

ACCESS TO INTENSIVE CARE AND ARTIFICIAL INTELLIGENCE. A CONSTITUTIONAL PERSPECTIVE

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Abstract

In this paper, after analyzing documents on access to intensive care in the pandemic period, we will focus on the use of new technologies for the priority assessment of access to intensive care in the event of a health emergency. The issue of automatic (based on “automatic” criteria) or automated (based on algorithms) decisions is a central constitutional issue as its analysis is further capable of suggesting values and principles that may even refine the approaches to the use of AI in the care relationships.

We argued in the paper that a risk-based approach, aimed at allowing European circulation of artificial intelligence devices and services, must be accompanied by a fundamental rights-oriented approach which therefore does not prevent the uniformity of the European space, but allows, where provided for by the European constitutional system, guarantees and measures to protect the fundamental rights at stake.

TABLE OF CONTENTS

1. Introduction.....	595
2. SIAARTI documents on access to intensive care during the covid-19 pandemic.....	597
2.1 Criticalities regarding the allocation of resources and the definition of health priorities.....	601
2.2 Criticalities regarding appropriateness of care.....	604
3. Artificial intelligence and the healthcare sector.....	606
3.1 Documents on artificial intelligence at international and European level.....	606
3.2 Artificial intelligence and triage of covid-19 patients to access intensive care.....	612
4. Concluding remarks.....	616

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1. Introduction

From the moment the coronavirus first spread in China at the end of 2019 and then to the rest of the world, it became clear that the respiratory problems caused by this virus would place enormous pressure on hospitals and particularly on intensive care.

The spread of the virus has highlighted a series of allocative suffering which in all Western countries has characterized the evolutionary trends in the financing of health systems. Healthcare resources, as is well known, are scarce in the face of ever increasing and greater need.

In particular, the scarcity of personal resources emerged, of ventilator support (more or less invasive) and of beds. Moreover, in Western countries, for decades, de-hospitalization policies have been in place which has led to rapidly reallocated resources from hospital care to territorial care.

In this context, documents relating to the priority criteria for access to intensive care have been published in many countries in order to cope with the first waves and peak moments of the pandemic¹.

¹ We have to mention, among others, the following fundamental documents: in Spain, the document produced by the Sociedad Espanola de Medicina Intensiva Critica y Unidades Coronarias (SEMICYUC) y Sociedad Espanola de Enfermeria Intensiva y Unidades Coronarias (SEEIUC) and entitled "Plan de Contingencia para los Servicios de Medicina Intensiva frente a la pandemia COVID-19"; the document of the Belgian Society of Intensive Care, "Medicine Ethical principles concerning proportionality of critical care during the 2020 COVID-19 pandemic in Belgium: advice" of 2020; the Hastings Center document of 17 March 2020 entitled "Health Care Institutions & Guidelines for Institutional Ethics Services Responding to the Coronavirus Pandemic. Managing Uncertainty, Safeguarding Communities, Guiding Practice"; the document of 13 March 2020 of the Comité Consultative National d'Éthique entitled "Enjeux éthiques face à une pandémie"; the Nuffield Council on Bioethics document entitled "Ethical considerations in responding to the COVID-19 pandemic" of 2020. In Italy, the issue was addressed in an opinion of the National Committee for Bioethics (NCB), entitled "COVID-19: the clinical decision in conditions of lack of resources and the criterion of triage in pandemic emergency", published on 15 April 2020.

All these documents, with the exception of the Spanish one, refer to the need to use criteria of justice that are not likely to determine discrimination in access to intensive care, asking in some cases to report the possible allocative conflict, determined by the situation of a disproportion between people requesting access to available care and health resources, to a clinical bioethics committee (this is the position expressed in the French document and in the Hastings Center document) and in other cases to refer to criteria that guarantee a greater impartiality and objectivity, such as the criterion of medical urgency (this is the

The debate on the subject has developed in a broad and participatory manner and the scientific contributions have been numerous².

The subject undoubtedly raises some unavoidable questions to contemporary constitutionalism and tests the “resilience” of the European common fundamental principles and standards.

In particular, it highlights the need to investigate the linkages between ethics, law, health and technology³ and how these connections are reflected and respond to the protection of people’s fundamental rights.

In this paper, after analyzing documents on access to intensive care in the first pandemic period – i.e. before the vaccination processes began from the end of December 2020 in the

position expressed in the Belgian document) and the clinical criterion (this is the main position that can be deduced also from the aforementioned opinion of the NCB).

²With reference to the European scientific debate, see J. Bauer, D. Brüggmann, D. Klingelhöfer, W. Maier, L. Schwettmann, D. J. Weiss & D. A. Groneberg, *Access to Intensive Care in 14 European Countries: a Spatial Analysis of Intensive Care Need and Capacity in the Light of COVID-19*, 46 *Intensive Care Medicine* 2026 (2020); F.G. Zampieri, M.B. Skrifvars & J. Anstey, *Intensive Care Accessibility and Outcomes in Pandemics*, 46 *Intensive Care Medicine* 2064 (2020). See also A. Le Bret, T. Minssen, *Digital Health, Artificial Intelligence and Accessibility to Health Care in Denmark*, 1 *Eur. Hum. Rts. L. Rev.* 39 (2021).

With reference to the Italian scientific debate, see M. Piccinni, A. Aprile, P. Benciolini, L. Busatta, E. Cadamuro, P. Malacarne, F. Marin, L. Orsi, E. Palermo Fabris, A. Pisu, D. Provolo, A. Scalera, M. Tomasi, NO. Zamperetti & D. Rodriguez, *Considerazioni Etiche, Deontologiche e Giuridiche sul Documento SIAARTI “Raccomandazioni di etica clinica per l’ammissione a trattamenti intensivi e per la loro sospensione, in condizioni eccezionali di squilibrio tra necessità e risorse disponibili”*, 111 *Recenti Progressi Medici* 212 (2020); G. Razzano, *Riflessioni a Margine delle Raccomandazioni SIAARTI per l’Emergenza Covid-19, fra Triage, Possibili Discriminazioni e Vecchie DAT: Verso una Rinnovata Sensibilità per il Diritto alla Vita?*, 3 *Rivista AIC* 107 (2020); S. Rossi, *Società del Rischio e Scelte Tragiche al Tempo del Coronavirus*, 3 *Rivista AIC* 246 (2020); L. Conte, *Covid-19. Le Raccomandazioni di Etica della SIAARTI. Profili di Interesse Costituzionale, Federalismi* (1 April 2020).

³On this issue see S.M. Carter, W. Rogers, K.T. Win, H. Frazer, B. Richards & NO. Houssami, *The Ethical, Legal and Social Implications of Using Artificial Intelligence Systems in Breast Cancer Care*, 49 *The Breast* 25 (2020); M. Robles Carrillo, *Artificial Intelligence: from Ethics to Law*, 44 *Telecommunications Policy* (2020); A. Azevedo, P.A. Azevedo, *Digital Education, Work and Artificial Intelligence: Health and Law*, European Distance and E-Learning Network (EDEN) Proceedings 2020 Annual Conference, Timisoara (22-24 June 2020); I. Habli, T. Lawton & Z. Porter, *Artificial Intelligence in Health Care: Accountability and Safety*, *Bulletin of the World Health Organization* (1 April 2020).

Western countries -, we will focus on the use of new technologies for the priority assessment of access to intensive care in the event of a health emergency. The documents analyzed will be some international and national documents (in particular, for the Italian context those elaborated by SIAARTI - Italian Society of Anesthesia, Analgesia, and Intensive Care) and documents drawn up in the field of artificial intelligence by the Institutions of the European Union.

The main “lens” of analysis of the documents in this sector will be constituted by the Italian constitutional principles and by the relevant and copious case law of the Italian Constitutional Court in the matter of care relationships, determination of the levels of care, appropriateness and allocation of health resources.

This methodological perspective has been chosen since the renowned richness of the Italian Constitution and Italian constitutional case law in this scope can provide a fundamental rights-based approach and relevant parameters in respect to the analysis and evaluation of the developing European regulatory framework regarding the use of new technologies in the health sector.

2. SIAARTI documents on access to intensive care during the covid-19 pandemic

In Italy, during the first wave of the covid-19, the Northern Regions were heavily impacted by the spread of the virus.

It should be specified that the transfer of services from the hospital sector to the territorial sector has not been completed in Italy because on the one hand, there has been a rapid reallocation of resources from the hospital setting, and on the other, territorial care has not been symmetrically developed, meaning that in many regions organizational and allocative deficits and deficiencies have arisen.

In some northern regions, for example in Veneto, local care has been strengthened, while in others, such as Lombardy, economic resources have been invested mostly in the hospital sector.

In addition, the specific situation of intensive care in the regions of Northern Italy also presented itself in an ambivalent way. Some intensive therapies, especially those in Lombardy, had been better equipped with respect to health crises by virtue of previous

exercises attributable to the H1N1 epidemics, MERS and Ebola⁴. In other Regions, however, such preparation was not possible. The situation in the face of the health crisis has therefore been shown to be very diverse in the various territories both in terms of response methods and preparation for such an event.

In this context of inhomogeneity both in regard to the spread and impact of the virus and in regard to the response capacity of the territories, SIAARTI published on 6 March 2020 - therefore in the initial moment of the first wave of the pandemic - its "Recommendations of clinical ethics for admission to intensive treatments and for their suspension, in exceptional conditions of imbalance between needs and available resources" and on 13 January 2021 - in full pandemic and in anticipation of the second wave - it published with the SIMLA (Italian Society of Forensic Medicine and Insurance) the Guidelines "Decisions for intensive care in the event of disproportion between care needs and available resources in the course of a covid-19 pandemic"⁵.

The common goal of these documents was to provide a support tool for professionals involved in the health crisis.

What are the continuities and discontinuities between the two documents?

The first aspect of continuity between the two documents concerns the identification of appropriateness in intensive care⁶.

⁴ Influenza from the H1N1 virus developed from April 2009, originating in Mexico, and has spread to over 80 countries. MERS, or Middle Eastern coronavirus respiratory syndrome, developed from September 2012, while the initial infection of Ebola is documented in West Africa in December 2013.

⁵ From a formal point of view, the Recommendations constitute a non-binding policy act produced by a Scientific Society. The Guidelines were produced according to the procedure provided by the national system of guidelines provided for by article 5, paragraph 3, of the law no. 24 of 2017. In this framework, the Higher Institute of Health, through the National Center for Clinical Excellence, Quality and Safety of Care, plays the role of methodological guarantor and national governance of the production process of Good quality Guidelines, informed by the best available evidence. Article 6, paragraph 1, of law no. 24 provides for a case for exemption from criminal liability for professionals who have complied with the Guidelines.

⁶ See SIAARTI, *Clinical Ethics Recommendations for Admission to Intensive Treatments and Their Suspension, in Exceptional Conditions of Imbalance Between Needs and Available Resources*, 6 March 2020, pp. 3 and followings; SIAARTI-SIMLA, *Decisions for Intensive Care in the Event of Disproportion Between Care Needs and Available Resources During the Covid-19 Pandemic*, 13 January 2021, at 4.

This notion intercepts the clinical aspects concerning the effectiveness of the treatments and then declines them in relation to the effects of the treatment in the medium and long term and the correct allocation of very expensive and therefore very scarce intensive care resources.

A first important aspect of difference between the recommendations of March 2020 and the Guidelines of January 2021 concerns the theoretical context of reference of the two documents that we consider to be radically changed. In the first case, reference is made to a utilitarian perspective inserted in the context of Disaster Medicine in which the collective interest in health is considered absolutely preponderant over the individual's right of access to care⁷.

In our opinion, the Recommendations, as formulated, constitute indications provided strictly for the health emergency situation but present some major criticalities and some friction with the ordinary constitutional framework of our country.

The Recommendations, formulated in a context of stringent health emergency, establish criteria that are not compatible with the needs of solidarity and personalization that are the basis of the relationship of care between professional and patient.

The age criterion, provided there as an autonomous criterion⁸, constitutes an "automatic" criterion not compatible with the constitutional principles underlying the care relationship also by law n. 219 of 2017 on informed consent and advance provisions of therapeutic treatment⁹. This is a criterion that allows a quick assessment but does not take into account a personalized assessment that the Constitutional Court, following the

⁷ SIAARTI, *Clinical Ethics Recommendations for Admission to Intensive Treatments and Their Suspension, in Exceptional Conditions of Imbalance Between Needs and Available Resources*, 6 March 2020, at 3 ff.

⁸ SIAARTI, *Clinical Ethics Recommendations for Admission to Intensive Treatments and Their Suspension, in Exceptional Conditions of Imbalance Between Needs and Available Resources*, 6 March 2020, at 5.

⁹ Law no. 219 of 2017 establishes that the constitutional basis of the care relationship are the principles referred to in articles 2, 13 and 32 of the Constitution and articles 1, 2 and 3 of the Charter of Fundamental Rights of the European Union, protecting the right to life, health, dignity and self-determination of the person.

constitutional principles in this field, placed as the basis of the care relationship¹⁰.

The Guidelines of January 2021 recontextualize the problem of access to intensive care in conditions of disproportion between care needs and available resources through reference to the fundamental principles on the subject, such as the principles of equality and equal social dignity; universality and equity; self-determination¹¹. In the 2021 Guidelines, the issue of the health emergency and access to intensive care is, in our opinion, correctly placed within the Italian constitutional framework through reference to the principle of the dignity of the person and the guarantee of his/her inviolable rights.

There are two changes in particular that the Guidelines introduce on the subject, unlike the Recommendations: the reference to the principle of self-determination, and informed consent as a fundamental dimension of the relationship of care between doctor and patient necessary for the purpose of deciding the type of treatment to be given; and eliminating the age criterion as an independent criterion of evaluation.

In this second document, following the dramatic first wave of infections, the balance between the individual's right to access to treatments and the collective interest in saving the greatest number of people is recalibrated in a more weighted way.

As part of the definition of triage for intensive care, the Guidelines refer to a global assessment of the person that takes into account a series of parameters that do not have a hierarchical relationship between them and, finally, the age criterion must be considered in the context of the global assessment of the person and not on the basis of defined cut-offs.

In order to anticipate some considerations and reflections that will be carried out in the discussion, it is necessary to specify that the Guidelines immediately raise the question of whether

¹⁰ See what emerges in the matter of personalized evaluation of treatments in the judgments of the Constitutional Court no. 282 of 2002, no. 338 of 2003, no. 151 of 2009, no. 169 of 2017.

¹¹ SIAARTI-SIMLA, *Decisions for Intensive Care in the Event of Disproportion Between Care Needs and Available Resources During the Covid-19 Pandemic*, 13 January 2021, at 5.

technology can “help in managing the disproportion between the demand for assistance and available resources”¹².

The question arises because artificial intelligence tools and algorithms have been used in other countries.

In the context outlined, the Guidelines establish that in our country, in the triage of the person, it is not possible to use algorithms as an appropriate evaluation tool¹³.

2.1 *Criticalities regarding the allocation of resources and the definition of health priorities*

The SIAARTI documents had the important advantage of dealing transparently with such a delicate issue as that of the allocation of health resources and the definition of priorities, and they did so at a particularly pressing moment from many points of view.

The issue of the allocation of health resources and the definition of priorities raises a number of critical issues in relation to the identification of the relevant actors, the criteria identified, and the decision-making processes implemented to achieve the set objectives.

First of all, the matter of resource allocation and the definition of priorities is a matter that has a high political gradient and which intercepts numerous problems that arise in contiguous sectors.

In particular, the Italian Constitutional Court has affirmed on several occasions that the determination of the essential core of the right to health constitutes a determination that is the responsibility of the state legislator¹⁴ and that the determination of the essential levels of care constitutes an area in which the protection of health intersects with the need to prepare the resources to cope with it¹⁵.

¹² SIAARTI-SIMLA, *Decisions for Intensive Care in the Event of Disproportion Between Care Needs and Available Resources During the Covid-19 Pandemic*, 13 January 2021, at 6.

¹³ SIAARTI-SIMLA, *Decisions for Intensive Care in the Event of Disproportion Between Care Needs and Available Resources During the Covid-19 Pandemic*, 13 January 2021, at 11.

¹⁴ Decision no. 455 of 1990 of the Constitutional Court. In the same sense, the Constitutional Court, 16 March 1990, no. 127; Constitutional Court, 31 January 1991, no. 40; Constitutional Court, 15 April 1992, no. 180; Constitutional Court, 3 June 1992, no. 247; Constitutional Court, 23 June 1992, no. 356.

¹⁵ See the decisions of the Constitutional Court no. 169 of 2017 and no. 62 of 2020.

The “essential core”, outlined in constitutional case law¹⁶, can be defined as a threshold of constitutional protection of the right to health and, in particular, functions as a “counter-limit” to the discretion of the legislator in matters of social rights¹⁷.

On this, the Constitutional Court affirmed that there is a “constitutionally necessary expense” concerning the financing of essential levels of care¹⁸. This expenditure is inevitably connected to what the legislator decides to fall within the essential levels of care and which corresponds to the constitutional priorities in the matter of the right to health.

On the other hand, the Constitutional Court affirmed the transversal nature of the matter of the “determination of the essential levels of assistance” and the “transcendent” nature of the same with respect to the purposes of protecting human dignity¹⁹.

There is no doubt that the matter of the allocation of health resources is a competence in which the legislator should play a fundamental role while respecting the constitutionally established constraints on the protection of the equality and dignity of the person. It is not only a question of establishing the quantity of the necessary resources but also establishing the distribution between care sectors and between possible patients in the same care sector. This represents a fundamental area in which the preeminent political nature of the relative choices is expressed.

Especially in a situation of health emergency, such as the one that occurred following the spread of covid-19, it should be asked whether the ordinary rules established by the legislator on the allocation of resources and access to care can somehow “hold up” in the face of a wave of pressures that lead to a reversal of the usual arguments regarding the balance between individual rights and collective interests. The emergency situation has inevitably led to a shift in focus to the collective interest in saving the greatest number of people, causing a decline in the individual’s right to access intensive care, even and especially in the case of frail and elderly people.

¹⁶ See decisions no. 267 of 1998 and no. 304 of 1994.

¹⁷ See ruling no. 304 del 1995 and no. 275 del 2016. On this see S. Rossi, *Società del Rischio e Scelte Tragiche al Tempo del Coronavirus*, 3 *Rivista AIC* 265 (2020).

¹⁸ See paragraph no. 9.3.2 of the decision of the Constitutional Court no. 169 of 2017.

¹⁹ See paragraph no. 4.5 of the decision of the Constitutional Court no. 62 of 2020.

On this aspect, the law doctrine has already confirmed for some time that the collective interest can prevail over the individual's right to health in a strict emergency context, while in an ordinary situation there can be no prevalence of the collective interest over an individual's right to health²⁰.

In this sense, an intervention by the legislator that declined the constitutional principles on the subject could have been considered appropriate when the period of exceptional peak of the health emergency was exceeded in order to rebalance a situation that was going to affect especially fragile and elderly people who could be excluded from access to ventilation support, not necessarily invasive, since the required interventions could be considered long, very expensive and, in cases where the clinical situation was very compromised, even of lesser clinical utility.

In addition to the constitutional principles of equality, dignity, and personalistic dimension that should guide the implementation of the rights and actions of public powers, contained in articles 2 and 3 of the Italian Constitution, a fundamental role in the health emergency was played by the judgment on the appropriateness of care. In fact, appropriateness represents a synthesis criterion between the clinical dimension of the evaluation and the economic dimension of the evaluation. That is, it includes a judgment on the correct distribution of resources aimed not at economizing but at guaranteeing a reasoned distribution that allows the greatest number of people to be treated in the best possible way.

The canon of appropriateness constitutes a very important distribution criterion at the micro level that cascades down other criteria and principles set at a general level, both constitutional and legislative.

Having said that, we believe that the judgment of appropriateness is unlikely to be able to reconcile in a proportionate manner with respect to the needs that have arisen in the health emergency, which have very different dimensions, such as clinical and economic, and in any case cannot represent the only criterion, resource allocation regulations, at a time of such a serious global health emergency.

²⁰ B. Pezzini, *Il Diritto alla Salute: Profili Costituzionali*, 23 *Diritto e Società* (1983); D. Morana, *La Salute come Diritto Costituzionale. Lezioni* (2018).

2.2 *Criticalities regarding appropriateness of care*

As anticipated, the criterion of clinical appropriateness in intensive care represents, more than in other sectors, a multidimensional evaluation instrument that summarizes different dimensions relating to the clinical efficacy of a treatment, the judgment on prognosis and the outcome of a treatment, on the correct and fair allocation of resources.

Intensive therapies in fact represent very high technological intensity wards and each patient admission (so-called direct triage) and discharge (so-called reverse triage) represents an allocation and reallocation of important resources that could imply a series of choices on inclusion and exclusion from the care.

Given the high technological intensity that characterizes intensive care, the problem of choices in a situation of scarcity of resources in intensive care can be considered an indicator of a more general problem that highlights a general misallocation of resources and concerns in our healthcare system that has been directly affected by numerous seasons of disinvestments in healthcare.

Furthermore, it must be considered that in intensive care there is likely to be more and less invasive action in ventilatory support and life support. In each case, characterized by different degrees of invasiveness of the treatment, the risk/benefit balance requires that the need for ventilatory and life support, the probability of survival, and the quality of life of a patient be evaluated in proportion to the degree of invasiveness of the treatment.

On the evaluation of these factors, the Constitutional Court has repeatedly stated that the personalized evaluation of these aspects is part of the context of the relationship of care and trust that is constituted by the encounter between the autonomy of the person and the professional responsibility of the doctor²¹. In this context, legislative discretion is limited and the legislator must be guided in their choices by scientific evidence that is documented by the technical-scientific bodies appointed to do so²².

The assessment of appropriateness, on the other hand, is correctly attributed by constitutional decisions to the doctor, who, in the context of autonomy and professional responsibility, is called

²¹ See the decisions of Constitutional Court no.no. 282 of 2008, no. 338 of 2003, no. 151 of 2009, no. 169 of 2017.

²² See the decisions of Constitutional Court no. 151 of 2009 and no. 162 of 2014. See the decision of the Constitutional Court no. 185 of 1998.

upon to choose treatments, together with the patient, on the basis of the most up-to-date scientific knowledge²³.

The personalistic dimension of the right to health and healthcare, which must therefore disregard automatisms (which could be considered as the one connected to the definition of age as a criterion for inclusion or exclusion from intensive care), requires that the autonomy of the doctor, with the informed consent of the patient, is paramount in making the necessary therapeutic choices.

Any tension that may exist between the orientation of the legislator on the allocation of resources and on the definition of appropriateness, on the basis of the data provided by the technical-scientific bodies, and the choices of the doctor is particularly taken into consideration in the ruling n. 169 of 2017 of the Italian Constitutional Court.

This ruling declares the groundlessness of the question of constitutional legitimacy promoted by the Veneto Region with reference to articles 3, 32, 97, 117, second and third paragraphs, article 120 of the Constitution, of article 9-quarter, paragraphs 1, 2, 4, 5 and 6 of the legislative decree n. 78 of 2015, converted with amendments into law n. 125 of 2015, which provide that by decree of the Minister of Health, subject to agreement in the State-Regions Conference, the conditions of derogation and indications of prescriptive appropriateness of the outpatient specialist assistance services are identified, as well as the application of sanctions and liability towards the prescriber. The contested provisions are not, in fact, deemed to prejudice the prerogatives of the prescriber to operate according to knowledge and conscience, having to be understood as an invitation to make the permitted faculty to depart from the ministerial indications transparent, reasonable and informed.

In this case, the prescriber, also in order to keep under control any serious deviations from the physiology of medical practice, is called to justify any deviations from the ministerial indications, but the prescriber's autonomy is not considered to be affected by the validity of these indications.

On the other hand, indications on the appropriateness of the services, mostly in its declination of organizational appropriateness, are contained in the Prime Ministerial Decree on

²³ See the decisions of Constitutional Court no. 282 of 2002 and no. 338 of 2003.

the essential levels of care of 2001²⁴ and in the decree updating the essential levels²⁵. These indications have the purpose of guiding health practice and guaranteeing uniformity throughout the territory and the good performance of the system.

In fact, the legislator's interventions on the subject are manifold²⁶ precisely because, since the appropriateness clause is a multidimensional clause, it is inevitable that its evaluation will be affected by actors placed at different levels with clearly different tasks.

3. Artificial intelligence and the healthcare sector

3.1 Documents on artificial intelligence at international and European level

In this context, many international institutions and scientific societies have published guidelines and recommendations in order to support healthcare professionals on the issue of the use of new

²⁴ See attachment 2C “Services included in Essential Levels of care that have a potentially inappropriate organizational profile, or for which it is necessary to identify more appropriate methods of disbursement” to the Prime Ministerial Decree of 2001. See also the Prime Ministerial Decree of 16 April 2002 “Guidelines on priority criteria for access to diagnostic and therapeutic services and on maximum waiting times” concerning temporal appropriateness.

²⁵ See the Prime Ministerial Decree of 12 January 2017 on the essential levels of care that has replaced the Prime Ministerial Decree of 2001. For organizational appropriateness, see article 39 on the appropriateness of ordinary hospitalization; article 41 on the appropriateness criteria of day surgery; article 43 on the appropriateness of admission to day hospital; article 45 on the appropriateness of admission to rehabilitation; see the indications on prescriptive appropriateness contained in Annex 4D.

²⁶ See law no. 311 (2005 Finance Law): paragraph 169 entrusts the Minister of Health with the task of setting “the qualitative, structural, technological, process and possibly outcome, and quantitative standards, referred to in the essential levels of assistance”, also to ensure that the procedures for providing the services included in the essential levels of care are uniform throughout the national territory; the State-Regions Agreement of 23 March 2005 provides for the establishment, at the Ministry of Health, of the Standing Committee for the verification of the provision of the Essential Levels of Assistance which is entrusted with the task of verifying the provision of the essential levels of care in conditions of appropriateness and efficiency in the use of resources, as well as the congruity between the services to be provided and the resources made available by the National Health Service; the Ministerial Decree of 21 November 2005 establishes the permanent essential levels of care verification Committee.

technologies in triage decision-making processes for covid-19 patients starting from March 2020.

Artificial intelligence (AI) technologies can be used to make therapies smarter and more targeted and help prevent life-threatening diseases. Doctors and healthcare professionals can potentially perform a more accurate and detailed analysis of a patient's complex health data, even before they become ill, and prescribe *ad hoc* preventive therapy.

AI can also make contributions on a larger scale. For example, it can examine and identify general trends in healthcare and treatment, help to diagnose diseases earlier, develop medicines more efficiently, decide on more targeted therapies, and ultimately save more lives.

In three international documents we find different references that allow us to develop even antithetical reflections on the subject. Consider Unesco's "Ethical considerations from a global perspective" and, in particular, the ninth statement which reads: "Digital technologies like mobile phones, social media, and artificial intelligence can play a substantial role in dealing with pandemics, by making it possible to monitor, anticipate and influence the spreading of the disease and the behaviour of human beings. It is of crucial importance to make sure that the ethical, social and political issues related to the use of these technologies are adequately addressed. Human rights should always be respected, and values of privacy and autonomy should be carefully balanced with values of safety and security"²⁷; as indicated in the following: "Ethical implications of the use of AI to manage the covid-19 outbreak" in which we read "AI-based algorithmic models can help hospitals and doctors make decisions in light of limited time and resources. [...] However, AI needs ethical guidelines to work effectively and with regard to intrinsic human rights"²⁸; the Italian guidelines for decisions in intensive care in the event of a disproportion between care needs and resources available in the covid-19 pandemic, which states: "The outcome of the triage for intensive care cannot depend on the score resulting from the use of

²⁷ Statement of the UNESCO International Bioethics Committee (IBC) and the UNESCO World Commission on the Ethics of Scientific Knowledge and Technology (COMEST), *Statement on Covid-19: Ethical Considerations From a Global Perspective* (26 March 2020), at 4.

²⁸ TUM Institute for Ethics in Artificial Intelligence, *Ethical Implications of the Use of AI to Manage the COVID-19 Outbreak* (April 2020), at 2 ff.

any tool or algorithm, even if proposed or used in other countries, as inappropriate. In case of previous comorbidities, the assessment of the severity and stage of the disease must be based on objective criteria and parameters”²⁹.

At European level, in the Communications of 25 April 2018 and 7 December 2018 of the European Commission, a sort of AI manifesto is drawn up, in support of “an ethical, safe and avant-garde ‘made in Europe’ AI”³⁰.

The possibility of having an impact in the case of the use of artificial intelligence from an ethical and regulatory point of view is highlighted in the White Paper on artificial intelligence of 19 February 2020³¹ and in the Ethical guidelines for reliable AI of the Group of Experts set up by the European Union Commission on artificial intelligence³².

Artificial intelligence has the potential to contribute to the improvement of services but can involve a series of potential risks, such as opaque decision-making mechanisms, discrimination based on gender or otherwise, violations of privacy, and issues of responsibility for actions and conduct.

In the White Paper on artificial intelligence, the compatibility of artificial intelligence with the framework of democracy and the rule of law is brought back to the framing of artificial intelligence within an approach that is anthropocentric, ethical and respectful of fundamental rights.

In particular, the principle of human surveillance is aimed at guaranteeing human autonomy in decision-making processes in which artificial intelligence is involved³³. Basically, human intervention is required to be guaranteed in the various stages of the decision-making process, in the design phase, validation of the

²⁹ SIAARTI-SIMLA, *Decisions for Intensive Care in the Event of Disproportion Between Care Needs and Available Resources During the Covid-19 Pandemic*, 13 January 2021, at 11.

³⁰ Communication from the Commission of 25 April 2018, *Artificial Intelligence for Europe*, COM (2018) 237 final; Communication from the Commission of 7 December 2018, *Coordinated Plan on Artificial Intelligence*, COM (2018) 795 final.

³¹ See White Paper on Artificial Intelligence - *A European Approach to Excellence and Trust*, 19 February 2020, COM (2020) 65 final.

³² Artificial Intelligence High Level Expert Group, *Ethical Guidelines for Trusted AI*, 8 April 2019.

³³ See White Paper on Artificial Intelligence, *A European Approach to Excellence and Trust*, 19 February 2020, COM (2020) 65 final, at 23-24.

decision, review of the decision, and in monitoring of the functioning of the system.

The White Paper incorporates some of the main indications that the High Level Expert Group set up by the European Commission and published in 2019.

The document on a trusted AI states that it must have three dimensions: legality, i.e. the AI must comply with all applicable laws and regulations; ethics, i.e. the AI must ensure adherence to ethical principles and values; robustness, from a technical and social point of view, since, even with the best of intentions, AI systems can cause unintended damage.

In the document of the Group of Experts, the distinction between human intervention and surveillance is functional to establish a different degree of human participation in automated decisions.

In particular, on the basis of article 22 of the privacy regulation - regulation n. 679 of 2016, General Data Protection Regulation (GDPR) -, the right not to be subjected to a decision based solely on automated processing when this produces legal effects on users or if it significantly affects them in a similar way³⁴.

In the proposed regulation of 21 April 2021, characterized by a very detailed framework aimed at regulating the use of artificial intelligence³⁵, the approach used by the Commission, as it has been already analyzed in some scientific works³⁶, is to divide the activities on the basis of the degree of risk they involve³⁷. Already

³⁴ High Level Expert Group on artificial intelligence, *Ethical Guidelines for Reliable AI*, 8 April 2019, at 18.

³⁵ Proposal for a Regulation of the European Parliament and of the Council laying down harmonized rules on artificial intelligence (artificial intelligence act) and amending certain union legislative acts, COM (2021) 206 final.

³⁶ NO.A. Smuha, *From a 'Race to AI' to a 'Race to AI Regulation': Regulatory Competition for Artificial Intelligence*, 13 *Law, Innovation and Technology* 57 (2021); S. Wray, *Europe Proposes Risk-Based Regulation for AI*, *Cities Today* (26 April 2021).

³⁷ The risk is classified as unacceptable risk (anything that is considered a clear threat to EU citizens), high risk, limited risk, minimum risk. Article 6 of the proposed regulation defines three categories of high-risk systems. The list is not exhaustive, and may be supplemented by the European Commission: systems explicitly mentioned in Annex 3 to the proposed regulation (for example artificial intelligence systems intended to be used to evaluate the access to and enjoyment of public services and benefits, and, specifically, artificial intelligence systems intended to be used for sending or for establishing priority in sending services' first response to emergencies, including firefighters and medical help); AI

in the European regulation on privacy n. 679 of 2016 (GDPR), the approach used is based on the degree of risk and the use of new technologies is considered to be a risk factor for the fundamental rights and freedoms of users³⁸, so much so that before using new technologies, article 35 of the regulation requires an impact assessment on user rights.

Healthcare is a public service in which the use of artificial intelligence can represent a high risk of impact on user rights, since it could impact on the access to and enjoyment of public services and benefits and, specifically, AI systems could be used to establish priority in the dispatching of emergency first response services, including by firefighters and medical aid³⁹.

High-risk systems need to satisfy a series of requirements: establishment of a risk management system; data governance (training, validation and testing of datasets); technical documentation; recording of events (traceability); transparency in relations with users; human supervision; robustness, precision and safety⁴⁰.

At first reading, for example, article 29, which expressly regulates the obligations of the professional users (e.g. the healthcare workers), the latter are expressly called upon not only to follow the provider's instructions for use but also to control the system of AI, reporting problems or even interrupting the service if they consider the existence of a risk.

But the most interesting parts are perhaps those relating to the bridge created with the GDPR.

It is necessary to remember the provisions contained in articles 13.2, lett. f), and 14.2, lett. g), of the GDPR which establish the obligation to provide the data subject with information on the

systems intended to be used as a product or as a component of products covered by a series of pre-existing EU regulations indicated in Annex 2 (for example, the 2017/745 regulation on medical devices); AI systems in the event that the product whose security component is the artificial intelligence system, or the artificial intelligence system itself as a product, is subjected to a third party compliance assessment with a view to placing on the market or the commissioning of this product in accordance with EU regulations pre-existing in Annex 2.

³⁸ M.E. Gonçalves, *The Risk-Based Approach under the New EU Data Protection Regulation: a Critical Perspective*, 23 *Journal of Risk Research* 139 (2020).

³⁹ See Annex 3 of the proposal of regulation on artificial intelligence, paragraph no. 5.

⁴⁰ See the second chapter (articles 8 and following) of Title III of the proposed regulation on artificial intelligence.

existence of an automated decision-making process and, in cases where there is a profiling activity that may affect a person's rights, information on the logic used and on the possible consequences deriving from this activity. Article 22 of the GDPR, already mentioned, establishes in this sense that there is a "right" to human intervention in automated processes that affect the rights of the person. Only the hypothesis of a totally automated process is excluded; however, the intensity or level of this "human intervention" is not established by law.

A further field of interaction between the privacy sector and that of artificial intelligence is that of data governance taking into account that AI "works" on the data: indeed, to be more precise, the AI finds its "autonomy" (qualifying requirement the same for the EU) precisely in that activity of "data correlation" that humans are not able to do, or not at that speed. In particular, article 10 of the mentioned proposal on AI which governs in detail the governance to be followed to process data in order to train the AI models, establishing that the same must be relevant, representative, error-free, complete, and in possession of all the statistical properties appropriate for the context and with reference to the specific groups of people to whom the AI system will apply.

There are two main guarantee instruments in place: on the one hand, the risk management system that was previously used, in different ways, also in the privacy sector (e.g. data governance) and on the other hand the reference to human supervision provided for by the European strategy on artificial intelligence which also incorporates some indications of the Group of Experts set up on the subject in 2018 by the Commission.

The provision that there is always a human intervention aimed at guaranteeing control of the functioning of the system and of the decision-making process undoubtedly contributes to making the process more humanized but does not constitute an inescapable guarantee that human decision-making autonomy is protected. In distinguished studies it has been highlighted that the risk of a strong conditioning and flattening of the human decision-making process on that of the machine exists and it is not such a strange hypothesis considering the saving of energy and time that the decision of the machine allows⁴¹.

⁴¹ See A. Simoncini, *L'Algoritmo Incostituzionale: Intelligenza Artificiale e Futuro delle Libertà*, 1 *BioLaw Journal* 53 (2019); A. Galiano, A. Leogrande, S. F. Massari, A. Massaro, *I Processi Automatici di Decisione: Profili Critici sui Modelli di Analisi e*

It would undoubtedly be necessary to establish some more stringent characteristics of this human intervention. In some cases, simple surveillance may be required; in other cases, where there is a greater risk to people's rights, human decision-making may be required to be equally developed and then compared, in order to exploit the advantages that technology allows, with that of artificial intelligence.

3.2 Artificial intelligence and triage of covid-19 patients to access intensive care

The uses of artificial intelligence and algorithms to support clinicians' decisions are old and multifaceted⁴².

It should be specified that there is not yet a shared international definition of AI and conventionally at scientific level it could be defined as a digital technology that provides a robot with computing qualities that allow it to perform complex and accurate operations and "reasoning" in a short time through algorithms⁴³. Artificial intelligence is, therefore, based on algorithms that make a series of predictions through the use of large data sets.

These algorithms represent instructions that are based on large datasets that allow "reasoning" and predictions which are much more accurate than those made with other methodologies.

Think of the use of robotics, the support of intelligent technology in research, in particular through the use of deep

Impatti nella Relazione con i Diritti Individuali, 2 *Rivista Italiana di Informatica e Diritto* 55 (2019).

⁴² A. Becker, *Artificial Intelligence in Medicine: What is it Doing for Us Today?*, 2 *Health Policy Technol.* 198 (2019); S. Reddy, S. Allan, S. Coghlan, P. Cooper, *A Governance Model for the Application of AI in Healthcare*, 27 *Journal of American Medical Informatics Association* 491 (2020); D.A. Bluemke, *Are you Working with Artificial Intelligence or Being Replaced by Artificial Intelligence?*, 2 *Radiology* 365 (2018).

⁴³ L. Floridi, J. Cowls, M. Beltrametti, R. Chatila, P. Chazerand, V. Dignum, et al., *AI4People – an Ethical Framework for a Good Artificial Intelligence Society: Opportunities, Risks, Principles, and Recommendations*, 28 *Minds and Machine* 689 (2018); S. Samoili, C. Montserrat Lopez, E. Gomez, G. De Prato, F. Martinez-Plumed, B. Delipetrev, Blagoj, *AI Watch. Defining Artificial Intelligence. Towards an Operational Definition and Taxonomy of Artificial Intelligence*, Technical Report. Joint Research Centre (Seville site) (2020); D. Zandi, A. Reis, E. Vayena, K. Goodman, *New Ethical Challenges of Digital Technologies, Machine Learning and Artificial Intelligence in Public Health*, 97 *Bull World Health Organization* 2 (2019).

learning aimed at identifying breast or lung cancer, in diagnosis and treatments, and the implications for the workforce⁴⁴.

Furthermore, studies have been demonstrating the importance of technology in monitoring patients in home care for some time.

During the pandemic in Italy and in many parts of the Western world, intensive care has represented a specific test of the resilience of these systems because they are characterized by a very high technological intensity and have been at the centre of the pandemic discourse because the respiratory infection to which the coronavirus gives rise requires action to support respiratory and vital functions.

There is no doubt that the use of technology at such a delicate juncture of the pandemic has been justified by the need to support the professionals involved in the “tragic choices”⁴⁵ that have emerged in the triage processes of covid-19 patients.

If the reasons that require the support of artificial intelligence are understandable, it is also necessary to highlight that a whole series of questions exists on the classification of the uses of artificial intelligence in healthcare, especially when the use of new technologies affects the decisions of admission or exclusion from treatment and suspension of treatment for individuals who may have reduced chances of recovery.

Artificial intelligence was used in the pandemic period for different and multiple purposes⁴⁶.

Its use has been characterized differently according to the phases of the health crisis. In particular, it has been used in order to identify covid-19 cases and diagnose them (e.g. computed tomography scans - CT scans), to predict a person's likelihood of contagion, to respond through chatbots, and to speed up the search for therapies and vaccines against covid-19.

⁴⁴ T. Davenport, R. Kalakota, *The Potential for Artificial Intelligence in Healthcare*, 6 *Future Healthcare Journal* 94 (2019); E. Gomez-Gonzales, E. Gomez, *Artificial Intelligence in Medicine and Healthcare: Applications, Availability and Societal Impact*, Publications Office of the European Union (2020); F. Jiang, Y. Jiang, H. Zhi, et al., *Artificial Intelligence in Healthcare: Past, Present and Future*, 2 *Stroke and Vascular Neurology* 230 (2017).

⁴⁵ The reference is to the book by P. C. Bobbit, G. Calabresi, *Tragic Choices* (1978).

⁴⁶ See OECD, *Using Artificial Intelligence to Help Combat Covid-19*, 23 April 2020.

With regard to triage in intensive care, artificial intelligence, i.e. the deep learning machine, has been used in some countries in order to predict the need for intensive care⁴⁷.

Another use of artificial intelligence has resorted to algorithms to interpret the results of tests and examinations in order to speed up identification of covid-19 cases⁴⁸.

We will proceed to analyze the artificial intelligence tools that have been used for the triage of covid-19 patients.

The artificial intelligence tools for triage of covid-19 patients are many and of different types: some are able to detect cases of covid-19 through technologies applied to image x-ray; others are able to predict clinical deterioration in the ICU (Intensive Care Unit); others are also able to predict the needs of ICUs in a given area⁴⁹.

AI approaches also have the potential to predict high-risk patients, enabling doctors and hospitals to better manage patient care and predict and allocate the resources needed to reduce deaths.

Artificial intelligence tools have shown immense potential for medical imaging analysis (lung CT scans).

The artificial intelligence tools used in the triage of covid-19 patients refer to algorithms used to read diagnostic images more quickly and accurately.

In the very first use of AI in the triage of a covid-19 patient, i.e. medical imaging for diagnosis, artificial intelligence with a deep learning algorithm has been used to help recognize lesions in CT images and even quantitatively characterize results and compare changes between examinations, which works at a considerably greater speed and accuracy. Some algorithms can even help differentiate covid-19 from normal viral pneumonia. When a suspected covid-19 CT image is detected, the AI alerts the doctor and brings the case to the top of the doctor's work list, suggests a

⁴⁷ D.Y. Kang, K.J. Cho, O. Kwon et al., *Artificial Intelligence Algorithm to Predict the Need for Critical Care in Prehospital Emergency Medical Services*, 28 Scandinavian Journal of Trauma Resuscitation and Emergency Medicine 17 (2020); E. Klang, B.R. Kummer, N.O.S. Dangayach, et al., *Predicting Adult Neuroscience Intensive Care Unit Admission from Emergency Department Triage Using a Retrospective, Tabular-Free Text Machine Learning Approach*, 11 Scientific Reports 1381 (2021).

⁴⁸ S.B. Jang, S.H. Lee, D.E. Lee, S.-Y. Park, J.K. Kim, J.W. Cho, et al., *Deep-Learning Algorithms for the Interpretation of Chest Radiographs to Aid in the Triage of COVID-19 Patients: a Multicenter Retrospective Study*, 15 PLoS ONE 11 (2020).

⁴⁹ See J. Bullock et al., *Mapping the Landscape of Artificial Intelligence Applications against COVID-19*, 69 Journal of Artificial Intelligence Research 807 (2020).

possible infection, and recommends pre-set interventions based on the results. This significantly improves the detection rate and consistency of treatment of covid-19 cases.

In the second fundamental use of AI in the triage of covid-19 patients, i.e. the field of patient prognosis prediction, using approaches such as the XGBoost algorithm⁵⁰ and Support Vector Machines⁵¹ aims to identify key measurable characteristics for predicting mortality risk, which can later be tested in hospitals upon patient admission and during the hospital stay.

The advantages of using AI in the triage of covid-19 patients have already been highlighted and focus on the possibility afforded by AI to carry out very precise and accurate assessments, where the data entered is of good quality.

The disadvantages undoubtedly reside in the possibility of undermining the autonomy of the decision-making process that leads to the choice of one specific treatment rather than another, and in the possibility of errors due to incompleteness or inconsistency of the data, or errors due to machine problems; in such cases it becomes important to establish precise and punctual responsibilities.

This stripping away of autonomy concerns both the medical decision-making process and the decision-making process of choosing by the patient expressed in the informed consent process.

Therefore, AI could affect, in terms of medical responsibility, the assessment of the appropriateness of treatment and, in terms of the patient's fundamental rights, the right of self-determination and the right to access intensive treatments.

We believe that the risk of conditioning the relative decision-making processes must be taken into serious consideration and that therefore in the health sector the principle of human surveillance must be understood in a "strong sense". That is, the decision-making processes must be developed independently of the AI which should simply represent, in the health sector where a fundamental right could be affected, a factor of comparison of the human decision-making process and should not be the main actor

⁵⁰ T. Chen, C. Guestrin, *Xgboost: a Scalable TreeBoostingSystem*, Proceedings of the 22nd ACM SIGKDD International Conference on Knowledge Discovery and Data Mining 785 (2016).

⁵¹ C. Cortes, V. Vapnik, *Support-Vector Networks*, 3 Machine Learning 273 (1995).

of the decision-making processes that affect responsibilities and rights.

4. Concluding remarks

The analysis conducted in the paper allows us to carry out some concluding remarks.

We have seen how extensive the debate has been on priority criteria for access to intensive care during the pandemic. International organizations and national scientific societies have intervened and offered their contribution on this point.

We concluded that in this field the use of “automatic” criteria, e.g. the age criterion, cannot allow a personalised evaluation of the situation of the patient that is at the core of the relationship of care and trust, as the Constitutional Court underlined in the mentioned decisions.

In this context, an analysis of the relevant issue of the use of new technologies in the field of evaluating the priority of access to intensive care is considered to be an extremely topical matter.

The issue of automatic (based on “automatic” criteria) or automated (based on algorithms) decisions is a constitutional central issue as its analysis is further capable of suggesting values and principles that may even refine the approaches to the use of AI in the care relationships.

On these aspects, the European documents on the subject up to the proposal for a regulation of 21 April 2021 introduced the first rules on the matter which were subjected to analysis and reflection during the course of the discussion. The application of artificial intelligence systems in the field of access to intensive care certainly represents a very relevant sector for evaluating the compatibility of artificial intelligence with the protection of the right of access to treatment, the protection of the autonomy of the doctor and of self-determination of patient in the relationship of care.

We have concluded that, also in the context of the mentioned rules issued at European level, in our system the principle of personalization of care does not allow for a complete substitution of human evaluation with a machine. While having to maintain an openness to the use of technologies in the care sector, we must be aware of the risks that exist, in particular with respect to the critical issues that may arise in the decision-making processes in reference to the connection between AI and professionals and AI and

patients. Where these processes are not transparent, it is not possible to distinguish between human reasoning and that of the computer program.

Above all, we think that there is still a space and a reason for a constitutionally and ethically oriented framework that should be developed for AI uses in healthcare and that this should complement the European rules in this field.

As we have seen, the proposed regulation on artificial intelligence contains very precise and timely rules and in the course of its approval it is possible that some provisions will be modified.

We believe that a risk-based approach, aimed at allowing European circulation of artificial intelligence devices and services, must be accompanied by a fundamental rights-oriented approach which therefore does not prevent the uniformity of the European space in terms of artificial intelligence systems, but allows, where provided for by the European constitutional system, further guarantees and measures to protect the fundamental rights at stake.

In Italy, as we have seen, constitutional case law has repeatedly highlighted the personalistic principle that underlies the care relationship⁵².

The relationship between doctor and patient is a relationship of care and trust that is constituted by the encounter between personal autonomy and professional responsibility⁵³.

In the Italian constitutional decisions, it is stated that the doctor's reasoning must be transparent and reasonable and the doctor may be called upon to explain the reasoning followed in identifying the appropriateness of a treatment⁵⁴.

From this constitutional case law a series of assumptions, that should inspire the regulation on the use of AI in the healthcare sector at European level as well, can be listed as follows:

a) the personalistic principle of care emerges in a way that, therefore, the personal dimension should prevail in the healthcare service. In such a system, the principle of personalization of care

⁵² See decisions of the Constitutional Court no. 282 of 2002, no. 338 of 2003, no. 151 of 2009, no. 169 of 2017.

⁵³ See Constitutional Court decision no. 438 of 2008 on informed consent as a "right of synthesis" between the right to be treated effectively according to the best scientific evidence and the right to self-determination.

⁵⁴ See paragraph no. 8 of the decision of the Constitutional Court no. 169 of 2017.

does not allow a complete replacement of decision-making professionals with the tools of AI;

b) the care relationship is a meeting of two autonomies (personal and professional). Autonomy refers to a space of freedom that is based on a dual notion of freedom: freedom *of* and freedom *from*. In this field there should be a freedom *of* choice, and a freedom *from* guidelines and *from* automatic and automated decisions, etc.;

c) the principle of explicability becomes especially important when artificial intelligence is brought into medical decision making. Beside this principle, the possibility of distinguishing between the AI decision-making process and the professional decision-making process is the basis of the legal and social acceptance of the processes.

Thus, professionals need to be able to understand AI systems in order to use them fairly. This requires inclusive and transparent processes and well understood governance.

Establishing ethical guidelines and constitutional boundaries requires an even more deeply developed supranational and multidisciplinary exchange between constitutional lawyers, professionals, ethicists, informatics and algorithm developers.

The European rules that we have seen in this analysis, of which the proposal of a regulation for artificial intelligence is only the latest act of the European Union in this field, represent a good basis but we think that they should be complemented with a fundamental rights-oriented approach which should also be interpreted as a normative tool that could increase the value of artificial intelligence with a view to achieving a standard of excellence by guarantees and measures aimed at protecting fundamental rights.

In conclusion, therefore, we believe that there is space and reason to develop further, starting from the analyzed European rules in this field, a constitutionally and ethically oriented framework for AI in healthcare based on the principle of personalization of care and the protection of the care relationship as, principally, a human relationship between a doctor and a patient.