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LETTER TO THE EDITOR

Big Data Analysis and Machine Learning in Intensive Care Medicine: Identifying new ethical and legal challenges☆

Big Data Analysis y Machine Learning en medicina intensiva: identificando nuevos retos ético-jurídicos

Dear Editor,

The review article published by Núñez Reiz et al.[1] makes some valuable remarks on disruptive technologies that will probably revolutionize modern care of critically ill patients. However, we would like to make some considerations on the ethical and legal questions associated with the use of such models for the clinical decision-making process.

The current medical literature agrees that a fundamental component to achieve the safe and effective implementation of these tools of Big Data Analysis (BDA) and Machine Learning (ML) is developing regulatory frameworks to address the unique challenge posed by the actual pace of innovation, the significant risks involved, and the potentially fluid nature of the models of automatic learning[2].

In the design of these regulatory frameworks, the remarks made by Núñez Reiz et al. on the privacy and safety of patients whose data are used to build these models are obviously relevant; however, the greater risks involved when implanting these technologies affect, precisely, the critically ill patient who is at the center of the clinical decision-making process with the use of these BDA and ML tools. This means that the patient has a legitimate interest too in the automated management of these data. Actually, the Data Protection General Regulation guarantees the right to obtain sensitive information on the logic used by the algorithm to make this or that prediction on a patient's health status (the making of a profile according to the regulation).

We would like to mention that the individual damage that BDA and ML tools can cause may go misdiagnosed or be irreparable from the very perspective of the individual who is the sole holder of his rights. However, it can also massively affect the fundamental rights of sectors or clusters of society in a relevant way in this collective dimension[3]. In this sense, the medical literature has shown growing preoccupation due to the reproduction of biases of race or sex in these mechanisms[4] that may discriminate these social groups.

Bottom line, the critically ill patient is the paradigm of this problem since exercising one's own rights can prove unfeasible and ineffective in practice. Also, establishing a regulatory framework based on the protection of collective rights with special attention to the processes of validation and supervision of these models or the role of ethics committees the authors talk about can significantly reduce the risks individuals are exposed to when these technologies are implemented.

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In reply to ''Big Data Analysis and Machine Learning in Intensive Care Medicine: Identifying new ethical and legal challenges''☆

En respuesta a «Big Data Analysis y Machine Learning en medicina intensiva: identificando nuevos retos ético-jurídicos»

We wish to thank professors Lazcoz Moratinos and de Miguel Beriain for their comments[1]. We fully understand their preoccupation on the scientific and legal challenge posed by the use of artificial intelligence in the management of critically ill patients. However, we wish to make some considerations on this regard.

The clinical decisions made by intensivists are also based on a learning process much like the one used by the algorithm. Also, the concept of ''intuition'' that we use in our daily routine clinical practice could be interpreted as unfounded or unexplained, and yet it is actually based on a process that is similar to that used by artificial intelligence. These decision-making processes are subjective and do not fall within any legal framework. However, in a manner of speaking clinicians are somehow ''natural artificial intelligence''.

When doctors use antibiotics, they may not fully understand the molecular mechanisms involved that make the drug kill the bacteria. Although it is desirable that the mechanism of action and ''biological plausibility'' are known, if clinical studies with enough numbers of patients shows that the use of antibiotics improves the diagnosis of the patient, using them is completely justified. Fleming did not know how penicillin worked when he started using it. But also, antibiotics can have side effects and even death in very isolated cases. Should we then stop using them?

The excessively rigorous implementation of the regulatory framework in the management of data in clinical studies is already having negative consequences in the progression of conditions like Alzheimer's disease or diabetes[2]. A reasonable regulatory framework would give artificial intelligence the same recognition antibiotics and other drugs have and require the same verification procedures of their safety and efficacy in clinical trials. However, if the use of an artificial intelligence-based algorithm for the management of shock in septic patients would positively improve mortality with fewer side effects in clinical trials, should we stop using it simply because the clinician does not exactly understand how it works? This degree of demand is not applied to other novel therapies especially assuming the human cost associated with living without new therapeutic tools like this one.

Also, progress is being made trying to understand the ''reasoning'' processes behind artificial intelligence-based tools[3] (similar to those used to understand how pencillin broke the bacterial wall) to a point that a few years from now we may be able to understand why algorithms make this or that decision.

Artificial intelligence can be a very useful tool in the coming future and improve our management of critically ill patients. As a matter of fact, it is already being used in other specialties[4]. We hereby recommend not doing a disservice to ourselves with extreme legal arguments of protecting patients who would probably suffer the consequences of certain therapeutic opportunities derived from the use of artificial intelligence taken away from them. With a very demanding legal framework we would still die of pneumonia for not being able to use penicillin.

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