Bird & Bird

Artificial Intelligence Systems for Medical Diagnosis

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The Italian Ministry of Health has published a document on its website entitled "Artificial Intelligence Systems as a Diagnostic Support Tool", which was drawn up by the Superior Council of Health in order to explore the subject of artificial intelligence ("AI") systems applied to medical diagnostics, in the light of the growing spread of AI-based technologies in the healthcare world.

1. Definition of AI

AI is defined as "*software or programmes capable of successfully carrying out, with a greater or lesser degree of autonomy, operations similar to the human activity of learning and decision-making in order to achieve specific objectives, thanks to the use of technologies based on processes of machine learning, deep learning and the use of neural networks programmed to function on the model of the human brain*".[1]

2. Use and regulation of AI for medical diagnosis

AI and related technologies are increasingly widespread in contemporary society and play an increasingly important role, including in the healthcare context.

Currently, AI-based technologies control large imaging equipment (CT scan or MRI), standardising acquisition protocols and reducing examination acquisition times.

Such technologies have the potential to transform many aspects of patient care.

AI is already used as a support diagnostics, for example, in the following circumstances:

- risk prediction and diagnosis of various diseases, especially oncological ones, in their types, features and levels of complexity;
- identification of potential clusters, biomarkers or clinical phenotypes as predictors of risk;
- identification of genomic and molecular elements sensitive to existing or innovative treatments to predict adverse events;
- identification of new associations between diseases and their triggers.

There are, in fact, numerous studies suggesting that AI can anticipate diagnoses, if not improve them, and enable faster, more targeted, and effective patient care.

However, the use of AI systems in an ordinary care setting cannot be done without their scientific validation. Tests and clinical studies are therefore needed to prove, by way of example, that a diagnosis made by an AI system is just as reliable as one made by a specialised physician.

All of this requires the need for rigorous governance by regulatory agencies to enable prior verification of the reliability of such technologies.

[1] Ugo Ruffolo, *L'Intelligenza artificiale in sanità: dispositivi medici, responsabilità e "potenziamento"*, Giurisprudenza Italiana, February 2021

In both the United States of America (US) and the European Union (EU), AI systems applied to the medical sector have been subjected to the rules applicable to medical devices that require their prior authorisation and certification, respectively.

In particular, AI systems with a medical purpose in the US have been subjected to specific regulation by the competent authority, the Food and Drug Administration. In the EU, Regulation (EU) 2017/745 regulates medical devices[2] in general and is also applicable to software with a medical destination (which clearly includes AI systems with diagnostic functions[3]). There was also a new Proposal for a Regulation of the European Parliament and of the Council, presented by the Commission in April 2021, concerning the European approach to AI (the "Proposal for a Regulation").

Under this Proposal for a Regulation, it has been set that human diagnostics and decision support systems, which are increasingly sophisticated, shall necessarily be reliable and accurate.

In fact, although there are many studies whose results seem to provide evidence regarding the reliability of AI systems used in a diagnostic context, there are also some analyses that question the scientific validity and methodology used to obtain such results.

There are those who claim that there are few direct comparative clinical studies, *i.e.* those studies that compare the diagnosis made using an AI or machine learning system with the diagnosis made by a healthcare professional; and that in any case, many of the clinical studies carried out would be retrospective, *i.e.* based on previously acquired data, and not, on the contrary, prospective studies conducted in a “real world” context and based on the randomised controlled clinical trials model.

3. Risks and implications of using AI in healthcare

The Superior Council of Health points out in its document mentioned in the introduction how an uncontrolled development of AI is not without potential risks, arising, for example, from the following aspects:

- from the use of AI systems lacking rigorous scientific validation;
- from possible violations of users' privacy;
- from the unpreparedness of healthcare personnel to use AI systems correctly;
- from discrimination (e.g. race and/or gender) introduced by algorithm programming;
- by the lack of rules on the professional liability of doctors when interacting with algorithms.

The potential risks arising from the use of AI have also been highlighted by the European Commission which:

- in its White Paper on Artificial Intelligence of 19th of February 2020, points out that one of the main problems with the use of AI is the uncertainty regarding the allocation of responsibilities among the various economic operators involved in its development and use;
- in the Proposal for a Regulation, uses the risk factor to distinguish between the various AI systems and regulate their marketing and use.

In particular, the Proposal for a Regulation provides that:

- that the placing on the market of a high-risk AI system is subject to the carrying out of a series of prior checks to ensure the safety of the system, through a conformity assessment (Articles 6-51);
- that high-risk systems are subject to effective and efficient oversight by natural persons when the system is in use (Article 14);

[2] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC

[3] Software that, among other functionalities, allows the use of a patient's personal data for the purpose of detecting contraindications, drug interactions and overdoses, constitutes a medical device as far as that functionality is concerned, even if that software does not act directly in or on the human body, Court of Justice EU, Court of Justice EU, case *Snitem - Syndicat national de l'industrie des technologies medicales,* C-329/16

- that the obligations on operators in the distribution chain (*i.e.* suppliers, importers, distributors, users or other third parties) are proportionate according to their role in relation to the high-risk IA system (Articles 16-29)[4].

The level of risk of AI systems is also taken into consideration by the European Commission when, with reference to AI systems with a specific risk profile, it invites stakeholders to express their views on the possibility of introducing strict liability schemes, to which compulsory insurance could possibly be associated, so as to guarantee compensation for damage regardless of the solvency of the actual responsible party and contribute to reducing the costs of damages. This happened on the occasion of the *Report on the safety and liability implications of Artificial Intelligence, the Internet of Things and robotics* published in 2020.

Lastly, it should be noted that the provisions set out in the Proposal for a Regulation are substantially in line with the recommendations expressed in 2017 by the European Parliament in its Resolution containing "*recommendations to the Commission regarding civil law rules on robotics*" (the "Parliament Resolution"), in which it called on the Commission to draw up a proposal for a Directive aimed at regulating the use of robotics[5] in the healthcare sector.

The recommendations in the Parliament Resolution include, among others, the following:

- there should be no limit on the type or extent of damages that can be compensated;
- liability should be proportional to the level of instruction given to the robot and the degree of the robot's autonomy; thus, the longer the duration of a robot's training and the greater the robot's capacity for autonomy, the greater should be the liability of its trainer (as of today, under the applicable rules, liability should always be attributed to a human being and not to a robot);[6]
- a possible solution to the problem of liability arising from the use of robots could be a compulsory insurance scheme.

4. Conclusions

AI systems have great potential and therefore represent a great opportunity, also in the health sector, including for diagnostic applications.

However, it is necessary to subject such systems to a more specific regulation, which could be based on the rules currently applicable to traditional medical devices, to which additional specific rules should be added to take account of the peculiar risk profiles, and consequently also the liability profiles, of AI systems.

It is suggested, therefore, that practitioners (developers, manufacturers, and users) carefully monitor regulatory developments in order to ensure the compliance of the relevant AI systems and to enable adequate risk management.

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[4] For example, the supplier is obliged to ensure that high-risk AI systems comply with the requirements of the Draft Regulation and is obliged to draw up the technical documentation of this system (Art. 16); whereas, under Art. 27, it is the responsibility of the distributor to verify that "*high-risk AI system bears the required CE conformity marking, that it is accompanied by the required documentation and instruction of use, and that the provider and the importer of the system, as applicable, have complied with the obligations*".

[5] AI is one of several robotic technologies that are used, for example, in production systems, to automatically manage processes that would otherwise have to be handled by people, but without the benefits that these technological systems are able to provide, such as greater safety, reduced time, greater control. AI therefore not only replicates the functions of the human mind, but thanks to robotics is able to improve and increase its capabilities and potential.

[6] Paragraph 56 of the Parliamentary Resolution reads as follows: "*considers that, in principle, once the parties bearing the ultimate responsibility have been identified, their liability should be proportional to the actual level of instructions given to the robot and of its degree of autonomy, so that the greater a robot's learning capability or autonomy, and the longer a robot's training, the greater the responsibility of its trainer should be; notes, in particular, that skills resulting from "training" given to a robot should be not confused with skills depending strictly on its self-learning abilities when seeking to identify the person to whom the robot's harmful behaviour is actually attributable; notes that at least at the present stage the responsibility must lie with a human and not a robot*."

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