

# Robotic surgery: revisiting “no innovation without evaluation”

National registries must be created so that this technology can be properly evaluated

**Subroto Paul** assistant professor of cardiothoracic surgery, Department of Cardiothoracic Surgery, Weill Cornell Medical College, New York, USA

**Peter McCulloch** reader in surgery, Nuffield Department of Surgical Science, University of Oxford, Oxford, UK

**Art Sedrakyan** associate professor of public health and director, Patient-Centered Comparative Effectiveness Program, Department of Public Health, Weill Cornell Medical College, New York, NY 10065, USA

Far from being restricted to the realm of science fiction, robots are now used in many spheres—creating cars, taking inventories, and even cleaning homes ([www.irobot.com](http://www.irobot.com)).<sup>1, 2</sup> Robots have also become part of healthcare, particularly surgical procedures. Recent articles such as that in the *New York Times*, “When Robotic Surgery Leaves Just a Scratch,” reinforce this image.<sup>3</sup> But what is the evidence to support the use of robotic technology in surgery?

The safety and effectiveness of surgical devices and corresponding outcomes after surgery have consistently come under scrutiny in the past two decades. Despite concerns over safety, effectiveness, and sometimes costs, new devices and technologies for surgery are constantly developed. These new technologies are often rapidly adopted with minimal scientific evidence.<sup>4</sup> The da Vinci robotic system made by Intuitive Surgical was approved by the United States Food and Drug Administration in 2000 under its much criticized 510(k) device provisions with minimal clinical evidence of safety or effectiveness. The FDA has recognized the need for reform of device regulation and recently announced its new postmarket surveillance vision.<sup>5, 6</sup> The proposal relies on physicians, hospitals, patients, and device manufacturers to report device malfunction, implement unique device identifiers, and build prospective data registries.

The case of robotic surgery illustrates the need to establish proactive systems of evaluation and surveillance. More than 360 000 robotic surgery procedures were performed worldwide in 2011 (based on a report by Intuitive Surgical, the only approved manufacturer of robotic surgical systems). Urologists and gynecologists were early adopters of this technology. Robotic procedures in 2011 accounted for more than 100 000 prostatectomies and 125 000 hysterectomies worldwide. Orthopaedic surgeons have followed suit with introduction of MAKO's RIO system and Blue Belt Technology's NavioPFS system for certain knee and hip surgeries.

In the US, where robotic surgery has become a symbol of providing advanced care, the number of procedures performed is expected to rise dramatically as more hospitals purchase the robotic plat-



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● Feature: Robots in theatre: tomorrow's world? (*BMJ* 2011;343:d6624)

● Personal view: Robots don't perform surgery, surgeons do (*BMJ* 2011;343:d6830)

form. Competition among specialists and hospitals, and natural curiosity of the professionals about a new tool, has facilitated aggressive marketing. By the end of 2011, 2132 da Vinci robotic systems had been installed worldwide, 1548 of them in the US.<sup>7</sup> The technology is not cheap. Fixed costs range from \$1.25m (£0.83m; €0.96m) to \$2.3m; instruments cost \$1300-\$2200 and can be used a maximum of 10 times (which typically adds an extra \$1300 cost per case).<sup>8</sup>

What is the added benefit that justifies this considerable effort and expense? Robotic orthopaedic systems allow for more precise measurements and therefore more accurate placement of hip and knee prostheses. Although robots can act autonomously without human control, the systems currently in use are servo systems rather than true robots, so human surgeons still make the decisions. Furthermore, surgeons trained in minimally invasive techniques can perform the same procedures without the robot. Technology also brings new risks—the power assisted robot arms are powerful but give the surgeon no tactile feedback, and the field of view is narrow, so care is needed to avoid unintended trauma to organs off-screen which can be neither seen nor felt.

So is this new and expensive cutting edge technology justified by improved surgical outcomes? The answer is: we don't know. Several case series suggest that short term morbidity and length of stay after robotic procedures are better than with open surgery for abdominal and chest procedures.<sup>9-11</sup> However, robotic surgery may not be superior to non-robotic minimally invasive approaches, because there have been no randomized trials or well designed observational studies comparing these two options in abdominal and chest surgery, and no comparative studies of robotic systems in orthopaedic surgery. Such studies may never be

performed as surgical technology continues to evolve and be rapidly adopted without proper evaluation. Although well conducted database studies examining surgical outcomes after some robotic assisted surgery are possible, there is a dearth of such studies.<sup>12</sup>

Enthusiasts for new techniques argue that trials are hard to conduct, usually because patients and surgeons develop strong preferences on the basis of subjective impressions and are reluctant to accept randomization. In addition, the smaller the difference in outcome sought, the larger the trial needed, so it may be difficult to conduct “large enough” trials. Technology also changes rapidly and is often obsolete by the time trials are completed.<sup>13</sup> But difficulties in conducting timely trials are not a justification for leaving technology without proper evaluation.

The IDEAL framework and recommendations provide guidance on how to evaluate surgeries throughout their lifecycle,<sup>13</sup> taking account of both strong preferences and rapidly changing technology. For this situation, IDEAL proposes the creation of registries for devices and surgical technologies. National registries would allow continuous evaluation of the outcomes of robotic based procedures and devices. Recording the results of comparable minimally invasive non-robotic procedures along with the robotically assisted procedures would help to ensure that high quality comparative effectiveness studies can be conducted. Registries can also help to evaluate training programs to determine which ones are associated with better outcomes and help develop metrics for surgical proficiency, both crucially important advantages of maintaining registries. To ensure transparency, registries should be administered by respected national or international bodies with appropriate representation from specialist surgeons, rather than by companies.

It is now insupportable that new technologies should be adopted without a robust system of post-marketing surveillance and professional oversight to evaluate safety, efficacy, and cost. Many may argue that the horse has bolted and robotic surgery is here to stay. No doubt it is, but the effort and cost of creating device specific or procedure specific national registries (or making existing systems fit for purpose) are worth while. Such registries would help to evaluate not only the safety and effectiveness of current technologies but also those of the future. In this way, registries can help safeguard public health at large.<sup>14</sup>

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