



AMA Journal of Ethics®

August 2023, Volume 25, Number 8: E637-642

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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Tenny R. Zhang, MD is a fifth-year urology resident at New York-Presbyterian/Weill Cornell Medical Center in New York City. She previously worked as a research associate at the Presidential Commission for the Study of Bioethical Issues. She is interested in pediatric urology and plans to continue research in bioethics.

Elijah Castle is an associate research coordinator in the Gender-Affirming Surgery Program at NYU Langone Health in New York City, where he is also the co-chair of the LGBTQ+ Advisory Council. He is pursuing a master's degree in bioethics at the NYU School of Global Public Health.

Lee C. Zhao, MD, MS is a reconstructive urologist and associate professor of urology and plastic surgery at NYU Langone Health in New York City.

Citation

AMA J Ethics. 2023;25(8):E637-642.

DOI

10.1001/amajethics.2023.637.

Conflict of Interest Disclosure

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

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