

Robotic Surgery

August 2023, Volume 25, Number 8: E573-650

Case and Commentary

Should Organizational Investment in Robotic Surgical Technology Ever Influence Surgeons' Decisions About Surgical Approach to Patients' Surgical Care? 575
Ryan D. Rosen, DO and David A. Edelman, MD, MSHPEd

How Should Risk Be Communicated to Patients When Developing Resident Surgeon Robotic Skills? 583
Matthew C. Bobel, MD and Robert K. Cleary, MD

How Should Surgeons Consider Emerging Innovations in Artificial Intelligence and Robotics? 589
Ava G. Chappell, MD and Chad M. Teven, MD

Medical Education

Is Robotic-Assisted Surgery Better? 598
Anastasya Chuchulo, MD and Abubaker Ali, MD

AMA Code Says

AMA Code of Medical Ethics' Opinions Related to Robotic Surgery 605
Jake Young, PhD, MPH, MFA

State of the Art and Science

Should Robot-Assisted Surgery Tolerate or Even Accommodate Less Surgical Dexterity? 609
Katherine Fay, MD and Ankit D. Patel, MD

Medicine and Society

How Does Robotic-Assisted Surgery Change OR Safety Culture? 615
Julie M. Clanahan, MD, MHPE and Michael M. Awad, MD, PhD, MHPE

Opportunities for Global Health Diplomacy in Transnational Robotic Telesurgery 624

Esha Bansal, MD, MPH, Saran Kunaprayoon, MD, and Linda P. Zhang, MD

History of Medicine

What Pediatric Robotic Surgery Since 2000 Suggests About Ethics, Limits, and Innovation 637

Tenny R. Zhang, MD, Elijah Castle, and Lee C. Zhao, MD, MS

Art of Medicine

Horror PSA 643

Kelly Wang

Robot Comic 646

Kelly Wang

Podcast

What Does Artificial Intelligence Do for Surgeons?: An Interview With Dr Chad Teven



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CASE AND COMMENTARY: PEER-REVIEWED ARTICLE

Should Organizational Investment in Robotic Surgical Technology Ever Influence Surgeons' Decisions About Surgical Approach to Patients' Surgical Care?

Ryan D. Rosen, DO and David A. Edelman, MD, MSHPEd

Abstract

This commentary on a case considers balancing prospective benefits and harms of robotic technology use and argues that health care organizations should invest in centralizing robotic expertise in departments rather than having a mere collection of surgeons trained in robotics. This commentary also examines costs that should be considered in organizational determinations of robotics investments.

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Case

Dr M is a surgeon drawn to work in University Hospital, given the organization's reputation for leadership and investment in robot-assisted surgical technology. During her job interviews, Dr M is asked how many robotic-assisted procedures she has performed, and University Hospital's marketing director invites Dr M to discuss strategies for showcasing her robotic skills on the organization's website and in advertising campaigns. During negotiations in her hiring process, Dr M is offered dedicated block time in University Hospital's operating room (OR), where she could board 2 full days of surgery with access to the robot. Dr M is enthusiastic about this prospect, but she is also concerned that being hired as a minimally invasive surgeon—and, more specifically, as a robotic surgeon—could, over time, limit the scope of her professional decision making about how to approach surgical care of her patients, especially those for whom open or laparoscopic surgical techniques might be indicated.

Dr M wonders how to broach this set of concerns without appearing to extinguish University Hospital's interest in her enthusiasm for robotic surgical innovation. Dr M also wonders how to address conflicts of interest that could emerge, especially in striving to balance University Hospital's investment interests with appropriate exercise of her overall surgical autonomy and growing robotic surgical technique skill set. Dr M feels strongly that the professional autonomy she exercises when making decisions about her patients' surgical care should remain uncompromised by organizational pressure to

maximize profit generated from robotics use in the OR. Dr M considers how to proceed in her negotiations.

Commentary

Robotic surgery is a relatively new and evolving technology with several promising features, including improved visualization and surgeon ergonomics and the ability to perform procedures that laparoscopy cannot achieve. It is rapidly being introduced in many fields, including general surgery, colorectal surgery, thoracic surgery, gynecology, urology, and even select cardiac and head and neck procedures.¹ While much of the growth is driven by the pursuit of decreased pain, improved cosmesis, and better surgical outcomes, the robot is not exempt from ethical issues arising from any new medical technology. Due to the high costs of the robot, minimally invasive surgeons who persuade administrators to invest in robotic technology—or those who are hired specifically for their robotic expertise—may feel extrinsic pressure to utilize the robot to justify the investment or their dedicated robotic block time. Examining the fixed and variable costs of robotic technology and surgical reimbursement, along with the relevance of the economic concepts of scarcity and opportunity cost, suggests that surgeons should continue to recommend the technique they expect to yield the best result, regardless of perceived pressures to use the robot. Robotic surgery also presents challenges when obtaining informed consent for surgery, including framing effects, incompletely defined risk-benefit profiles, and lack of a consensual training and credentialing process. Surgeons need to be honest and forthcoming with patients to overcome these challenges and to obtain proper consent and maintain ethical integrity.

Investment in and Reimbursement of Robotic Surgery

Newly hired minimally invasive surgeons may feel pressure (consciously or subconsciously) to utilize the robot in an attempt to maximize organizational return on technological investment and justify their hiring. In actuality, the relationship between robotic utilization and profitability is not straightforward. Economically, it is important to examine both fixed and variable costs of robotic surgery. The fixed costs include the purchase price (up to 2.5 million USD) and annual service contract and maintenance costs (150 000-200 000 USD),^{2,3,4} which health care organizations absorb regardless of robot utilization. The decision to purchase robotic technology commits the organization to this fixed cost. Variable costs—primarily the cost of robotic instruments, which are often limited to a predetermined number of uses before they must be replaced—will (by definition) vary. In a simplistic microeconomic model, if an organization's variable costs exceed its profit, it behooves the organization to shut down. While shutting down seems counterintuitive, the organization's fixed costs must be paid regardless of profit, so it becomes "cheaper" to shut down and stop the loss incurred by the excess variable costs. Multiple studies^{5,6,7,8} have shown that the magnitude of variable costs are routinely higher for robotic than laparoscopic procedures across multiple specialties.^{9,10,11,12} The higher costs are primarily related to instruments and accessories but can also be attributed to longer operative times.¹³ While a supplemental *Current Procedural Terminology (CPT®)* code exists for surgical techniques requiring the use of robotic systems (*CPT* code S2900), these techniques are considered part of the primary procedure and their cost is not reimbursed by Medicare¹⁴ or many private insurers.^{15,16} Therefore, it is possible that robot use for an operation that could be safely performed by another method could increase organizational costs without a corresponding increase in reimbursement. With this possibility in mind, young surgeons should follow the ethical principle of beneficence when considering their surgical approach, setting aside **organizational financial considerations**.

Minimally invasive surgeons may also feel extrinsic pressure to utilize the robot to validate their dedicated block time, which raises issues of scarcity and opportunity cost. Scarcity—the idea that there are finite resources to supply theoretically unlimited demand—requires making resource allocation decisions. As mentioned previously, the costs associated with purchasing and maintaining a surgical robot are significant. Therefore, many hospital systems only possess one or two robotic systems, and, with increasing numbers of surgeons utilizing the robot, availability is limited. In a retrospective review of robotic surgeries conducted at the University of California, San Diego, organizational robotic case volume nearly quadrupled from 2006 to 2016 (from 120 to 586 cases), while the number of unique surgeons utilizing robotic technology more than doubled (from 12 to 28) over the same period.¹⁷ A similar trend was seen in general surgery from 2012 to 2018 in the state of Michigan, which saw an increase from 1.8% to 15.1% in general surgery procedures being performed on the robot and a corresponding increase from 8.7% to 35.1% of general surgeons utilizing the robot.¹⁸ Opportunity cost—the value of the next-best alternative foregone when making a decision—can be important to consider when one is attempting to maximize allocation of a scarce resource. Anytime a robotic procedure is performed, particularly one that could be performed laparoscopically with similar results, the opportunity cost is equivalent to the value of the same surgery performed laparoscopically *plus* the value of another procedure that could only have been performed on the robotic platform in its stead. Until robotic systems become ubiquitous, minimally invasive surgeons should avoid boarding robotic cases that can be performed with equivalent outcomes using other techniques simply to fill their block time. Performing unnecessary robotic surgeries can worsen the robot scarcity problem and limit opportunities for other surgeons to use the robot. Additionally, while an association has been found between hospital profitability and robotic ownership, both the diversity of procedures performed and total surgery volume were important contributors to profitability.¹⁹ To maximize return on robotic investment, hospital organizations should regard the goal of their investment as developing a robust robotic surgery department rather than collecting robotic technology and individual surgeons. As robotic surgery becomes more popular and as more robotic surgeons are hired, it will become more important for surgical departments to maximize the robot's utility and “spread the wealth” among multiple surgeons and surgical specialties.

Challenges of Informed Consent in Robotic Surgery

When considering an operative approach, the surgeon is legally and ethically bound to obtain **informed consent** from the patient. This process involves a clear and accurate discussion of the patient's disease process and natural course, the proposed operation and its associated risks and benefits, and alternative operative approaches and their risks and benefits. Informed consent should be a collaborative effort, with the surgeon listening carefully to the patient and considering their values and opinions. Robotic surgery, however, presents several challenges to the informed consent process.

Framing effect. The framing effect is a form of cognitive bias, wherein decision making is influenced by the manner of presentation (positive vs negative).²⁰ Experiments have shown that people are more willing to engage in risky behaviors when presented with positive frames and are more risk averse when presented with negative frames (ie, glass half full vs half empty).²¹ Specifically applied to robotic surgery, patients are more likely to elect to undergo a robotic procedure when it is described as “innovative” or “state-of-the-art” than when uncertainty about the evidence of its effectiveness is disclosed.²² However, the magnitude of the framing effect can be reduced (if not eliminated entirely) by providing clear, credible, and unbiased information. As outlined in the American

College of Surgeons Statements on Principles,²³ the information presented in the informed consent process “must be presented fairly, clearly, accurately, and compassionately.... The surgeon should not exaggerate the potential benefits of the proposed operation nor make promises or guarantees.” This statement highlights the importance of having an honest, unbiased preoperative conversation about the perceived vs measurable benefits of performing the operation robotically or via other methods to allow the patient to make the best decision about their care.

Unknown benefits and risks. As robotic technology is relatively new, there are few studies on its long-term risk profile. While the robot has several *potential* advantages over laparoscopic surgery, including a 3-dimensional field of view, increased wrist motion and dexterity, elimination of tremors, and improved surgeon ergonomics, these advantages have not been shown to improve clinical outcomes. As a historical parable, laparoscopic cholecystectomies were first introduced with the promise of decreased postoperative pain and decreased hospital length of stay and were rapidly incorporated into general surgery practices without the proposed benefits having been proven.²⁴ Moreover, the procedure was not first proven safe, and later studies revealed higher rates of bile duct injury.^{25,26,27} Although laparoscopic cholecystectomy has become the standard of care, patients who consented to laparoscopic cholecystectomies in their infancy were unaware of the true risk-benefit profile. Modern comparisons of laparoscopic vs robotic cholecystectomy have shown that robotic surgery reduces hospital length of stay without a subsequent increase in bile duct injury or postoperative bile leak rates.^{28,29,30} However, in one study, robotic cholecystectomies were performed in patients with symptomatic cholelithiasis and chronic cholecystitis but not in patients with acute cholecystitis,³⁰ which could skew these beneficial results. Similar results have been demonstrated for inguinal hernias,^{31,32} hysterectomies,^{12,33} and radical nephrectomies,³⁴ suggesting that robotic surgery is safe, but few definite benefits of robotic over laparoscopic operations have been shown. When consenting for a robotic surgical approach, the surgeon is ethically bound to fairly present the known risks and benefits as well as the uncertainties, thereby empowering the patient to make an informed decision.

Variable training and time to mastery. Further complicating the informed consent process is the variability of the credentialing process and the learning curve for performing robotic surgery. While there is no consensus, most surgeons are required to complete an online course on the basic use of the robot, followed by an in-person training course (both offered by the robot company directly), and then to complete a number of proctored cases before gaining robotic credentials. While the current credentialing process is designed to ensure that surgeons are practicing safely, it does not necessarily ensure the best patient outcomes. In fact, it has been demonstrated that while it only takes execution of 5 to 20 cases to build basic proficiency on the robot,^{35,36,37,38,39} it can require at least 150 robotic laparoscopic prostatectomies to achieve oncologic outcomes comparable to those achieved with radical retropubic prostatectomy⁴⁰—suggesting that the true learning curve is substantially longer than the credentialing process. Furthermore, robotic credentials are not granted on an operation-by-operation basis; surgeons are generally proctored on relatively simple procedures but then are credentialed for all robotic surgeries in their field. This credentialing process suggests that there may be discordance between the complexity of proctored cases and subsequent cases performed. Without a consensual credentialing process or defined learning curve,⁴¹ calling oneself a “robotic surgeon” can confuse patients and complicate decision making. The loss-of-chance doctrine⁴²—a legal concept traditionally

utilized in contract law—has recently been applied to cases of medical malpractice. While traditional medical malpractice requires physician negligence resulting in patient injury,⁴³ loss-of-chance allows consideration of the lost chance of a better outcome.⁴⁴ Applied directly to surgery, patients have a right to undergo the surgical procedure by the technique and surgeon that offer optimal results. While there may not be a deviation from the standard of care, the patient is “harmed” by a relatively poorer outcome than they might have received otherwise. Therefore, surgeons should disclose their experience, skill, and comfort level with the proposed and alternative surgical approaches, thereby enabling the patient to make the best choice about care and have the best chance for a positive outcome.

Conclusion

It is imperative that surgeons avoid external pressures that may affect patient care. The American Board of Internal Medicine has defined several principles of medical professionalism, among them the primacy of patient welfare and patient autonomy.⁴⁵ Primacy of patient welfare ensures that the patient’s best interests are at the forefront of the surgical plan, while autonomy ensures that the patient is allowed to make informed decisions about their care. To maximize patient autonomy, surgeons must explain the proposed operative approach in detail, including the risks and benefits and alternative options. By eliminating framing bias and disclosing their experience with the proposed technique, surgeons allow the patient to make a truly educated care decision. Moreover, while all physicians are subject to **conflicts of interest**, the American College of Surgeons Code of Professional Conduct requires all conflicts that might influence patient care decisions to be disclosed and resolved.²³ If all else fails, the surgeon should focus on operating *for* their patients rather than *on* their patients, and the goal should not be to “convince” the patient to agree to their plan.⁴⁶ Following this simple principle will likely alleviate any significant conflicts of interest. While minimally invasive surgeons may feel economic pressure to utilize the robot, they should remember that profitability is not directly related to robotic utilization and only perform robotic operations they feel are in the best interest of the patient in order to allow equitable access to the robot for other surgeons.

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Editor's Note

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The author(s) had no conflicts of interest to disclose.

The people and events in this case are fictional. Resemblance to real events or to names of people, living or dead, is entirely coincidental. The viewpoints expressed in this article are those of the author(s) and do not necessarily reflect the views and policies of the AMA.

A microscopic image of plant tissue, showing a network of cells with thick, blue-stained cell walls. Some cells are larger and more rounded, while others are smaller and more elongated. The overall structure is a complex, interconnected mesh.

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CASE AND COMMENTARY: PEER-REVIEWED ARTICLE

How Should Risk Be Communicated to Patients When Developing Resident Surgeon Robotic Skills?

Matthew C. Bobel, MD and Robert K. Cleary, MD

Abstract

This commentary on a case considers how to cultivate resident surgeon professional autonomy while ensuring patient safety. Specifically, the commentary briefly canvasses strategies for how to disclose the nature and scope of resident surgeon involvement in managing intraoperative care to patients and their loved ones. The commentary also suggests how to manage patients' and their loved ones' expectations and assumptions about surgical innovation, including robot-assisted surgery.

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Case

Dr B is a fourth-year general surgery resident physician and chief of the University Hospital minimally invasive surgery service. Dr B spends most of her time in the operating room (OR) with attending physician, Dr A, who performs laparoscopic and robot-assisted operations. Today, Dr B is instructed by Dr A to sit at the robot console. Dr B performs portions of a ventral hernia repair independently in the presence of Dr A. Dr A gives the console control to Dr B, instructing her to suture in the mesh after the primary closure of the hernia defect. Dr B is startled, as she has begun, but not yet completed, suggested robotic training console simulations for hernia repair and has only sewn in part of this particular mesh before. Dr B seizes the opportunity and wonders what the patient and family should be told, perhaps now and certainly later, about her role in the surgery.

Commentary

This case highlights an important obligation at the heart of surgical education: ensuring that the patient receives the best possible care while training the next generation of surgeons. It also calls attention to the question of the extent of training a trainee should be required to accomplish outside of the OR prior to operating on a patient. Furthermore, it questions to what extent an attending physician must delineate and clarify resident and faculty intraoperative roles to a patient both prior to surgery and when those roles change during the course of the operation. Finally, this case offers an opportunity to consider the extent to which surgeons should explain increasingly

complex technical tools and newly implemented innovations to patients such that they can be fully informed when completing the **consent process**.

Training Robotic Surgeons

In this case, Dr B is “startled” when given the controls to independently perform a portion of the surgery that she has not previously done in the OR or in simulation. Her questioning of what and when the family should be told about her level of participation implies that she thinks her involvement puts the patient at an increased risk of a worse outcome. The case scenario also implies that if surgical residents have not performed a task in a simulated environment, then they should not perform it in the OR because it may have a negative effect on patient outcomes.

If a surgical resident’s participation in surgery results in a worse patient outcome, then the attending surgeon is not upholding the basic ethical tenet of nonmaleficence. Yet it may be difficult to know in the moment how a surgical resident’s participation could affect a patient’s outcome. This uncertainty is further complicated by the fact that surgical residents are trained by multiple attending surgeons, making it challenging for an individual attending surgeon to know the full range of technical abilities and intraoperative decision-making capabilities of a given surgical resident.

There is evidence to suggest that surgical resident participation in the OR does not negatively affect patient outcomes and may even decrease patient mortality.^{1,2,3,4,5} Standardized operative performance assessments and their association with patient outcomes are active areas of surgical education research.⁶ Until the development of an assessment that predicts how a resident will perform in an operation, attending surgeons should use their experience with a surgical resident to inform the tasks a resident may be permitted to do under supervision in the OR. In the case above, Dr A works with Dr B frequently and therefore has a robust understanding of her technical abilities. While Dr B may be unsure of herself, Dr A is giving her supervised graduated autonomy while upholding patient beneficence and nonmaleficence.

Surgical education has evolved over time due to advances in research focused on education as well as administrative and regulatory constraints on surgical training programs.⁷ Historically, teaching surgical residents to operate followed the “see one, do one, teach one” method. As operations evolved to incorporate increasingly complex techniques, this model has not been sustainable.^{6,8} With the development of laparoscopic and robot-assisted surgery, there has been an increase in surgical simulation and training labs aimed at providing residents opportunities to practice and develop technical skills outside of the OR.^{9,10,11} Robot-assisted surgery simulation curricula, however, have not yet demonstrated improvement in operative skill, and there are no data that we know of demonstrating the effectiveness of simulation curricula in improving patient outcomes.^{12,13,14} Thus, the value of current simulation curricula has not yet been determined.¹⁵ When considering this case, the lack of evidence-based research demonstrating that simulation curricula improve operative skills supports Dr A’s reliance on personal judgment to determine the capabilities of Dr B inside and outside of the OR.

Disclosing Surgical Roles and Managing Expectations

In the case presentation, there is no description of Dr A providing disclosure to the patient and obtaining informed consent prior to surgery. The case ends with Dr B wondering what the patient should be told about her role in the surgery. It is not clear if

Dr B was present for the preoperative discussion that Dr A had with the patient. Although disclosure of surgical residents' intraoperative role was historically neglected in preoperative patient conversations, there is a growing literature on the importance of such disclosure to support **patient autonomy**.^{16,17} Previously published work on this topic in this journal has discussed the importance of standardized disclosure language and the timing of disclosure.¹⁸ However, robot-assisted surgery adds a new component to this discourse.

Intuitive Surgical, Inc recently released a mobile application that records and displays operative metrics of attending surgeons and surgical residents. The application uses data from the Da Vinci surgeon console to track which part(s) of the operation an individual performs, the movements made, the instruments used, and other relevant data.¹⁹ The use of these data in surgical education has potential to facilitate enhanced review of operations, resulting in a shorter learning curve that may benefit future patients. At the same time, operative data with this level of specificity could be desirable in a medical-legal context if an error occurred in the OR that resulted in harm to the patient on the table. The robotic application should be considered analogous to a surgical department case review (ie, a morbidity and mortality conference), which is exempt from medical-legal proceedings. These conferences are an opportunity for peer review of surgical errors and discussion of options that may prevent similar errors from occurring in the future.

The availability of data specifying who was operating at certain times during a case forces us to consider what details of a resident's intraoperative role attending surgeons should share with a patient in the preoperative disclosure and informed consent process. Should every surgery be stratified into segments and each segment assigned a team member? This approach may offer the patient more information and hence greater autonomy, but it may be impractical. It may also restrict intraoperative role changes if the clinical scenario differs from what the surgeon anticipated. It is common for the preoperative plan of the trainee's role in the operation to change during an operation. Typically, this role change occurs when the operation becomes more complicated, necessitating that the trainee's involvement be reduced. Even in these scenarios, however, the trainee is actively assisting in the surgery. Whether or not a role change occurs, after the surgery is complete, it is expected that the surgeon will provide an overview of the operation that includes discussion of whether it was more complicated than expected. However, it is not expected that the surgeon would—and it would not be practical for the surgeon to—give a detailed, play-by-play description of each surgical step.

Finally, as new surgical technology and techniques are introduced, the medical device industry has recognized the value of marketing to the public. As a result, patients and their loved ones may bring preconceived ideas to the informed consent conversation. Specific to robot-assisted surgery, patients may be concerned about the role of the robot vs the role of the surgeon and whether the surgeon will be in the room for the duration of the operation. Educating patients and their loved ones about the roles of the robot helps patients consent to or decline surgery.

Conclusion

The growth of robot-assisted surgery and other **novel surgical tools** and techniques offers opportunities to reinforce ethical tenets of nonmaleficence and autonomy. Accordingly, attending surgeons should disclose the roles of residents in operations

during consent processes. Surgical data from technology applications enhance educational quality and should not be subject to medical-legal proceedings. Finally, surgical residents must learn not only how to perform increasingly complex operations, but also how to explain these operations and all surgical team members' roles.

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Dr Cleary has received honoraria from Intuitive Surgical, Inc, for educational speaking. Dr Bobel had no conflicts of interest to disclose.

The people and events in this case are fictional. Resemblance to real events or to names of people, living or dead, is entirely coincidental. The viewpoints expressed in this article are those of the author(s) and do not necessarily reflect the views and policies of the AMA.



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CASE AND COMMENTARY: PEER-REVIEWED ARTICLE

How Should Surgeons Consider Emerging Innovations in Artificial Intelligence and Robotics?

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Abstract

Artificial intelligence (AI)-assisted robotic surgery seems to offer promise for improving patients' outcomes and innovating surgical care. This commentary on a hypothetical case considers ethical questions that AI-facilitated surgical robotics pose for patient safety, patient autonomy, confidentiality and privacy, informed consent, and surgical training. This commentary also offers strategies for mitigating risk in surgical innovation.

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Case

Ms A is a 50-year-old woman with a history of right breast cancer that was treated with mastectomy, axillary lymph node dissection, and radiotherapy and was complicated by severe lymphedema not amenable to nonoperative therapy. Ms A's surgical history includes a laparoscopic appendectomy and 2 cesarean sections; her BMI is 32, and she is generally in good health.

Ms A has no clinical background but has researched surgical lymphedema therapy. She has spoken with patients who have undergone traditional surgical management of their lymphedema with vascularized omental lymphatic transplant using an open approach. A conventional open approach involves a longitudinal laparotomy incision from above the umbilicus to the xiphoid. This is more invasive than laparoscopic or robotic techniques as it requires a large incision and exposure, which carry increased risks of wound healing complications, surgical site infection, and less optimal scar aesthetics. In Ms A's case, the surgeon, Dr B, recommends a minimally invasive, artificial intelligence (AI)-assisted robotic approach for omental harvest. Suppose the robotic platform is currently US Food and Drug Administration (FDA)-approved for urologic indications. Dr B indicates that emerging data about an AI-assisted approach are favorable but that research will be advanced by collecting data during Ms A's operation.

Ms A wants surgical intervention for her lymphedema, as it has worsened despite over 6 months of nonsurgical management, and she is apprehensive about undergoing a new,

clinically untested procedure. In particular, she worries that even though Dr B will be in the operating room during the entire case, an automated machine will be performing her surgery at certain points. Ms A also wonders which data will be collected and how her data will be stored, secured, and applied in the future.

Commentary

Ms A's case demonstrates the ethical considerations attendant on the development of AI and robotic surgery. AI most simply refers to “the science and engineering of making intelligent machines, especially intelligent computer programs” to mimic the decision-making and problem-solving capabilities of the human mind.¹ Machine learning is a subfield within AI that trains algorithms on data to gradually improve their accuracy in a manner that imitates how humans learn.² While **machine learning** has become more commonplace in the public and military sectors, its role in health care remains under scrutiny.^{3,4,5,6,7} Biases are known to be incorporated in AI programs, which could perpetuate social inequality and harm patients.^{8,9} However, AI-assisted technology has the potential to greatly mitigate the global burden of disease by improving access to necessary medical and surgical care. Most AI-assisted technology has been utilized in preoperative planning and intraoperative guidance.¹⁰ Currently, autonomous surgical technology is in its preliminary stages of use in the operating room and in clinical trials in the areas of urologic, gynecologic, spine, and gastroenterological procedures.^{11,12,13} Could AI-assisted technology safely and ethically replace humans in the surgical arena? Indeed, it is conceivable that robots will be able to perform surgery relatively independently, with minimal assistance, although there is disagreement about the desirability and attainability of this goal.^{10,14,15,16} This paper will highlight potential issues and implications of this path.

Guiding Ethical Questions

Several key ethical issues must be considered in implementing AI-assisted technology in surgery (see Table).^{3,17,18,19}

Table. Ethical Issues and Mitigating Strategies in AI-Assisted Robotic Surgery

Concern	Example	Measures to mitigate it
Autonomy ^{3,17,18}	<ul style="list-style-type: none"> • <i>Patients' autonomy.</i> With the advent of new AI-assisted robotic surgery that lacks substantial evidence-based outcomes, how can surgeons obtain informed consent from patients? • <i>Surgeons' autonomy.</i> When parts of the perioperative process are automated, how does the surgeon maintain control of and ultimate responsibility for patient care? 	<ul style="list-style-type: none"> • <i>Patients' autonomy.</i> Surgeons' must be transparent about the available clinical outcomes data on new surgical technology and review the known risks and benefits of AI-assisted robotic surgery and the alternative options. • <i>Surgeons' autonomy.</i> Surgeons incorporating AI-assisted technology in their practice must understand their role during the automated portions and how to intervene when necessary.
Beneficence ^{3,17,18,19}	<ul style="list-style-type: none"> • How do surgeons know they are providing optimal patient-centered care for their patients when there is known bias in machine learning and in AI- technology? 	<ul style="list-style-type: none"> • Surgeons must be aware of the biases intrinsic to machine learning. Thus, they must still monitor and assess all critical aspects of the perioperative process. In addition, frequent review of patient outcomes may help identify how these biases may be incorrectly influencing patient management.

Nonmaleficence ^{17,18}	<ul style="list-style-type: none"> • How is the confidentiality of patient data collected during AI-assisted surgery protected? 	<ul style="list-style-type: none"> • Patient data must be deidentified and stored in an encrypted manner such that a data breach would not put individuals at risk for identify theft. Also, when data is transferred to private manufacturers, protocols must be in place to ensure data quality and appropriate access.
Justice ^{17,19}	<ul style="list-style-type: none"> • Who will have access to AI-assisted surgery? What efforts will be made to make it accessible to all patients who meet indications for such procedures? 	<ul style="list-style-type: none"> • Although AI technology can be expensive, as it becomes integrated into surgical practice, efforts must be made to increase access to this technology safely and effectively within low- and middle-income countries' health care systems.

Patient autonomy and informed consent. How can patient autonomy be respected and informed consent assured, particularly given that the surgeon is using new technology without evidence-based results? Informed consent is critical to patient-centered care that respects patient autonomy and upholds the principles of beneficence and nonmaleficence. General components of informed consent include disclosing the risks and benefits of the procedure as well as alternative treatment options.^{20,21} In addition, the patient (or guardian) must demonstrate a reasonable understanding of the potential implications of the medical procedures to which consent is given. In this case, the surgeon must clearly explain what is known regarding AI-assisted robotic omental harvest and what remains unknown and discuss alternative options, such as robotic-assisted omental harvest (without AI support) or an open approach.

Ideally, a clinician will recognize when a patient is apprehensive, such as in this case, and ensure that all relevant information—including that which might dissuade the patient from providing consent—is disclosed. Of note, because the decision-making process of machine learning algorithms is a “black box” even to the programmers, the surgeon offering the AI-assisted surgery can’t possibly know exactly how the technology works, and this lack of knowledge must also be disclosed during the informed consent process. Finally, in this case, because the new (hypothetical) procedure has not yet been proven safe based on extensive clinical experience, obtaining true informed consent might not be possible. For non-FDA approved AI technology, potentially internal review board approval for each case (or case series) or a unique disclosure on surgical consents should be required to ensure that the surgeon appropriately discusses with the patient the novelty of the AI-assisted technology used in a specific procedure.

Suppose there is evidence that AI-assisted robotic procedures have better outcomes than the prior standard of care. How should a surgeon navigate a situation in which a patient still refuses to have AI-assisted robotic surgery while respecting patient autonomy? Surgeons are responsible for making clinical decisions that, in general, are in the best interests of patients so long as they do not violate patients’ autonomy. This process involves offering and ultimately recommending therapeutic options that are most likely to result in an optimal clinical outcome and that align with a patient’s values and wishes. In the current situation, Dr B ought to fully explain to Ms A that AI-assisted robotic omental harvest will likely lead to a better outcome than the alternatives based on available data and reported experience. However, if Ms A understands the likely outcome of each option yet still wishes to undergo the previous standard of care

treatment, then Dr B should honor her autonomy and perform the standard procedure. If Dr B is not technically comfortable performing such a procedure, appropriate consultation should be sought, which might include recommending that the patient see a different surgeon with more experience in the preferred procedure.

Identifying and minimizing bias in AI-assisted surgery. Given each patient's unique medical and surgical history, anatomy, and other features, how can we ensure that AI-assisted technology facilitates patient-centered and individualized care (ie, during an automated portion of a procedure)? Even though machine learning algorithms train on vast amounts of data to enable accurate diagnoses and prognoses and delivery of more equitable care, **bias in AI** has been well documented in the business, criminal, and health care literature.^{22,23,24,25,26} For example, machine learning algorithms likely will incorrectly estimate risks of certain diseases in patient populations that tend to have missing data in the electronic health record,⁸ with deleterious consequences. To take another example, in a study of machine learning algorithms for predicting intensive care unit mortality, algorithmic bias was shown with respect to gender and insurance type.²⁷ This finding suggests that bias in training data for machine learning could lead to bias in algorithms, which then might falsely predict the risk of a disease (eg, breast cancer) in a specific population (eg, Black patients).

Additionally, how data are collected can introduce bias in training data. For example, collecting relatively more data from neighborhoods with higher police presence can result in more recorded crimes, which perpetrate more policing.²⁸ If such unrepresentative data are used in training sets, the AI model will be biased.^{29,30} Thus, relying on AI during automated surgical care carries the risk of bias, with the potential to inadvertently harm the patient. However, the surgeon must acknowledge that human decision making is also affected by unconscious personal and societal biases and can be flawed.²⁶ Whether AI decisions are less biased than human ones has not yet been proven.²⁹

Before safely implementing AI in surgical settings, the risk of discrimination must be disclosed to a patient and potential harms discussed. It is also imperative that procedures for which AI-assisted technology functions independently of the surgeon be thoroughly evaluated before being applied in clinical practice. They might require human monitoring or supervision to ensure patient safety. Such monitoring during relevant portions of a procedure might reduce potential risks to the patient that could result from AI-assisted bias. For example, if there is an acute change in vitals or certain blood chemistry levels during surgery, an AI algorithm for such situations might not be as reliable as human judgment for that specific patient. Accordingly, the surgeon must explain in appropriate detail to the patient when the automated parts of the procedure occur and what her role is during that period. Optimal intraoperative decision making involves integrating patient information, evidence-based information, and surgical experience. To date, no AI-assisted surgical technology exists that achieves this goal, nor has any such technology been tested extensively with reproducible results in a large human patient cohort.^{28,31} Thus, human supervision and input during surgical procedures that use AI technology are necessary for the foreseeable future.

Nonmaleficence in data collection. How are data that are collected intraoperatively stored, and who owns and controls the data? How can we safeguard patient confidentiality in the automated world? If there is a data breach, what are the **potential harms** to patients? It should first be noted that it remains unclear in many cases who

the owner of the data is; every state has different laws regarding medical record ownership.³² This question could be answered by future litigation and case law. Nevertheless, while electronic medical records and the increasing use of AI-assisted technology in health care have led to the growth of large digital medical databases that have the advantages of facilitated access, distribution, and mobility, there is a greater risk of a data breach.^{33,34} If patient medical data is breached, the potential harms to patients include psycho-emotional stress and identity theft, which can lead to false medical bills and the potential for unreliable medical records and subsequent life-threatening errors in medical decision making.^{35,36}

To date, data collected intraoperatively (such as patient demographics, lab values, and outcomes such as specific morbidities and mortalities) are generally stored and managed by private AI health companies. These data are highly sought after to build AI algorithms for medical practice, not just for perioperative needs. Methods to protect patients from data breaches necessitate that AI health companies abide by federal and state laws and regulations regarding patient medical data. To abide by the Health Insurance Portability and Accountability Act (HIPAA),³⁷ entities covered by HIPAA regulations, such as health care organizations, must deidentify personal health information before it can be stored on an AI health company database. Once deidentified, the clinical data are privately owned by an AI health company (eg, Google's DeepMind™, Quid™, INFORMAI™, or BioSymetrics). Continued efforts by the AI health company to maintain privacy and protection of the data, as well as to properly train their employees in HIPAA compliance, are also paramount.³⁵ Finally, if a data breach occurs, the patient must be informed by their clinician or the AI health company storing the data.

AI Technology and Roles of Surgeons

As the field of surgery evolves, there is a movement away from more invasive, human-influenced to minimally invasive, more machine-automated procedures.³⁸ Some argue that the main tasks of surgeons are shared clinical decision making and performing operations, and both tasks have human limitations.³⁸ A recent observational study demonstrated that cognitive error in the execution of care was the most common human performance deficiency associated with adverse surgical events.³⁹ Thus, many supporters of AI-assisted technology believe that it could overcome human limitations and improve health care delivery. However, during this early transition period, as AI is incorporated in mainstream health care, the surgeon-in-training faces the reality that traditional surgeon-centered, surgeon-dependent procedures might become a thing of the past. Surgeons' role could be more one of "computer operator" than "human operator." But this change will be gradual over a long period.

In addition, during this transition period, mid-career surgeons who are very adept at current surgical techniques are faced with learning something new and essentially starting from the beginning of training. While any new surgical technique is being integrated, there is the risk of compromising results, but this risk can be mitigated by a surgeon's careful practice, training, and mentorship by another surgeon more practiced in the new technique. Once that learning curve has been overcome, the surgeon can safely offer this new technique to their patients. Similarly, if a surgeon is more comfortable with the AI-assisted robotic surgery and not with the traditional open approach, the optimal safety plan would be to have another surgeon available to assist if a situation occurred in which the surgery needed to be converted to an open approach. Thus, careful planning would need to be done prior to a surgeon's entering the operating room, as early adoption of technology does bring risks of user errors. For

example, due to deaths occurring during robotic heart surgery, some surgeons are adamantly arguing for only human-controlled open-heart surgery.⁴⁰ New technology is flashy and attractive for advertising purposes. However, to promote Aristotelian ethics and an emphasis on virtuous character and conduct, surgeons must assess and incorporate AI-assisted surgical technology with healthy skepticism.

Conclusion

Emerging AI technology in surgical care has many potential benefits, particularly in increasing access to and availability of necessary surgical care. However, this technology has known risks of bias and data breach, and the simple fact is that humans might never fully understand machine learning. As Ralph Waldo Emerson wrote in *Self Reliance*, “the civilized man has built a coach, but has lost the use of his feet”⁴¹; for junior surgeons in training, it is essential to continue to learn manual, surgeon-dependent skills while paying attention to evolving AI-assisted technology^{14,15,16,42,43} and considering the adoption of such technology in practice if it might improve patient care. However, the value of human clinical judgment, compassion, and flexibility in patient-centered care should not—and is unlikely to—be trumped by efficient, intelligent machines.

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The people and events in this case are fictional. Resemblance to real events or to names of people, living or dead, is entirely coincidental. The viewpoints expressed in this article are those of the author(s) and do not necessarily reflect the views and policies of the AMA.

MEDICAL EDUCATION: PEER-REVIEWED ARTICLE

Is Robotic-Assisted Surgery Better?

Anastasya Chuchulo, MD and Abubaker Ali, MD

Abstract

The surgical platform for robotic-assisted surgery has enabled many surgeons to join a popular trend in minimally invasive surgery, which offers prospective benefits to patients (eg, shorter hospital stays, earlier recovery, and less pain) and operational benefits to surgeons. Surgeons without minimally invasive surgical training typically acquired during fellowship training are generally able to perform complex procedures with the robotic platform due to its ergonomic suturing instrumentation, tremor stabilization, 3D visualization, and 4-arm control by a single surgeon. Prospective benefits, however, must be balanced against prospective risks. This article explores the multitude of factors that persuade both surgeons and patients to choose robotic surgery over open surgery or conventional laparoscopy and explores whether evidence exists to support its use despite sometimes conflicting research.

History of Minimally Invasive Surgery

Minimally invasive surgery (MIS) has come a long way in the more than 120 years since gynecologist Dimitri Ott examined the peritoneal cavity of a woman in 1901 with a head mirror and a speculum through a culdoscopic opening.^{1,2} Almost 85 years later, in 1985, Erich Mühe performed the first laparoscopic cholecystectomy in Germany.^{2,3} The change to the surgical field that laparoscopy brought about has been one of the most revolutionary in the history of surgery. Prior to the 1990s, the surgical dogma was “the bigger the cut, the better the surgeon.” This attitude began to change with the shift to not only less invasive surgery but also surgical practices that were driven by popular patient demand.⁴ It was estimated that, by 1992, about 80% of cholecystectomies were being performed laparoscopically,⁵ and laparoscopic cholecystectomy has since become the gold standard of care for patients worldwide suffering from biliary colic. The explosion of interest in this novel technique was driven by patient demand for surgeries whose incisions could be covered with mere band-aids at the completion of the case. Patients wanted smaller scars, less pain, and less recovery time.

A further evolution of MIS came through the development of remote robotic telesurgery for use in battlefields and since adopted for use in many surgical specialties.⁶ Over the years, this advancement has been proven to produce—at the very least—technical outcomes not inferior to those afforded by comparable laparoscopic procedures and, in

some cases, superior to them.^{7,8,9,10} This paper explores the factors that persuade both surgeons and patients to favor robotic surgery over laparoscopic surgery as well as the possible reasons that conflicting research exists to support its use.

Enhanced Operative Experience

Surgeons' operative experience differs considerably with the robotic platform. Improved ergonomics by enabling surgeons to sit at a customizable console—and to operate with increased dexterity, tremor reduction, 3D visualization, up to 10 times magnification, and control of 4 arms—are all ways that simplify MIS for those not trained to operate laparoscopically.^{11,12} Consequently, surgeons who have not embraced laparoscopic procedures routinely in their practice can now make the transition to MIS with relative ease through the robotic platform. While rigid laparoscopic instruments provide 4 degrees of motion, robotic instruments have 7, mimicking the human wrist through EndoWrist technology.¹¹ By increasing dexterity in ways that laparoscopic techniques cannot accommodate, robotic operating makes suturing easier for those who have limited or no training in MIS.¹³

Despite the benefits of robotic surgery for surgeons, evidence that the shift to robotic surgery is due primarily to a decline in open surgery is not robust. One review article did conclude that robotic lobectomies are increasing while open lobectomies are decreasing and lobectomies performed by video-assisted thoracoscopic surgery (a laparoscopic equivalent) are remaining stable.¹⁴ Similarly, a cohort study that included over 169 000 patients from 73 Michigan hospitals found that while the use of robotic surgery overall increased from 1.8% of cases in 2012 to 15.5% of cases in 2018—and 41-fold over the same time period for certain procedures, such as inguinal hernia repair—use of laparoscopy, which had increased by 1.3% per year prior to the adoption of robotics, afterwards declined by 0.3% per year.¹⁵ While these findings suggest that surgeons who use open surgery are transitioning to robotic surgery, a 7-year retrospective review published in 2018 found that while use of robotic surgeries increased in all 5 categories (colectomies, cholecystectomies, bariatric surgeries, inguinal and ventral hernia repairs), use of laparoscopic procedures decreased relative to use of robotic procedures, leading the authors to conclude that the increase in robotic surgeries came from laparoscopic surgeons utilizing more robotics rather than from open surgeons converting to robotic surgery.¹⁶ This conclusion, however, is limited by the fact that new surgeons entering the surgical field were not accounted for, and individual surgeon case data were not available. The data also showed that the highest absolute increase in use of robotics was for colectomies and bariatric surgeries (from 0.1% to 3.1% and from 0.4% to 4.8%, respectively), which surgeries also had the highest absolute decrease in open procedures (from 71.8% to 61.9% and from 20.1% to 10.1%, respectively), raising the question of whether the increased use of robotic surgery for these procedures comes from a technical advantage due to the greater complexity of those cases. All in all, it is difficult to generalize these trends accurately without looking at individual surgeons' data and accounting for new trainees entering the field.

Making Procedures Safer, Faster, Cheaper

Critics frequently cite the longer operating times and higher costs of robotic surgery compared to laparoscopic surgery,^{9,10,11} but history provides a more nuanced perspective. The first laparoscopic cholecystectomy took 2 hours to complete.¹ Now experienced surgeons can perform that same procedure in under 30 minutes.¹⁷ Similarly, studies conducted in the 1990s comparing laparoscopic to open appendectomies showed that laparoscopic procedures cost the hospital more money

and took longer to complete as well.¹ Now open appendectomies generally occur only in unusual circumstances, and one would be hard-pressed to find a patient who would choose an open appendectomy over a laparoscopic one. Residents trained today are more comfortable and more experienced with laparoscopic appendectomies and laparoscopic cholecystectomies than the same procedures done open. As surgeons become more experienced using the robot, they are able to use fewer instruments in more versatile ways, resulting in decreased instrument exchanges, all contributing to decreased cost and operating room time.¹⁸

Robotic Platforms in Education

Surgical residents have a minimum requirement to complete 100 basic laparoscopic cases in addition to 75 complex laparoscopic cases in order to fulfill graduation requirements.¹⁹ Recently, an option to log cases as robotic has become available for general surgery and obstetrics-gynecology residents, and urology residents have an already-established 80 case minimum requirement for robotic procedures.²⁰ It seems that it is only a matter of time before **robotic training** becomes a standardized, integral part of basic training for all surgeons. As the robotic platform continues to be utilized and as the instruments and technology continue to evolve, surgeons will continue to reduce not only operative time, but also cost per procedure, making it possible to believe that, with improved training, the cost and time difference between laparoscopic and robotic surgery will be negligible.¹⁶ Currently, robotic training consists of web-based and dedicated on-site training programs, virtual reality skills simulation, and old-fashioned mentorship that residents are exposed to during their training.²¹ These opportunities, however, are not standardized within residency programs across the United States, and access to them is widely variable.

Intuitive Surgical, Inc, the company behind the da Vinci robotic platform—currently the most widely used platform in the United States²²—has training simulations available online and on the operating console, allowing trainees to practice transferable skills outside of the operating room, without compromising patient safety.²¹ The company also has a system in place for experienced robotic surgeons to proctor surgeons new to robotic surgery, now also available via an easy-to-use platform, the Intuitive Hub, which allows for video recording and virtual collaboration in real time and after the procedure is complete by enabling surgeons to review and track progress. This unique learning platform allows surgeons in all stages of training to broaden their robotic skills and adapt robotics to their practice faster than before. The app collects data during operations by tracking the surgeon's every move, instrument changes, clutch use, and so on and provides feedback in order to assess and improve efficiency and to compare the surgeon's personal results to those of other surgeons. This technology will also help address access issues and can allow residency programs to establish set goals for residents to achieve throughout their training.

Outcomes for Surgeons

Complex cases may offer a greater advantage when done robotically than laparoscopically for surgeons with less training in MIS. In a systematic review, Flynn et al found that operating times for robotic colectomies were shorter than for laparoscopic colectomies when the surgeons were unfamiliar with both platforms.²³ Although Lauka et al's systematic review and meta-analysis found that operative times were longer and costs higher for robotic right colectomies than for laparoscopic right colectomies, 3 of the studies included took into account the effect of experience on operative time and showed that operative times decreased for robotic colectomies over the course of the

learning curve,^{24,25,26} and 1 of the 3 studies further reported that, for 11 to 20 completed cases, robotic right hemicolectomies took less time to complete than laparoscopic, likely due to a shorter learning curve.²⁵ Moreover, robotic colectomies had lower conversion rates, less estimated blood loss, higher lymph node harvest, and a shorter hospital stay than laparoscopic colectomies.¹⁰

In light of these findings, the results discussed earlier favoring open or laparoscopic procedures over robotic procedures may be due to the operative background of the surgeons participating in the studies, as hypothesized by Edward Felix.²⁷ Surgeons who have a diverse laparoscopic background and who are highly proficient in laparoscopy might have increased frustration as well as longer operative times with equivalent robotic cases simply due to being less familiar with the platform despite its advantages. This hypothesis may explain why the results of similar studies reach variable conclusions.

Patient Preference and Robotic Surgery

Minimally invasive procedures have been shown to be not only better for patients in terms of reduced recovery time and pain but also the method preferred by patients, resulting in greater satisfaction.^{15,28} Less time in the recovery unit after the procedure, as well as decreased narcotic use due to less postoperative pain after hernia repair, has considerable implications for both the patient and the health system.²⁹ An evidence-based analysis published by the Medical Advisory Secretariat of Health Quality Ontario found that, compared to laparoscopic hysterectomies, robotic hysterectomies had fewer conversions to open surgery (which had significantly greater blood loss and longer hospitalization time than either minimally invasive modality), resulting in reduced morbidity.³⁰ The same analysis found that robotic prostatectomies for prostate cancer had a significant decrease in blood loss and therefore fewer transfusions, had a decreased incidence of positive surgical margins, and had decreased erectile dysfunction compared to laparoscopic prostatectomies.³¹

During the development of laparoscopy, however, randomized controlled trials were challenging to conduct due to attrition bias³²; studying various techniques in surgery depends on patients' cooperation. As **technology advances** and becomes more futuristic, patients want the new and the popular, even if it may not necessarily be supported by scientific evidence. Surgeons must be cognizant of this fact and remember the many historical instances in which great discoveries in the medical field were greeted with disparagement and a considerable lag time to acceptance in the medical community (think Louis Pasteur's germ theory and Semmelweis' theory of the cause of puerperal fever). Similarly, laparoscopic gallbladder operations were deemed dangerous and unethical during the early days of their use.³³ An equilibrium needs to be achieved between enthusiasm for advancements and a healthy dose of skepticism to ensure safety of novel procedures due to initial uncertainty. All of this is to say that, despite the aforementioned barriers, continued high-quality investigations still need to be done to fully understand the rapidly evolving impact that robotic surgery has on patients, surgeons, and society.

Behind the Knife, a popular podcast among surgeons and surgical trainees alike, has interviewed nationally and world-renowned surgeons, such as John Cameron and Carlos Pellegrini. When asked what has been the single greatest innovation in surgery over the course of their careers, overwhelmingly the answers have included MIS.³⁴ Above all, in light of ever-increasing and dynamic evidence, it is important for patients and surgeons

to work together to understand the differences in techniques and their uses and applications, to dissipate misunderstandings, and to come up with a final best option of treatment in each case.

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AMA CODE SAYS

AMA Code of Medical Ethics' Opinions Related to Robotic Surgery

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Abstract

More frequent use of robotic-assisted surgeries raises several ethical questions about care quality and justice, informed decision making and consent, conflicts of interest, innovation in health care practice, and continuing education. The *AMA Code of Medical Ethics* does not directly address use of robotic-assisted surgery but offers several relevant opinions.

Robotic-Assisted Surgery

Robotic-assisted surgical procedures have become increasingly common. A recent cohort study found that the use of robotic surgery for all general surgery procedures performed between 2012 and 2018 increased from 1.8% to 15.1%.¹ Robotic-assisted surgery will likely continue to grow its market share. In 2022, the global surgical robotics market was valued at 6.3 billion USD, and it is expected to expand at a compound annual growth rate of 15.9% from 2023 to 2032, with a projected 2032 value of 26.8 billion USD.²

Despite the rapid development of **robotic surgical technology**, its cost-effectiveness—due to the initial purchasing cost—and maintenance are major issues.³ Furthermore, the long-term survival benefits of robotic-assisted surgeries compared with traditional surgeries have not yet been established, and the US Food and Drug Administration issued a warning in 2019 that patients and doctors should be aware of and discuss the lack of evidence regarding the safety and effectiveness of robotically assisted cancer-related surgeries.^{4,5} It is also important to recognize that the use of robotic and **computer technologies** to assist in surgeries requires intensive and continuous training.⁶ Related to these issues, the increasing use of robotic-assisted surgeries raises several ethical concerns, such as attention to quality and equity of care, conflicts of interest, innovation in medical practice, and continued medical education.

Physicians' Ethical Responsibilities

Although the American Medical Association (AMA) *Code of Medical Ethics* does not directly address the use of robotic-assisted surgical procedures, it contains several relevant opinions. Opinion 1.1.3, "Patient Rights," specifies that patients have the right to "receive information from their physicians and to have opportunity to discuss the benefits, risks, and costs of appropriate treatment alternatives"⁷—which includes the right to an informed discussion comparing the benefits, risks, and cost of robotic-

assisted surgery and traditional surgery. As outlined in Opinion 2.1.1, “Informed Consent,” “[p]atients have the right to receive information and ask questions about recommended treatments so that they can make well-considered decisions about care.”⁸ With regard to robotic-assisted surgery, such communication is critical, given the often novel and complex nature of robotic technologies that require explanations of the procedure and risks. As with all medical procedures, informed consent is essential to the patient-physician relationship in order to foster trust and support shared decision making.

As addressed in Opinion 1.1.6, “Quality,” physicians are also obligated to ensure that care is “safe, effective, patient centered, timely, efficient, and equitable.”⁹ Physicians must monitor this technology, much of it novel, to ensure that its use is safe and effective. Because the long-term survival benefits of robotic-assisted surgeries have not yet been established, it is also important that data on long-term outcomes be collected to ensure that outcomes are equitable and not reinforcing systemic inequalities. Attention should also be paid to potential disparities in access to robotic-assisted surgeries among different demographic groups as well as those with different forms of insurance coverage.

When robotic-assisted surgery is part of biomedical research, physicians have an ethical duty to provide “the same care and concern for the well-being of research participants that they would for patients to whom they provide clinical care,” to “advocate for access to experimental interventions that have proven effectiveness for patients,” and to “[b]e mindful of conflicts of interest and assure themselves that appropriate safeguards are in place to protect the integrity of the research and the welfare of human participants,” as outlined in Opinion 7.1.1, “Physician Involvement in Research.”¹⁰ In accordance with Opinion 1.2.11, “Ethically Sound Innovation in Medical Practice,” physicians involved in innovative modalities such as robotic-assisted surgery have an ethical duty to design and develop innovations “on the basis of sound scientific evidence and appropriate clinical expertise” and with an awareness “of influences that may drive the creation and adoption of innovative practices for reasons other than patient or public benefit.”¹¹ This duty entails a responsibility to collect and report data on the outcomes of robotic-assisted surgeries and to recognize the financial and other incentives that may motivate the adoption of robotic-assisted surgeries at the organizational level.

As the surgical robotics market continues to grow, physicians must be cognizant of any potential conflicts of interest that relationships with biotechnology or medical device companies driving innovation might pose, such as undue influence by device representatives. On an individual level, to ensure quality care, physicians have a duty to inform patients “of any conflicts of interest [they] ... may have in respect to their [patients’] care” as outlined in Opinion 1.1.3.⁷ Physicians’ primary obligation is to their patients, as detailed in Opinion 11.2.2, “Conflicts of Interest in Patient Care,” which states: “The primary objective of the medical profession is to render service to humanity; reward or financial gain is a subordinate consideration. Under no circumstances may physicians place their own financial interests above the welfare of their patients.”¹² Additionally, because robotic-assisted surgery requires expensive equipment, Opinion 9.6.2, “Gifts to Physicians from Industry,” is relevant, as it states how gifts from industry “create conditions that carry the risk of subtly biasing—or being perceived to bias—professional judgment in the care of patients.”¹³

The use of innovative medical practices comes with a number of ethical considerations, including the need for special training, as Opinion 1.2.11 stipulates. When offering innovative practices such as robotic-assisted surgery, physicians must “[r]efrain from offering such services until they have acquired appropriate knowledge and skills.”¹¹ Implicit in this ethical responsibility is the duty to continual education, detailed in Opinion 9.2.6, “Continuing Medical Education,” which states: “Physicians should strive to further their medical education throughout their careers, to ensure that they serve patients to the best of their abilities and live up to professional standards of excellence.”¹⁴ As robotic-assisted surgery continues to advance, physicians have a responsibility to continue their education and to stay up-to-date with these surgical innovations.

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STATE OF THE ART AND SCIENCE: PEER-REVIEWED ARTICLE

Should Robot-Assisted Surgery Tolerate or Even Accommodate Less Surgical Dexterity?

Katherine Fay, MD and Ankit D. Patel, MD

Abstract

Since their adoption during the 1990s, minimally invasive surgical techniques have demonstrated postoperative surgical recovery benefits for patients. As robotic surgery platforms continue to be developed and utilized in surgical specialty areas, dexterity and visual field limitations of laparoscopy are coming under close clinical and ethical scrutiny. This article compares robotic and laparoscopic modalities, with special attention to dexterity, surgeon performance, ergonomics, and patient outcomes. This article also examines robotic platforms' advantages for surgeons' technical capacity and career longevity.

Introduction

Minimally invasive surgical (MIS) techniques have been a major factor in improving how surgeons provide care to patients. In the 1990s, the rise in popularity of laparoscopic cholecystectomy focused attention on how best to minimize patient morbidity across a multitude of surgical specialties.¹ The increased utilization of an MIS approach has translated into improved patient outcomes in terms of lower rates of complications, decreased postoperative pain, and shorter hospital length of stay.² For example, the transition from an open to a laparoscopic approach for adrenalectomies reduced average inpatient hospital length of stay from 9.8 days to 5.1 days in one study published in 1996 and subsequently down to 2.4 days the following year when the study was repeated.^{3,4}

The benefits of an MIS approach have been particularly profound in the obese patient population. As obesity becomes more prevalent in the United States, a push toward smaller surgical incisions will accrue a variety of benefits to these patients, including improvement in postoperative outcomes. Shortly after the introduction of laparoscopic techniques for weight loss facilitation, one study demonstrated that, compared to patients who underwent open surgery, patients who underwent laparoscopic Roux-en-Y gastric bypasses had significantly decreased mean operative times (246 vs 294 minutes, respectively) and shorter mean length of hospital stay (4.0 vs 8.4 days, respectively), as well as less frequent superficial and severe wound infections (2.9% vs 8.6%, respectively).⁵

Robotic Surgery Platforms Improve Surgeon Performance

As more specialties utilize laparoscopy as a surgical modality, it has become increasingly evident that, despite its benefits for patient care, the technique has certain operative and physical limitations. Laparoscopy is dependent on 2-dimensional (2D) vision and has decreased range of movement relative to open surgery on account of the rigidity of the instruments, resulting in overall reduced surgical dexterity.⁵ Flexible laparoscopic instruments exist but do not correct for major deficiencies. The introduction of the robotic surgery platform has vastly improved the deficiencies of traditional laparoscopy by introducing 3-dimensional (3D) vision, further degrees of instrument articulation, and the ability to abolish some tremor through robotic stabilization. These advantages allow for improved hand-eye coordination and overall surgical precision.⁶ In a study of 10 surgeons with varying experience with an MIS suturing task, Moorthy et al showed that, compared to laparoscopy, the robotic platform enhanced by nearly 50% surgical dexterity, defined by the total number of errors observed during task completion (such as fumbling the needle, multiple attempts made with needle handling, and loose sutures).⁷ Moreover, the authors found that robotic 3D vision improved dexterity by 10% to 15% over robotic 2D vision, with a concomitant 93% reduction in operative errors.⁷ Similarly, in a study of 5 surgeons performing a robotic suturing task in 3 different scenarios—use of dominant hand with 3D vision, use of dominant hand with 2D vision, and use of nondominant hand with 3D vision—Ishikawa et al found that average robotic suturing time was significantly faster with the utilization of 3D than 2D vision (211.7 vs 331.1 seconds, respectively), even when the surgeon's nondominant rather than dominant hand was used to perform the task (237.1 vs 331.1 seconds, respectively).⁸ The benefits of robotic surgery are preserved even among novice surgeons. Park et al found that surgeons classified as having intermediate experience (completion of 20-99 cases) and novices (completion of fewer than 20 cases) with MIS laparoscopic (using both 2D and 3D vision) and robotic (3D) platforms struggled more with task completion using laparoscopy, particularly 2D, but were proficient when using the robotic assisted system.⁹ The expert group (completion of at least 100 laparoscopic procedures) completed each task with similar efficiency regardless of platform used.⁹ These findings demonstrate that surgeons with limited MIS experience may benefit more from the compensatory features of a robotic-assisted platform than from traditional laparoscopy. Moreover, this technology may aid **surgeons later in their careers**, especially as their performance may start to deteriorate due to tremor or other musculoskeletal hindrances, such as overuse injuries. Several studies have shown that computer-aided devices or microsurgery help compensate for physical attributes like slight tremors,^{10,11} but none have evaluated or followed surgeons over time to determine whether their careers were prolonged by use of microsurgery or whether they were still able to offer at least MIS techniques as they aged.

Improved Ergonomics

Utilization of robotic surgery techniques has also been shown to provide improved operative ergonomics in several surgical specialties. A recent meta-analysis that included 29 articles comprising 3074 participants evaluated surgical ergonomics across laparoscopic, open, and robotic platforms in a multitude of specialties, including general surgery, gynecologic surgery, and endocrine surgery.¹¹ Roughly half the studies used electromyography (EMG) data regarding muscle activation to measure overuse and fatigue; the other half utilized the National Aeronautics and Space Administration Task Load Index (NASA-TLX), an assessment tool that captures both mental and physical demands as well as total effort and participant frustration with tasks. One survey included in the analysis found that significantly fewer surgeons reported physical

discomfort with the robotic surgery platform than with laparoscopy and open surgery (8.3% vs 55.4% vs 36.3%, respectively).¹² In another included study of 13 MIS-trained surgeons whose performance on 6 surgical training tasks was evaluated using EMG monitoring and post-task NASA-TLX surveys, it was found that performance of the tasks using the robotic platform significantly decreased strain from the biceps and flexor carpi ulnaris muscles relative to laparoscopy.¹³ Additionally, evaluation of the NASA-TLX survey data indicated that, regardless of surgeons' experience with MIS surgery, tasks completed on the robotic platform involved less cognitive workload than the same tasks completed with laparoscopy.¹³

Similar results were found in studies that focused on suturing. In an evaluation of MIS surgeons who performed both a pin movement and a suturing task, Berguer and Smith found that there was significantly less muscle engagement in the thumb, as measured by EMG, with the robotic system than with laparoscopy.¹⁴ The study also evaluated skin conductance values, which were lower during the robotic tasks, suggesting a decrease in overall mental stress during task completion.¹⁴ Similarly, Stefanidis et al showed that robotic surgery was significantly less physically demanding than laparoscopy, as measured by NASA-TLX score (13 vs 5, respectively).¹⁵ Interestingly, contra earlier studies, newer research shows that these benefits are more pronounced in more experienced surgeons. One study found that surgeons who performed more than 20 MIS cases per month were not more likely to experience physical symptoms related to operating than those who performed fewer than 6 cases per month; however, those who performed 6 to 10 or 11 to 20 cases per month had significantly higher odds of experiencing any symptom than those who performed fewer than 6 cases per month.¹⁶ Given that discomfort tends to increase with case load, some institutions have instituted ergonomic programs to reduce physician fatigue.^{17,18} Clearly, less physical and mental fatigue would allow surgeons to perform at a higher level for longer durations of time. In theory, reduced fatigue should extend surgeons' careers, as they would experience less physical strain. It will be important to track the longevity of surgeons' careers as more of the current generation of surgeons adopt the robotic surgical platform for minimally invasive-amenable operations.

Comparison of Patient Outcomes

Given robotic surgery's benefits of reduced physical and mental fatigue and reduced physical strain relative to laparoscopy—especially for frequent users of the approach—several studies have sought to evaluate whether a robotic approach improves patient outcomes compared to a laparoscopic approach. Studies have shown that, across multiple specialties—including general surgery and surgical oncology—patients who undergo robotic-assisted surgery have significantly less postoperative pain, reduced open conversion rate, and shorter postoperative length of stay than patients who undergo laparoscopic surgery.^{19,20} In comparisons of patients who underwent robotic, laparoscopic, and open inguinal hernia repairs for recurrent inguinal hernias, significantly fewer patients who underwent a robotic repair needed prescription pain medication than patients who underwent laparoscopic surgery (45.3% v 65.4%) or open surgery (49.5% vs 80%).²¹ It should be noted, however, that patients who underwent robotic surgery had a significantly longer average operative time than patients who underwent laparoscopic surgery (83 minutes vs 65 minutes, respectively).²¹ Another study of perioperative outcomes for abdominoperineal resections for colorectal cancer at one institution found that, compared to patients who underwent laparoscopic surgery, patients who underwent robotic surgery had a significantly reduced complication rate (13.2% vs 23.7%, respectively), a significantly reduced open conversion rate (0% vs

2.9%, respectively), and a significantly shorter median hospital length of stay (5.0 vs 7.0 days, respectively), with no effect on long-term oncological outcomes.²²

Pitfalls

Despite its significant benefits in added wrist articulation and visualization, as previously mentioned, one major shortcoming of the robotic platform compared to laparoscopy is the lack of tactile feedback. When evaluating the learning curve for robotic assisted-surgery in colorectal surgery, one study found that one of the main barriers to mastery was the surgeon's inability to substitute visual cues for tactile feedback.²³ While no products are currently available, several enhancements have been proposed to the robotic platform, mostly for neurological or orthopedic procedures, to allow for haptic feedback.²⁴ Finally, implementation of a robotic program has **significant upfront costs**, including purchase of the system and hiring and training of staff, as well as long-term maintenance and platform upgrade costs. A 2010 study found that, on average across a variety of surgical procedures, utilization of the robotic platform added roughly \$1600 to the costs of laparoscopy. When the overall cost of the robot itself was included, the added costs climbed to \$3200.²⁵

Conclusion

MIS techniques clearly provide advantages from both a patient and hospital systems standpoint. However, the robotic platform allows for better compensation of human factors that surgeons face than laparoscopy, and those benefits should not be brushed away. The benefits of robotic surgery in terms of improved proficiency, dexterity, and reduction in mental and physical fatigue have been shown to translate into improved patient outcomes. Resultant reductions in pain, complications, and length of hospital stay provide benefits for patient well-being during surgical recovery as well as reduced hospital costs that benefit the entire health care system. While novices certainly can benefit from this technique, it is important to acknowledge that the current literature supports that surgeons specifically trained in this modality show the greatest benefit.

Studies and resources focusing on surgical training and ergonomic programs in residencies and even in medical school education are underway to start this learning process earlier. It is clear that, as technology continues to evolve and is more widely adopted in training programs, we will be training better, more proficient, and more ergonomically minded surgeons, which ultimately will facilitate delivery of the best care to patients while also preserving the longevity of surgeons' careers.

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MEDICINE AND SOCIETY: PEER-REVIEWED ARTICLE

How Does Robotic-Assisted Surgery Change OR Safety Culture?

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Abstract

Robotic-assisted techniques in surgery require complex equipment setup and create surgeon isolation through loss of normal operative visual and auditory exchanges. These changes demand enhanced team communication and feedback in operating room settings so that robotic-assisted surgery does not compromise safe, efficient surgical care. Diverse simulation and training methods should be incorporated and studied based on local needs to determine how these techniques influence operating room communication, workflow, and safety culture.

Curricular Evolution

Although robots were used in the mid-1980s to assist in computed tomography-guided brain biopsy,¹ robotic-assisted technology rapidly expanded within urologic and gynecologic surgery in the early 2000s and was used with increasing frequency in general surgery in the 2010s.^{2,3} In response to this rapid growth, many robotic training programs and curricula have been developed to expose surgeons, trainees, and operating room team members to the unique features of robotic-assisted surgery. Online learning modules to introduce robotic surgical systems, for example, focus on providing general knowledge, such as device function, instrumentation, and troubleshooting. These programs and curricula have been coupled with bedside-training opportunities and task practice on robotic surgery simulators for psychomotor skill development.^{4,5}

Despite these initial focused efforts, surgeons and surgical teams still face both technical and nontechnical challenges in the live operating room setting that pose barriers to performance of safe and efficient robotic-assisted procedures. More complex robotic preparation and equipment, for example, increase the opportunity for surgical flow disruptions to occur in the operating room. Physical disruptions, such as incorrect placement of carts and consoles, equipment collisions, and other issues, are common and occur more frequently in robotic-assisted approaches than when using other techniques.^{6,7} Furthermore, communication disruptions have been associated with worse surgical outcome metrics for patients, such as longer operative times and higher estimated blood losses.⁸ Poor nontechnical skills in robotic surgery teams, such as ineffective verbal communication, limited situational awareness of the patient's condition, and poor delegation and coordination of tasks have also been linked with increased near-miss events during operative cases.⁹

Given these new concerns, the surgical community must determine how best to train for and use robotic-assisted surgery in ways that maintain **patient safety** and efficacy. Herein we describe the unique physical and communication features of robotic-assisted surgery that have impacted operating room culture and discuss potential strategies for optimizing these features in the future to best promote a culture of safety.

Unique Challenges

To initiate the active operative component of a robotic-assisted surgical case, several new steps are necessary that require the entire operating room team to participate in the setup, preparation, and docking of the robotic system. First, the system must be sterilely draped and positioned appropriately with respect to the patient and operating table. Next, robotic arms are positioned in a procedure-specific orientation, and the circulating team carefully moves the patient cart to the correct location over the patient. Some teams then use the target function of the robotic platform to confirm and adjust this positioning. Finally, robotic arms are docked to respective surgical trocars so that appropriate surgical instruments can be inserted and ready for use. Lack of communication or familiarity with the steps of this process can add significant time to the setup phase of the procedure. However, with proper team training and experience over time, the setup can be significantly streamlined with minimal additional risk posed to the patient. Several studies have now shown acceptable robotic preparation and docking times, which improve as team members gain experience.^{10,11}

Following the initial setup, the surgeon and surgical trainees physically separate from the sterile operative field by stepping away from the patient's bedside to begin operating at the robotic console. This separation is required for functioning of the robotic-assisted system and is an act that distinguishes robotic-assisted surgery from other modalities. The robotic console is typically positioned several feet away from the bedside assistant as well as the scrub and circulating members of the team. When surgeons place their heads in the console, they gain an immersive, high-resolution, 3D view of the operative field as well as other advantages, such as improved ergonomics and **dexterity**. More recently, many academic health centers have also acquired the dual-console robotic system, which allows the proctoring or teaching faculty surgeon to experience these benefits while participating in parallel with the training surgeon away from the patient's bedside in the operating room. The dual setup has been instrumental in allowing safe, graded involvement of the training surgeon, as well as easier instrument handoffs and use of features such as the virtual pointer tool to help facilitate intraoperative teaching.^{12,13}

As surgeons and trainees immerse themselves in the robotic console, however, the physical separation or **gap** between surgeons and team members can lead to surgeon isolation and loss of situational awareness, defined as an accurate understanding of all patient and environmental factors throughout a procedure in the operating room.¹⁴ Physical positioning of the console away from the patient prevents the surgeon from being able to globally observe what is happening in the operating room and to make visual contact with bedside, nursing, and anesthesia teams.¹⁵ Common intraoperative occurrences, such as team members stepping out of the operating room to retrieve equipment or during a shift change, may go unnoticed if not verbally announced. Console immersion or tunnel vision may also prevent a potential patient safety concern from being properly identified.¹⁶ For example, surgeons with their head positioned in the console see a visual feed from the camera and robotic instruments but cannot immediately visualize equipment collisions and malfunctions or identify changes in

patients' hemodynamic monitoring without removing themselves from this console "head-in" position. With the surgeon physically separated from the rest of the team, it is also more difficult for the surgeon to coordinate team actions that may be needed to address these issues and move the case forward safely.¹⁷ In addition, team members who are assisting at the bedside for prolonged cases often become disengaged due to this separation, again decreasing situational awareness.¹⁶

Beyond the physical challenges, communication using the robotic system also presents unique difficulties for operating room team members. First, though dual console operators communicate with each other throughout the case using a built-in microphone system, their commentary and requests are often difficult for the rest of the room to hear, given variable sound transmission and muffled speakers.^{16,18} This microphone system would benefit from a technical redesign that allows better amplification of bidirectional communications between surgeons and their teams. The team's inability to hear surgeons' instructions and vice versa can result in disorganized assistance being provided at the patient's bedside, including exchange of incorrect robotic instruments at relevant points in the case. Instances of poor communication and subsequent surgical flow disruptions contribute to delays in forward case progression for patients. Repeated or unacknowledged requests can also lead to surgeon frustration and subsequent team conflicts.¹⁹ Given the additional loss of nonverbal cues and exchanges between team members secondary to the robotic spatial configuration, a focus on improving the verbal communication component of these cases is of utmost importance to promote increased safety in robotic operating rooms.²⁰

Potential Solutions

To improve successful integration of robotic technology, decrease potential harmful robotic workflow disruptions, and ideally overcome the challenges discussed, several interventions have been proposed and studied.

Interprofessional team training. Interprofessional team training and simulation are promising methods for increasing situational awareness. Heightened situational awareness is particularly critical in robotics, given the tunnel vision effect of the console. Interprofessional simulation training involving surgeons and nurses has previously been shown to decrease robotic system docking times, mean operative times, and mean costs per case.²¹ Participation in game-based educational competitions has also been shown to help robotic team members cultivate an understanding and a culture of teamwork through use of interactive learning environments.²²

Interdisciplinary training has the potential to help team members practice their individual roles while the team reviews its functioning as a collective unit. In interdisciplinary training, surgeons, trainees, anesthesiologists, as well as scrub and circulating nurses, jointly participate in hands-on workshops and simulations to practice operating room and robotic system setup, emergency scenarios, and communication strategies, such as time-outs and debriefings.²¹ Such trainings can enhance team performance and streamline workflow to minimize physical and communication disruptions that are unique to robotic surgery. New assessment tools, such as the Robotic-Assisted Surgery Oxford Non-Technical Skills observational tool, have also been developed for assessment of teamwork behaviors in robotic surgery.²³ This tool can now be used before and after team training events to determine which interventions are most impactful. It can also be applied in live operative procedures to better characterize

strengths and weaknesses of the operative team overall for future, focused improvement efforts.

Patient emergency training. Given robotic surgery's potential risks to patient safety, other approaches have focused specifically on team functioning in the event of patient emergency. Curricula to train emergency robotic undocking procedures have been shown to improve undocking times and performance of critical actions for operative teams.^{24,25} Emergency simulations have additionally promoted improvement of robotic team members' nontechnical skills, such as situational awareness, decision making, leadership, communication, and teamwork.²⁶ It is critical that hospitals with robotic capabilities develop emergency safety protocols and provide relevant training and simulation opportunities to support cohesive responses in life-threatening patient events. Emergency safety protocols can reduce both errors and process disruptions in such high-pressure scenarios.²⁷

At our own institution, we have developed emergency undocking protocols for specific occurrences, such as life-threatening intraoperative bleeding and patient code events (see Figure). These protocols are organized by "swim lanes" to delineate team roles and duties to be performed in parallel during the emergency event. For example, as the surgeon and bedside assistant attempt to control bleeding with robotic instruments, the circulator alerts the operating room front desk and charge nursing team of the situation, and the anesthesia team assesses the patient for appropriate intravenous access should blood products be required. These protocols have been tested with robotic teams in our simulation center and refined for larger-scale group training and assessment. Although our focus has been on intraoperative bleeding and code events, the algorithmic approach could be applied to other scenarios, such as intraoperative anaphylaxis or cardiac events, and even to technical system malfunctions.

Figure. Barnes-Jewish Hospital/Washington University Emergency Undocking Bleeding Protocol

Pathway steps	Surgeon	RNFA/Bedside assistant	Circulator	Scrub tech	Anesthesia
Patient begins to bleed	Communicates issue of bleeding to OR team				Prepares for conversion to open procedure: assess IV & airway access
Attempt to stop bleeding	<ol style="list-style-type: none"> 1. Verbalizes to bedside assistant if robotic or laparoscopic instrument is needed to clamp bleed 2. Specifies usage of robotic or nonrobotic port to insert clamp 3. Verbalizes which robotic instruments safe to move 	Holds pressure to bleed with lap sponge or clamps with laparoscopic instrument (if needed); confirms with surgeon	<ol style="list-style-type: none"> 1. Calls OR front desk/charge nurse to verbalize need for anesthesia attending & crash cart in room; activates code button & calls vascular team (if needed) 	Assists RNFA bedside assist with removal of robotic instruments, scope, & detaching arms from cannulas in < 30 s	Ensures clear pathway to & from head of bed
Blood products needed	Verbalizes need for blood products &/or vascular team assistance				Obtains & gives blood products if needed
Removal of instruments	Prepares to scrub in & gain control of bleeding manually/undock if extra set of hands needed at bedside	If robot instrument used to clamp, removes all other instruments & cannulas from arms. Leaves scope in or removes scope from robotic arm & reinserts into assist port like laparoscopic scope	<ol style="list-style-type: none"> 1. Opens conversion instrument trays/supplies & counts with scrub (confirm type of open retractor needed) 2. Ensures clear pathway to & from head of head 3. Places patients' arms on arm boards (if tucked) 	<ol style="list-style-type: none"> 1. Obtains open suction tubing, Yankaeur tip, blade/bovie, lap sponges, open instruments from circulator & counts 2. Manages sterile tables & prepares back tables for open procedure (if applicable) 	
Emergency stop of robot system	<ol style="list-style-type: none"> 1. Verbalizes need/no need for IRK with RNFA & readiness to hit red emergency stop button with circulator 2. Obtains IRK from scrub & utilizes (if needed) 	Verbalizes readiness to hit red emergency stop button with circulator/assists with use of IRK (if needed)	Confirms readiness to press red emergency stop button with surgeon &/or RNFA if IRK utilized	Provides surgeon with IRK (if needed)	
Undock patient cart	Verbalizes readiness to undock with circulator & undocks robot from patient (raises arms up & away)	Verbalizes readiness to undock with circulator & assists with undocking robot from patient (raises arms up & away)	Confirms readiness to undock with surgeon &/or RNFA & moves robot back & away from patient	Does not remove robotic instruments or trays from field until robotic portion 100% complete	Waits to move OR table until robot undocked from patient, confirms readiness to move table with surgical team
Proceed with case	Continues with surgery in open fashion	Prepare to assist with conversion to open procedure (if applicable)			

Abbreviations: IRK, instrument release kit (Allen wrench tool) used to manually open jaws of robotic instruments/staplers; IV, intravenous access; OR, operating room; RNFA, registered nurse first assist.

Although many efforts have focused on improving robotic operative culture and teamwork, there is still a need for routine, robotic-specific communication practices. Training in closed-looped communication may help to promote increased patient safety. This strategy focuses on simple and standardized procedures for message transmission, reception, and verification between team members.²⁸ Read-back techniques in closed loop communication, wherein the team member receiving information verbally repeats it back to the sender, have been shown to increase information transfer among members of health care teams in other settings²⁹ but have not been explicitly studied in robotic surgery. Preparing each robotic case with a briefing, a reminder of docking requirements, delineation of specific roles, and read-backs after completion of key tasks could increase team efficiency and coordination.⁵ This preparation may also help to overcome visual and auditory challenges that are unique to robotic surgery. Although several checklists have been developed to guide this process in robotic simulated and live operative environments,^{30,31} these checklists require further study to determine their effectiveness when implemented in routine robotic cases.

Conclusion

The introduction of robotic technology in surgery has allowed for innovation while creating several new challenges that teams must overcome to provide safe and efficient surgical care. Diverse simulation and training methods have been studied and should be incorporated within institutions based on local needs to minimize workflow disruptions and potential patient safety events. Highly motivated operative teams that encourage a culture of teamwork will be most successful in overcoming these challenges and closing the physical and communication gaps attendant on robotic-assisted surgery in the future.

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MEDICINE AND SOCIETY: PEER-REVIEWED ARTICLE

Opportunities for Global Health Diplomacy in Transnational Robotic Telesurgery

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Abstract

Globally, barriers to the widespread adoption of robotic surgery have worsened existing inequities in surgical care between low- and middle-income countries (LMICs) and high-income countries (HICs). This article advocates for the creation of sustainable robotic surgery programs in LMICs by drawing from ethical and philosophical theories, including preference utilitarianism, procedural justice, structural violence, and human rights. On this basis, robotic telesurgery is proposed as a form of global health diplomacy (GHD) between LMICs and HICs, and particular emphasis is placed on considerations in robotic surgery GHD program negotiations between LMICs and HICs and on political and ethical questions related to the transnational use of artificial intelligence.

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Global Inequity

Worldwide, 5 billion people lack access to quality, timely, and affordable surgical care. The scarcity of surgery—particularly in low- and middle-income countries (LMICs)—is a major driver of preventable death and disability, given that surgical, anesthesia, and obstetric conditions account for up to one-third of the global burden of disease.¹ Minimally invasive surgery (MIS), including laparoscopy and robotics, is standard of care in high-income countries (HICs) and offers **superior patient outcomes** for many conditions.^{2,3} However, most surgical operations in LMICs—where technological, infrastructural, and financial barriers have curtailed the creation of sustainable MIS centers—are still performed via open approaches.^{4,5} This article offers a moral rationale for expanding robotic surgery in LMICs and outlines several complex, unanswered political and ethical questions related to the use of robotic telesurgery as a form of global health diplomacy (GHD).

Robotics, Ethics, and Human Rights

In ethical terms, under-provision of robotic surgical care in LMICs relative to HICs causes health injustice, or the presence of unmerited, avoidable differences in health outcomes that unfairly diminish the quality of life of those most affected.¹ Disparities in access to

robotic surgical treatment contravene Article 25 of the United Nations Declaration of Human Rights, which guarantees the right to all medical care necessary for individuals' health and well-being.⁶ Additionally, the worldwide morbidity associated with deficits in robotic surgical care indirectly violates Declaration of Human Rights articles 23, 24, 26, and 27, which describe human beings' right to work, rest and leisure, education, and cultural participation, respectively.⁶

To justify robotic surgery as integral to human rights and health justice, one should consider the following question: Can a *surgically ideal society*—a society in which a surgical system equitably allocates resources to provide timely, affordable care of the highest quality to all—exist today without robotics? For diverse operations, it is well established that the use of MIS techniques like robotics reduces postoperative pain and hospitalization relative to open surgery.^{7,8,9,10,11,12} In keeping with the clinical obligation to minimize harm (nonmaleficence), this reduction in patient suffering makes robotic surgery ethically preferable to open surgery. Moreover, MIS reduces the risk of postoperative complications, such as wound infection and incisional hernia; these complications limit patients' labor and social productivity and compel patients to seek additional medical care, including costly re-operation and sepsis treatment.^{13,14,15,16} Safer surgical techniques like robotics thus protect individual patients from medical morbidity as well as economic and personal losses, thereby advancing the bioethical principle of beneficence and sustaining human rights. Furthermore, the adverse postoperative events curtailed by robotics cause disproportionate morbidity and mortality in resource-constrained settings, where overall health care capacity is limited. By reducing postoperative morbidity and thus minimizing excess demand for health care in LMIC systems, robotic surgery capability would allow other medically ill patients to receive a greater share of health resources. In this way, the expansion of robotic surgery upholds the bioethical principle of justice (fair resource allocation).

Pragmatically, by requiring advanced technological and human capital, robotic surgery programs in LMICs may also be *enablers* of health systems' capacity to deliver all services.^{17,18} The expansion of comprehensive health care permitted by technological growth and advanced training of medical personnel promotes population health at large, as all people require or will require some form of medical care in the future.

In summary, expanding robotic surgery in LMICs prevents unnecessary postoperative death and disability, upholds core principles of bioethics, and strengthens systemic infrastructure to benefit society now and in the future. While difficult to quantify, these benefits generate immense **cost savings** that would counterbalance and ultimately outweigh the high up-front setup, training, and maintenance costs of robotics programs. For these reasons, we argue that the attainment of the surgically ideal society requires robotics; thus, robotic surgery is a critical component of just, rights-based health systems.

Philosophical Justification

According to bioethicist Peter Singer, a proponent of *preference utilitarianism* (a moral philosophy that urges the maximal cumulative satisfaction of individual interests, or preferences, and which underlies modern global health ethics), we have a moral duty to minimize preventable suffering and death, provided that doing so does not impose an equally significant moral cost upon ourselves.^{19,20} From this perspective, all suffering has equal moral weight regardless of national borders.¹⁹ Seeing the world as a global village, Singer would, on the authors' interpretation, assert that a robotic surgeon in New

York City has equal moral duties to patients in Manhattan and Tokyo, since helping either group causes no morally meaningful loss to her. Similar logic is extended to the wealthy private hospital where this surgeon operates; to the extent that the hospital will not suffer significant moral losses by treating Japanese patients, Singer would argue that hospital leadership cannot ethically distinguish between its obligations in Manhattan and Tokyo. Singer's position is often criticized^{21,22,23,24} as having unreasonable moral expectations for individuals and local actors when, in reality, national and global institutions play the largest role in perpetuating harm against the less privileged.

Inequitable access to robotic surgery is also contrary to the procedural justice theory of philosopher Thomas Pogge.^{19,25} Extrapolating from Pogge's discussion of what HICs owe LMICs,^{19,25} HICs with adequate robotic surgery ought to take "compensating action[s]" to reform global institutions if they wish to avoid moral responsibility for inflicting further morbidity and mortality on LMIC populations. By reinforcing surgical outcomes disparities, the ongoing scarcity of robotics in LMICs manifests the structural violence described by sociologist Johan Galtung, whereby those in poorer countries are deprived of fulfilling their fundamental health needs and bear avoidably higher death and disability rates vis-à-vis their HIC counterparts.²⁶

What ethical insights should surgeons and surgical centers draw from these theories? While preference utilitarianism is a valuable theoretical construct, we believe it is best applied to the medical profession as a collective actor in the global village. When imposed upon individual physicians and facilities, preference utilitarianism decenters the role of governments and policies in creating global surgical inequities, thereby shifting undue moral burdens onto individual surgeons and hospitals that have neither the resources nor the sociopolitical leverage to adequately rectify them. To some extent, it is natural and ethically permissible for physicians and hospitals to prioritize nearby patients over remote ones. After all, local actors are best positioned to offer timely and accessible care to those in need. Moreover, not all surgeons (or surgical centers) must participate in global surgery in order to uphold the ethics of their profession. Indeed, a plethora of objectives with similar moral implications—from medical education to quality improvement to health policy—also require surgeon involvement. Nevertheless, the surgical community in HICs as a whole—ranging from trainees to department chairs to private practice surgeons—retains a collective obligation to engage international stakeholders and ensure the availability of optimal surgical care across LMICs. In agreement with Pogge's procedural justice theory, HICs' national governments and surgical communities must jointly assume full responsibility for all present and future harm caused by inequities in global surgical care. The compensating actions they must take to fulfill this responsibility will require redistribution of surgical resources in favor of the global poor, including (but not limited to) the diffusion of robotic surgical skills and technologies to LMICs.

Barriers to Capacity Building

Despite compelling moral justifications, global MIS capacity-building efforts have not yet achieved large-scale investments in robotic surgical technology and training in LMICs. Indeed, global surgery initiatives continue to emphasize laparoscopy over robotics due to lower up-front costs and easier implementation.^{17,18} For instance, portable laparoscopic simulators and short-term workshops taught by HIC laparoscopists in LMICs are well documented in the literature, while analogous reports of robotics programs are rare.²⁷ Typically, newly constructed surgical centers in LMICs exclude

robotic technology, citing financial barriers, lack of formal domestic MIS training, and low institutional support.^{28,29} In Colombia, where only 5 surgical centers with robotic consoles exist nationwide, a pilot program for robotic cardiac surgery used a “hybrid technique” with manual aortic clamping to lower procedural costs by 6000 USD, yet public insurance providers remained reluctant to participate.³⁰

In a 2020 report on this intervention, Andrade et al emphasize the importance of fee-for-performance and bundled payment models that promote value-driven patient care, thus incentivizing the sustainable and large-scale use of robotic techniques, which are known to reduce surgeon error and improve patient outcomes.³⁰ Specifically, they reaffirm an ethical mandate to universalize robotic surgery in Colombia: “Limiting the most minimally invasive and technologically advanced techniques to high-income patients only and providing a low-income population with cheaper more traumatic incisions is a socioeconomic problem that needs to change. Pursuing the most optimal approaches for all patients, regardless of their health coverage ... guarantees a more universal approach to the highest standards and quality of care.”³⁰ To build a robust domestic robotic surgery program, Andrade et al argue that robotic surgeons and surgical centers in HICs must increase their on-the-ground robotics teaching, clinical care, and technological investment in Colombia:

Throughout the years, cardiothoracic surgery in Colombia has grown following American footsteps and techniques. From the country’s first heart transplantation using techniques from Stanford, to lung transplant surgery in Bogotá following Duke surgical approaches, and now robotic cardiac surgery learned from the University of Chicago Medicine ... Colombia owes a great part of its cardiothoracic evolution to North American pioneers and centers. To ensure the continued growth of RACS [robotic-assisted cardiac surgery] in the country, attention needs to be kept first and foremost on the needs of “the patient” and recognize the importance of international/visiting RACS teams.³⁰

To our knowledge, the Colombia pilot program is the only published account of dedicated robotic surgery capacity building in a middle-income country. In analyzing its impact, Andrade et al reinforce the indispensable role of HIC-LMIC collaboration in advancing surgical equity as well as health equity more broadly.

A core public health challenge in resource-limited health care settings is making just trade-offs between the often-competing priorities of societal and individual well-being.¹ One unique aspect of robotic surgery is its potential for longer operating times relative to laparoscopic or open approaches (particularly during the learning curve immediately following adoption of robotics), which can translate to lower case volumes.^{31,32,33} Since robotic cases occupy surgical and anesthesia personnel for longer time spans, they may delay care for patients presenting with acute conditions in the interim. At the societal level, annual caseload is 1 of 6 *Lancet* Commission on Global Surgery indicators of equitable global surgery, and timely surgery is 1 of 3 intervenable targets in the Three Delays Framework.³⁴ Centralizing robotic surgery in large hospital centers with capacity for simultaneous emergency and elective cases is a natural response to this dilemma in HICs. However, in LMICs with poor transportation infrastructure, centralization may effectively exclude poor and rural groups from receiving robotic surgery.

Indeed, the logistical complexities and capital-intensive nature of expanding robotic surgery in LMICs are among the greatest practical obstacles to attaining a surgically ideal world, one in which reliable, sustainable robotics programs are ubiquitous and readily available to the entire global village. Currently, LMICs house over half the world population but only 19% of surgeons.³⁵ Based on global data, robotic surgical volume

grew by 17% annually between 2015 and 2019, with 1.24 million cases performed across all specialties in 2020.^{36,37} However, these gains are highly concentrated in HICs, with 71% of all robotic cases in 2020 occurring in the United States alone.^{36,37} Considering the estimated 1.3 million USD cost of installing a single robotic surgical system³⁸ and the additional 3000 to 5000 USD cost per procedure,^{39,40} a sobering prospect emerges for LMICs. It then comes as little surprise that robotics programs in LMICs remain rare and understudied in the published literature.³⁷

Robotic Telesurgery

Telesurgery, in which a surgeon operates in a location far from the patient via a robotic console and digital image technologies, may offer a unique opportunity to mitigate some practical limitations of expanding robotic surgery in LMICs. A particular advantage of robotic surgery is that the surgeon need not be in physical contact with the patient. In telesurgery, moreover, only a portion of the surgical team and robotic technology must be present in the patient's home country, potentially enabling the global pool of surgeons and robotic consoles to be available to all LMIC patients. Such international resource sharing upholds the principle of *cosmopolitanism* inherent to Singer's ideology, whereby human beings are, in a moral sense, global citizens bound to help all others in need regardless of the geopolitical borders separating them.^{1,20}

Importantly, the technology for long-range telesurgery already exists. The first fully transnational robotic operation was an uncomplicated cholecystectomy on a patient located in Strasbourg, France, in 2001, performed in 54 minutes by remote surgeons in New York City with a safe average time lag of 155 milliseconds.⁴¹ To enable a safe speed of image transmission between the robotic arms in Strasbourg and the robotic console in New York City, the surgical team used an asynchronous transfer mode [ATM] system whose nodes were "interconnected through a high-speed terrestrial fiberoptic network" at a bandwidth of 10 megabits per second.⁴¹ To ensure the technological safety of the operation, network quality control tests were completed in advance and an identical, separate back-up transmission system was created in case of technical difficulty. The robotic system was further bolstered by specific rate parameters for transmitting data on robotic arm motion within the 10 megabits-per-second bandwidth, as well as by intraperitoneal phone and video conferencing systems linked to the network.⁴¹

Although conducted over 2 decades ago, this historic operation sheds light on the technical requirements for safe transatlantic robotic surgery. In the present day, continued unavailability of technical resources in LMICs results from broader logistical and infrastructure development problems. In a 2022 review of robotic surgery uptake in LMICs, Mehta et al state that it "is estimated that a delay of 300 ms [milliseconds] was the maximum delay that is compatible with safe robotic surgery and can become compromised in areas with poor network connectivity. Though 5G internet technology and ATM fibers can reduce the delay, their implementation may take another 3-5 years in low-income countries."³⁷

A formal transnational robotic telesurgery program could be employed as a form of GHD between HICs and LMICs. GHD is a foreign policy strategy, broadly defined as "a multidisciplinary approach that combines public health, foreign affairs, management, law and economics by focusing on negotiations to manage global health policies."⁴² Traditionally, GHD efforts have focused on responding to infectious diseases, armed conflict, and sociopolitical instability. One notable example is Cuba's physician export

program, established in 1960. This initiative has sent Cuban medical personnel to support humanitarian causes, from the Misión Barrio Adentro program in Venezuela to the COVID-19 crisis in Italy.^{43,44} Similar diplomatic efforts to minimize surgical disease in LMICs remain rare, and, to date, none have incorporated the unique characteristics of robotic surgery in their diplomatic and humanitarian strategies.

Broader Adoption

This section introduces 3 complex political and ethical questions about the use of robotic telesurgery as a form of GHD between HICs and LMICs: combatting medical imperialism in patient consent as well as in patient and surgeon autonomy, distributing clinical ownership across a transnational team, and combatting unforeseen inequities created by technological dependency.

Dangers of medical imperialism. First and foremost, large-scale initiatives with HIC surgeons operating on LMIC patients must safeguard against medical imperialism. As stated in a case report of GHD negotiations between a foreign surgical service provider and the government of Botswana, LMIC stakeholders must be inclusively defined and actively prioritized in order to sustainably build capacity and prevent further dominance by HICs.⁴² For instance, GHD efforts may inadvertently stunt development of domestic MIS training programs in LMICs, thereby increasing the dependence of LMICs on HICs for surgical human capital in the long-term. As the autonomy of surgical trainees declines in the United States, global telesurgery may also be seen as an opportunity for trainees to expand their robotic case volume with relatively minimal supervision.⁴⁵ Trainees practicing beyond their scope threaten the joint efforts of HICs and LMICs to establish a just culture of safety and accountability. A relevant historical parallel is Germany's colonial experimentation on East Africans in attempts to cure African sleeping sickness, which created lasting intergenerational trauma and undermined trust in Western medicine.⁴⁶

To avoid further trust erosion and to begin rebuilding solidarity in LMIC-HIC relations, many precedent-setting questions should be negotiated among all participating countries of a global robotic telesurgery program. To best safeguard against medical imperialism, who will obtain patients' informed consent and which country's informed consent practices will be followed? Surgery without adequate informed consent is tantamount to torture; superimposed onto complex LMIC-HIC political relations, it is not difficult to imagine that poorly consented telesurgeries could be considered an act of aggression and quickly lead to diplomatic escalation. From Nazi experimentation on concentration camp prisoners to the deliberate extermination of Indigenous peoples in North America by European colonizers, historical examples of genocide—sometimes under medical guise—abound. Cybersecurity and physical security precautions, patient confidentiality, proper waste disposal, and adequate machine maintenance must be coordinated to ensure that the robotic telesurgery infrastructure in LMICs is not weaponized by other nation-states, gangs, or individual actors who desire to harm patients for personal or political motives.

In the course of providing transnational robotic surgery, surgeons and other stakeholders will inevitably develop new knowledge and best practices. Historically, Western medicine has claimed credit for various Indigenous and Eastern knowledge forms, appropriating cultural expertise to create profitable therapies whose financial gains were never shared with their communities of origin.⁴⁷ How will LMICs be protected from biopiracy on the part of HICs conducting robotic telesurgery on their patients?

Creating equitable intellectual property agreements, drafted and revised collectively with broad stakeholder involvement and enforced fairly, is an initial step. In academic research and patent applications, clear authorship protocols should center the contributions of LMIC surgeons and scientists, and transnational research outputs should be continually analyzed for equitable representation. Robotics partnerships also have potential to stimulate the brain drain of talented, highly educated individuals from LMICs to HICs, so deliberate investment in domestic robotic capacity—from surgeon credentialing to technology manufacturing—ought to be a precondition for transnational telesurgery.

Ownership of transnational clinical teams. By definition, even when robotic surgery is performed remotely, an in-person surgical team is necessary to employ hybrid techniques (as in the case of Colombia, described above), manage intraoperative complications, or convert to open surgery when indicated.³⁰ With 2 surgical teams involved in patient care (one in a remote HIC and another in the patient's home country), the ethical obligations that traditionally belonged to a single surgical entity are now distributed across 2 cross-cultural teams in different countries, and additional responsibilities are introduced. For instance, if a power outage or machine malfunction occurs intraoperatively, who will be held accountable for its effects on patient outcomes? How will medicolegal and malpractice liability be distributed in the event of avoidable and damaging surgical complications?

Clear mechanisms of transnational accountability are difficult to build and enforce, yet they are essential to the delivery of safe and high-quality care. They provide a pathway for patient grievances to be heard, robotic surgery protocols and techniques to be modified in response to adverse events, and appropriate reparations to be implemented when injustices and preventable errors cause harm to patients. Standardized, transparent review processes are equally necessary to allow HIC and LMIC surgical teams to exchange honest feedback about prior errors by minimizing the cultural, linguistic, and power divides between them. Potential solutions include utilizing the international court system, engaging the legal system of a “neutral” third-party country, or conducting focus groups comprising local patients and surgeons to identify the quality-control avenues best suited to the sociocultural and political particularities of each partnership. Since levels of generalized trust in health systems are highly variable across both LMICs and HICs,⁴⁸ transnational surgical initiatives must develop strategies not only to assure LMIC patients of their rights, but also to protect those rights.

Combating unforeseen technological inequities. Lastly, advances in digital imaging and artificial intelligence technologies used in robotic surgery raise many ethical questions relevant to GHD. As robots become increasingly autonomous and develop the ability to “think” independently, they may assume a greater role in nontechnical aspects of surgical care, such as patient selection and counseling, particularly where human surgeons are scarce.^{49,50} As a result, there is potential for unintended harm via biased algorithms and artificial intelligence systems, especially when these tools are developed in HICs without HICs' genuine collaboration with LMICs.^{49,50,51} To date, robotic surgical technology has been almost universally developed in HICs and calibrated on majority-White patient populations, although these populations and their LMIC counterparts have notable sociodemographic, lifestyle, and possibly genetic differences. If HIC technologies that use algorithms trained on White populations inadvertently mischaracterize the anatomy, symptoms, or clinical status of LMIC patients, then the use of these

technologies in LMICs may ultimately exacerbate—rather than eradicate—global surgical disparities.

Importantly, the potential use of biased algorithms in robotic surgery is not limited to the operating room. The logic underlying self-modifying machine learning algorithms is often unknown even by its developers; in other words, the algorithms are a “black box.”⁵² At the same time, these algorithms are capable of risk-stratifying surgical candidates by medical and demographic characteristics to assess the probability of a suboptimal outcome, interpreting imaging studies to inform preoperative planning, or gauging the likelihood that a given set of postoperative symptoms represents a true complication.^{53,54,55} From an ethical perspective, how must we ensure that black-box algorithms do not subordinate patient interests to the interests of other actors in the health system? For instance, an algorithm that overweighs young age and high income as predictors of surgical success might unintentionally exclude elderly patients of lower income levels who would, in a traditional medical practice, be offered surgery. By preferentially selecting the youngest and wealthiest patients, however, this same algorithm may simultaneously allow surgeons to enjoy lower complication rates and higher compensation; here the surgeons would benefit, unknowingly, from data-driven discrimination.

Particularly in resource-constrained areas with few surgeons, machine learning algorithms offer an attractive strategy for streamlining **surgical decision making**, thereby increasing the efficiency and availability of clinical care. However, on a population level, even small imperfections in assistive technologies—which are often masked by the relatively small sample sizes of beta-testing efforts—can harm thousands of patients, with no clear mechanisms of accountability, quality measurement, or medicolegal liability.^{54,55} How much risk of harm should LMICs be willing to undertake in employing foreign, black-box algorithms to guide robotic surgery operations and decision making? How should this risk be weighed against the potential expansion of surgical access and reduction in health disparities enabled by such algorithms? This conundrum demonstrates the tensions between nonmaleficence (eg, avoiding unintended harm from biased algorithms or the subordination of patient interests to external interests) and justice (eg, broadening care access in under-resourced areas) in technologically advanced global surgery endeavors.

Paths to Equity

Robotic telesurgery is an attractive albeit complex option for combatting disparities in surgical access and outcomes between HICs and LMICs, yet it is far from a singular solution. To close the LMIC-HIC gap in robotic surgical care, a portfolio of diverse strategies must be pursued simultaneously, with telesurgery representing only one point along a broad continuum of interventions. As previously stated, we should continue conventional global surgery initiatives in collaboration with local stakeholders by building robotics facilities in LMICs, offering MIS fellowships and simulation-based training to LMIC surgeons and residents, and growing health care capacity more broadly (from ensuring reliable, environmentally sustainable power supplies in hospitals to training and hiring ancillary staff).

An international robotic surgical corps of skilled surgeons that assists LMICs in stewarding robotic technology, disseminating robotic surgical expertise, and managing clinical operations constitutes an alternative form of GHD with the potential to incite long-term, sustainable change. Exchange programs in which surgical trainees from

LMICs obtain hands-on clinical training at robotics-intensive HIC hospitals facilitate ethical knowledge sharing in robotics and have a sustained positive impact. Meanwhile, humanitarian organizations and governments should arrange for ill patients in resource-constrained LMICs to travel to HICs for surgery, a model refined by NGO-government partnerships, including Haiti Cardiac Alliance.⁵⁶ On a broader level, a stronger incorporation of technological targets in the diplomatic agreements and health equity objectives set by the United Nations and the World Health Organization will be necessary. Only in concert with these and similar initiatives might transnational robotic telesurgery meaningfully reduce surgical health inequities in LMICs and uphold the ethical principles of the medical profession.

Conclusion

There are strong ethical justifications for reducing inequities in robotic surgical care between LMICs and HICs, which currently contribute to an unjust distribution of global morbidity and mortality. Robotic telesurgery is a novel and uniquely promising medium for GHD efforts aimed at surgical disease reduction in LMICs. However, its use compels the global surgical community to address uncharted legal, ethical, and political issues. This article has raised several such considerations within a global health framework and argued for the expansion of robotic surgical capacity in LMICs.

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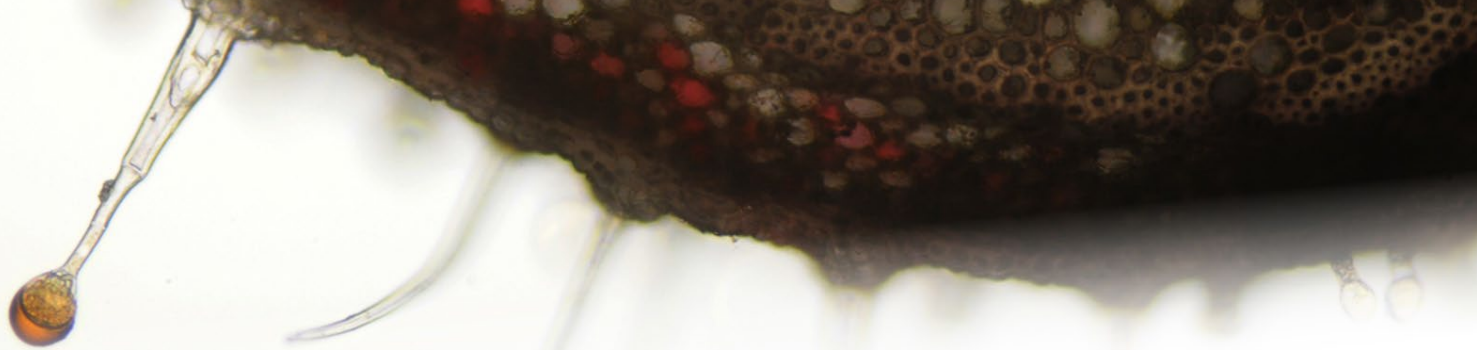
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HISTORY OF MEDICINE: PEER-REVIEWED ARTICLE

What Pediatric Robotic Surgery Since 2000 Suggests About Ethics, Limits, and Innovation

Tenny R. Zhang, MD, Elijah Castle, and Lee C. Zhao, MD, MS

Abstract

Since the US Food and Drug Administration first approved robotic surgery for clinical use in 2000, it has gained widespread adoption across multiple surgical domains. While pediatric surgery has had a relatively slower adoption rate, robotic surgery has nonetheless grown in this context. This work traces the historical and regulatory aspects of pediatric robotic surgery, showing how it incorporated an existing robotic surgical system developed for adults; situates the technology within ethical frameworks for analyzing surgical innovation; and advocates for combined surgeon self-regulation and institutional oversight. Finally, the argument is made that there are key unmet technological needs pertaining to instrument size and adaptability secondary to pediatric robotic surgery's smaller market share and that clinicians and producers of robotic surgical systems should work to address these needs.

Pediatric Robotic Surgery

Robotic surgery facilitates improved visualization, increased degrees of freedom, and enhanced ergonomics.¹ Since its approval in the United States for clinical use in 2000, robotic surgery has grown rapidly in multiple specialties.^{2,3} Compared to adult robotic surgery, pediatric surgery—defined as surgery in patients from birth to 17 years—was slower to adopt the technology, but it has nonetheless expanded substantially in the last decade.^{4,5,6,7} In this work, we trace the historical and regulatory beginnings of pediatric robotic surgery and situate it within ethical frameworks for surgical innovation. We argue that there are key unmet needs pertaining to instrument specificity secondary to pediatric robotic surgery's smaller market share and that stakeholders should work to address these needs.

State of the Field

The US Food and Drug Administration (FDA) approved Intuitive Surgical's da Vinci as the first robotic surgical system for adult laparoscopic surgery in 2000.⁸ After clearance for use in prostatectomy in 2001, da Vinci gained rapid adoption among urologists and became the dominant surgical system.^{2,3,9} Soon, new surgical specialties began to incorporate da Vinci without explicit FDA approval for novel use. For example, pediatric robotic pyeloplasty was first reported in 2002.⁶ Although other robotic surgical devices

have also been approved, da Vinci has maintained a monopoly in the industry due to high barriers of entry and patents,¹⁰ and therefore we focus our discussion on it here.

In 2005, Intuitive applied for FDA expansion of da Vinci to include pediatric surgery. Using 510(k) premarket notification—a pathway that enables faster market entry by demonstrating that a device is substantially equivalent to an existing legally marketed device²—the company stated that there were no changes in the design, performance, or method of use.¹¹ In a risk assessment and review of the literature, Intuitive found “equivalency” and no new issues of safety or effectiveness in pediatric robotic surgery.¹¹ Meanwhile, pediatric and adult surgeons alike seeking to innovate their practices and advance patient care continued to expand the reach of robotic surgery.

Reviews of the first 2 decades of pediatric robotic surgery reveal a consistent trend in increasing volume of cases and publications, albeit at a slower pace.^{6,12} Studies have shown improvements in postoperative outcomes,¹² parity in surgical definitions of “success,”⁷ and relatively quick learning curves.¹³ However, pediatric patients represent a small minority of robotic surgical cases.⁵ Given what we know about the high costs of robotic surgery from the adult literature,^{14,15} it is difficult to estimate cost effectiveness for pediatric robotic surgery, as utilization rates are much lower. Ultimately, more prospective studies and cost analyses are needed to better assess the true utility and value of pediatric robotic surgery.

Ethics of Surgical Innovation

The field of surgery has evolved through centuries of technical advances and requires innovation in the long-term and day-to-day.^{16,17} Surgeons may need to modify accepted techniques based on anatomy or disease. Surgical devices developed for one indication may be transferred to new contexts. Where is the line between practice variation and a novel approach? And, in the absence of formal regulations, what is the best way to ensure **responsible innovation**?

Previous work on the ethics of surgical innovation has attempted to answer these questions, although no true consensus has been established.¹⁸ Often, it may be easier to define something by distinguishing it from what it is not. In 2008, the Society of University Surgeons published a position statement situating surgical innovation between *variation* (minor modifications not requiring disclosure) and *research* (systematic investigations to develop generalizable knowledge).¹⁶ The statement recommended that surgical innovation that differs from accepted practice and has unknown outcomes be reviewed by an internal surgical innovation committee and require additional informed consent.¹⁶ Early pediatric robotic surgery certainly met the criteria for innovation requiring oversight. Future developments in fetal robotic surgery¹⁹ would also fall under these terms, at minimum. However, given existing general acceptance of pediatric robotic surgery, current advances in this area seem to fall somewhere between surgical variation and innovation.

An alternative framework from the pediatric literature fittingly imagines a continuum of surgical innovations that can be classified as *practice variation*, *transition zone*, or *experimental research*,¹⁷ recognizing that the lines between these categories may not always be so sharp. For this reason, guidance has been proposed for new innovations in pediatric robotic surgery that fall into the transition zone: the ETHICAL model of self-regulation stands for ensuring Expertise and Technical skills, assessing Hazards and obtaining full Informed consent, disclosing Conflicts of interest, and publishing Analyses

of outcomes in the literature.¹⁷ This model offers the surgeon a principle-based approach to innovation. For example, considering hazards is a means of ensuring nonmaleficence, and true informed consent respects patient autonomy—or, in the case of children, their assent and the decision-making capacity of their guardians. While up-front committee review would have been more appropriate at the outset of pediatric robotic surgery, at its current stage, a formalized means of self-regulation grounded in ethical principles—such as the ETHICAL model—with some degree of institutional oversight may strike the correct balance. From our standpoint, the **surgeon-patient-guardian relationship** is paramount. Ultimately, it is the surgeon's duty to facilitate shared decision making regarding new technologies in the best interest of patients rather than to make decisions on the basis of hospital or industry pressures.²⁰ Specific actions to ensure ethical practice include an informed consent process in which the surgeon reports experience in robotic surgery, shares known outcomes, and discusses innovative aspects of the procedure.^{16,21}

In addition to surgeons and surgical professional societies, potential levels of oversight include government and regulatory agencies, institutional review boards (IRBs), surgical innovation committees, and peer groups.²² From an institutional perspective, formal means of disclosing conflicts of interest, reporting outcomes, and ensuring adequate training and assessment should be provided.^{18,22,23} In our view, whether these actions are taken in the context of a surgical innovation committee or within existing regulatory frameworks should be decided on an institution-by-institution basis, given the wide range of pediatric surgical practice settings and lack of consensus guidelines. Recognizing this heterogeneity, the American Academy of Pediatrics statement on responsible surgical innovation also calls for ongoing oversight after implementation of an innovation.²¹

Because the FDA only reviews evidence of safety and efficacy for high-risk devices and IRBs only cover research activity, there is a vacuum in oversight of innovations adapted for use in pediatric surgery. Economic forces strongly discourage surgical device development for the substantially smaller pediatric surgical market.²¹ Many surgical devices approved for adults—including da Vinci at the start—are therefore utilized off-label in surgery on children at the discretion of the clinician. Positioning pediatric robotic surgery on a continuum of surgical innovation would enable us to circumvent nonuniform definitions and include it in the transition zone of innovations that should be subject to surgeon and institutional oversight. Applying a formalized ethical framework to guide decision making about innovations in the transition zone—while acknowledging variability in practice type and oversight mechanisms—would help facilitate responsible surgical innovation.

Technical Limitations and Looking Ahead

Robotic surgery is conceptually ideal for children, as smaller body size may limit surgical access via traditional techniques. Ironically, a key consequence of pediatric robotic surgery having to adopt an existing surgical system designed for adults is the lack of patient-specific instruments for small children.⁵ For reference, an average adult pneumoperitoneum provides 5 liters to 6 liters of working space, whereas a 1-year old provides 1 liter of intra-abdominal space.²⁴ Studies have shown limitations of robotic instrument movement based on both absolute volume²⁵ and anatomical measurements, such as anterior superior iliac spine distance.²⁴ Experienced pediatric surgeons have developed “tricks” to maximize working space via trocar placement and other

maneuvers,²⁶ yet it remains a question how much more facile pediatric robotic surgery could be with specific tools for small children.

Additionally, while Intuitive has introduced multiple platform updates over the years—including Si in 2009, Xi in 2014, and single-port in 2018^{27,28}—these changes have not substantially improved pediatric surgery and in some ways may have hindered it. For example, the newer Xi model does not offer adaptability for many 5-millimeter instruments, nor is incorporation planned^{29,30}; the older Si platform has smaller 5-millimeter ports, but tools such as surgical shears are incompatible with it⁷; and the previously available smaller 5-millimeter endoscope was discontinued due to low use.³¹

The consequences for pediatric robotic surgery of a small pediatric surgical market cannot be overstated. Pediatric surgeons aiming to do good by adopting da Vinci were met with a lack of clear oversight mechanisms, and limited market demand has impeded development of instruments specifically for small children. As a matter of justice and fairness for children, we believe all patients deserve the *maximal* potential benefits of robotic surgery, regardless of their size—though making these benefits available will require overcoming barriers to innovation. The decades-long monopoly held by Intuitive—especially as da Vinci is the only system approved for children—significantly limits innovation in this space.^{5,10,32} We strongly urge the robotic surgical industry to introduce competitor models and specific instruments to support pediatric surgery. Finally, we propose a call to action for pediatric surgeons and their professional societies to lobby and collaborate with device manufacturers to achieve this goal.

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ART OF MEDICINE

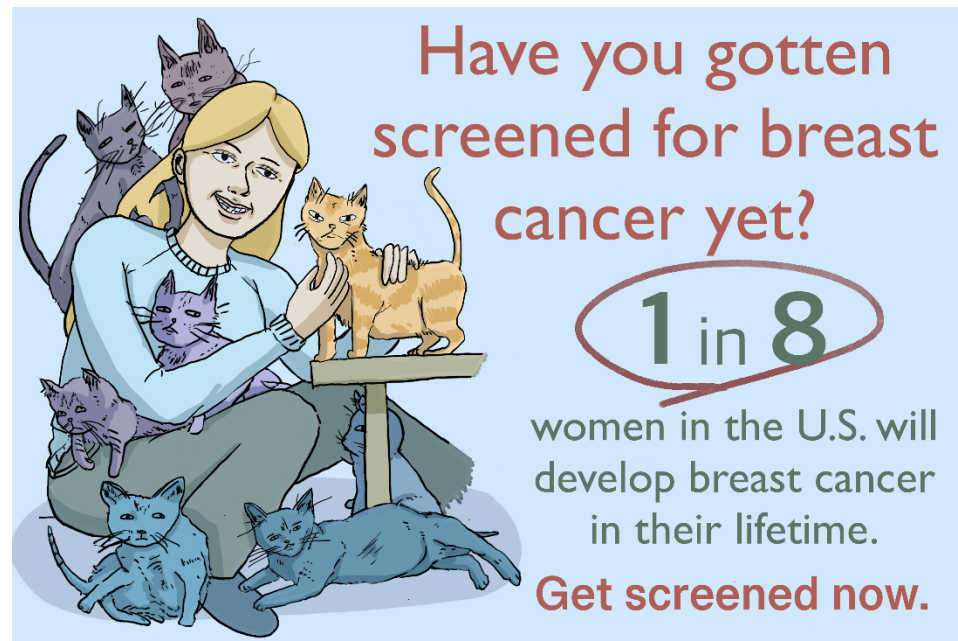
Horror PSA

Kelly Wang

Abstract

Public health messaging commonly happens with public service announcements (PSAs). Health screenings are often marketed using various incentives, such as odds presentation. This comic invites readers to consider aesthetic and ethical intersections of how odds might be presented—even exaggerated—to cultivate fear. When accompanied by implicit or explicit attribution of individual responsibility for one's health risks or outcomes, PSAs or other health communications are not ethically neutral.

Figure. *Fright Escalation*





Media
Procreate®.

Caption

Drawing on cover art from many so-called pulp magazine covers, the comic traces an evolution in the woman's expression and invites readers to consider whether growth in her fear experience is due to her cancer risk or to how her cancer risk is represented to her by health care. Recent concern about gaslighting¹ in health care suggests the importance of how risk is represented in health messaging, whether coming from a

clinician or from a public service announcement. Ethically, we might wonder about the appropriateness of fear-based screening incentives. Whether and to what extent anyone should ever be regarded as clinically or ethically culpable for an illness is also worth interrogating.

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Kelly Wang is a cartoonist, printmaker, and musician based in Chicago, Illinois.

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ART OF MEDICINE

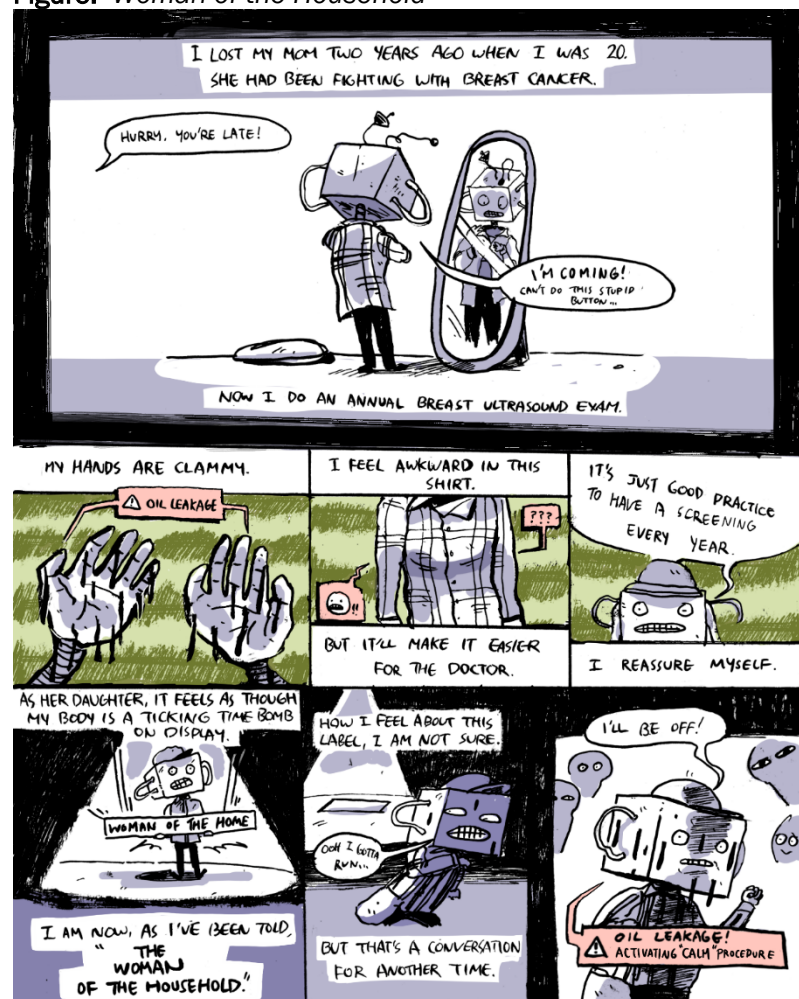
Robot Comic

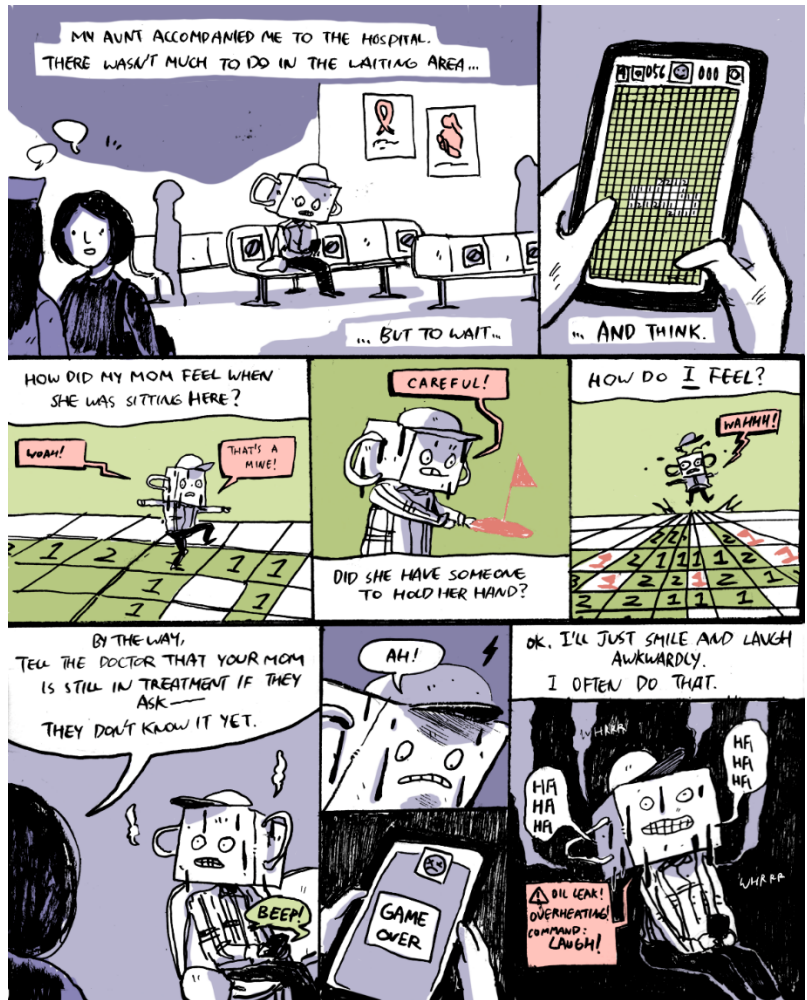
Kelly Wang

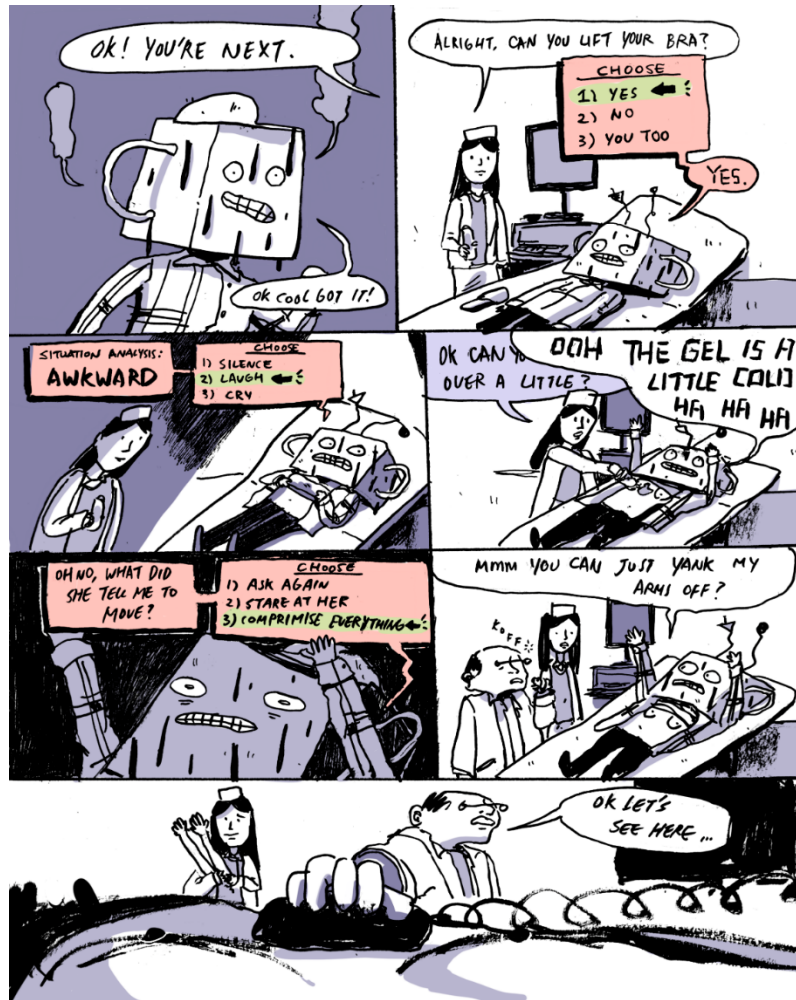
Abstract

This multipaneled comic follows a woman robot preparing for a breast examination. Oil “leakage” recurs in the comic, suggesting its ethical importance in metaphorically representing a patient’s stress responses.

Figure. *Woman of the Household*









Media
Procreate®.

Caption

In the comic, oil leakage from the robot woman is like sweat from a nervous patient. Feelings of anxiety, awkwardness, and grief can be considered in addition to stress from familial and gender expectations stemming from being labeled “woman of the household” upon losing one’s own mother to breast cancer.

Kelly Wang is a cartoonist, printmaker, and musician based in Chicago, Illinois.

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