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Artificial Intelligence and Self-determination in Medical Field

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Abstract

The use of artificial intelligence in medicine raises many legal issues. This essay examines how medical AI intersects with the right to informed consent and the principle of self-determination. The author highlights that the complexity and opacity of machine learning could dissuade the patient from consenting AI treatment and, therefore, induce him to give up the benefits that this technology usually brings to his health. Consequently, the author suggests adjusting the content of the information due to the patient, taking into account the limited knowledge that ordinary people have about artificial intelligence, and, more generally, redefining the boundaries of the principle of informed consent.

Keywords: artificial intelligence; machine learning; self-determination; informed consent; data protection.

1. Introduction.

Every generation of legal experts has had to perform the task of investigating the effects that the advent of new technology has had on one or more areas of application of the law. For example: the generation of the early twentieth century investigated the changes brought by the motorization of road traffic on tort law, the generation of the last part of twentieth century had to investigate the impact of digitalization on the format of contracts, as well as the violation of copyright law. The current generation, on the other hand, has had to study the extraordinary changes, both positive and negative, that the development of artificial intelligence (henceforth, AI[1]) seems capable of causing within every area of law. One of the areas most affected by the progress of AI is health law, owing to the success that AI devices have had in the medical field. As a matter of fact, synergy between humans and AI systems bring important benefits to the guarantee of the right to health, with respect to the right to obtain high standards of medical care and adequate therapeutic treatments.

As the European Parliament highlighted in two Resolutions on AI and civil law,[2] and as the EU Commission restated in the "White Paper on Artificial Intelligence",[3] AI medical tools are particularly suitable for carrying out high-precision surgical procedures (such as, for example, analysis of exams, radiographs and CT scans), or even carry out personalized assistance tasks (such as, for example, the so-called continuous glucose monitoring system, which measures the glucose level continuously throughout the day, and also predicts the progress glycemic rate in diabetic patients). The Resolutions and the White Paper also stressed that when AI supports diagnostic decisions of the physicians, diagnostic times, costs and medical errors significantly decrease.

1 It is worthy of being highlighted that, both in common speech and specialistic language, there are many definitions of AI: see A Bertolini, *Artificial Intelligence and Civil Liability. Bruxelles* (European Parliament, 2020, Committee on Legal Affairs) 15 ff. In this essay AI will mainly mean branch of computer science that studies and reproduces mechanisms of human intelligence, using self-learning techniques and their applications. Even the "Proposal of the European Parliament and of the Council laying down harmonized rules on artificial intelligence (artificial intelligence act) and amending certain union legislative act", which was adopted on 21st April 2021 (henceforth, Artificial Intelligence Act Proposal or, more briefly, Proposal), addresses the issue of how to describe adequately AI technology. Indeed, the 6th recital argues that, 'The notion of AI system should be clearly defined to ensure legal certainty, while providing the flexibility to accommodate future technological developments', and the art. 3, n. 1, of the Proposal states that, 'artificial intelligence system […] means software that is developed with one or more of the techniques and approaches listed in Annex I and can, for a given set of human-defined objectives, generate outputs such as content, predictions, recommendations, or decisions influencing the environments they interact with.'

2 European Parliament Resolution of 16 February 2017 with recommendations to the Commission on Civil Law Rules on Robotics and European Parliament Resolution of 12 February 2019 on comprehensive European Industrial Policy on Artificial Intelligence and Robotics.

3 White Paper on Artificial Intelligence. A European approach to excellence and trust (19th February 2020).

Moreover, the recent Artificial Intelligence Act Proposal[4] explains that, 'By improving prediction, optimising operations and resource allocation, and personalising service delivery', the use of AI in the High-Impact Sector (for example, the medical sector), 'can support socially and environmentally beneficial outcomes and provide key competitive advantages to companies and the European economy.' In particular, the usage of robotics and AI could bring further advantages in terms of economic savings to health care, thus allowing the allocation of more money for prevention strategies and biomedical research. As it is widely known, biomedical research is becoming more and more efficient because of the support provided by AI techniques.

The benefits in medical treatments and scientific developments, as mentioned in previous paragraphs, are however accompanied by empirical risks, technical complexity, ethical concerns and therefore legal issues. As is sometimes the case, new problems emerging from the use of AI in healthcare require the implementation of new rules by the legislator; this is for cases where intelligent medical devices have caused damage during routine procedures carried out autonomously by these devices, thus creating problems as current liability law doesn't cover these new aspects of AI. Furthermore, the issues raised by medical AI at the moment only require the adjustment of existing rules or principles; it is not a legal requirement to write new laws for AI at this time. This is likely the case of the several problems that appear when the pitfalls related to development and use of AI in the medical sector intersects with the right of self-determination.

In this article I am going to demonstrate the issue raised in the previous sentence. Specifically, in the next three paragraphs I am going to determine if and to what extent AI's involvement in treatment should be disclosed to the patient under the current regulation and doctrine of informed consent. In the fourth paragraph I will consider the difficulty in processing the large amount of data necessary for the development of AI medical systems in compliance with the requirements imposed by the General Data Protection Regulation (GDPR) to protect the right of natural persons to control the use of their personal data. In the last paragraph I will consider some scenarios that could arise in the near future and I will present my final considerations.

2. Legal issues of informed consent with regards to AI in healthcare.

As I anticipated in the introduction, the medical applications of AI brings not only many important benefits in terms of efficacy and accuracy of treatment[5] and in terms of safety and timeliness of diagnosis,[6] but also raises certain concerns.

First of all, it is necessary to consider the difficulty of humans to understand

4 The Proposal classifies applications of AI in healthcare among the, 'High-risk AI systems': see article 6.1 and annex II.

5 See, for example, R Tregunna, 'Artificial intelligence for intrarenal access' [2021] Nat Rev Urol18 ff.

6 See, for example, S Goto, K Mahara, L Beussink-Nelson and others, 'Artificial intelligence-enabled fully automated detection of cardiac amyloidosis using electrocardiograms and echocardiograms' [2021] Nat Commun 2726 ff.; A Rao, H Fishman, 'Accessible artificial intelligence for ophthalmologists' [2022] Eye.

and explain how AI technology works. The so-called 'opacity' of AI[7] depends on the right of intellectually property, but also on the complexity of the computational language and on the machine learning methods (ML); on which the development and the functioning of the so-called autonomous systems are based on. In particular, ML gives rise to the black box problem. By looking at the source code, programmers and experts are able to understand the logic of the system, the algorithm architecture used and the structure of the data set. However, not even the designers of the intelligent machine fully understand how it works and arrives at individual and concrete outputs.[8]

The lack of transparency or even inscrutability of AI leads to some further questions. Therefore, the doctor could blindly rely on the diagnostic or therapeutic solution suggested by the machine, refraining from making critical assessments and, if necessary, independent choices.[9] Moreover, because of the opacity of AI technology, the doctor could be prevented from providing the patient with a clear and reliable diagnosis and consequent therapy, by which the patient may be able to rationally come to a self-determined decision about their treatment.[10] There is a serious danger that the patient will know that AI medical technology will be used in the course of treatment but will not understand how the technology works. They therefore will make their decision about treatment based on a lack of understanding of the technology involved, or even more worrying on a preconceived opinion or, sometimes, even fear[11] of technology in general.

In the development and practical use of AI there are also some negative factors that could inhibit the success of the treatment. First, there is the risk that AI-based machines could contain cognitive biases that have been trained on a set of data that is not sufficiently representative and, therefore, not fully suitable for carrying out the task for which the system was created.[12] To give a hypothetical example an AI medical device could be used in the diagnosis of breast cancer, which has been developed using a training data set made up only of Caucasian women, although they have a breast density which is different from that of African American women. As a result, the algorithm is likely to give information that is less reliable for the African American population.

Secondly, there is the issue of the ethical lack of AI and, therefore, the inability of intelligent devices to make ethical decisions which frequently occur in the medical field. For example, the decision whether to perform surgery on a young

7 Article 13 of the Artificial Intelligence Act Proposal states that, 'High-risk AI systems shall be designed and developed in such a way to ensure that their operation is sufficiently transparent to enable users to interpret the system's output and use it appropriately.'

8 On the black box problem see: F Pasquale, *The Black Box Society: The Secret Algorithms that Control Money and Information* (Harvard University Press 2015); W Nicholson Price II, 'Black-box Medicine' [2015] Harv. J L. & Tech. 419 ff.; Id, 'Regulating Black-box Medicine' [2017], in Mich. L. Rev. 421 ff.; P Vogel, 'A "right to explanation" for algorithmic decisions', in A Santosuosso, G Pinotti, *Data-Driven Decision Making. Law, Ethics, Robotics, Health* (Pavia University Press 2019) 50; C A Tschider, 'Beyond the "Black Box"' [2021] Denv. L. Rev. 683 ff.; K Astromske, E PeiČius P. Amstromkis, 'Ethical and Legal Challenges of Informed Consent Applying Artificial Intelligence in Medical Diagnostic Consultations' [2021] AI Soc. 512.

9 Comitato Nazionale per la Bioetica, Report 'Intelligenza artificiale e medicina: aspetti etici' (2020) 11; Astromske, PeiČius, Amstromkis, 'Ethical and Legal Challenges of Informed Consent' (n 8) 514.

10 D Schiff, J Borenstein, 'How should clinicians communicate with patients about the roles of artificially intelligent team members?' [2019] AMA J. Ethics 139 f.

11 P Costa, 'Cosa ci spaventa dell'intelligenza artificiale?' (2021) 1 BioLaw J. 303 ff.

12 See article 10, par. 2 and 3, of the Artificial Intelligence Act Proposal. See also S Scalzini, 'Alcune questioni a proposito di algoritmi, dati, etica e ricerca' [2019] Riv. it. med. leg. 169 ff.

woman suffering from a malignant neoplasm of the genitalia, either a radical dissection which could save her life, but will prevent her from having children, or to carry out a more standard operation which will not prevent her from having children but that may not save her life.

Finally, it must be considered that the use of AI medical tools decreases but does not eliminate the risk of adverse events that could be harmful for the patient's health; indeed, sometimes, exceptional failures of such devices could damage the patient's health and could lead in some cases to death. This could happen, for example, if a hospital's IT system is hacked causing the sudden arrest of the robot at the most critical moment of an operation in which time is the most important factor.[13]

In the light of the framework outlined above, many questions are raised with regards to medical AI and informed consent.

First of all, if the doctors chose to conceal the use of AI during diagnostic consultation or during treatment, are they violating the patient's right to informed consent? Secondly, to what extent should the patient be informed about their treatment with respect to medical AI? Is it sufficient to give the patient a generic description of AI technology and its benefits, or is it also necessary to fully disclose all the risks? In particular, must the doctor communicate the possibility, however miniscule, of a system malfunction? Is it correct to expect the doctor to explain to the patient fully how AI medical systems work, to the extent that the patient can give a truly 'informed consent'? Finally, if the medical device auto updates its algorithms and is self-learning and is therefore not under the control of the developer, is the doctor obligated to inform this to the patient?

The questions raised in the previous paragraph have so far received surprisingly little attention in the Italian literature and have not given rise to any debate at the time of writing. Indeed, opinions expressed in this regard are few and are all concerned with upholding the doctrine of informed consent in the wake of the advancement of AI technology and, therefore, in support of enclosing every details of medical AI involvement to the patient.[14]

The overview is a bit different in the United States where, as it is well known, both the doctrine of informed consent[15] and the science of AI are studied much more widely and have been so much longer than in Italy. In fact, in American literature there are still only a few studies on the intersection between medical AI and informed consent but they do have certain mitigating circumstances in America which relieve the doctor of the onus of explaining to the patient the full details of the treatment; something that we do not have in Italy.

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13 To prevent similar accidents the Artificial Intelligence Act Proposal states that high-risk AI should, '… be designed in such a way that they achieve, in the light of their intended purpose, an appropriate level of accuracy, robustness and cybersecurity, and perform consistently in those respects throughout their lifecycle': see art. 15, par. 1.

14 R Messinetti, 'La tutela della persona umana versus l'intelligenza artificiale. Potere decisionale dell'apparato tecnologico e diritto alla spiegazione della decisione automatizzata' (2019) 3 Contr. impr. 861 f.; C Casonato, L Violante, 'Forum: AI and Law' (2020) 1 BioLaw J. 463 ff.; E Tozzi, G Cinelli, 'Informed consent and artificial intelligence' [2021] BioLaw J. Special Issue 106 ff.

15 The informed consent doctrine was expressly stated in *Salgo v Leland Stanford Jr University Board of Trustees* [1957] 154 Cal. App. 2d 560, 317 P.2d 170. However, a duty to tell the patient, '… what is about to done to him …' e duty to obtain the consent was already recognized in *Slater v Baker and Stapleton* [1767] 95 Eng. Rep. 860, 2 Wils. K.B. 359.

In particular, a recent article[16] says that common law exempts the physician from explaining to the patients all the complicated elements, which a doctor has studied in the course of their professional training and in the course of their career; for example: university studies, further academic reading, participation in top up courses etc. These form the basis of decisions, both diagnostic and with respect to treatment, that the doctor must make. Therefore, the article concludes that the doctor could be allowed to conceal the use of AI, all the more so because the opacity of this technology would risk inducing most patients to reject it and, thus, all the benefits it entails.

3. The regulatory framework.

Moving on to the Italian legal system, we need to determine whether to disclose the involvement of AI/ML in medical treatment to the patient and how much to disclose, under Italian informed consent law.

This consists of articles 2, 13 and 32 of the Italian Constitution and article 3, second paragraph, of the EU Charter of Fundamental Rights and articles 1-3 of the Law No. 219/2017 (which is the specific legislation on informed consent and advance directives). In addition to these, there are articles 16 and 33-39 of the Code of Medical Ethics[17] (approved in 2014 and modified later) and in addition, case law. In this matter, legal sources are organized on a basis of sharing rather than on a basis of status.[18] It is well known that the informed consent principle was formerly expressed in international documents,[19] therefore, established by the Codes of Medical Ethics;[20] and subsequently was accepted and reinforced by the courts on the basis of the Constitution;[21] and at the end of this process, was laid down in ordinary legislation which, due to complexity and mutability of the matter involved, still needs to be specified and integrated with other sources.[22] This is also true for the questions arising from the use of AI systems in medical diagnosis and treatment.

The article number 1 of Law No. 219/2017, paragraph number 1, presents the principle of free and informed consent and in paragraph number 3 describes what information must be conveyed to the patient and the way in which it should be conveyed. In this description, the legislator simply acknowledged some of requirements that our courts had already previously identified on the basis of

16 G Cohen, 'Informed Consent and Medical Artificial Intelligence: What to Tell the Patient' [2020] Geo. L. J. 1432 ff.

17 On the binding value of the Code, see Cass., sez. un., 20th December 2007, n. 26810, in Foro it., 2009, 3167; and, even previously, E Quadri,' Il codice deontologico medico nei rapporti tra etica e diritto' (2002) 4-5 Resp. civ. prev. 925 ff.

18 As V Calderai, 'Consenso informato', *Enciclopedia del diritto*, *Annali* VIII (Giuffrè, 2015) 233, well explains.

19 World Medical Organization, Declaration of Helsinky, Ethical Principles for Medical Research Involving Human Subjects (1964); United Nations, International Covenant on Civil and Political Rights (1976); and Oviedo Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine (1997).

20 Firstly by Codes of Medical Ethics (1995).

21 Cass. pen., 21st April 1992, n. 5639, in Cass. pen., 1991, 1333.

22 As A Nicolussi, 'Al limite della vita: rifiuto e rinuncia ai trattamenti sanitari' [2010] Quad. cost. 274 f., clearly explains.

general principles and other legal sources.[23] These rules do not clarify whether it is the duty of the doctor to inform or indeed not to inform the patient or to what extent to inform the patient that the treatment involves these computational methods and related exceptional risks.

The letter of the third paragraph of article number 1 of the Law No. 219/2017, does not indicate clearly if the doctor is obligated at all to communicate to their patient the devices and techniques which will be involved in their treatment. The rule establishes that the doctor must inform the patient about 'diagnosis' and 'prognosis'; terms which are ambiguous in their scope; do they refer only to the results of those particular activities, or do they also refer to the operating methods. Furthermore, the law says that the information must include the, '(…) benefits and the risks (…) related to the medical treatment', without clarifying if the patient must be warned about only the foreseeable risks, or about the unforeseeable risks also. These doubts unfortunately are not reduced by considering the adjectives which the legislator uses in describing the characteristics of the information that must be conveyed to the patient. Indeed, the adjective, 'complete' seems to suggest full disclosure, whereas the adjective, 'comprehensible' seems to suggest selecting the information on the basis of patient's cognitive and rational skills.

The aforementioned confirms the need to refer to other sources, these however do not specifically answer the questions arising from the diffusion of AI in the medical field but do provide ideas on which we can reflect in order to suggest a balanced and reasonable solution.

Firstly, the sources which generated the doctrine of informed consent, in the absence of ordinary legislation, remind us that the patient's self-determination is an essential basis of the medical relationship; yet this does not constitute its sole and exclusive role in the aforementioned relationship.

Therefore, on the one hand, there is no doubt that article number 32, read in conjunction with articles number 2 and 13, of the Italian Constitution represents a cornerstone of the constitutional matrix of informed consent. However, on the other hand, article 32 also requires the medical relationship to be based on the right to individual and collective health and, therefore, on the correlative duty to treat the patient. In spite of this, the majority of Italian jurists perceive the right to health protected by the Constitution as an individual right equal to that of the right to self-determination.[24]

This theory, which reduces healthcare to the basis of will (i.e. self-determination), has been argued from the spiritual notion of the former given by the World Health Organization. According to them, 'Health is a state of complete physical, mental, and social well-being and not merely the absence of disease or infirmity'.[25] In addition, the common interpretation of the constitutional right to

23 S Cacace, 'La nuova legge in materia di consenso informato e DAT: a proposito di volontà e di cura e di comunicazione' [2018] Riv. it. med. leg. 935 ff.

24 P Zatti, 'Rapporto medico-paziente e «integrità» della persona' (2008) 12 NGCC 403 ff.; E Rossi, 'Profili giuridici del consenso informato: i fondamenti costituzionali e gli ambiti di applicazione' [2011] Riv. AIC 5 ff.; I Rapisarda, 'Consenso informato e autodeterminazione terapeutica' (2019) 1 NGCC 43 ff.; L Chieffi, *Il diritto all'autodeterminazione terapeutica. Origine ed evoluzione di un valore costituzionale* (Giappichelli, 2019) 99 f.; Corte cost., 22nd June 1990, n. 307, at www.cortecostituzionale.it; Trib. Milano 14 maggio 1998, in NGCC, 2000, 92 ff.

25 See Constitution of World Health Organization (22.7.1946-7.4.1948), 2.

health has been justified by a reasoning which underestimates or even ignores the social relevance of the legal protection of personal rights. Because of the mainstream, the patient's self-determination appears to be an absolute power that has neither limits nor any substance and, therefore, the doctor seems to have a duty to provide them as much information as possible.[26]

In considering this theory, there are some authors who dissent from the majority and deem that the patient's right to health is broader in sense than that of right to self-determination.[27] The opinion of this minority is based on a more complete reading of article number 32 of the Italian Constitution. By reading this article in its entirety and in considering its constitutional context it becomes clear that the right to health is closely related to the values of human dignity (art. 32, 2nd par.) and the duty of solidarity (art. 32, 1st par.; and art. 2) and, consequently, has a scope that goes beyond the patient's personal sphere and also affects public protection of health and social function of medical activity.

In connection with these further aspects, the right to health takes on an autonomous meaning and can serve to limit and shape the right to informed consent. In this way, self-determination regains its substance with regards to mental and physical well-being, as well as the competences of the doctor as a guide, and the patient's weaknesses as a limit. Instead, if (in accordance with the majority) the medical relationship were based only on the patient's will, the medical relationship would become purely "contractual", and therefore the effectiveness of the patient's right to self-determination could be potentially compromised.

This has been demonstrated in other legal contexts (for example labour law, consumer law, banking and financial market law) in which the freedom to choose can be diminished because of the weak negotiating position of a contracting party and consequently some precautions are necessary.[28] For example, rules that adjust the quality and the amount of information on the particular condition of the fragile party, who may be confused by an explanation which is too detailed.[29]

A similar risk has been perceived also by some judges during rulings on self-determination in healthcare. Indeed, Italian courts sometimes consider it necessary to diminish, to a certain extent the amount, of information to be provided to the patient. This is because of their vulnerability and in order to safeguard their health. For instance, several judgments state that doctors must inform the patient about the normal associated risks of treatment but they must not communicate abnormal and / or remote risks, which don't normally occur in the course of standard treatment.[30] The rationale of this rule is well explained by

26 As A Carminati, *Libertà di cura e autonomia del medico. Profili costituzionali* (Cacucci, 2018) 26 ff., highlights.

27 Nicolussi, 'Al limite della vita' (n 22) 275 ss.; F D Busnelli, 'Problemi giuridici di fine vita tra natura e artificio' (2011) 1 Riv. dir. civ. 161 ff.; A Nicolussi, 'Testamento biologico e problemi del fine-vita: verso un bilanciamento di valori o un nuovo dogma della volontà?' [2013] Eur. dir. priv. 457 ff.; G Razzano, *La legge n. 219/2017 su consenso informato e DAT fra libertà di cura e rischio di innesti eutanasici* (Giappichelli, 2019) 20 ff.

28 Nicolussi, 'Al limite della vita' (n 22) 294 f.; L Eusebi, 'Note sui disegni di legge concernenti il consenso informato e le dichiarazioni di volontà anticipate nei trattamenti sanitari' [2006] Criminalia 253.

29 See R Costi, *Il mercato mobiliare* (11th edn., Giappichelli 2018) 56, with regards to public offer of financial products.

30 Cass., 20th May 2016, n. 10414; Cass., 11th December 2013, n. 27751; Cass., 30th July 2004, n. 14638, in Resp. civ. prev., 2007, 688; App. Bologna, 2nd February 2006; Trib. Milano, 28th January 2020.

some courts, saying that to communicate in addition to the normal risks, abnormal and/or remote risks could instill in the patient an unjustified amount of fear which could discourage them from giving permission for treatment which is both safe and standard in modern medical practice.[31] Therefore, in case law we have this idea of quantity versus quality i.e. that the quality of information provided to the patient is more important than the quantity of information. there is the idea of quantity and quality of information.

Thus, the doctor must provide information to the patient, but this should be regulated on the basis of the emotional state and cognitive skills of the patient and, therefore, the quantity of information provided could be reduced based on this principle. Considering the quality of information over the quantity will in fact enable the patient's recovery rather than hindering it. The same idea is expressed by article 33 of the Code of Medical Ethics which states that the doctor must always communicate to the patient whilst being fully aware at all times of their mental competence and emotional sensitivity.

It would be wrong, therefore, to suppose that such a rule and the aforementioned judgments are based on Hippocratic privilege or the paternalistic concept of the medical relationship.[32] Indeed, the case law and the Code of Medical Ethics carry out a 'synthesis of concurrent interests';[33] on the one hand there is the patient's informed consent and on the other the doctor's duties and the patient's health. It is better to talk about synthesis instead of balancing because such rules do not intend to restrict the former right of informed consent in order to extend the protection of the patient's health but merely to take into account the inherent limits to the principle of informed consent. Cognitive psychology research shows that the patient's vulnerability and potential lack of comprehension significantly limit their ability to understand the dynamics of the treatment, assess costs and benefits and therefore make rational choices. In such conditions, as Professor Calderai states, 'multiplying the information would be like trying to put out a fire by throwing petrol on it.' Instead, it would be more appropriate to create '(…) communication and decision-making contexts in which it is possible to select information in relation to its relevance and comprehensibility (…)'.[34] In short, the patient's weaknesses in this context suggest that a realistic approach to the data aimed at medical consent would be preferable. In particular, the choice of communicating technical details should be at the discretion of the doctor, who should be permitted to make choices based on reasonableness.[35] Therefore, the doctor makes a decision that does not adhere ideologically to only one of the contrasting values: self-determination and health. Instead, the doctor makes their decision weighing up the patient's right to self-determination against that of their health requirements in that specific moment. Such an approach is necessary to prevent the outcome of the communication of too much information thus affecting both the patient's self-determination and health.

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31 Cass., 30th July 2004, n. 14638, ibid; Trib. Bologna, 8th August 2005. See also M Foglia, *Consenso e cura. La solidarietà nel rapporto terapeutico* (Giappichelli, 2018) 69.

32 See G Azzoni, 'Il consenso informato: genesi, evoluzione, fondamenti', in G Viafora, A Gaiani, *A lezione di bioetica. Temi e strumenti* (Franco Angeli, 2015) 172 ff., with regards to the evolution of the relationship between doctors and patients.

33 Corte cost., 23rd December 2008, n. 438, in Foro it., 2009,1328.

34 Calderai, 'Consenso informato' (n 18) 238.

35 G Criscuoli, 'Ragionevolezza e consenso informato del paziente' [1985] Rass. dir. civ. 486.

4. A realistic approach?

In answering the questions previously asked in the second paragraph, it is possible to deduce that if the doctor were to conceal the involvement of technology in the treatment, on the basis of a diligent evaluation of their patient, they would not be violating the principle of informed consent. This conclusion has been arrived at using the current regulatory framework and seems to remain valid even in the face of future developments that could affect the legislation on AI applications in healthcare in the future. The first paragraph of article 52 of the Artificial Intelligence Act Proposal establishes some, 'Transparency obligations for certain AI systems,' and, in particular, states that '(…) providers shall ensure that AI systems intended to interact with natural persons are designed and developed in such a way that natural persons are informed that they are interacting with an AI system.' However, this provision seems to impose a duty on the providers to inform the doctor (i.e., the subject who interact with AI system) about the interaction with AI system and therefore it is not a duty of the doctor to inform the patient (i.e., the subject who undergoes the interaction between doctor and AI system).

Instead, the statement made at the beginning must be adjusted to meet specific features that the situation in front of the doctor may present, primarily, to the scenario in which the patient asks specific questions regarding the type of instruments used in the diagnosis or treatment.[36] It is well established that the duty to satisfy the patient's curiosity is more restrictive than the duty to inform them because a lie is generally more serious than silence and also because specific questions could be a sign of rationality and competence. For example, it has been argued that the doctor is not obligated to communicate the statistics of the hospital in which they work, the accidents occurred during treatment, and abnormal and/or remote risks of the treatment to be performed. However, such information should be given to the patient only and specifically if they ask for it. In the same way, the doctor is obligated to answer all questions that the patient has with regards to instruments involved in their treatment and therefore potentially any questions regarding the use of robots or AI devices as well. Furthermore, depending on the type of treatment it may be necessary to include the instruments and technology that will be used in the information pack given to the patient. This in particular is true for the field of cosmetic surgery,[37] where it is the rule to communicate more comprehensively to the patient the facts of the treatment and the instruments involved. This is because the treatment is aimed at improving the patient's physical appearance or certain functions, rather than safeguarding their life or health.[38]

The third and final example in which the use and consequences of using

36 See M Graziadei, 'Il consenso informato e i suoi limiti', in S Rodotà, P Zatti, *Trattato di Biodiritto* (Giuffrè 2011) 254 f.; M G Di Pentima, *Il consenso informato e le disposizioni anticipate di trattamento. Commento alla l. n. 219/2017* (Giuffrè 2018) 63.; Foglia, *Consenso e cura* (n 31) 66.

37 Specifically, when the cosmetic surgery is only aimed at improving physical appearance: I Pizzimenti, 'Il diritto di conoscere o non conoscere il proprio stato di salute: modalità e contenuto dell'informazione' (2019) 1 NGCC 75.

38 Cass. 6th October 1997, n. 9705, in Resp. civ. prev., 1998, 667.

medical AI must be communicated to the patient is when they use such devices in their own home. In this case, the information must include simplified explanations of how the instruments work. However, it is necessary to remember that the doctor often does not have the necessary skills to explain how the AI devices work in full detail.[39] Moreover, the doctor cannot involve an engineer in the process of informing the patient[40] because of Article 1, Second paragraph, of the Law No. 219/2017 which states that the duty to inform the patient cannot be delegated to non-medically qualified professionals. To bypass this question, it can be assumed that the patient has a right to informed of the use of all technology involved in their treatment, however, only in the public health service. This is according to the changes made recently to the Italian rules on telemedicine for all cases in which medical diagnosis and/ or treatment is made online.[41]

Firstly, based on what was written in the previous paragraph, it could be possible to deny that the doctor, finding themself in one of the situations that requires them to communicate to the patient the use of AI in treatment, doesn't have to clarify the technicalities (i.e., algorithms and data mining) on which the development and the operation of such devices is based on.[42] In fact, the doctor does not have the competence that would be needed for the purpose of an in-depth explanation and indeed the patient cannot have the training and the experience that is necessary for a full comprehension of all that is involved in the procedure. Therefore, the doctor fulfills the obligation to inform their patient about AI, providing a generic but understandable description (given the patient's capacities) of the technology involved in the treatment and presenting the benefits and limits that it normally entails. Instead, in order to avoid refusal of permission caused by unjustified fears on the patient's part, the doctor should conceal the unforeseeable risks; namely, the remote possibility that a breakdown of the device or software could cause injury to the patient's health. With this same rationale as a basis, it could be argued that the doctor should also refrain from explaining to the patient that the devices used in treatment operate using self-learning methods and, therefore, are not fully intelligible to humans, and indeed not infallible. Indeed, as it has been observed, to communicate opaque elements to the patient could compromise the relationship of trust between them and the doctor, and induce the patient to refuse also other therapeutical options.[43] Instead, it is always convenient to inform the patient that the AI system involved in the treatment can be effectively overseen by the doctor, who can tackle potential problems which occur in the system in real time.[44]

39 Comitato Nazionale per la Bioetica, Report "Intelligenza artificiale e medicina: aspetti etici" (29th May 2020), 15.

40 As Astromske, PeiČius, Amstromkis, 'Ethical and Legal Challenges of Informed Consent' (n 8) 516 suggest.

41 See Italian Ministry of Health, National Guidelines for Telemedicine (27th May 2020), 13.

42 The doctor is not obligated to provide an *ex post* explanation, yet an *ex ante* explanation could be deemed sufficient: U Pagallo, 'Algo-Rythms and the Beat of the Legal Drum' [2017] Philos. & Technol. 515.

43 Astromske, PeiČius, Amstromkis, 'Ethical and Legal Challenges of Informed Consent' (n 8) 521.

44 If Artificial Intelligence Act Proposal were approved, human oversight would be juridically binding (see art. 14 of the proposal).

5. Personal data for health and AI.

The field of self-determination with regards to health involves not only the principle of informed consent to treatment but also the consent which should be given for the purpose of processing personal data. The development of AI could cause some issues also with regard to the second area of law.

Firstly, AI technology represents a factor that exposes privacy to new potentially harmful situations. This is because the creation of predictive models is carried out through intensive data research, that is to say, research which requires a large amount of data.[45] Therefore, Evidence-Based Medicine (EBM) makes use of a volume of data which can be measured in megabytes or gigabytes, whereas the development of AI medical devices requires a size of data which can be quantified in terabytes or petabytes and extrapolated from a very large sample.[46] Moreover, AI systems make it possible to collect large amounts of data in a short period of time. Therefore, the EBM is an empirical approach based on a few clinical cases, whereas AI allows the analysis of data drawn from a wide range of sources: electronic health records, medical devices that measure biological variables (the so called Internet of Medical Things: IoMT), genomic banks, social networks and internet browsers.[47] Finally, it should be noted that the logic of Big Data and machine learning techniques facilitate the re-identification of data originally anonymized; and furthermore, they facilitate the creation of derived personal data.[48] This second problem has given rise to an intense debate in the United States, where Ascension - a healthcare giant that consists of two thousand six hundred medical facilities, including over one hundred and fifty hospitals - sold health data relating to millions of patients to Google, with the aim of allowing the latter to develop a software that enables its healthcare professionals to collaborate in real time and improve the quality and effectiveness of care. This has caused concerns that Google may use its experience in data mining to cross-reference the information obtained with that collected from its users and, thus, obtain new personal data relating to them.

For the reasons explained above AI technology represents an essentially antagonistic element with respect to the protection of the right the collection and processing of people's personal data. However, the Big Data applications seem to bring many advantages with respect to the protection of individual and public health. As we have already highlighted, these applications are involved in medical diagnostics and treatment in a way that is both useful and helpful to the patient. Moreover, as covid-19 pandemic experience has been showing, Big Data and computational methods improve the efficiency of pharmacological research and enable the developing of contact tracing systems.[49]

Therefore, the arrival of AI raises a potential conflict between individual self-determination and other fundamental interests not only in the area of physical

45 G Comandè, 'Ricerca in sanità e data protection: un puzzle … risolvibile' [2019] Riv. med. leg. 187.
46 N Musacchio, G Guaita, A Ozzello, and others, 'Intelligenza artificiale e Big Data in ambito medico: prospettive, opportunità, criticità' [2018] J AMD 214.
47 Ibid.
48 T Sharon, 'Data- driven Decision Making, AI and the Googlization of Health Research', in Santosuosso, Pinotti, *Data-Driven Decision Making* (n 8) 42; C Colapietro, A Moretti, 'L'intelligenza Artificiale nel dettato costituzionale: opportunità, incertezze e tutela dei dati personali' (2020) 3 BioLaw J. 377.
49 A Santosuosso, S Azzini, *La giusta distanza. Le nostre libertà dopo Covid-19* (Mondadori, 2020) 76 ff.

body management but also in the field of controlling the 'electronic body'.[50] This conflict cannot always be resolved in favor of individual self-determination when its presumed superiority in the hierarchy of values is taken into consideration in the resolution process.[51] In the field of data protection, the conflict between self-determination and health appears in less direct and final terms than what usually happens in the context of the therapeutic relationship. This is because the refusal by the data subject to give permission for the collecting and processing of their personal data does not immediately harm either their health or that of the collective. Therefore, it seems reasonable to argue that, at least in principle, the data subject should be fully informed of the computational methods involved in the treatment of their personal data.[52] However, in both areas the actual realization of the self-determination principle faces some empirical difficulties due to specific characteristics of AI technology. Secrecy, complexity and sometimes inscrutability of AI systems are factors which prevent the data subject from fully understanding how their personal data will be used, therefore the consent given to the computational treatment is never true consent and consequently the implementation of the right to self-determination cannot ever be fully effective.

A problem, which occurs only in the field of data protection regulation with regards to AI, concerns the need of identifying the purposes for which the treatment is carried out. The first paragraph of article number 6 of the GDPR states that the consent must be given by the data subject, 'to the processing of his or her personal data for one or more specific purposes'. In addition, the second paragraph of article n. 9 repeats the same rule with regards to, '(…) special categories of personal data (…)' for example '(…) data concerning health.' However, in the course of the development of AI software the purposes of data processing are not always fully predictable because the system learns and evolves autonomously.[53] Moreover, even when the purpose of the data processing is fully known to the designer of the AI system, it could be necessary to use large amounts of personal information which has been collected on the basis of consent given by data subject for purposes other than development of the AI system. An example of this is EyeArt, an AI software capable of detecting serious eye diseases in diabetic patients with a degree of accuracy of approximately 95%. To develop this AI system, it was necessary to analyze and classify a large database of health data which had been collected from people located in different geographical areas of the world for medical diagnosis or treatment purposes; therefore, for purposes other than the implementation of an intelligent screening system. It is clear that a re-use of personal data such as this could not realistically proceed through a new interrogation of all data subjects. Therefore, the re-use of health data should be permitted without requesting a new expression of consent.

In addition, computational methods and, particularly, deep learning methods could obstruct the data subject in exercising the right to withdraw the consent at any time and this right is one of the specific conditions fixed by the third paragraph of article n. 7 GDPR with regards to the treatment legally based on self-

[50] Expression coined by S Rodotà, *La vita e le regole. Tra diritto e non diritto* (Feltrinelli, 2006) 81.
51 See: rec. n. 4 GDPR.
52 See: Cass., ord. 25th May 2021, n. 14381, at www.leggiditalia.it.
53 See G Olivi, 'Big data, metadati e intelligenza artificiale' [2020] Dir. ind. 181.

determination.

Most of the critical issues highlighted above do indeed arise whenever the consent of the data subject serves as a legal basis for processing personal information in scientific research, regardless of the methods by which it is carried out.[54]

In consideration of such set of problems, the European legislator has paved the way for the processing of personal data justified by legal grounds other than the consent of the data subject. Specifically, the second paragraph of article number 9, GDPR allows for the processing of sensitive data for, '(…) reasons of public interests in the area of public health (…)', '(…) scientific research purposes (…)' and '(…) statistical purposes (…)' (see Lett. I & J, GDPR), aside from the explicit consent of the data subject.

Nevertheless, even with the reference to the processing of data based on one of the grounds mentioned above, the European legislator has established certain legal requirements which computational techniques cannot adhere to. Consequently, even when Big Data and AI applications are developed for scientific research or public health purposes, these types of technology will not be able to fully comply with privacy legislation.[55] Therefore, for example, Letter A of the first paragraph of article number 5, GDPR states that, 'Personal data shall be processed […] in a transparent manner in relation to the data subject (…)' (principle of transparency), whereas a characteristic of AI is its opaque mode of functioning. In addition, Letter B of the same paragraph prescribes that, 'Personal data shall be (…) collected for specified, explicit (…) purposes (…)', whereas computational techniques and self-learning approaches prevent the designer from predicting every potential use of the collected data. Furthermore, Letter C of the first paragraph imposes the principle of, '*Data Minimalization*' which conflicts with the large amount of information which is usually necessary to develop AI systems.

It is clear, then, that computational innovation and related advantages in the medical sector could be curbed by privacy guarantees and, consequently, it is desirable that the legislator should adjust the latter to include new technologies.[56] In the meantime, current data protection legislation should be interpreted from an evolutionary perspective to achieve a reasonable balancing between data protection and health promotion. In this direction, some jurists have highlighted that lot of rules, laid down by GDPR to govern the processing of personal data, contain general clauses that is to say terms and concepts which are not precisely formulated and, therefore, can be applied in varying degrees depending on

54 G Comandè, **'**Ricerca in sanità e data protection' (n 45) 187 ss.; A Bernes, 'La protezione dei dati personali nell'attività di ricerca scientifica' (2020) 1 NLCC 175 ff.

55 G Finocchiaro, 'Intelligenza artificiale e protezione dei dati personali' [2019] GI 1657, explains that GDPR was designed without considering issues which raise from AI technology and Big Data.
With regards to the topic of data protection, Artificial Intelligence Act Proposal states only that, 'To the extent that it is strictly necessary for the purposes of ensuring bias monitoring, detection and correction in relation to the high-risk AI systems, the providers of such systems may process special categories of personal data referred to in Article 9(1) of Regulation (EU) 2016/679, Article 10 of Directive (EU) 2016/680 and Article 10(1) of Regulation (EU) 2018/1725, subject to appropriate safeguards for the fundamental rights and freedoms of natural persons, including technical limitations on the re-use and use of state-of-the-art security and privacy-preserving measures, such as pseudonymisation, or encryption where anonymisation may significantly affect the purpose pursued.'

56 See: Olivi, G Olivi, 'Big data' (n 53) 185; A Cinque, 'Privacy, Big-Data e contact tracing: il delicato equilibrio fra diritto alla riservatezza ed esigenze di tutela della salute' [2021] NGCC 957 ff.

contextual circumstances.[57]

Therefore, the principle of '*Data Minimization*' should be interpreted precisely and fully when personal information is transferred to an entrepreneur in a commercial relationship for economic purposes.[58] However, this should be interpreted in a broader sense when the health data is shared with a doctor in a therapeutical setting for medical research purposes.[59]

6. Perspective and conclusions.

The use of AI in the medical field has already highlighted some of the limits of the logic of self-determination. Further limits could emerge from the expansion of AI applications in the near future, that is unless the legislator intervenes to control them.[60]

First, computational technology could be applied to an even-greater extent to guide people in their personal decisions. Once the numerous traces strewed by the user online have been collected and profiled, the predictive algorithms are able to create and transmit impulses which gradually and imperceptibly induce the user to make choices predetermined by other people. As the President of the Italian Data Protection Authority has been highlighting,[61] 'This is a very strong type of nudging (…) which shows how vulnerable people are in the face of digital power (…)' and how the freedom of choice is actually more of an illusion than real.[62]

Therefore, when algorithms guide the user on health-related issues, the exercise of right to self-determination will conceal the result of a process of determination which is taken by a third party.[63] Which is particularly worrying, when therapeutic decision affects not only the health of subject who makes it but also the collective health. For instance, this is the case when deciding whether or not to get vaccinated against contagious diseases.

This scenario stresses the idea that the voluntaristic logic is becoming more and more precarious in the face of the developments of AI. This technology not only reveal intrinsic limits of individual self-determination, as we have seen in the previous paragraphs, but also threatens individual self-determination as an external agent.

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57 A Ottolia, *Big Data e innovazione computazionale* (Giappichelli 2017) 101 ff.

58 Ibid 131.

59 See: D Mastrelia, 'Gestione dei bigdata in una prospettiva orientata alla tutela della privacy degli individui' [2018] Dir. ind. 364 ff.; T Sharon, 'Data- driven Decision Making' (n 489 42 f.; McGraw, K. D. Mandl, Privacy Protection to Encourage Use of Health-relevant Digital Data in a Learning Health System [2021] Digit. Med. 6. See also: Judgement of 22nd June 2021, *Latvijas Republikas Saeima*, C-439/19, EU:C:2021:504, paragraphs 105-106.

60 See n 63 below.

61 P Stanzione, Annual Report (2020).

62 A broad explanation of the nudging is in R H Thaler, C R Sustein, *Nudge: Improving Decisions About Health, Wealth and Happiness* (Yale University Press, 2008). On the same topic see also: C R Sunstein, *Human Agency and Behavioral Economics. Nudging Fast and Slow* (Springer 2017); R Viale, *Oltre il nudge* (Il Mulino, 2018).

63 Considering such negative effects, the recent Artificial Intelligence Act Proposal forbids, '… the placing on the market, putting into service or use of an AI system that deploys subliminal techniques beyond a person's consciousness in order to materially distort a person's behaviour in a manner that causes or is likely to cause that person or another person physical or psychological harm …'

Another perspective, which is worthy of being considered, concerns the role of AI in the implementation of Human Enhancement.[64] Human Enhancement consists of technologies and tools which can be used to improve physical and/or mental capacity of an individual overcoming normal human standards. For example, neuronal microchips can be used to increase mnemonic and concentration abilities and in addition, genetic engineering can be used to intensify muscular strength or sensorial capacity. The development of such techniques has possible implications with regards to the principle of self-determination in the medical field. To understand what these implications could be, it is useful to consider that Human Enhancement interventions affect not only the condition of the specific patients but also rights, principles and values which go beyond the individual sphere; for example, the improvement of sensorial capabilities of certain persons might endanger privacy protection.[65] Moreover, Human Enhancement in the private medical sector could infringe the principle of equality and Human Enhancement in the public sector could aggravate the budget for public healthcare and therefore affect the collective health. Finally, Human Enhancement seems to be in contrast with the principle of human dignity which safeguard the uniqueness of each human being.

Some authors are of the opinion that the issues mentioned above can be overcome, and that individual self-determination is sufficient to legitimise Human Enhancement practices. This opinion has been argued from the point of view that self-determination in medical field can now even legitimise the patient's death.[66] However, this latter point is not sufficiently decisive to solve the problem with the lack of legality of Human Enhancement techinques. In fact, the elimination of a human life actually represents something less, not something more than the obliteration of human condition and dignity.

In the first paragraph, we considered the idea that the advent of new technology has often has effects on one or more areas of application of the law. At the end of this paper, it is useful to add that the advent of new technology often implicates the reconsideration of some legal doctrine. For example, the spread of motor vehicles has triggered a process that led to the debunking of the idea that fault is the only possible basis for civil liability. Later, the introduction of digital technology and telematics undermined the real nature of the protection of copyright, sometimes even causing the latter to be degraded to a mere right to compensation. At present, medical applications of AI seem to prompt a critical rethinking of the voluntaristic "dogma", highlighting that the right to self-determination cannot be conceived as an absolute prerogative. On the one hand, it postulates the full capacity of the individual to understand and decide in his own interest and, on the other hand, it is subject to comparison with other rights and principles, which sometimes present an autonomous ultra-singular scope, and, therefore, should be considered prevailing.

64 On the issues related to human enhancement, see: Comitato Nazionale per la Bioetica, Report 'Diritti umani, etica medica e tecnologie di potenziamento (enhancement) in ambito militare' (22nd February 2013).

65 E Palmerini, 'Robotica e diritto: suggestioni, intersezioni, sviluppi a margine di una ricerca europea' [2016] Resp. civ. prev. 1820.

66 U Ruffolo, A Amidei, 'Intelligenza artificiale e diritti della persona: le frontiere del "transumanesimo"' [2019] GI 1658 ff.