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# The Regulation of Artificial Intelligence on Issues Related to Medically Assisted Reproduction

**Florencia Marina Daud***
University of Buenos Aires

## Abstract

Medically assisted reproduction techniques do not escape the new tendency to automate medical processes due to the vertiginous advances of bioengineering. The main objective of automating *in vitro* fertilization is to be able to perform many more treatments at a lower cost. In addition, better results are less the cycles to which patients should be submitted. An issue that emerges in the field of reproductive medicine is that artificial intelligence (AI) applications could quickly begin to be operated by people who have no specific knowledge in this branch of medicine. In turn, the number of biologists specialized in embryology necessary in laboratories could be diminished, who would lose their job if they were not trained in the use of AI. It is likely that the occupational market will be redirect and the new graduates turn more to that type of formation. However, the human factor remains an important value for the trust that the patient deposits in the medical professional who advises and reassures him. Recall that in assisted fertility treatments this is carried out more by doctors specializing in reproductive medicine than by embryologists.

**Keywords:** Artificial intelligence; Medically assisted reproduction

***Correspondence to:*** Florencia Marina Daud, University of Buenos Aires, E-mail: florenciamarina@hotmail.com

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## Introduction

### Automation in reproductive medicine has already begun

Recently, in mid-April 2023, the birth of the first two babies conceived by means of AI [1] was announced in an assisted reproduction laboratory, something that until now had not been achieved since all sperm injections in an oocyte were performed manually. The procedure was carried out at the New Hope Fertility Center clinic in New York [2]. Engineers of the company Overture Life [3] located in Barcelona designed a robot for sperm injection in an ovule in *in vitro* fertility processes. *In vitro* fertilization automation could reduce the costs of treatments by decreasing the number of specialized biologists necessary in the laboratories of fertility centers, but being an incipient technology for now the human criteria remains necessary for the selection and manipulation of sperm and ovules.

An issue to highlight in the case of this news is that it is alleged that the instrument was sent disarmed from Barcelona to New York where it was assembled and commanded by an engineer without previous experience in reproductive medicine. When observing a human egg through a camera, the robot advanced on its own, penetrated it and dropped sperm. This could open the door for professionals not trained in assisted fertility - and even in medicine - to carry out at least part of the assisted reproduction processes.

There are theories, perhaps exaggerated, about the future of AI progress that estimate that professionals of certain branches of medicine such as radiologists will become redundant. Should this begin to worry about embryologists?

In general, patients do not know what happens within an assisted fertility laboratory, nor who they are or what tasks do the people who work there. So, patients almost do not have contact with embryologists so it can be not very relevant if the process is performed by a robot or a human hand, provided that the result is expected. However, until now, the entire process has not been automated but only injection. In addition, we will have to see if access to this technology will be economically accessible for assisted reproduction clinics of the different countries of the world. It must also be borne in mind that this automated procedure has not yet obtained the approval of the FDA [4].

### Regulatory regimes

As it is likely that AI applications generate ethical and legal problems in health care, the world tendency is to specify the normative requirements that must be met so that the devices obtain their approval and the respective access to the market. Automation can bring a democratization of expensive treatments, but also some problems at the ethical and legal level. When this automation progresses, the right must be able to give answers. He is currently the doctor responsible for ensuring the best interest of his patient. Already in the European Union, the US and China medical devices that have AI or Automatic Learning Technology are beginning to have specific regulatory regimes to guarantee their safety and effectiveness.

It is not yet known with certainty how existing regulatory approaches will continue to evolve. The path that is glimpsed goes to the achievement of a participatory and collaborative regulation between the various actors involved in the automation processes. In the main digital health markets the existing supervision regulations of

supervision seek to achieve a commitment to prioritize the protection of privacy - the protection of personal information and data security - professional responsibility and intellectual property rights. Thus, the worldwide trend is to specify the regulatory requirements that medical devices must meet AI to obtain approval and access to the market and probably that is the path of automation of in vitro fertilization.

AI applications can assume an important role that does not imply that the doctor ceases to be in the center of the attribution of ethical and legal responsibilities, the collection of the fees and the organizational leadership. Trust in medical care can be maintained through regulatory means and harmonized ethical standards.

According to the regulatory approach proposed by the International Forum for Medical Devices (IMDRF) (SAMD). Regulatory principles and standards have mainly occupied in ensuring that these applications are safe and effective throughout their life cycle, from their design to its development and use. To meet these requirements, a combination of ethical and regulatory standards is normally applied, including a recently updated standard of the International Organization for Standardization, which provides guidance to developers and clinical research professionals on the specifications and requirements of good clinical practices before and after marketing.

Ethical values are explicitly incorporated through principles of good practices that are online with the provisions of the International Conference on Harmonization of Good Clinical Practices and in the Guide for Ethics Committees of the World Health Organization. The Normative AI approach is essentially based on the fact that the risk is something inherent in these devices and the determination of risk is carried out based on the information provided by its developer referring to the planned use.

The risk assessment carried out to determine the categorization of risks of a SAMD includes considerations regarding patient safety, clinical environment and the technology and systems environment. Because the risk profile of a SAMD - this applies more to those who are capable of performing DL - can change over time, IMDRF has placed considerable emphasis on surveillance after implementation.

For effective surveillance it is necessary that developers, regulators, medical care providers and patients work together to achieve clinical objectives. While the developer has the responsibility of monitoring the real performance of its SAMD and making the data available through periodic updates, regulators and medical care providers are expected to work in close collaboration with the developer to evaluate and monitor the software from its development to its implementation. Regulatory supervision is becoming more interactive and collaborative when evaluating the impact of the optimization of the device on patient safety.

## Conclusion

In reproductive medicine, currently all medical care is provided by professionals with enrollment in medical facilities that have obtained prior authorization to function. We believe that the intervention of professional associations and new public policies will be necessary to guarantee the access of market automation in optimal safety conditions and to manage labor displacement, as repetitive tasks are automated, creating new jobs and roles inside of medical care, as medical data scientists, and to reduce the friction of the transition.

### Annexes

1. The concept of AI refers to a machine that is capable of imitating human reasoning.

2. New York New Hope Center was the first assisted fertility center to announce, in September 2016, the birth of a child through the technique of transfer of mitotic spindle (badly called DNA of three parents)

3. Overture Life was founded by an Argentine. The news was published by the Massachusetts Institute of Technology magazine which has given it scientific credibility and has opened an international debate.

4. The FDA is the United States and the United States Food Regulatory Agency.

5. Machine learning is a subset of AI that focuses on the analysis and interpretation of patterns and data structures that make learning, reasoning and decision making possible without human interaction. This allows the user to feed a computer algorithm with an amount of data, from which the computer analyzes all the information and is able to make decisions and make recommendations based only on the data entered. In the case of identifying corrections, the algorithm can incorporate that information to improve future decision making.

6. The definition of the IMDRF to refer to the term software as a health product or SAMD is any computer program whose objective is to carry out one or diverse medical purposes. It refers to an independent software device that has medical use. Performs these medical functions being independent software without being part of a medical team; The software device is the medical equipment or health product by itself. It is usually installed on computer platforms with non -medical use, which can be connected to virtual networks, traditional medical devices or other general hardware.

7. The International Organization for Standardization, sometimes called the International Organization of Standardization and known by the Acronym ISO of the English International Organization for Standardization is an organization for the creation of industrial and commercial international standards and is composed of various national normalization organizations. It was founded on February 23, 1947, and its headquarters is in Geneva, Switzerland.

8. The good clinical practices of the International Harmonization Conference (BPC ICH) are the guidelines for the design, address, performance, monitoring, auditing, registration, analysis and reporting of a clinical study, such that it is guaranteed that data and Results obtained are precise and credible, in addition to that through these guidelines the rights, integrity and confidentiality of the subjects of the study have been protected.

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### Conflict of Interest

The authors declare that they have no conflicts of interest.

### Ethics Statement

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