doi.org/10.1016/j.eururo.2014.01.039.; G. Gandaglia, F. Abdollah, J. Hu, S. Kim, A. Briganti, J. D. Sammon, A. Becker, F. Roghmann, M. Graefen, F. Montorsi, P. Perrotte, P. I. Karakiewicz, O.-D. Trihn & M. Sun. Is Robot-Assisted Radical Prostatectomy Safe in Men with High-Risk Prostate Cancer? Assessment of Perioperative Outcomes, Positive Surgical Margins and Use of Additional Cancer Treatments" J *Endourol* 2014; 28(7):784-791. There is one recent systematic review that suggests a slight advantage for robotic prostatectomy in terms of margin clearance, although the authors note that the evidence informing the review has limitations due to the lack of randomized studies. (See A. Tewari, P. Sooriakumaran, D. A. Bloch, U. Seshadri-Kreaden, A. E. Hebert & P. Wiklund. Positive Surgical Margin and Perioperative Complication Rates of Primary Surgical Treatments for Prostate Cancer: A Systematic Review and Meta-Analysis Comparing Retropubic, Laparoscopic, and Robotic Prostatectomy. *Europ Urol* 2012; 62:1-15).

[31] Continence has the greatest impact on quality of life assessments following prostatectomy, and is therefore regarded as the next most important outcome after cancer-related outcomes. See, for example, A. Sood, W. Jeong, J. O. Peabody, A. K. Hemal & M. Menon. Robot Assisted Radical Prostatectomy: Inching Toward Gold Standard. *Urol Clin N Am* 2014; 41: 473-484, p. 476.

study with five year follow up showed that whereas 87% of participants had total urinary control prior to prostatectomy, the percentage with full urinary control after the procedure peaked at 39%. The same study found that whereas 81% of participants were able to achieve erections firm enough for intercourse prior to their prostatectomy, the number who were able to achieve this after the procedure peaked at 28%.[32] The likelihood of these side-effects occurring, particularly impotence, is dependent on a range of factors, including tumor size and location, and patient age, which makes comparison of surgical approaches more challenging. In theory, the high degree of control and the ability to scale down the movements of the instruments, as well as to eliminate any effects of hand wobble, give robotic surgery an advantage over open or laparoscopic surgery in terms of achieving margin clearance while sparing the nerves associated with continence and sexual function. Furthermore, the 3D camera gives an in-principle advantage to robotic surgery over standard laparoscopic surgery in terms of an enhanced view of the operative field. Some studies appear to confirm this in-principle advantage, showing slightly better outcomes for the robotic procedure,[33] however others find no significant difference.[34]

The third set of surgical outcomes concern recovery time and blood loss. We take these to be of lower importance than cancer-related outcomes, continence and sexual function, because they do not generally have significant long-term implications for the patient (although blood loss sometimes results in a blood transfusion and its associated risks). Studies consistently show that the robotic procedure is associated with reduced blood loss and a significantly shorter hospital stay compared to open prostatectomy (e.g. Lowrance et al. found a 35% shorter stay with laparoscopic treatment compared to open surgery).[35] These differences are to be expected in any minimally invasive surgery, since they primarily relate to the smaller incision size required – blood loss and length of hospital stay are largely determined by the surgical wound. There is also some evidence that robotic surgery may offer a small advantage over standard laparoscopic surgery for blood loss and hospital stay.[36] While a reduction in wound size and associated morbidity are of less importance than treatment effectiveness, and generally do not have an impact on long-term outcomes, such factors would come into play in assessing comparative effectiveness, and therefore cost-effectiveness, if the treatment options were otherwise equivalent.

[32] Note that for sexual function the percentage able to achieve erections firm enough for intercourse was highest at 60 months follow up, whereas for urinary continence the percentage with full control was highest at 24 months follow up. This data is from D. F. Penson, D. McLerran, Z. Feng, L. Li, P. C. Albertsen, F. D. Gilliland, A. Hamilton, R. M. Hoffman, R. A. Stephenson, A. L. Potosky & J. L. Stanford. 5-Year Urinary and Sexual Outcomes After Radical Prostatectomy: Results from the Prostate Cancer Outcomes Study *J Urol* 2005; 173:1701-1705.
[33] A. Tewari et al. *op. cit.* note 30.
[34] M. Alemozaffar et al. *op. cit.* note 30.; G. Gandaglia et al. op. cit. note 30.
[35] W. T. Lowrance et al. *op. cit.* note 30.
G. Gandaglia et al. *op. cit.* note 30.
[36] A. Tewari et al. *op. cit.* note 30, p. 13.

It is obvious from the above that limitations in the evidence available pose a challenge for assessing the overall benefits, and therefore the cost-effectiveness, of robotic surgery. These are left uncertain, and high levels of uncertainty rightly increase a government's hesitation to publicly subsidize an intervention, in effect reducing its perceived value for money. This is explicitly stated in the funding policies of Australia and comparable countries.[37]

These limitations in the evidence on the safety and effectiveness of robotic prostatectomy are likely to translate to other surgical innovations, as they are at least partly a result of difficulties in evaluating surgical interventions.[38] The pattern of diffusion for surgical innovations is such that evidence about comparative effectiveness is often available only after the technology is well-established, and randomized trials may never be undertaken due to practical challenges.[39] This in turn means that the uptake of often expensive treatment with dubious advantages over conventional treatment is likely to be relatively widespread in surgery. Another complication arises due to the likelihood that the results from early studies are confounded by the impact of the learning curve, since there is evidence that surgeons' outcomes continue to improve after performing more than 100 procedures.[40] Refinement of the equipment and technique may also mean that outcomes for later patients are better than those for the first patients.[41] Should we accept the methodological difficulties of producing high-quality evidence in the case of surgical interventions, and accordingly subject surgical interventions to lower standards of evidence? Rogers and co-authors have clearly and persuasively argued 'no'.[42] So, there is an important question of what to do. Staged approaches to treatment introduction and evaluation, as proposed by the authors of the

[37] Australian Government Department of Health and Ageing. *Proposal for changes to the Medical Services Advisory Committee (MSAC) processes for applications for public funding*, Australian Government: Canberra 2010; Australian Government Department of Health and Ageing, *Guidelines for preparing submissions to the Pharmaceutical Benefits Advisory Committee*. Australian Government: Canberra 2008; Scottish Medicines Consortium, *Guidance to Manufacturers for Completion of New Product Assessment Form (NPAF)*. Glasogow 2013; National Institute for Health and Care Excellence, *Guide to the methods of technology appraisal 2013*, in *Process and methods guides*. 2013.; National Institute for Health and Care Excellence, *Diagnostics assessment program manual*. 2011.; and Canadian Agency for Drugs and Technologies in Health (CADTH), *Guidelines for the Economic Evaluation of Health Technologies: Canada*. 2006: Ottawa.
[38] P. L. Ergina, J. A. Cook, J. M. Blazeby, I. Boutron, P. A. Clavien, B. C. Reeves & C. M. Seiler. (2009) Challenges in evaluating surgical innovation. *Lancet* 2009; 374: 1097-1104.
[39] P. L. Ergina, J. S. Barkun, P. McCulloch, J. A. Cook & D. G. Altman., IDEAL framework for surgical innovation 2: observational studies in the exploration and assessment stages. *BMJ* 2013; 346:f3011.
[40] N. L. Sharma, A. Papadopoulos, D. Lee, J. McLoughlin, S. L. Vowler, H. Baumert, A. Y. Warren, V. Patil, N. Shah & D. E. Neal. First 500 cases of robotic-assisted laparoscopic radical prostatectomy from a single UK centre: learning curves of two surgeons" *BJU International* 2010; 108: 739-748.
[41] Some refinements are described in Sood et al. op. cit. note 31.
[42] W. Rogers, C. Degeling & C. Townley. Equity under the knife: justice and evidence in surgery. Bioethics 2014; 28(3): p. 119-26.

IDEAL framework, might make it easier to manage the challenges associated with evaluating surgical interventions.[43]

A final set of considerations that are arguably relevant to justice, but may not straightforwardly reduce to cost-effectiveness or equity, are the preferences of patients and surgeons. These preferences are sometimes motivated by aesthetic considerations or convenience, but for particular patients, such as those who are older, physically weaker or with compromised immune systems, the choice of a minimally invasive procedure might be clinically indicated.[44] Publicly funding a variety of treatment modalities supports equity by making appropriate interventions available to particular individuals for whom they are clinically indicated. Surgeon preference may also be relevant to questions of justice insofar as the technical difficulty of standard laparoscopic prostatectomy prevents many surgeons from taking it up despite patient demand. Sundi and Han note that "robotic assistance has rendered minimally invasive radical prostatectomy technically feasible for many surgeons, whereas laparoscopic prostatectomy without robotic assistance is technically daunting and has a steep learning curve". They go on to suggest that robotic surgery "has significant merit as an enabling technology." [45] This claim is supported by the trend for recent comparative studies to omit non-robotic laparoscopic prostatectomy on the basis that it is now rarely performed – surgeons undertaking laparoscopic prostatectomy generally use the robot.[46]

The above reflections on justice at the health system level will play an important role in informing our recommendations regarding surgical innovation. However, despite limited evidence that public subsidy of robotic prostatectomy will improve prostate cancer outcomes

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[43] P. McCulloch, J. A. Cook, D. G. Altman, C Heneghan & M. K. Diener . IDEAL framework for surgical innovation 1: the idea and development stages. *BMJ* 2013; 346:f3012.; Ergina et al. op. cit. note 39; and J. A. Cook, P. McCulloch, J. M. Blazeby, D. J. Beard, D. Marinac-Dabic & A. Sedrakyan. IDEAL framework for surgical innovation 3: randomized controlled trials in the assessment stage and evaluations in the long term study stage. *BMJ* 2013; 346:f2820.

[44] In the case of robotic prostatectomy, however, it is not clear whether patient preferences are driven by such considerations, or by the widespread perception that robotic surgery is associated with better outcomes than other treatment options. This perception may be encouraged by claims made in mainstream media and on hospital websites, as reported in S. Alkhateeb & N. Lawrentschuk. Consumerism and its impact on robotic-assisted radical prostatectomy. *BJU International* 2011; 108: 1874-1878.

[45] D. Sundi & M. Han. Limitations of Assessing Value in Robotic Surgery for Prostate Cancer: What Data Should Patients and Physicians Use to Make the Best Decision?. *Journal of Clinical Oncology* 2014. Available online before print. Accessed January 2015 doi: 10.1200/JCO.2013.54.9741 This quote p. 1394.

[46] See, for example, M. A. Pilecki, B. B. McGuire, U. Jain, J. Y. S. Kim John & R. B. Nadler National Multi-Institutional Comparison of 30-Day Postoperative Complication and Readmission Rates Between Open Retropubic Radical Prostatectomy and Robot-Assisted Laparoscopic Prostatectomy Using NSQIP. J Endourol 2014; 28 (4): 430-436. In another article (T. J. Vidovszky, W. Smith, J Ghosh & M. R. Ali. Robotic Cholecystectomy: Learning Curve, Advantages and Limitations. J Surgl Res 136: 172-178) the authors note the advantages of the robot in terms of these technical matters.

or reduce associated inequities, and despite its higher cost, it appears that increased uptake by health systems is inevitable. In Australia, robotic prostatectomy is already subsidized by the government through Medicare as a form of 'prostatectomy', although only at the same rate as open and laparoscopic procedures.[47] And while robotic prostatectomy is not yet widely available within the public health system – most *da Vinci* robots are currently owned by private hospitals – the recent acquisition of a *da Vinci* robot by the New South Wales (NSW) state government makes robotic surgery available for the first time to public patients in that state. In a press release, the NSW Minister for Health declared that "[r]obotic-assisted surgery is the next phase in the evolution of healthcare and I am delighted that it will improve clinical care for those public patients requiring surgery".[48] The Minister's words echo Sundi and Han's recent observation that when it comes to robotic prostatectomy we "are truly in the […] postdissemination era. Whether it will become widely adopted is no longer in question – despite increased costs, it already has." Once an innovative treatment has been adopted, a different set of justice questions arise. These questions relate to whether individual patients have equitable access.

Justice issues at the patient level

There is evidence that access to robotic prostatectomy is not currently distributed based purely on morally relevant characteristics such as medical necessity or the capacity to benefit from treatment. Research from the US shows that individuals from minority or disadvantaged backgrounds (African American, Hispanic and lower socio-economic patients) do not access robotic surgery in the same relative proportions as Caucasian men of higher socio-economic status.[49] This may be particularly concerning in the case of African American men, who tend to have prostate cancers with a younger onset and worse prognosis.[50] There are also issues of justice on geographical grounds, with evidence that robotic surgery is offered more frequently in teaching hospitals than non-teaching hospitals, more in urban areas than rural ones, and that patients on average need to travel further to access robotic surgery, thereby

[47] Radical prostatectomy is refunded under Medicare Benefits Scheme codes 37210 and 37211 irrespective of whether it is an open, standard laparoscopic, or robotic procedure. See Medicare Benefits Schedule Online: http://www9.health.gov.au/mbs/search.cfm?q=37210%2C37211&sopt=I (accessed January 2015)

[48] New South Wales Ministry of Health. Da Vinci Robot Lands at Nepean Hospital. 2012, http://www.health.nsw.gov.au/news/Documents/20121011_00.pdf

[49] S. P. Kim, S. A. Boorjian, N. D. Shah, C. J. Weight, J. C. Tilburt, L. C. Han, R. H. Thompson, Q. – D. Trinh, M. Sun, J. P. Moriarty & R. J. Karnes. Disparities in Access to Hospitals with Robotic Surgery for Patients with Prostate Cancer Undergoing Radical Prostatectomy. *J Urol* 2013; 189: 514-520.

[50] Wells et al., op. cit. note 25.

limiting the treatment to patients who either live near, or can get transport to, a hospital with a robot.[51]

Hunter rightly urges caution when considering whether injustices associated with innovative treatments early on are likely to become entrenched.[52] It is inevitable, for example, that a new surgical treatment will initially be available in a limited number of treatment centres. There are, however, some features of surgery that might increase the likelihood of entrenched injustice. Unlike most new pharmacological agents, the volume of cases encountered is relevant for skills acquisition and skills maintenance in surgery. Surgery has learning curves such that the more a procedure is performed both by an individual surgeon and by a surgical team, the better their proficiency and outcomes will be.[53] This explains the results of a number of studies that show better outcomes for early robotic prostatectomy procedures when performed by higher-volume surgeons and at higher-volume centres. Given the link between high throughput and better outcomes, it seems there might be (understandable) pressure for the procedure to be undertaken, particularly early in its development, by just a few surgeons and teams at busier, more centrally located hospitals, with implications for justice in terms of which patients access these hospitals. However, this issue is not only associated with new procedures during the learning curve. There is strong evidence that surgical outcomes are better when surgeons, surgical teams, and institutions have higher volumes of the procedure in question, even after learning curves have been overcome. Thus consideration of likely ongoing volume of robotic procedures will result in pressure to centralize robotic surgery, and to limit the number of hospitals where it is practiced. In the US, where uptake is higher than in Australia and the UK, there is evidence that some populations are more proximate to hospitals offering robotic surgery (either because they live closer, or because they have better access to the transport and other supports that make traveling for surgery a viable option).[54] In Australia, uptake is in its early stages, so it is inevitable that services are currently located at only a few major hospitals. However, it is likely that the geographical location of robotic surgery will entrench these geographical inequities. It is important to be particularly mindful of this in countries such as Australia, where the concentration of Indigenous populations and people of lower socio-economic status is higher in regional communities.

There are other related factors which contribute to patients being selected for robotic prostatectomy on grounds that are not morally relevant. These involve the cost of the robot, both in terms of the initial outlay and the ongoing use and maintenance. Hospitals with a robot need to use it regularly to improve its cost-effectiveness, since the robot is expensive to

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[51] K. B. Stitzenberg, Y. –N. Wong, M. E. Nielsen, B. L. Egleston & R. G. Uzzo. Trends in Radical Prostatectomy: Centralization, Robotics and Access to Urologic Cancer Care. *Cancer* 2011; 118(1): 54-62.
[52] Hunter, op. cit. note 10.
[53] There is some disagreement over the duration of the learning curve. However, for robot-assisted prostatectomy, there is evidence that surgeons are still improving after more than 100 procedures. See, for example Sharma et al., op. cit. note 40.
[54] Kim et al., op. cit. note 49.

maintain. This may lead to pressure to maximize its value, which poses a number of potential risks for patients. First, there may be a widening of indications for robotic prostatectomy, where an alternative surgery or non-surgical intervention might otherwise be preferable.[55] Although widening indications represents value for money through maximizing the use of the equipment, doing so is not warranted if the cost is still higher in absolute terms or if an alternative treatment would have been safer or more effective for the patient. In treating prostate cancer there are alternatives to surgery and surgery is not the best choice for all patients. Malcolm et al. compared prostatectomy with two non-surgical approaches and found that, for localized prostate cancer, the non-surgical interventions were associated with better quality-of-life scores and statistically similar scores for margin clearance compared to any surgical approach.[56] In addition, Bill-Axelson et al. compared prostatectomy with watchful waiting and their subgroup analysis suggested that surgery may be no better than watchful waiting in men over 65.[57] Furthermore, in the case of technology that has other applications, as the robot does, its use might be further extended to treat additional conditions. Again, though the robot might be operating more cost-effectively with more frequent use, and might benefit the patients it is used on, this is only desirable if robotic surgery is an appropriate and cost-effective intervention compared to alternatives.

We are not suggesting any intentional or deliberate strategy on the part of surgeons, hospitals or policy makers to discriminate against patients from particular groups or locations. However, in effect certain patients may be adversely and unfairly impacted by the reality of how the robot has diffused into practice. To recall Hunter's distinctions, this comprises a potentially ongoing pattern of injustice.[58]

Justice and innovative surgery – recommendations

Based on our analysis, there are a number of important considerations for policy makers when introducing new surgical interventions, particularly those associated with expensive technology. At the health system level, it is necessary for decision makers to consider the following questions before funding new surgical interventions, particularly interventions based on expensive technology:

1. Who will benefit from the introduction of this procedure? Do those who benefit fall disproportionately within one or more social groups (e.g. based on gender, race, class)? Are those groups already better or worse off?
2. What is the expected degree of benefit to the patient, and is it temporary (e.g. faster recovery time) or ongoing (e.g. better cancer survival rates)?

[55] It would be difficult to determine whether and to what extent this was occurring. However, there is evidence that the number of radical prostatectomies has increased at the same time that uptake of the robotic procedure has increased, see Lotan, op. cit. note 26.
[56] Malcolm et al., op. cit. note 27.
[57] Bill-Axelson et al., op. cit. note 28.
[58] Hunter *op. cit.* note 10.

3. How important is the benefit, both to individual patients (e.g. in terms of surgical outcomes) and to society (e.g. in terms of productivity and quality of life measures)?
4. What are the possible future benefits, particularly in terms of foreseeable refinement of the procedure?
5. In view of all of the above, is the procedure cost-effective, and what is its potential to compound or, conversely, alleviate extant injustices, namely in how social goods are distributed over time?

Based on these questions, decision makers will glean some sense of the innovation's implications for justice in the healthcare system as a whole. Answering these questions will involve analyzing cost-effectiveness as well as dimensions of inclusion – that is, considering the distribution of benefits and risks, particularly as these impact members of marginalized groups. We further recommend that decision makers adopt a framework for the ongoing evaluation of the effectiveness of innovative surgical procedures, such as the IDEAL model proposed by the Balliol collaboration.[59] Decisions about diffusion and funding should continue to be sensitive to the growing body of evidence about the effectiveness of the procedure and associated risks.

Furthermore, our analysis suggests that even if the system-level analysis is favourable, surgical innovation is associated with a set of challenges to justice at the individual patient level. Because surgical interventions need to be provided at a set location by a specialist, they are not equally accessible to all patients. Some patients may need to travel or arrange care and support for themselves or their dependents in order to obtain treatment. This issue is compounded by the importance of ensuring sufficient patient volumes are maintained by surgeons and centres, because a negative correlation between volume and poor outcomes has been demonstrated for many surgical interventions. In the case of very expensive technology, such as robotic surgery, these issues are further compounded – even if volume requirements could be met with widely diffused technology, cost-effectiveness considerations might warn against broader dispersal of such technology.

Given this potential source of entrenched injustice, we recommend that the introduction of innovative surgical interventions, particularly those associated with high-cost technology such as the robot, is accompanied by a plan and funding to maximize equity of access for those who are located far afield. Use of this funding should not be narrowly constrained – the funding should be available to patients to meet any of the needs arising from the necessity of traveling for treatment, including needs for carers, transport, and accommodation.

Conclusion

[59] See, for example Ergina et al., op. cit. note 39, McCulloch et al., note 43. and Cook et al., note 43.

In this paper we have used the case of robotic prostatectomy to explore the implications of surgical innovation for justice in healthcare. We have identified a number of factors associated with surgical innovation that raise challenges for justice at the health system level and at the individual patient level. At the health system level, we note that surgical innovation is often diffused ahead of high-quality evidence of effectiveness, and that early evidence may be compromised by the learning curve. Nonetheless, evidence of benefits to patients must be considered, alongside reflection on the importance of those benefits. Benefits to surgeons (such as comfort, safety or ease of use) might also be relevant, especially where they enable surgeons to take clinical indications of the particular patient, and patient preferences into account. Furthermore, it is important for decision makers to consider whether members of marginalized groups are likely to be under or over-represented in the treatment population. These factors should be weighed against the expected cost of diffusing the treatment, especially via public subsidy.

Once a treatment is made widely available (e.g. through public subsidy or mandated private insurance coverage), surgical innovations are often associated with further problems concerning justice at the level of individual patients. Surgical innovations, particularly those associated with difficult procedures and procedures requiring expensive technologies, often need to be centralized in order to maximize cost-effectiveness and achieve the best possible outcomes. This can lead to injustice for patients who are not located near these centres, and the patients affected are likely to disproportionately include Indigenous populations and patients of lower socio-economic status. Therefore, we also recommend that new surgical interventions are accompanied by funding to eliminate, or at least ameliorate, these sources of injustice, particularly funding for travel, accommodation and the support of carers. The cost of such justice-oriented support services ought to be incorporated into the funding package and projections for the new treatment. Surgical innovation has the potential to contribute to patient longevity and enhanced quality of life, but we ought to ensure that these benefits are justly distributed.