Studying Liability Policies of Robotic Surgical Systems to Ensure Accountability Among Hospitals and Device Manufacturers

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On my honor as a University Student, I have neither given nor received unauthorized aid on this assignment as defined by the Honor Guidelines for Thesis-Related Assignments

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Introduction

Robotic surgery, a once unimaginable tool, has surged in use as new technological innovations are coming to light in the healthcare field. A study published in 2023 showed an increase in robotic surgery use from 1.8% to 15.1% between the years of 2012 to 2018 (McCartney, 2023). This increase in use reflects the numerous advantages that robotic surgery serves in medical practices from enhanced precision to more efficient procedures. For example, some robotic surgical procedures often result in less discomfort and faster recovery periods in patients compared to conventional surgical practices (McCartney, 2023). This is due to the enhanced precision that is often paired with the implementation of robotic-assisted surgical device in conventional procedures. The main purpose of robotic surgery is to help facilitate surgery through mimicking movement of the surgeon's hands as it is remote controlled by the surgeon. While this concept holds immense promise, device malfunction or failure are inherent risks associated with the device. These malfunctions can lead to potential complications during surgery, raising concerns about patient safety and surgery efficacy.

One primary example of a widely known robotic surgical device is the Da Vinci Robotic Assisted Surgery Device, a technical intervention created to aid surgeons in conducting surgeries. The surgeon controls the arms, and the device replicates the movements, mimicking the surgeon's hands. This, in turn, increases precision and control. This device is also known to have certain safety features, such as a binocular-like device for the surgeon to see incisions, a LED screen to display every action, and a speaker system for effective communication (Bramhe & Pathak, 2022). These safety features ensure that the system operates properly, minimizing risk of failure and overall safeguarding both the patient and the surgeon. While this system is equipped for safe procedures and enhanced precision, there are inherent risks associated with

robotic-assisted surgical devices. Legal trials involving complications with this device necessitate a closer examination of liability policies regarding robotic surgery.

The legal processes surrounding liability in cases of robotic surgery malfunction are rife with ambiguity. Unlike conventional surgical practices where responsibility falls primarily on the physician in charge, robotic surgery introduces new variables including the device itself and the manufacturers. The lack of clear legal guidelines regarding robotic surgery malfunctions presents a significant barrier to technological innovations. The potential consequences of device failures could discourage surgeons from adopting beneficial technology, thus hindering growth in innovation. Moreover, if manufacturers are shielded from accountability by legal processes, there is less incentive to invest in rigorous safety tasting. Overall, the ambiguity in the legal landscape surrounding robotic surgery malfunctions poses a threat to patient safety and hinders innovation that could revolutionize the healthcare field.

In this paper I argue that currently, liability frameworks for robotic surgical devices distribute accountability among hospitals and device manufacturers, but the lack of understanding amongst legal professionals can lead to challenges in determining who is at fault in cases of device malfunction. In my literature review section, I present the medical and legal considerations involved with robotic surgery failures. Moreover, I delve into perception of the technology and research on complication rates. I also address the sociotechnical framework I will be utilizing in my analysis and how I will be analyzing the politics of liability policies using Langdon Winner's politics of artifacts framework. I gather data from secondary sources such as journals, academic research, as well as legal texts related to trials involving robotic surgery. In my analysis I investigate the legal challenges surrounding robotic surgery malfunctions and the impact of unclear legal frameworks on patient safety and innovation.

Literature Review

Over time, robotic surgery has increasingly become perceived as a standard of care that offers a safer and more precise alternative to conventional surgical practices. Among the various robotic surgery devices, studies have shown that the robotic-assisted laparoscopic radical prostatectomy (RALP) has been found to have low rates of medical complication compared to traditional surgery (Pessoa et al., 2021). Moreover, patients undergoing procedures using robotic surgery, specifically colectomies, have experienced shorter hospital stays and overall lower rates of complications after surgery (Farah et al., 2023). This indicates that contrary to common perception, robotic surgery offers a safer and more efficient alternative to traditional surgical procedures. Furthermore, hospitals with robotic surgery program have seen a quick or wide increase in robotic surgery use indicative of the shift from conventional surgical methodologies (Sheetz et al., 2020). This increased use of robotic surgical instruments points to wider acceptance and confidence in the adoption of technological innovations in the healthcare field.

While robotic surgery has made significant advancements in the medical field, there are numerous medical and legal considerations involved to protect patient safety. The safety of patients while robotic surgery is used to perform medical procedures relies on skill and standardized training of the surgeon (Pai et al., 2023). The implementation of comprehensive training programs is essential for surgeons using robotic technology to mitigate risks and protect patient safety during surgical procedures. Alongside surgeon's proficiency, the process of informed consent is crucial to building trust and transparency between the surgeon and the patient (Pai et al., 2023). This includes communication between the surgeon and the patient on a detailed explanation of the procedure using robotic surgery and the potential risks or complications involved.

Apart from this there are two legal terms to consider with the use of robotic surgery: medical malpractice and product liability. Medical malpractice involves accountability of the physician for any negligence occurring during surgery. To determine medical malpractice, "[t]he injured patient must show that the physician acted negligently in rendering care, and that such negligence resulted in injury. To do so, four legal elements must be proven: (1) a professional duty owed to the patient; (2) breach of such duty; (3) injury caused by the breach; and (4) resulting damages" (Bal, 2008). On the other hand, product liability holds manufacturers of medical devices accountable for device failures or complications. To avoid product liability lawsuits, manufacturers of medical devices argue that if adequate information such as warning about risks are delivered to the treating physician, subsequent actions result in the physician being fully accountable for medical complications or device failures (Husgen, 2014). While medical malpractice focuses on physician's conduct and decisions during surgery, product liability addresses the safety and efficacy of the medical devices, highlighting the relationship between technology and medical practice in ensuring patient safety.

While robotic surgery has made great advancements in the field of medicine, there are inherent risks that have caused skepticism and resulted in legal trials involving failures and complications during medical procedures. Contrary to these concerns regarding potential complications, studies have suggested that robotic surgery has overall low failure rates. One study found through analyzing mechanical failures and malfunctions of the da Vinci Surgical System that there were only 2.4% of cases that had a complication occur leading to the conclusion that mechanical failure in robotic surgery is rare (Kim et al., 2009). Moreover, among these complications, the most common malfunction in the Da Vinci System was that output or power limit was exceeded in the robotic arm due to arm collision which is a recoverable error

(Rajih et al., 2017). Despite low failure rates highlighted in studies on robotic surgery, legal challenges emphasize the need for proper surgeon training. In a slip opinion filed by the court regarding a lawsuit against Intuitive Surgical they state that doctors must be credentialed, and that hospitals must clear surgeons to use the Da Vinci System and the hospital must have warnings about risks provided by the manufacturer (Carlson, 2017). Robotic technology has enhanced surgical precision and outcomes; however, recognizing the potential risks is essential to ensuring patient safety and physician accountability.

The framework that I will be using to address the issue of accountability among hospitals and device manufacturers with regards to robotic surgical systems is Langdon Winner's politics of artifacts framework. This framework centers around the concept that "[i]n controversies about technology and society, there is no idea more provocative than the notion that technical things have political qualities" (Winner, 1980, p. 121). There are two main ideas that this framework promotes: (1) Artifacts promote or favor a particular political order or value; (2) Artifacts are inherently political or are strongly compatible with a particular political arrangement. Through the lens of this framework, I analyze the political properties of robotic surgery and whether the current liability frameworks in place promote or favor specific policies or values.

Methods

To address my research question, I researched liability policies for hospitals and device manufacturers through secondary sources such as scholarly journals. Additionally, I researched legal texts such as slip opinions as well as articles related to trials on robotic surgery complications and failures. The specific liability policies that I focused on in my research are product liability for medical device manufacturers specifically for robotic surgical systems and medical malpractice for hospitals and physicians. The specific medical device manufacturing

company that I focused on in my analysis is Intuitive Surgical, Inc., the company that developed the Da Vinci Robotic Surgical System. I also utilized a legal trial involving a robotic surgery device mechanical failure in my research; this was the *Taylor v. Intuitive Surgical, Inc.* lawsuit. The parties involved in this lawsuit were the plaintiff, Josette Taylor on behalf of Fred E. Taylor and the defendant, medical device company Intuitive Surgical. I also reviewed Harrison Medical Center's, the private hospital where Fred Taylor's surgery using the Da Vinci Surgical System occurred, response to the lawsuit. In my review of this literature, I examine journals and legal texts to analyze robotic surgery liability frameworks with a focus on understanding what policies or values are favored by the frameworks through the lens of Langdon Winner's politics of artifacts framework.

Analysis

The complexity behind product liability framework presents significant challenges in pinpointing responsibility and determining when medical device manufacturers should be held accountable for device failure. The concept of product liability demands clear evidence that the unsafe product is the direct cause of the harm experienced. The pressure to compensate individuals encourages judicial decisions to link harm and the product (Foote, 1988). This requirement highlights the challenges within legal processes of holding medical device manufacturers accountable. Moreover, it emphasizes the difficulty in proving that a product's lack of safety directly resulted in harm, especially in complex cases where causality between device failure and patient harm is not straightforward. In addition to the challenge of establishing causation, a gap in accountability exists due to the potential for device manufacturers to deflect responsibility onto the physician. A settled law in many states known as the learned intermediary doctrine limits device manufacturer's responsibility to warn treating physicians of product risks,

who then act as “learned intermediaries” and must assume the duty of communicating potential product warnings to the patients (Husgen, 2014). The law of learned intermediary doctrine creates a situation where device manufacturers can deflect blame onto physicians, raising concerns about accountability. This emphasizes the need for physicians to understand product liability and how to be informed to protect themselves and patients. This investigation reveals not only the stringent requirements for establishing correlation between the device and harm, but also the complex balance between protecting public safety and the shifting of accountability among parties within the healthcare system.

Winner’s politics of artifacts framework suggests that liability policies are inherently political, promoting and favoring certain social values and groups. One study proposes that the core purpose of federal safety regulations is to deter activities that pose unacceptable risks to the general public (Breyer, 1982; Lowrance, 1976, as cited in Foote, 1988). The author elaborates by citing Medical Device Amendments of 1976 as prime example of social regulation (Foote, 1988). This focus on protecting the public aligns with Winner’s arguments that artifacts, such as liability policies embody and protect specific social values. In this instance, medical device regulations are an embodiment of societal commitment to public safety; a value, liability policies are designed to protect and promote.

The blurring distinction between physician error and technological failure in medical malpractice cases challenge the effectiveness and clarity of current medical liability policies. To prove medical malpractice, “[t]he injured patient must show that the physician acted negligently in rendering care, and that such negligence resulted in injury” (Bal, 2008). The current requirement for patients to demonstrate a physician’s negligence and harm’s direct causation is a challenging task, creating a significant obstacle in holding hospitals and doctors liable for

technological failures. Understanding how medical malpractice is determined is necessary for ensuring safe procedures using robotic surgical systems. Moreover, ambiguity within legal framework governing medical malpractice poses significant challenges to fostering innovation in the healthcare sector. Evidence argues that there is "potential for far-reaching effects on physicians (and other care providers) in their willingness to adopt new technologies, given ill-defining but perceived malpractice liability risks associated with doing so" (Greenberg, 2009, p. 425). This emphasizes the need for clearer understanding of liability frameworks to increase physician's willingness to adopt new technology. Amidst the adoption of more complex medical devices into clinical practice, physicians face significant risks and uncertainties paired with the ambiguity of potential legal ramifications. The greater the risk that a medical device has, the greater the ambiguity making it more difficult for physicians to know how the malpractice standard of care applies and through this the potential for malpractice liability becomes greater (Greenberg, 2009, p. 431-432). This suggests that the more risk a medical device poses, the more necessary it is to have greater transparency on liability policies. Robotic surgical systems especially carry great risk for medical complications; therefore, it is essential for hospitals and physicians to be able to properly use the technology to avoid being held liable for any device failures.

Lawsuits surrounding the Da Vinci Surgical Robotic System highlight the need for clarity surrounding accountability among device manufacturers and hospitals to ensure patient safety. One particular lawsuit that highlights this argument is the Taylor v. Intuitive Surgical, Inc. trials. In a slip opinion, it states that, "[t]he manufacturer argues that since it warned the physician who performed the surgery, it had no duty to warn any other party. We disagree because the doctor is often not the product purchaser" (Carlson, 2017, p-2-3). This lack

of clarity surrounding accountability resulted in the author of the slip opinion demanding a retrial as the court failed to inform the jury that the manufacturer did not warn the hospital. More evidence on this case sheds light on contrasting opinions in assigning fault during this trial. One author argues that the death occurred due to lack of warning regarding risks of the robotic surgical device and negligence of the surgeon (Kreisman, 2017). This underscores the need for clearer understanding of accountability relating to medical device complications by exemplifying the differing views of the Supreme Court and the plaintiff's lawyers on who is at fault. In the wake of this legal dispute, Harrison Medical Center has taken a stance on its practices, particularly emphasizing the importance of comprehensive training for physicians operating complex medical equipment. The hospital stated that Taylor's situation is the only robotic surgery case that has had complications, but that they will look carefully at Intuitive's training program in the future (Ostrom, 2013). The hospital's commitment to a thorough review and improvement of training for physicians recognizes the necessity in better preparation in handling advanced surgical technologies. This also acknowledges the hospital's role in ensuring that patient safety is protected by adhering to stringent operational standards and physician training.

Establishing a clear liability framework can also create potential legal repercussions, which could inadvertently impede technological advancements in robotic surgery. One paper "analyzes the logic suggesting that the legal ambiguities in the malpractice standard of care might lead to systematic disincentives for physicians (or hospitals) in adopting new medical technologies, at least under some circumstances" (Greenberg, 2009, p. 425). This evidence underscores the need for clarity in malpractice standard of care to incentivize physicians and hospitals to adopt innovative technology. Moreover, research has shown that "[d]espite the immense technological advances in robotic surgery, there is still an overwhelming lack of clarity

on the surgeon's legal responsibility for surgical robot malfunctions" (Pai et al., 2023). This suggests that surgeons are less likely to train or adopt new surgical innovations into their practice over concerns of legal responsibility. Through improving transparency in liability framework this can ensure proper accountability and overall ease hesitation over implementing new robotic surgical systems. Medical devices and robotic surgical systems have made immense contributions to the healthcare field. However, "it is a business that frightens many [and t]his fear is largely a consequence of the possibility of liability exposure in the event of device malfunction or failure" (Citron, 1994, p. 58). The fear of legal consequences acts as a significant barrier to innovations in medical devices. As technology continues to grow rapidly, the establishment of comprehensive liability frameworks becomes imperative. Clarity in policies not only ensures accountability, but also facilitates an environment for technological progress through reassuring manufacturers and physicians that while risks cannot be eliminated, there is a structured approach to managing and mitigating these risks. This in turn can lead to greater innovation and adoption of new medical technologies such as robotic surgical systems which have proven to be beneficial and effective.

Conclusion

Robotic surgery has emerged as a powerful tool in the healthcare field, offering enhanced precisions and efficiency. However, as with any innovative technology the adoption of robotic surgery into traditional surgical practice has been met with challenges. This analysis revealed the difficulty in balancing the potential benefits of robotic surgery with ambiguity surrounding liability in cases of malfunction. The greatest consequence of unclear legal frameworks is the potential threat to patient safety. The lack of clarity between physician error and technological failure demands a need for understanding and reassessment of legal standards for ensuring

patient safety. Without proper training or safety testing, patients are more exposed to potential risks. From this paper, healthcare professionals and medical device manufacturers can gain a better understanding of liability policies in cases of malfunction to better protect and promote patient safety through fostering a culture of transparency and promoting training for surgeons regarding robotic surgery technology.

Reassessment of legal standards is essential to fostering continuous technological advancements in healthcare. By mitigating uncertainty, clearer legal frameworks can encourage physicians to adopt more precise and beneficial technology, such as robotic-assisted surgery. This, in turn, can lead to improved patient outcomes and precise and efficient procedures. Overall, improve current legal frameworks and fostering innovation is crucial to ensuring that the healthcare industry continues to evolve and uphold patient safety.

One limitation to my analysis is that the majority of the research focused on two liability frameworks: product liability and medical malpractice. Apart from this there are many other liability frameworks that are relevant to understanding accountability among physicians and device manufacturers. Additionally, my paper focused on specifically the Da Vinci Robotic Surgical System and there are a variety of other robotic-assisted surgical devices aimed at different medical procedures and pose various levels of risks. Despite these limitations, this research can aid in policymakers and physicians better understanding legal processes and upholding patient safety during medical procedures.

As I have argued in this paper, understanding of liability frameworks for robotic surgical devices is necessary for distributing accountability among physicians and device manufacturers in cases of device malfunction. Robotic surgery presents a beneficial opportunity for the future of the medical field. However, challenges posed by unclear legal processes are necessary for

advancements. By establishing a framework that prioritizes patient safety and fosters responsible innovation, we can ensure that robotic surgery continue to revolutionize surgical care for patients worldwide. Despite risks involved, robotic surgical systems offer a variety of patient benefits and overall promote an opportunity for significant technology advancements to be made to surgical practices.

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