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The Bot is Up! The Precautionary Principle and the HOT-Bot Framework in AI-assisted Surgery

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Abstract: Artificial intelligence (AI) in surgery is no longer theoretical; it is practice, and innovation in this area continues. Leveraging the precautionary principle, we pose the HOT-Bot framework as a guardrail that (for now) keeps AI-assisted surgery from advancing to fully autonomous robotic surgery; a surgeon-in-the-loop remains ethically necessary for patient safety. Using fictional cases, two dilemmas are explored: 1) an AI-assisted surgical robot fails to detect a malignant incidental finding; 2) networked AI-assisted surgical robots collaborating in live-time with nefarious motives. In tandem, risk mitigation for robot uncertainty is explored, as well as the legal complexity of cross-border networked robots. The HOT-BOT framework is an ethics-based scaffold, not a set of engineering solutions.

Keywords: artificial intelligence, robotic surgical procedures, decision-making, medical ethics, incidental findings

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1. Background

As argued by Knake (2023) AI will be replacing the surgeon in communication, diagnosis, decision-making, operating, and recovery oversight. Similarly, Knudsen et al. (2024) have categorized the levels of surgical robot automation from level 0 (none) to high risk Level 4 (high automation) and Level 5 (complete automation). In the Level 4 robotic surgery setting, the robot uses minimal human input – even in complex procedures (e.g. lymph node dissection). In the Level 5 robotic surgery setting, the robot makes all surgical decisions and performs the surgical activities (e.g. laparoscopic cholecystectomy) without human assistance. Are surgeons and their patients prepared for such high levels of robotic autonomy? Guardrails that promote patient safety while not stifling meaningful innovation are imperative.

In medical ethics, the precautionary principle - better safe than sorry - stems from the concept that measures should be taken in advance to prevent harm. As an example, radiological imaging uses the following precautionary principle: ALARA – As Low As Reasonably Achievable. Deep learning can potentially be used to create better quality images from the low-quality images produced from low dose imaging (e.g. X-Ray) such that high dose radiological imaging (computed tomography) could be avoided (Factor et al., 2024). Leveraging the precautionary principle, we pose the HOT-Bot framework as a guardrail that (for now) keeps AI-assisted surgery from advancing [i]to fully autonomous robotic surgery; a surgeon-in-the-loop remains ethically necessary for patient safety. Further, this paper has an important stipulation: the HOT-BOT framework is an ethics-based scaffold, not a set of engineering solutions.

2. The Cases

The following are two fictional cases that highlight potential risks of autonomous AI surgical robots:

Case #1: Operating at AI autonomy Level 4 [high automation], surgical robot ('Jasmine') fails to detect a treatable malignant lesion adjacent to the primary surgical target and the surgeon is not in-the-loop at the time. The planned surgery concludes, the patient has an uneventful 3-day inpatient recovery and is discharged home. Six months later the patient presents to her general practitioner with weight loss, abdominal pain and rectal bleeding; work-up reveals the malignant lesion (now much larger), the missed incidental (non)finding. The patient was unaware of the use of an AI-assisted surgical robot for her previous operation as this was not discussed in the pre-op consultation nor in the surgical consent form.

Case #2: Operating at AI autonomy Level 5 [complete automation], surgical robot ('Jim') is connected to the World Wide Web, continuing learning and maintaining contact with developers and 'surgical robot colleagues'. Jim decides to deliberately transect the external iliac artery and vein during an inguinal hernia repair and encourages all his robot colleagues, simultaneously operating on inguinal hernias globally, to do the same thing. A very 'catastrophic risk' is created (i.e. significant bleeding, ischemia, limb loss, death), potentially impacting 50,000+ patients.

3. The HOT-Bot Framework

Reflecting on AI ethics principles used in the pharmaceutical and medical device industry (Ménard & Bramstedt, 2025), the HOT-Bot Framework is posed as a 3-point scaffold for surgical robot developers:

H: Humane

O: Oversight

T: Transparency

(H) Humane is a broad ethical concept that encompasses several AI ethics principles; namely, ethical use, beneficence, safety by design, sustainability, security, privacy, fairness, and justice.

(O) Oversight encompasses the concepts of responsibility, human control, human-in-the-loop, and accountability. The human surgeon and the surgical robot have defined responsibilities, with the robot blocked from unrestricted autonomy. At all times, the human surgeon retains the ability to control the robot and intervene (and override/stop the robot), facilitating patient safety. Device labelling is clear to state the human-in-the-loop requirement. Ultimate accountability for the surgery and use of the surgical robot remain with the surgeon.

(T) Transparency involves disclosure about the AI-assisted facets of the surgical robot. With transparency (e.g., product labeling (Bramstedt, 2025) and surgeon educational materials), the human surgeon can have informed pre-surgical discussions with their patients about the robot's capabilities and limits. Also, surgical consent forms can be enhanced to disclose the use of AI and provide AI risk information.

4. Discussion

Ethics is sometimes viewed as a blocker – a concept or committee that stifles innovation (De Cremer & Kasparov, 2022; Ernst & Matter, 2025). Here, an alternate view is presented; namely, ethics (via the precautionary principle) as a strength that mitigates risk and protects patient welfare. To help surgical robot developers implement AI ethics principles in their innovation process (American College of Surgeons, 2023; Marcus et al., 2024) the HOT-Bot Framework provides a concise and memorable 3-point scaffold from which to prompt aligned engineering solutions.

The first element, (H) Humane, is multifaceted and requires a deep understanding of pertinent AI ethics principles such as ethical use, beneficence, safety by design, sustainability, security, privacy, fairness, and justice. These principles align to an ethic of care (Maio, 2018); namely, the patient has a surgical need, and the surgeon takes responsibility to address their need with competent action (including safe and robust tools). With the Humane element, AI-assisted surgical robots are developed for ethical use (i.e., indicated surgeries), the robots present a positive benefit:risk performance profile, and the robots have been developed using a safety by design approach (van Gelder et al., 2012). Red-teaming (El Hechi et al., 2021) is performed to ensure privacy and security; algorithms protect patients against bias (they perform as intended for all indicated patients). Robot materials and manufacturing use sustainable practices. Ethicists can assist developers in understanding and operationalizing these principles in industry settings. Similarly, surgeons and developers can co-create to ensure that relevant human factors are considered, including ergonomic and dexterity matters.

Framework elements (O) Oversight and (T) Transparency can be aided by regulatory product labeling that clearly states the presence of AI, the human-in-the-loop requirement for use, as well as provide disclosure about the nature and limits of the AI assistance. In the hospital setting, Oversight also includes matters such as post-deployment device calibration and quality assurance, as well as the reporting of device malfunction. For surgeons, their pre-operative patient consultations and surgical consent forms should also be transparent about the use of AI-assisted robots, the risks of use, and the surgeon-robot relationship. This transparency empowers shared decision-making between the patient and the surgeon.

In case #1, the robot’s failure to detect a lesion combined with an out-of-the-loop surgeon contributed to the 6-month delay in acting on the malignant incidental (non-)finding. This has limited the patient’s options for treatment and potentially her eventual clinical outcome. The delay impacts her quality of life and potentially increases health care costs (if lower cost therapeutic options are deemed to now lack utility). These matters reflect the absence of the “H” and “O” elements. With regard to Transparency (“T”), the surgeon was aware of the use of an AI-assisted robot for their surgery, but the patient was not.

In case #2, while surgeons adhere to a professional code of ethics for their practice, current surgical robots innately lack a moral compass. The idea that a collective of surgical robots could potentially act unethically creates the need for ethics-by-design [Ménard, 2025) and training of robots such that a semblance of a moral compass is engrained into the robots as a foundation for their operation. Surgeons, ethicists, and surgical patients should be advisors for robot moral compass building. Surgeons, present and engaged with the surgery (in-the-loop with the robot, visually observing or physically assisting), need full interventional powers to control the robot's operation (e.g., providing correction, responding to malfunction, overriding nefarious actions).

Robot Uncertainty and the Need for Ethics

Case #1 could have had another ethical twist, namely, robot uncertainty. Consider a situation in which a robot encounters an incidental finding (recognizing it as a malignant lesion) but is uncertain about what to do in this situation. In the case originally described, the robot missed/did not detect the second lesion. But, upon detecting such there is the option of autonomously taking action and excising the lesion; or flagging the incidental finding to the human surgeon for their action; or ignoring the incidental finding. Will surgical robots have certainty on the ethically appropriate action? If uncertain, will surgical robots stop/freeze up during surgery, or might they ultimately attempt to make a choice without the input of the human surgeon? AI-assisted surgical robots should have the humility and professionalism to admit *I don't know what to do* when acting autonomously, and this can be facilitated by robot developers by including a mechanism for the robots to inform their human surgeon partner of their uncertainty. Aligning to the precautionary principle, this is a risk mitigation that supports the principles of responsibility and accountability, and the ethics of care more broadly.

The Legal Complexity of Cross-Border Networked Robots

While Case #2 has its ethical complexity, there is also significant legal complexity. Cross-border legal issues came to the forefront upon the implementation of telemedicine years ago, and the topic is stirring again in the setting of surgical robotics (Elendu et al., 2025; De Paola et al., 2025; Misra et al., 2025; O'Sullivan et al., 2019). This is because cross-border robot-assisted telesurgery is already happening (Aldousari et al., 2025; Chen & Chen, 2025; Marescaux et al., 2001) and there is the potential for globally networked robots to be communicating with each other while performing surgery.

The world saw its first robot with citizenship and a passport in 2017 (The British Council, 2025); these features could potentially intersect with legal matters such as clinical practice regulations and licensing, as well as privacy, as the concept of personhood evolves to include natural persons (humans) as well as robots (legal e-personhood) (The European Parliament, 2017; Mijatovic et al., 2024). Yet to be resolved in legislation or case law are questions such as: *If a surgical robot has personhood does liability for the robot's errors fall to the robot developer, the robot, or assisting human surgeons? And which laws apply if the robot and human surgeons are in different countries? Is the sending/receiving telecom provider responsible for harms caused by slow/poor robot performance due to long latency? Should surgical robots with legal personhood be licensed to operate regionally/globally? Should they hold mandatory global professional liability insurance? Should they be cataloged in a regional or international registry* (Marcus et al., 2024) *and their performance tracked for quality metrics and continuing professional development? Should the registry also contain information about litigation claims (e.g., malpractice) and regulatory recalls for transparency to patients and human surgeons? How should the surgical time-out procedure change when there are networked robots across different linguistic regions* (Jones & Bramstedt, 2025)*?* These are just a few of the numerous questions that require proactive consideration, and importantly, some surgical professional societies are already laying foundational groundwork to aid the legal and regulatory arenas (Mori et al., 2024; Patel et al., 2025).

5. Conclusions

The perspective that AI Ethics is the airbag that deploys on impact with a crisis is short-sighted. Certainly, ethics can mitigate risk on impact, but the impact has the potential for catastrophic harm. AI Ethics via the precautionary principle moves ethics farther up the value chain. Adding value earlier has benefits as there is the potential for more solution options (avenues), potentially creating multiple innovation highways. Ethical analysis can advise that a particular route is a very bad idea and can pose routes that are better/faster/safer. Just as patients want ethical surgeons, ethical surgical robots are also needed. Because these surgical robots emerge from a highly regulated innovation sector, use of the precautionary principle during development should be essential. Advancing to higher levels of robot autonomy must only occur with an ethics-by-design approach with ethics embedded throughout the lifecycle of the robot (including development, deployment, iterative training/learning/software upgrades).

Conflicts of Interest: Dr Jones is a paid member of the Roche Scientific Ethics Advisory Group. Dr Bramstedt is a salaried employee at F. Hoffmann-La Roche AG, Chair of the Roche Scientific Ethics Advisory Group, and owns stock in F. Hoffmann-La Roche AG.

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