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Editorial

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The health technology assessment in the artificial intelligence era: the AI surgical department

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Data are playing an unprecedented role in healthcare. The White paper by Schnelldorfer *et al.* is the long-awaited guidance that lays the foundation for a safe and feasible routine implementation of continuous health data collection during our clinical activities[1]. Data in the operating room (OR) are particularly complex to manage, both in terms of their quantity and quality. They are represented by multi-source data of various types (structured and unstructured), collected in real time over hours for each patient. A checklist of common requirements is very useful for the design and the implementation of an archiving strategy as well as for the validation of an existing one. It also defines a framework for the establishment of common standards, which are essential for interoperability. In addition to this, the strength of the checklist is that it could be adapted in non-OR settings and extended to the entire perioperative pathway. If we were to collect all the monitoring data of post-operative vital parameters on a continuous basis rather than just images, similar problems could arise to those in the intra-operative context.

The value of health data is now widely recognized: the idea of "wasting" all the information we could collect in the ORs and throughout the perioperative period because we do not know how to use it properly sounds anachronistic. In fact, nowadays, we have at our disposal intelligent systems of collection and data analysis

that give us the opportunity to exploit this "gold mine" and provide powerful tools capable of improving clinical practice, as well as the optimization of resources and the quality of services provided, aiming at a real precision medicine[2].

The use of health data raises many issues, especially ethical and legal, where even the definition of responsibility is not yet well defined[3,4]. Not having a data management program can result in severe privacy and regulatory violations. To ensure maximum transparency and reliability in the implementation of the checklist provided by the Authors, a multidisciplinary application is essential. The complexity of data and data pipelines, coupled with the growing importance of privacy and cybersecurity compliance, is increasing and both clinicians and administrators may not always be adequately prepared to manage all the data generated in healthcare practice. Data management, privacy, security, and informed consent are prerequisites both for the usability of the information collected and for their exploitation within intelligent systems which inherently require large amounts of data as fuel for their development: big data and artificial intelligence (AI) technologies have unique characteristics, and a flexible but standardized approach is needed to correctly manage them[5].

We attempted to provide a solution to this challenge by suggesting the establishment of an AI Surgical Department capable of identifying, analyzing, and managing most of the issues related to data management and the implementation of new technologies in the surgical and perioperative environment. The proposed composition was initially represented as follows: healthcare professionals, engineers, and data scientists. However, it is evident from Schnelldorfer's work that for proper and standardized implementation of these new technologies, clinical and technical-informatics knowledge is not sufficient. Although some authors[4] argue that clinicians need to be fully aware of how to comply with the requirements of the regulations, we believe that it is more important for them to be supported by legal staff, including the forensic unit and ethics committee delegates, so that clinicians can focus on the correct use from a clinical perspective, focusing on patients. Conversely, leaving the full assessment to the clinician alone would once again lead to the risk of overburdening clinical activity and risk delaying the implementation of these new technologies [Figure 1].

We therefore believe that the Health Technology Assessment (HTA) in the AI field should involve forensic physicians more than ever before, incorporating their role in a multidisciplinary approach. The potential for AI development is enormous and a prospective and anticipatory approach would be utopian as well as limiting or even risky since it cannot predict all variables. AI systems keep changing and learning from experience: the AI approach is an exception in classical HTA because of its characteristics[5], and we agree with Cecchi *et al.* when they argue that a classical and reactive approach is needed to intervene and correct implementation issues as they arise[6].

The AI Surgical Department model would become the benchmark for HTA in this area, at least in terms of evaluating comparative effectiveness, organizational impact, and possible ethical-social impact[7].

In the end, working with that reactive approach does not exclude the need to create AI systems that are ethical by design and privacy by design: in fact, when we sit in the AI Surgical Department, we are already walking through the next step from the creation phase, which is the study of technology's implementation and its consequences in a structural, interoperable and standardized basis with tools such as the White paper or the MAS-AI[1,8].

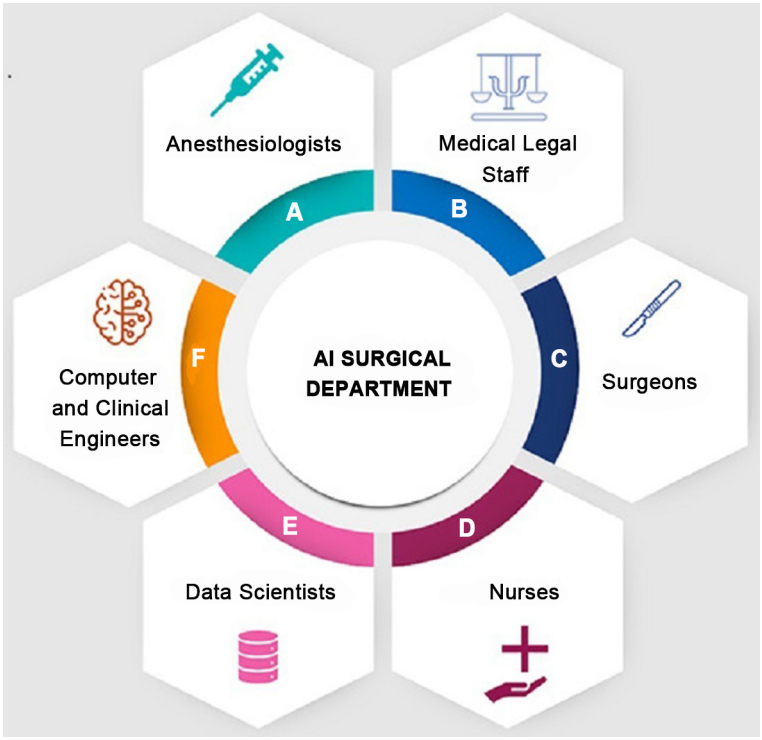

Figure 1. The AI Surgical Department is how healthcare professionals evaluate, implement, and supervise the use of AI systems in the perioperative period. On the one hand, healthcare professionals act as the link between the clinical reality and the technology; on the other hand, technical and legal figures provide support to physicians for the correct use and ensure compliance with current regulations during the implementation of the technology. Of particular importance is the medico-legal staff, including both the medico-legal unit and the members of the ethics committee, who are responsible for providing guidelines on the correct observance of informed consent, broader data protection, and support for medico-legal litigation.

The manuscript by Schnelldorfer *et al.* stands in this context: it is intended as a guide, not so much providing practical solutions, but rather firm points to be addressed whenever one wishes to undertake routine perioperative data recording[1].

DECLARATIONS

Authors' contributions

Substantial contributions to the conception and design of the work, data analysis and interpretation for the work; drafting the work and revising it critically for important intellectual content: Bellini V

Substantial contributions to the design of the work, data acquisition, analysis, and interpretation for the work; drafting the work: Panizzi M

Substantial contributions to the conception and design of the work, data acquisition, analysis, and interpretation for the work; revising the work critically for important intellectual content: Bignami EG

Final approval of the version to be published, agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved: Bellini V, Panizzi M, Bignami EG

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Conflicts of interest

All authors declared that there are no conflicts of interest. Bignami EG is the Editorial Board Member of the journal *Artificial Intelligence Surgery*.

Ethical approval and consent to participate

Not applicable.

Consent for publication

Not applicable.

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