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DATA GOVERNANCE in digital surgery☆

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A B S T R A C T

Technological and computer advances have led to a "new era" of Surgery called Digital Surgery. In it, the management of information is the key. The development of Artificial Intelligence requires "Big Data" to create its algorithms. The use of digital technology for the systematic capture of data from the surgical process raises ethical issues of privacy, property, and consent. The use of these out-of-control data creates uncertainty and can be a source of mistrust and refusal by surgeons to allow its use, requiring a framework for the correct management of them. This paper exposes the current situation of Data Governance in Digital Surgery, the challenges posed and the lines of action necessary to resolve the areas of uncertainty that have arisen in the process, in which the surgeon must play a relevant role.

Gobierno del dato en la cirugía digital

Palabras clave:
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Gobierno del dato
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Big Data
Inteligencia artificial
Aprendizaje automático
Ciencia de los datos
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R E S U M E N

Los avances tecnológicos e informáticos han conducido a una "nueva era" de la Cirugía denominada Cirugía Digital. En ella, el manejo de la información es clave. El desarrollo de la Inteligencia Artificial precisa del "Big Data" para crear sus algoritmos. La utilización de la tecnología digital para la captura sistemática de datos del proceso quirúrgico plantea problemas éticos de privacidad, propiedad y consentimiento. El empleo de estos datos fuera de control crea incertidumbre y puede ser una fuente de desconfianza y rechazo por parte de los cirujanos a permitir su utilización, siendo necesario un marco para el correcto manejo de los mismos. Este trabajo expone la situación actual de la Gobernanza del Dato en Cirugía Digital, los retos planteados y las líneas de acción necesarias para resolver las áreas de incertidumbre surgidas en el proceso, en el cual el cirujano ha de tener un papel relevante.

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Introduction

The dizzying upward trajectory of advances made in technology and computer systems is causing a revolution in all fields, including surgery. According to Moore's law,[1] these changes are unstoppable. This new ''surgical era'' has been called Surgery 4.0 or ''digital surgery'',[2] where the management of information becomes especially relevant, and its mismanagement can have significant consequences.

Surgery is a high-risk clinical environment that poses specific challenges, as the consequences of a technological failure can result in immediate and irreparable harm to patients, consequently leading to questions of liability. Furthermore, surgical results do not depend exclusively on the technical expertise of surgeons; instead, they are part of a multidisciplinary context that is difficult to audit. Likewise, the use of digital technology for the systematic capture of data related to the surgical process and recording of surgical procedures raises ethical problems of privacy, data ownership and consent. The use of these data beyond treatment or training, such as for commercial or judicial purposes, can be a source of distrust and refusal by surgeons to allow their use, which has a secondary effect on the slowdown of the digital expansion process.[3]

The aim of this study is to compile current evidence on data governance in digital surgery, which poses new challenges for surgeons in this context of innovation. We also discuss possible lines of action to resolve the uncertainties that have arisen in this process.

Evolution of surgery

Before reaching this new surgical era, the field of surgery had undergone fundamental changes, marked by 4 great moments in history.

''**Surgery 1.0**'' is what we now call the beginnings of open surgery in the 19th century, which was associated with progress made in the understanding of surgical anatomy as well as the techniques and procedures to treat different pathologies. Interventions were performed using invasive approaches, large incisions, and aggressive maneuvers, where radical treatment was synonymous with quality.

The foundations of surgical training also began. WS Halsted, father of modern surgery, summarized the learning method of the time as, ''See one, do one, teach one.''

''**Surgery 2.0**'' included the beginnings of laparoscopic surgery in the 1980s. New technologies were incorporated, such as the intracavitary optical lens, and incisions were reduced. Philippe Mouret performed the first laparoscopic cholecystectomy in 1987.[4]

''**Surgery 3.0**'' is robotic surgery, coinciding with the approval of the first robotic system[5] by the US Food and Drug Administration in 2000. With it, surgeons experience optimized conditions (ergonomic, vision, tremor control, etc), complex maneuvers like suturing are made easier, and the learning curve is reduced.[6]

''**Surgery 4.0**'' or digital surgery[2] incorporates digitization and data processing to previous technological improvements. It is the current era.

Meanwhile, the training process of surgeons has also evolved towards the ''democratization'' of surgery, using elements such as augmented reality and virtual reality[7] that will improve results and the efficiency of the learning curve. Furthermore, ''telementoring'', supported by 5G telecommunications technology, allows an expert surgeon to supervise a procedure remotely and in real time, turning the teaching of surgery into a discipline that has broken the barriers of time and space.[2]

Digital surgery

Digital Surgery, which is defined as the ''use of technology to improve preoperative planning, surgical performance, therapeutic support, or training to improve outcomes and reduce harm,'' is comprised of three key elements: data, analysis systems and applications[3] (Table 1).

Natural language processing investigates the way machines communicate with people through the use of written, oral or sign language, treating language computationally with mathematical modeling. This, together with advances in machine learning, deep learning and computer vision, have boosted the development of AI.[12]

But digital surgery (DS) is not merely limited to the operating room, even when used for training[13]; it also encompasses preoperative planning,[14] surgical risk prediction,[15] or the evaluation of surgical performance.[16,17]

DS offers benefits for patients (better clinical results, health care, diagnosis, specific treatment and early identification of adverse evolution) and for surgeons (preoperative planning, support for decision making, reduced cognitive load, process standardization and automation, prediction and detection of errors, improved ergonomics and surgeon health, performance evaluation, and acceleration of surgical education), while also improving organization (better surgical efficiency, profitability, quantification of results beyond survival, comprehension of the benefits and limitations of surgical strategies, understanding and improving team dynamics).[3]

Digital surgery and data

The key that marks the transition from Surgery 3.0–4.0 is the digitalization of information.[18] This has implemented pre-, peri- and postoperative data collection, analysis and processing systems of all kinds (video captures of procedures,[19,20] radiological images, analytical parameters, calculations of the surgeons' range of motion on the robotic console, monitor tracings, etc) to generate a network of global information for the entire surgical process (patient, surgeon, pathology, anatomy, procedure, etc). This large volume of information can be stored in multiple ways, using different physical or virtual devices (cloud storage).[21]

The concept of ''Big Data'' has appeared as a dataset of such magnitude and complexity that traditional computer applications for data processing are insufficient to handle the volume as well as the procedures used to find repetitive patterns within the data.[22]

Table 1 – Key elements of digital surgery (Adapted from Lam et al.[3]).

A. Data	B. Analysis systems	C. Applications
1. Capture	1. Artificial intelligence*	1. Imaging: virtual reality****/augmented reality*****
2. Annotation	2. Machine learning**	2. Surgical aids: decision support systems, navigation systems, computer-assisted training
3. Visualization	3. Computer vision***	3. Robotics
4. Storage		4. Remote care: telesurgery, remote monitoring, sensor technology
		5. Organizational: electronic health records, digital patient pathways

* Artificial intelligence (AI) is a branch of computing that uses machines to simulate human cognition.[8] It allows for data inputs hosted on a computer platform to be translated into learning through processing, while also allowing for individualized adaptation to the specific circumstances of the patient and the surgeon in an intelligent manner. The surgeon accesses a macro-network of information that evolves in real time and uses the platform's learning algorithms to reach the best decision, subsequently sharing this information for remote teaching purposes with other patients and/or surgeons who are potentially online.[9] AI requires an enormous volume of information, which must be supervised and classified for correct interpretation.

** Machine learning (ML) is a field within AI that studies how to give machines the ability to learn on their own by recognizing patterns from massive, multidimensional, digitally archived data in order to predict results or explore data.[8,10] ML can be supervised, unsupervised and semi-supervised.[10] Semi-supervised or reinforced learning uses complex algorithms, such as ''neural networks'', and is part of so-called ''deep learning''.

*** Computer vision is a part of AI that designs software systems associated with cameras or video cameras to perceive, acquire, process, analyze and comprehend images of the real world in order to produce numerical or symbolic information that can be processed by a computer.

**** Virtual reality is computer-generated simulation that hides the real environment through glasses and headsets, displaying images of an alternative, artificial, immersive and interactive world, which is experienced through sensory stimuli provided by a computer in which actions determine what happens in the environment.[11].

***** Augmented reality involves superimposing digital images over a real environment, which is enriched with additional contextually relevant information in real time.

Doug Laney[23] has described ''the three Vs of Big Data'': volume, velocity, variety. To these, others have been added, such as variability and veracity (Table 2).

Data can be classified as different types according to the storage structure:

a) Structured data: These are stored in the form of values or numbers as discrete data points that are easy to analyze by computer and easy to consult by people. Examples would be the data fields for age, gender, or diagnosis code of an electronic health record.[10]
b) Unstructured data: Data with no predefined format or organization.[24] The information is stored together. It can include different types of files (images, videos, audio, etc). For example, the note section of a clinical report.[10]
c) Semi-structured data: Data whose structure includes organizational features like tags to facilitate search capabilities, but no defined domains for structured data.[10]

However, the implementation of Big Data storage and management platforms in hospitals is not easy. There are security gaps and no clear guidelines on data ownership, consent, right to erasure and sharing. Ethical issues like privacy and confidentiality, or litigation and liability regulations, have yet to be defined.[3] For instance, if a surgeon followed AI decision support and this resulted in a negative result, who would be at fault? The American Medical Association on AI in Healthcare has stated that autonomous AI creators must take responsibility.[25,26]

Table 2 – The Vs of Big Data.

1. Volume	Large amount of data that requires appropriate software to process it
2. Velocity	Speed of incorporation and need for immediate processing
3. Variety	Diversity of data formats (structured and unstructured)
4. Variability	Unpredictable data flows, with variations during peak loads
5. Veracity	Reliability and quality of the data

It is not easy to identify the inflection point between the surgeon's individual decision based on the support of the AI system and the overall surgical technological process. Many machine learning models generate their results by operating in high dimensional correlations that are beyond the interpretive capabilities of human-scale reasoning and could generate unjustifiable and opaque results. In this situation, where cognitive functions that were formerly attributable exclusively to humans are now becoming automated, identification of the responsible parties becomes complicated, exposing the individual rights of the patient and the subject who is accountable.[27]

What has likewise not been resolved is the accountability of consequences resulting from defective digital surgical systems, as well as the surgeon's refusal to follow the indications of the surgical strategy derived from AI algorithms, or the unavailability of these technologies in the current context. Similarly, collecting surgical data outside of pre-established criteria raises the problem of indiscriminate subsequent assessment for legal purposes within lawsuits, compensation, or determination of medical negligence.[3]

In this context, the ''open data'' requirement of European Directive 2019/1024[28] for the access and dissemination of information has found a way around this with the 2018 Reform of the Organic Law on Data Protection and Guarantee of Digital

Rights[29] and European Regulation 2016/679,[30] which question the fundamental right to data protection (which had been firm until now) as well as the requirement of consent for the reuse of personal data in research or projects related to an initial study. In a report from April 28, 2020,[31] the Spanish Bioethics Committee stated that it is no longer possible to further maintain that data belongs to the person who generates it alone, and it is necessary to find a balance between the general interest and individual rights.

In this dizzying drift, surgeons find themselves facing a ''technological invasion'', in which they play an essential role. However, at the same time they are unaware of many of the fundamentals and algorithms used, as well as who directs and is responsible for managing the data, which affects their professional performance. Surgeons are likewise unaware of the consequences derived from accepting surgical digitalization as well as any discrepancies in the results provided by artificial intelligence during the interaction with a specific patient.

Right now, the legislation applicable to the use of data in digital surgery is not very specific. In Europe, the UK and EU General Data Protection Regulation (GDPR) oversees health data, regardless of the format or manner in which it is collected, with no mention of AI or associated technologies.[32] Most relevant legislation in the US is governed by the Privacy Rule of the Health Insurance Portability and Accountability Act (HIPAA), which only applies to protected health information that is identifiable. This, however, does not solve the issue of data ownership.

The lack of standardization of AI-related terminology in the law and regulation of digital clinical data, intellectual property or responsibility for data integrity, coupled with legislative discrepancies among different countries, has led to the significant regulatory vacuum that currently surrounds digital surgery.

Data science

Managing the complete life cycle of data (collection, processing, analysis and dissemination) is the essence of data science, which combines scientific methodology, statistics and data analysis to generate value and obtain significant information. It was first described by American statistician JW Tukey[33] in 1962 and was later introduced as an independent discipline of statistics in 2001 by William S. Cleveland. In 2002, the first scientific data journal, Data Science Journal, was launched.

''Data scientists'' analyze data to find patterns, extract meaning and discover knowledge, thereby obtaining optimal responses for decision making and detecting new trends. These scientists must have knowledge of data analysis, mathematics, statistics and programming languages. The source of information used is Big Data, which is processed with appropriate software. Machine learning and deep learning algorithms are then applied to obtain predictions, creating unprecedented opportunities for organizations and companies to discover patterns hidden in the data, and this information is used to make better decisions.

Data governance

In surgery and other fields, digital technology depends on enormous amounts of data, and significant consequences arise from the mismanagement of data.[34]

Data governance (DG) is the framework necessary to establish practices to access, monitor and evaluate the use of data.[10] It encompasses ''policies and procedures to ensure that an organization's data is accurate and managed correctly when they are processed, stored, handled, rescued and eliminated.'' In addition to setting the principles that govern data (what data is collected, who is responsible for its management, applications and limits of use, etc), the responsibilities of DG include: a) establish the infrastructure and technology for the storage, management and security of data; b) configure processes and policies; and c) identify the people in the organization who have the authority and responsibility to manage and safeguard the information. This requires a cultural change throughout an organization, and its implementation must be led and supported by the highest levels of the organization. To date, few organizations have developed a data governance system.

Governance provides benefits, such as obtaining reliable data and more accurate information on which to base decisions, using a single source of information, creating data regulation standards, and reducing costs derived from decisions based on erroneous or obsolete information.

The governance model establishes the rules, activities, responsibilities, procedures and processes that define how data flows are managed and controlled (inputs, storage, outputs). This governance framework will be unique to each organization and reflect specific factors for data systems, organizational tasks and responsibilities, regulatory requirements, and specific protocols.

Health data governance

The recent collaborative document on health data governance between the Pan American Health Organization (PAHO) and the World Health Organization (WHO) indicates that this new paradigm for data management requires improving the collection and quality of health data, the flow of information, and standardized and inter-operator data management to facilitate more informed decision making in Public Healthcare.[35]

The premises for health data governance include: the responsibility of the entire institution, trust in the data collected, the establishment of compliance and control procedures, and the coordination and exchange of data with the public health administration.[35] Nationwide healthcare data governance policies must be activated, along with regulations for related topics, such as privacy, management and ownership of healthcare information, standards for the adoption of technologies, information and communication technology (ICT) tools and experts in healthcare data management. A multidisciplinary committee will develop a strategic plan and perform auditing and technical advisory functions.

The principles for managing public health data are[36]; a) open data (complete, primary, obtained directly from an organization in an accessible manner, with no processing that distorts it, timely, automatically processable, non-discriminatory, with no proprietary exclusivity, and not patented); b) ethical usage (privacy, confidentiality and security, with explanation of objectives and procedures of use); c) assessment of unstructured data; d) quality data; e) subject to standards that allow interoperability (capacity of 2 or more systems or components to exchange information and use it)[37]; and f) strengthen vital statistics, as a public asset for decision making, resource distribution and policy making.

Ethics and data

The use of critical data should be linked to the assumption of well-defined responsibilities. The risks of mismanagement raise ethical issues arising from the potential harm due to the application of digital technology, such as bias and discrimination, invasion of privacy, poor quality, non-transparent or inexplicable results, or denial of autonomy and individual rights.[27,34]

AI ethics is a set of values, principles and techniques that use widely accepted standards of right and wrong to guide moral conduct in the development and use of AI technologies.[27] Its pillars are transparency, justice, equity, non-maleficence, responsibility and autonomy.[38–40]

The UK National Health Service (NHS) AI Lab has published documents for the safe implementation of AI systems in healthcare[41] and the WHO has published guidelines on ethics and AI in healthcare.[42] This provides a general framework for AI in healthcare, but it does not address specific questions regarding the ethics of AI in surgery.

Leslie[27] published guidelines for the values, principles and governance mechanisms necessary for responsible innovation (Table 3).

Data and digital surgery ethics

The operating room is a unique environment that poses specific challenges, where a large amount of high-value data is generated. Surgical decision making requires quick, highly contextual decisions about which the patient often cannot be consulted. Furthermore, surgery data sets are large, heterogeneous, and often unstructured, which come from surgical videos, sensor data or teamwork.[43,44] The management of this information raises issues of ownership, commercial associations, uncertainties regarding patient consent and privacy, but also of the surgical team that will be under constant scrutiny.[34]

The collection of data on surgical results and surgical performance (done by surgeons to evaluate their own performance or by an external auditor) is controversial.[20] Before starting to record data on the surgical process, express consent must be given by the surgeon and patient.[13] Under the UK and EU General Data Protection Regulation (GDPR), consent must be specific and informed, and must also include the purposes of the data processing as well as the right to withdraw consent at any time. When applied to digital surgery, this can generate problems related to future unknown applications or the right to erasure.[3]

Strategies should be implemented to minimize the impact on privacy, such as anonymization of data, justified selection of data by introducing only those relevant to the machine-learning algorithm, and auditing the process.[13] The centralized repository of surgical videos and subsequent anonymous analysis of technique and results (by other medical specialists initially, followed by AI where permitted) would provide a means for impartial evaluation and maintained standards (of both doctors and surgical instruments).[20] However, when surgical videos are aggregated in isolated collections, no matter how large, there is a risk of inadequate representation. Closed data sets also limit progress if they exclude others of relevant interest, which can result in monopolistic practices.[20]

The European Commission document Laying Down Harmonized Rules on Artificial Intelligence attempts to shape the future incorporation of AI into society.[45] This document emphasizes the enormous socio-economic potential of AI and shows that, while generating benefits, it also carries risks. Likewise, the Investigation of Competition in Digital Markets Report by the United States Subcommittee on Antitrust has indicated that, in many digital domains, few dominant

Table 3 – Basic elements for an ethical platform (Adapted from Leslie[27]).

Elements	1) Sum values	2) Fast-track principles	3) PBG framework
Components	"Support-Underwrite-Motivate"	"Fairness-Accountability-Sustainability-Transparency"	Process-Based Governance Framework
Definition	Ethical values that support, guarantee and motivate an ecosystem that is responsible in design and use of data.	Practical principles to guide the design and responsible use of AI systems.	Governance framework that puts into practice the SUM values and FAST Track principles throughout the AI project delivery workflow
Includes	Respect, Connect, Care, Protect	Equity, Responsibility, Sustainability and Transparency	
Objectives	1- Provide an accessible framework to reflect on the moral scope of the social and ethical impact of the project.	1- Provide the moral and practical tools to ensure that the project mitigates bias, is non-discriminatory, and is fair.	Establish transparent design and implementation processes that safeguard and enable justification of both your AI project and your product.
	2- Establish defined criteria to evaluate ethical permissibility.	2- Safeguard public confidence in the capacity of your project to deliver safe and reliable AI innovation.	

corporations had singular control of mass distribution channels in a way that allowed them to maintain power and absorb or eliminate competitors with ease.[46]

There are risks in using data to promote commercial interests, individuals or specific institutions, rather than the public good, which is why boards of directors must be created and high levels of transparency must be maintained.[20]

The creation of data governance regulations for surgical processes would require the collaboration of a multidisciplinary team of experts, involving surgeons, patients, industry representatives, administrators, researchers, computer engineers and ethicists.[13]

Ethics and training in digital surgery

The development of AI in surgical education and training must also consider the ethical implications of transparency and the ability to reproduce results in different training environments, following the scientific method.[13,47]

The application of AI in robotic surgical training is currently in the development phase; however, the preliminary data are promising.[48]

Training in laboratory environments can obviate many ethical limitations regarding direct practice on patients.[13]

Future lines of study

Awareness of the role of surgeons

Given the innumerable issues that arise around data governance in digital surgery, it is necessary to create awareness that the path of technological progress goes hand in hand with progress in information management, as the epicenter of this new surgical era. Moreover, surgeons cannot be left out of this process, but instead must take the reins and actively participate in the resolution of the issues raised.

Knowledge of limitations and resolution

There are still limitations to be resolved before implementing data governance in digital surgery. These are related to technical problems regarding support and data management infrastructures as well as organizational, ethical and legislative problems to better define the framework for the ownership and responsibility of surgical data.

Creation of a European legal framework

The creation of specific European legislation is urgently needed to respond to the issues raised around data governance in digital surgery, including standardized terminology regarding AI, which would provide for unified criteria among different institutions and countries, as well as interoperability.

Investment and institutional support

The resolution of issues such as interoperability, definition of surgical standards,[49] creation of platforms with Big Data storage capacity and management of heterogeneous health data, networks, and cybersecurity[50,51] require considerable investment and initiatives with government support. Something similar is happening in the United Kingdom, which has established a national Health Data Research Network to monitor and provide guidance to hospitals.[52]

Interdisciplinary education

Digital surgery also requires interdisciplinary education, including the participation of patients as the ‘‘heart’’ of surgery,[53] who should receive education about what data is collected and how it is used in order to provide duly informed consent to share data. Education is also necessary for the other interested parties (technologists, surgeons, managers, companies, etc).

Comprehensive training for ‘‘Digital Surgeons’’

Finally, the transformation of surgery is also forcing the transformation of surgeons. Future digital surgeons must become familiar with the basics of AI[12] and understand the technology it uses, as well as becoming aware of the legal, ethical and data governance issues related to its use. All of this must be incorporated into the wealth of knowledge and comprehensive training plan, playing a leading role in the changes for this new digital surgical era.

Conclusions

In the era of Big Data, no legal framework has been defined for digital surgery; therefore, there is a vacuum around data governance and the resulting ethical problems.

The participation of all parties involved (surgeons, technology companies, governments, patients, data scientists, etc) is necessary to respond to these challenges.

Modern surgeons should be concerned not only with academic learning and technical skills, but they should also be involved in technological and digital progress, while adopting a leading role in the governance of surgical data processes as a true driving force behind change.

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