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Research Note

Patient Lives In Our [Robotic] Hands: Risks and Implications of Robotic Surgery

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Abstract: This research note explores the risks associated with robotic surgery, as faced by both public and private sector organizations, including patient harm, legal liability and technical challenges.

Introduction

Technological innovations in healthcare have led to breakthroughs in the treatment of and care for patients. Conversely, these same innovations are hotly debated on the overall effectiveness, safety, and risks to patients. A recent healthcare technology under debate is robotic surgery, which involves a surgeon performing a procedure with the assistance of a robot. These surgeries have seen a steep rise in popularity during the last ten years; as of 2012, nearly one out of every four hospitals in the U.S. had at least one robotic surgery system.[i] However, popularity alone cannot vouch for the safety or reliability of these technologies; complications arise and even deaths occur.[ii] This is a problem for everyone involved, from the patients, to the manufacturers of robotic surgery systems, to the hospitals that perform the surgeries, and even for the federal agencies responsible for healthcare regulations. However, new technologies should not be abandoned in the face of difficulties, especially when there are clear benefits; a balance must be struck somewhere.

The U.S. Food and Drug Administration (FDA) highlights this idea of balance on the webpage that introduces the *Food and Drug Administration Safety and Innovation Act (FDASIA) Health IT Report: Proposed Strategy and Recommendations for a Risk-Based Framework*. It leads with this statement:

> "Health information technology (HIT) presents tremendous benefits to the American public, including greater prevention of medical errors, improved efficiency and health care quality, reduced costs, and increased consumer engagement. However, if HIT is not designed, developed, implemented, maintained, or used properly, it can pose risks to patients."[iii]

This statement perfectly illuminates the need to evaluate the risks in the case of robotic surgery: technological innovation must be in balance with patient safety.

The Current Robotic Surgery Landscape

Before the risks of robotic surgery can be explored further, we must have a clear picture of what the current robotic surgery landscape looks like, as well as view of the actual system. But first, a preparatory discussion of *what* exactly a surgical robot is must be conducted. In *A Consensus Document on Robotic Surgery*, robotic surgery is defined as "a surgical procedure or technology that adds a computer technology enhanced device to the interaction between a surgeon and a patient during a surgical operation and assumes some degree of control heretofore completely reserved for the surgeon."[iv] However, this definition is lacking in specific reference to the *physicality* of the robotic system, which is an important factor when considering the risks and implications of this technology. In his book, *Robot Futures*, Illah Reza Nourbakhsh alludes to the physical nature and action-oriented role of robots, calling them "a new form of living glue between our physical world and the digital universe we have created."[v] Ryan Calo takes this a step further in *Open Robotics*, in which he explains the robotic field's "potential for crippling legal liability" due to the fact that "robots are in a position to cause physical damage and injury directly."[vi]

All three of these characterizations of robots can be combined to form a cohesive definition of what a surgical robot is: a computer technology enhanced device that physically aids the surgeon in performing the surgery. However, it is interesting to note that the FDA's web page about "Computer-Assisted (Robotic) Surgical Systems" states that the computer-assisted surgical system "is not actually a robot because it cannot perform surgery without direct human control."[vii] This is a somewhat misleading statement, because it depends on the definition of "robot," which Nourbakhsh concludes that it changes too rapidly to be fixed or standardized.[viii] The rest of the FDA's definition is fairly consistent, if not slightly more detailed than the definition given in the *Consensus Document.* It describes more specifically what the device does, stating that not only is it a device that uses computer technology, but also one that is designed to "control and move surgical instruments through one or more tiny incisions in the patient's body (minimally invasive) for a variety of surgical procedures."[ix]

Now that a clearer definition has been given, the robotic system and its components can be better understood. The only commercially available, FDA-approved system in the U.S. currently is the da Vinci Surgical System, created and sold by Intuitive Surgical, Inc.[x] As detailed on the da Vinci Surgery Online Community website, the system is composed of four distinct parts:[xi]

1. *Surgeon Console*: Where the surgeon performs surgery using the master controls while viewing the patient's insides as a high-definition, 3D image.
2. *Patient-Side Cart*: The part of the system that is attached to the patient. Three or four robotic arms connect to instruments that are inside the patient's body, which carry out the surgeon's commands.
3. *EndoWrist Instruments*: Surgical instruments designed to fit onto the robotic arms, enhanced with a range of motion greater than that of the human wrist.
4. *Vision System*: Consists of a high-definition, 3D endoscope that provides the view inside the

patient's body, as well as the accompanying high-definition monitors that provide the operating room team with the same view as the operating surgeon.

All of these elements come together in the operating room (see Figure 1), where the surgeon performs the surgery in the surgeon console, at a distance from the patient (in the room, but outside of the sterile field), while the robot carries out the movements, directly inside the patient, that the surgeon inputs.[xii]

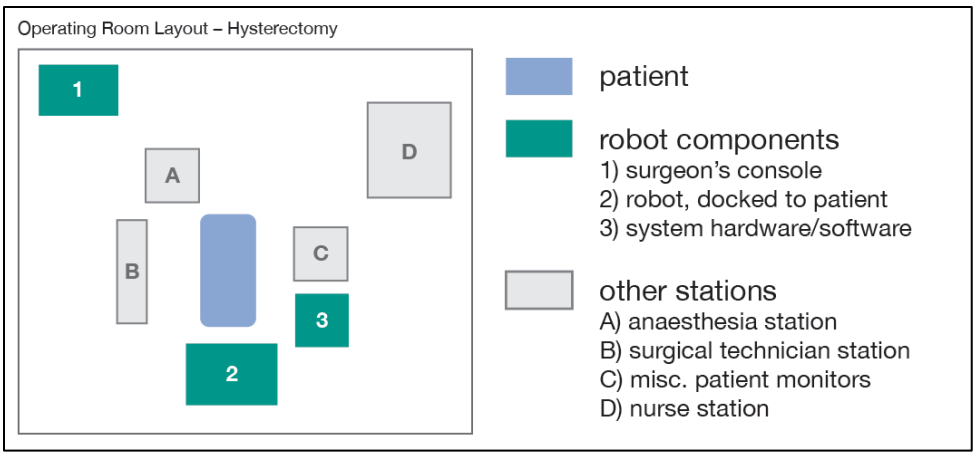

Figure 1: Potential Operating Room Layout For Robotic Surgery1

The FDA has approved the da Vinci surgical system for "laparoscopic surgical procedures in general surgery cardiac, colorectal, gynecologic, head and neck, thoracic and urologic surgical procedures."[xiii]

Robotic Surgery Risks

From the beginning of its commercial implementation, robotic surgery has continuously received both criticism and praise. It is criticized due to the harm it has caused patients, the costs it incurs, and the hype it receives.[xiv] This is tempered by the praise from doctors and patients alike, both of which extoll the benefits of robotic surgery over existing alternatives.[xv] These opposing attitudes create a push-pull dynamic, which is unsurprisingly encapsulated in the risks presented by this new technology. First, the risk of patient harm or death; and second, the risk of abandoning an emerging technology before the potential benefits are fully assessed.

Of these two overarching risks, it is easy to see the risk of patient harm or death as being the most threatening. If robotic surgery is harming, or even killing patients, why should it be allowed to continue at all? This is a fair question, and it can be answered first by saying that if there was a significant amount of harm and deaths resulting from robotic surgery, as opposed to regular surgery, it would not be allowed to continue. In 2013, the Medical Product Safety Network (MedSun), a program that was started in 2002 by the FDA designed to conduct studies on the use of medical devices, investigated this issue.[xvi] They

1 I designed this graphic after observing a robotic laparoscopic hysterectomy surgery. To protect the identity of those involved, the names of the patient, hospital staff, and hospital are withheld for confidentiality purposes.

conducted a small sample survey, in which eleven surgeons (who have used the da Vinci surgical system to perform 70 to 600 surgeries over the last three years) were asked about their training, patient outcomes, and any difficulties experienced with the device.[xvii] Overall, the responses indicated a strong consideration for patient safety, as opposed to a blind enthusiasm for the new technology.[xviii] Additionally, the surgeons reported the benefits posed to patients as well as the problems; in all cases, the number of benefits outweighed the number of problems.[xix] Even though the novelty of the device is one of its draws, this report demonstrates that surgeons do not elect to use it on anyone that may be harmed by it. On the contrary, surgeons appear to treat it as any other surgical option and embrace the risk for patient harm or death as they would with other more traditional options.

The results from the MedSun report seem to suggest a positive reaction to robotic surgery within the medical community, as well as a conclusion that the robot is safe to use on patients. However, this is not the only reaction – there is plenty of criticism present as well. Some of this criticism comes from the American Congress of Obstetricians and Gynecologists, which denounced the use of robotic surgery for hysterectomies in March 2013. The professional association said that "robotic surgery is not the only or the best minimally invasive approach for hysterectomy. Nor is it the most cost-efficient."[xx] Additionally, the organization criticized Intuitive Surgical, Inc. for their aggressive marketing campaigns, and argued that there is a lack of data to support robotic surgery over other types that have "*proven* track records for outstanding patient outcomes and cost efficiencies."[xxi] Other members of the medical community also do not accept the risk of patient harm or death presented by robotic surgery as any other risk associated with surgery. Instead, they see a volatile new technology, with an as-yet unproven track record, and therefore see it as untrustworthy.

Aside from the novelty and lack of proven success, others blame the manufacturers for the risk of patient harm, due to the difficulties associated with the robots themselves. Intuitive claims that the robotic movements are safe, stating that "repeated safety checks prevent any independent movement of the instruments or robotic arms."[xxii] However, in January 2014 an incident was reported of a robotic arm not letting go of tissue that was being grasped during a colorectal surgery, and another where a robotic arm hit a patient in the face.[xxiii] Whether the robot was moving of its own volition or not, it is true that the physical components of the robotic system are capable of harm. Similarly, several malfunctions were catalogued in the MedSun report.[xxiv] These included an arm missing its mark by a 0.5 to 1 centimeter at times, arm articulation (EndoWrist) lock, 1-second delay from the console, and a failure of memory function, all of which can result in serious problems.[xxv] Not only do difficulties arise from technical malfunctions, but from user error as well. This is also reflected in the report, which states, "all respondents report that learning how to use the da Vinci Surgical System is the biggest challenge because of the device's complex user-interface."[xxvi]

Others believe that the risk of patient harm comes from not only the procedures or robots themselves, but the fact that patients are often not fully informed of the risks, and that the complications associated with robotic surgery are underreported. With regard to informing patients, Lee Char et al. argue "while the introduction of new drugs and medical devices is strictly regulated, the vast majority of patients undergoing innovative surgery do so outside the protections of clinical trials, which require institutional

review board approval and detailed, comprehensive informed consent. Outside the context of clinical trials, patients still must consent to surgery, but there is no legal requirement to inform them of its innovative nature."[xxvii] There have also been several papers published on the underreporting of complications due to robotic surgery. Cooper et al. cross-referenced search results from a database of legal judgments and events that contained the terms "Intuitive" or "da Vinci" with the FDA adverse events databases.[xxviii] They found that over the twelve-year period they had investigated, there were eight cases where the FDA reports were inaccurate, filed late, or not filed at all.[xxix] Arguably, correct reporting contributes to the correct informing of patients, which in turn is critical to patient safety. The risk of patient harm is therefore increased by misinformation and underreporting.

The last factor associated with the risk of patient harm is due not to the newness of the technology, but instead to the *connectivity* of the technology. The da Vinci surgical system has computer components that run software, which is periodically updated.[xxx] Additionally, the hospital can choose to use da Vinci OnSite remote monitoring of the system, which entails real-time diagnostic feedback, issue identification and resolution, and minimization of technical issues.[xxxi] Both of these system enhancements require remote connectivity, which makes the system vulnerable to cyberattacks. This is especially troubling, given that hospitals are a main target for cybercriminals since healthcare data can be sold for high prices on the black market, as noted in the article by Dune Lawrence.[xxxii] What is worse is that healthcare companies do not have very good cybersecurity; in an analysis conducted by BitSight Technologies, healthcare was ranked lowest overall amongst the other industry groups, which included finance, utilities, and retail.[xxxiii] Specifically, the health sector sees the most security problems and takes the longest to fix those problems, about five days on average.[xxxiv] Though this problem extends throughout all technologies associated with healthcare, surgical robots are not immune; this is yet another way to cause patient harm. After hearing about all of the factors associated with the risk of patient harm, it could be easy to dismiss robotic surgery as an endeavor too perilous to pursue. However, it must be remembered that the risk of patient harm is offset by the risk of abandoning the benefits of this technology. In their article, "Robotic surgery: applications and cost effectiveness," Leddy et al. highlight the many benefits of robotic surgery, which include decreases in blood loss, post-operative pain, narcotic use, and length of hospital stay.[xxxv] Though many of these benefits are also associated with laparoscopic surgeries, robotic surgery offers improvements over traditional laparoscopy, specifically: "three-dimensional visualization, mitigation of surgeon tremor, ergonomic and intuitive hand movements, a magnified view and a range of motion approximating the human wrist."[xxxvi] Furthermore, the robot eliminates the confusing counter-intuitive fulcrum effect seen in laparoscopic surgery, in which the surgeon must move in the opposite direction of the target.[xxxvii] All of these improvements enhance the surgeon's ability to perform surgery, but if the technology is abandoned patients will not see these benefits.

The development of new technology is also at risk due to regulations enforced by U.S. government entities. Intuitive Surgical, Inc. cites this in their 2013 *Annual Report* in the "Risks" section, which articulates the impact of their regulation by the FDA. The report further elucidates these risk factors, first by stating that their products "are subject to a lengthy and uncertain domestic regulatory review process…the FDA regulates the development, bench and clinical testing, manufacturing, labeling, storage, record keeping, promotion, sales, distribution and postmarket support and reporting of medical

devices."[xxxviii] While this is understandable, the FDA also has a policy that dictates that new devices may be cleared if it is "substantially equivalent to another device" with preexisting clearance.[xxxix] This stance increases the threat to the improvement of existing technology because it creates an easier, less innovative path for companies to take. Another risk to the regulatory environment is the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Like many other healthcare technologies, robotic surgery systems make use of patient information, which according to HIPAA's Privacy Rule must be "properly protected while allowing the flow of health information needed to provide and promote high quality health care and to protect the public's health and wellbeing."[xl] Compliance with this rule also requires compliance with HIPAA's Security Rule, which "establishes national standards to protect individuals' electronic personal health information" and "requires appropriate administrative, physical, and technical safeguards to ensure the confidentiality, integrity, and security of electronic protected health information."[xli] Given these considerations, compliance with HIPAA can therefore be costly, time-consuming, difficult, and above all another threat to technological advancement.

An additional reason to mitigate the risk of abandoning this technology is because of the potential it has to continue to change surgery for the better. To see an existing surgical innovation that did just this, we can look to laparoscopic surgery. Lee et al. cite this as an example in their article on robotic surgery training, explaining that the *very first* laparoscopic nephrectomy (kidney removal) was successfully completed in 1990, then a very innovative surgery.[xlii] Now, 24 years later, this method has come to be considered the "gold standard" for use in this type of procedure.[xliii] As it continues to mature, robotic surgery could itself become a "gold standard," but only if we can objectively and intelligently weigh the risks that it presents.

Key Players On the Robotic Surgery Landscape

Just as the risk factors present in robotic surgery are very complex, so is the cast of characters. Entities from both the public and private sectors are involved, including regulators, vendors, and customers. The key players in the public sector are regulating bodies that are all located within the U.S. Department of Health and Human Services (HHS). These include the FDA, the Office for Civil Rights (OCR), and the Office of the National Coordinator for Health Information Technology (ONC). The FDA is the body that grants approval for the use of medical devices[xliv], while the OCR is the body that enforces HIPAA.[xlv] Finally, the ONC is the "principal federal entity charged with coordination of nationwide efforts to implement and use the most advanced health information technology and the electronic exchange of health information."[xlvi] Between them, these three public organizations have the responsibility to regulate new, technologically advanced healthcare devices, such as surgical robots.

Those involved in the private sector are the vendors and the consumers. The vendors, at the moment, include only Intuitive Surgical, Titan Medical, and various educational institutions. As noted previously, the only FDA-approved device presently on the market belongs to Intuitive Surgical.[xlvii] However, Titan Medical, a competing commercial surgical robot company, states on their website that their SPORT (Single Port Orifice Robotic Technology) Surgical System is expected to be available in 2015.[xlviii] Aside from this pair of bigger corporate players, there are also a handful of educational institutions that are working on surgical robots, including the University of Washington and the University of California

Santa Cruz, whose teams collaboratively developed a robot called the Raven.[xlix] The robot manufacturers, whether commercially- or research-driven, must factor the risk of patient harm into their system design considerations, so as not to be liable for injuries. This is an area that they are already facing consequences for, as evinced in Intuitive's *Annual Report*, which states that they are "currently named as a defendant in about 76 individual product liability lawsuits," by plaintiffs who allege that they were injured as a result of the da Vinci Surgical System.[l] Even though the company has a procedure in which they "model patient value as equal to *procedure efficacy/invasiveness*," and apparently maximizing procedure efficacy, they are still dealing with the risks of both harming patients and losing their ability to innovate due to these lawsuits.[li]

There are two types of consumers included in the robotic surgery landscape: healthcare organizations and patients. Healthcare organizations can actually be part of either the public or private sectors, and are arguably owners of the most risk. This is due to the fact that not only are they absolutely required to be compliant with government regulations, but they must also implement their own safety standards and organizational guidelines according to their policies, culture, and overall goals.[lii] Then they have to factor in an initial investment of $1-2 million for the robot and ongoing annual maintenance costs of around $340,000.[liii] Finally, they must consider their primary customers, their patients, above all else; all of these risks come with a hefty price tag.

Patients are perhaps the most interesting players on the robotic surgery landscape. They are the bearers of the most immediate and critical risk (their own harm or death), yet they also hold all of the veto power, that is, the ultimate power to say yes or no to robotic surgery. The patient assumption of both life-threatening risk and economic power makes them a key factor for the other players to consider when they are weighing their own responses to risk.

Recommendations

Now that we know the risks, and where those risks lie, what can be done about them? In his book *COSO Enterprise Risk Management*, Robert R. Moeller outlines what organizations can do about risk. He gives four types of risks responses:[liv]

1. *Avoidance*: Strategy of avoiding risk altogether.
2. *Reduction*: Strategy of reducing risk by taking action.
3. *Sharing*: Strategy of sharing risk with other players.
4. *Acceptance*: Strategy of no action.

Each of the players involved with robotic surgery has a reaction to the risks presented (see Figure 2). To begin, there are a few players that can neither avoid nor accept either risk; those are the regulators and the robot manufacturers. To reduce risk for themselves, the regulators must create rules and guidelines that allow them to share responsibility with entities such as robot manufacturers and health organizations. As noted previously, the FDA does this by enforcing specific standards and granting approval, while the OCR does this by creating and enforcing rules (HIPAA). Recently, the FDA, ONC, and Federal Communications Commission (FCC) created a report, as directed by FDASIA

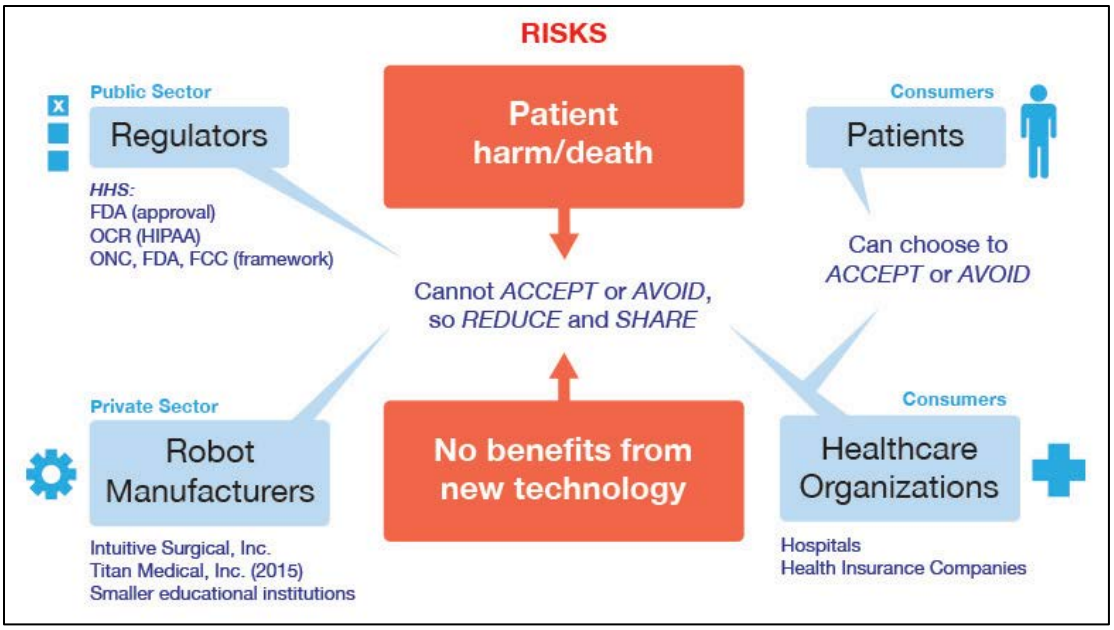

Figure 2: Robotic Surgery Risk Responses

(Public Law 122-144), that contains a recommendation for "an appropriate, risk-based regulatory framework pertaining to health information technology…that promotes innovation, protects patient safety, and avoids regulatory duplication."[lv] Some of the principles included in the framework are very sound, such as the directive to "facilitate, rather than impede, innovation," and to "promote transparency of product performance and safety."[lvi] The promotion of transparency is echoed in current medical literature, specifically Lee Char et al.'s article, which reports that "over 70% of patients reported they could not decide whether to have robotic surgery without the following information: a general description of the procedure, known risks and benefits, acknowledgement of potentially unknown risks and benefits, whether the surgeon was doing the procedure for the first time, and the surgeon's special training for the procedure."[lvii] The framework also addresses the need to "build upon and improve the evidence-based foundation for health IT safety by analyzing the best available data."[lviii] Cooper et al. echo this recommendation, emphasizing the importance of proper capture, reporting, and evaluation of data.[lix]

The FDASIA framework is a good start, but it does not cover all of the risk inherent to robotic surgery. Though there is reference in the document to "robotic surgical planning and control," the overall focus is very broad.[lx] It does not make any reference to the hazards of robotic physicality, such as harm from robotic movement. This is why I would like to propose a more specific risk-based framework, exclusive to robotic surgery, made by regulators in conjunction with both robot manufacturers and healthcare organizations (Figure 3).

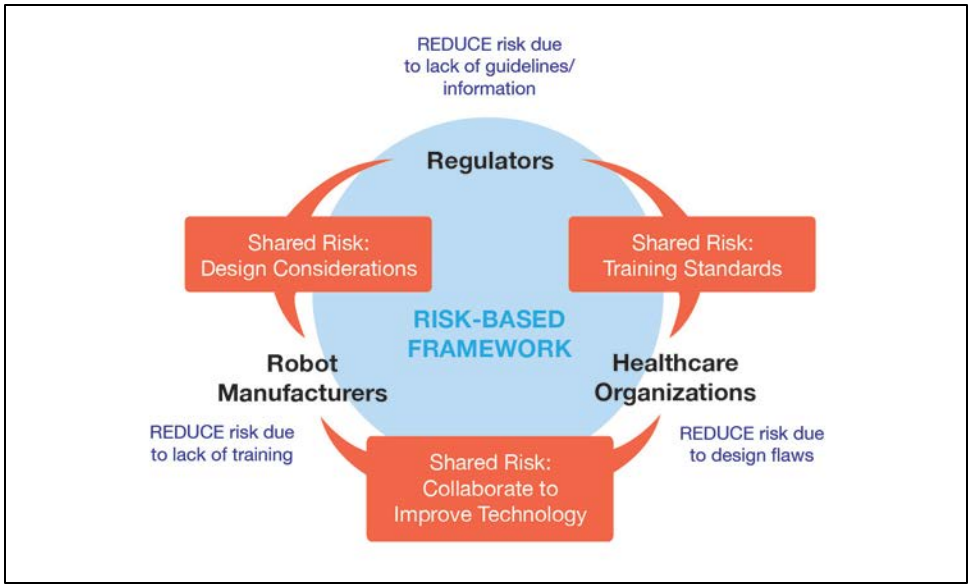

Figure 3: Proposed Robotic Surgery Risk Framework

The framework would cover the specific risk factors presented by robots, such as device design, surgeon training, and harm by robots. By doing so, regulatory bodies could not only reduce risk, but share it as well, creating an environment that could better foster collaboration and innovation. Robot manufacturers would benefit from this arrangement as well, since they would be able to reduce much of their risk by complying to design standards (especially those for ease of use), and collaborating with healthcare organizations in order to improve technology. Risks that could not be mitigated in that way would then be shared with healthcare organizations and regulators in the form of healthcare personnel training requirements. Right now there is no standardized training; though Intuitive offers training courses, it is ultimately left to the hospital and the surgeon to decide when a surgeon is ready to operate.[lxi] As Lee et al. conclude, a standardized robotic surgery credentialing process would be ideal.[lxii]

Though it would be beneficial to collaborate, healthcare organizations would not have to participate at all if they found the endeavor too risky. They have the most options regarding risk response: they can choose to avoid, accept, or reduce and share risk. Conversely, patients have the simplest option, though their decision about risk carries the most weight. They can choose to either accept the risks and have robotic surgery, or avoid the risks altogether and choose an alternative. Nevertheless, it would be the goal of the framework to make the decision of whether or not to have robotic surgery an easier one for the patient to decide than it is currently.

Conclusion

As with any new technology, the long-term consequences are not always immediately apparent. In response, caution should be used during the early stages of use. This is especially true when lives are at stake, and the consequences of mistakes are often irreparable and permanent. If anything, all of the key players must continue forward with patient safety at the front and center of concerns. This will help ensure continued growth in the field of robotic surgery.

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