ROBOTS AND SOCIETY

Medical robotics—Regulatory, ethical, and legal considerations for increasing levels of autonomy

Guang-Zhong Yang, James Cambias, Kevin Cleary, Eric Daimler, James Drake, Pierre E. Dupont, Nobuhiko Hata, Peter Kazanzides, Sylvain Martel, Rajni V. Patel, Veronica J. Santos, Russell H. Taylor

The regulatory, ethical, and legal barriers imposed on medical robots necessitate careful consideration of different levels of autonomy, as well as the context for use.

From minimally invasive surgery, targeted therapy, and hospital optimization to emergency response, prosthetics, and home assistance, medical robotics represents one of the fastest growing sectors in the medical devices industry. The regulatory, ethical, and legal barriers imposed on medical robots necessitate careful consideration of different levels of autonomy, as well as the context for use. For autonomous vehicles, levels of automation for on-road vehicles (1) are defined, yet no such definitions exist for medical robots. To stimulate discussions, we propose six levels of autonomy for medical robotics as one possible framework (Fig. 1):

Level 0: No autonomy. This level includes tele-operated robots or prosthetic devices that respond to and follow the user's command. A surgical robot with motion scaling also fits this category because the output represents the surgeon's desired motion.

Level 1: Robot assistance. The robot provides some mechanical guidance or assistance during a task while the human has continuous control of the system. Examples include surgical robots with virtual fixtures (or active constraints) (2) and lower-limb devices with balance control.

Level 2: Task autonomy. The robot is autonomous for specific tasks initiated by a human. The difference from Level 1 is that the operator has discrete, rather than continuous, control of the system. An example is surgical suturing (3)—the surgeon indicates where a running suture should be placed, and the robot performs the task autonomously while the surgeon monitors and intervenes as needed.

Level 3: Conditional autonomy. A system generates task strategies but relies on the human to select from among different strategies or to approve an autonomously selected strategy. This type of surgical robot can perform a task without close oversight. An active lower-limb prosthetic device can sense the wearer's desire to move and adjusts automatically without any direct attention from the wearer.

Level 4: High autonomy. The robot can make medical decisions but under the supervision of a qualified doctor. A surgical analogy would be a robotic resident, who performs the surgery under the supervision of an attending surgeon.

Level 5: Full autonomy (no human needed). This is a "robotic surgeon" that can perform an entire surgery. This can be construed broadly as a system capable of all procedures performed by, say, a general surgeon. A robotic surgeon is currently in the realm of science fiction.

For higher levels of autonomy, the ability of the surgical robotic system to respond to a variety of sensory data will need to be more sophisticated. A key requirement for full autonomy will be technology that replicates the sensorimotor skills of an expert surgeon. With decreasing human oversight and increasing robotic perception, decision-making, and action (the traditional "sense-think-act paradigm"), the risk of malfunction that can cause patient harm will increase. Cybersecurity and privacy are also major issues to consider.

As the level of autonomy in these devices increases, the regulatory challenges will also change. In the United States, the Food and Drug Administration (FDA) reviews and clears robotic-assisted devices via the 510(k) (premarket notification) process. Some future medical robots may instead be classified as high-risk devices (Class 3) requiring the most stringent PMA (premarket approval) regulatory pathway. The difference can be significant. For example, based on a 2014 survey (4), it costs an average of roughly $31 million to bring a medical device to market under the 510(k) program. For a PMA device, the average cost was $94 million. It took an average of 10 months for a 510(k) device from first filing (submission) to clearance. A PMA device took an average of 54 months from first communication to market (4). These regulatory issues may pose significant barriers to innovation, competition, and development, especially for technology start-ups.

At the higher levels of autonomy (specifically Level 5 and possibly Level 4), the robot is not only a medical device but is also practicing medicine. The FDA regulates medical devices but not the practice of medicine, which is left to the medical societies. Handling the overlap is therefore challenging and requires orchestrated effort from all stakeholders. One possibility is for the FDA to certify the safety of a surgical robot design but require licensing

Guang-Zhong Yang is the Editor of *Science Robotics* and the Director and Co-founder of the Hamlyn Centre for Robotic Surgery, Imperial College London, U.K. Email: g.z.yang@imperial.ac.uk. James Cambias is an American science fiction writer. Kevin Cleary is the Technical Director of the Bioengineering Initiative, Sheikh Zayed Institute for Pediatric Surgical Innovation, Children's National Health System, Washington, DC 20010, USA. Eric Daimler is a White House Presidential Innovation Fellow at the Office of Science and Technology Policy, Washington, DC 20504, USA. James Drake is Head of the Division of Neurosurgery, and Director of the Centre of Image Guided Innovation and Therapeutic Intervention, Hospital for Sick Children, Toronto, ON M5G 1X8, Canada. Pierre E. Dupont is the Director of the Pediatric Cardiac Bioengineering Laboratory, Department of Cardiovascular Surgery, Boston Children's Hospital, Harvard Medical School, Boston, MA 02115, USA. Nobuhiko Hata is an Associate Professor of Radiology at the Harvard Medical School, Boston, MA 02115, USA. Peter Kazanzides is a Research Professor at the Department of Computer Science, Johns Hopkins University, Baltimore, MD 21218, USA. Sylvain Martel is Head of the NanoRobotics Laboratory, Department of Computer and Software Engineering, Institute of Biomedical Engineering, Polytechnique Montréal, Montréal, Québec H3T 1J4, Canada. Rajni V. Patel is Director of Engineering, Canadian Surgical Technologies and Advanced Robotics (CSTAR), and Professor, Western University, London, ON N6A 5B9, Canada. Veronica J. Santos is Director of the Biomechatronics Lab and an Associate Professor of Department of Mechanical and Aerospace Engineering, University of California, Los Angeles, CA 90095, USA. Russell H. Taylor is Director of the the Laboratory for Computational Sensing and Robotics and of the Engineering Research Center for Computer-Integrated Surgical Systems and Technology, Department of Computer Science, Johns Hopkins University, Baltimore, MD 21218, USA.

Fig. 1. Different levels of autonomy as mapped to robotic surgery. It is possible that technology may advance faster than regulatory, ethical, and legal frameworks. Risk management during implementation is critical to avoid backlash that would impede progress.

and/or certification of the robotic surgeon by the medical establishment, as is currently done for human surgeons.

The implications will vary for different levels of autonomy for different usage contexts (e.g., Level 3 for a home-assistive robot and for a surgical robot can have very different technological challenges and regulatory implications). This is the key issue for medical robotics—unlike autonomous cars, the spectrum of tasks, environments, technology, and risk is practically limitless. A framework that establishes general categories for these areas is an important first step. As the autonomous capabilities of medical robotics grow (5), most of the role of the medical specialists will shift toward diagnosis and decision-making. This shift may mean that dexterity and basic surgical skills may decline as the technologies are introduced, with implications for training and accreditation. At the same time, pattern recognition and self-learning algorithms will improve, allowing medical robotics an increasingly larger role in higher levels of autonomy. If robot performance proves to be superior to that of humans, should we put our trust in fully autonomous medical robots?

Technology may advance faster than regulatory, ethical, and legal frameworks. Risk management during implementation is critical to avoid backlash that would impede progress. We are already at Level 3 for some devices and procedures, and therefore, the challenge will be in broadening the applications to more complex procedures and environments. For surgical robots, one key aspect of Levels 1 to 4 is that the treating physician is still in control to a significant extent. The robotic devices are essentially doing what the physician commands, with varying levels of detail being left to the automated system. Aside from evolving technology, the risk tolerance to autonomous robots is expected to change. As autonomous machines such as self-driving cars become commonplace, we anticipate that acceptance of risk from autonomous robots for medical applications will also increase.

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