

AI to support the horizontal approach in the treatment of psychiatric disorders

The 'open dialogue' model as a case*

Bruno Mercurio**

SUMMARY: 1. Democracy of care and 'open dialogue' as an approach to psychiatric disorders. What support from A.I.? Definition of the topic of investigation. – 2. 'Open dialogue' as an alternative organisational and therapeutic model in the health service. – 3. Legal perspectives on the use of A.I. in the public psychiatric health service. – 4. Potentialities and limits of the "open dialogue" in the Italian DSM and the role of A.I. in its implementation. Concluding remarks.

ABSTRACT:

Il cosiddetto "dialogo aperto" è una pratica terapeutica avviata in Finlandia e in Lapponia da Jaakko Seikkula agli inizi degli anni ottanta e oggi sperimentato anche in Italia su iniziativa del C.N.R. che ha sul tema un progetto in corso finanziato dal Ministero della Salute. Detto metodo è caratterizzato dal fatto che l'intervento istituzionale è svolto in una prospettiva di rete sociale, orientata a operare quanto più è possibile nel contesto di appartenenza della persona sottoposta a terapia, in modo da favorirne la comprensione da parte degli operatori e da porre in un atteggiamento più aperto e collaborativo il destinatario delle cure.

Il presente lavoro si interroga sulla possibilità che un supporto valido a superare le difficoltà applicative e a indirizzare in modo effettivo il descritto approccio terapeutico possa venire dall'impiego di sistemi di intelligenza artificiale (IA), il cui utilizzo in ambito psichiatrico è crescente.

In particolare, esaminato il modello terapeutico di prossimità e il quadro generale della normativa e della giurisprudenza in materia di intelligenza artificiale, si rifletterà sulle potenzialità e sui limiti

* Contributo sottoposto a revisione tra pari in doppio cieco.

** Researcher of administrative law in University of Naples "L'Orientale".

dell'uso della 'intelligenza artificiale (IA) a supporto del "dialogo aperto" sia sotto il profilo degli aspetti organizzativi di tale modello sia rispetto al metodo utilizzato, che enfatizza l'importanza della comunicazione e dell'interazione all'interno di una rete di supporto. Si tratta di attività in cui la tecnologia può certamente facilitare il lavoro, ma che richiedono un forte investimento in termini di spesa per implementare i sistemi e formare gli operatori e un attento bilanciamento con altri interessi rilevanti che non possono essere trascurati e che sono destinati a incidere fortemente sulla fattibilità e sui tempi di sperimentazione, valutazione e applicazione diffusa di questo modello terapeutico emergente.

The so-called 'open dialogue' is a therapeutic practice started in Finland and Lapland by Jaakko Seikkula at the beginning of the 1980s and is now also experimented in Italy on the initiative of the C.N.R., which has an ongoing project on the subject financed by the Ministry of Health. This method is characterised by the fact that the institutional intervention is carried out in a social network perspective, oriented to operate as much as possible in the context to which the person undergoing therapy belongs, so as to favour understanding on the part of the operators and to place the recipient of treatment in a more open and collaborative attitude.

This paper questions the possibility that a valid support in overcoming application difficulties and effectively addressing the described therapeutic approach could come from the use of artificial intelligence (AI) systems, whose use in the psychiatric field is increasing.

In particular, having examined the outreach therapy model and the general framework of legislation and jurisprudence on artificial intelligence, we will reflect on the potential and limitations of the use of artificial intelligence (AI) to support 'open dialogue' both in terms of the organisational aspects of this model and the method used, which emphasises the importance of communication and interaction within a support network. These are activities in which technology can certainly facilitate the work, but which require a big investment in terms of expenditure to implement the systems and train the operators, and a careful balancing act with other relevant interests that cannot be neglected and are bound to have a strong impact on the feasibility and timeframe of testing, evaluating and widely applying this emerging therapeutic model.

1. Democracy of care and open dialogue as an approach to psychiatric disorders. What support from A.I.? Defining the topic of investigation

In November 1962, Basaglia started the experimentation in Italy, in the psychiatric hospital in Gorizia, of the 'therapeutic community' based on the principle of the democracy of care¹.

The administration of the healthcare facility is, in fact, regulated through ward meetings and general assemblies in which the in-patients also take part, thus acquiring human dignity and a social role, being called upon to collaborate, also with their work, in the hos-

¹ The experience had originated in the 1950s by Maxwell Jones, who had invented, as an alternative to psychiatric hospitals, small communities formed by patients and psychiatric and social workers, run on collective participation and dynamics that were to realize the dispositions and qualities of each person. For an in-depth study, M. JONES, *The process of change. Birth and transformation of a therapeutic community*, Milan, 1988.

pital's daily life choices and initiated into a therapeutic pathway that becomes customised and not standardised, based on dialogue and not only on pharmacological treatments and which provides for continuous communication between the healthcare *team* and patients. It is considered, in fact, that «sharing serious responsibility with the staff is one of the most effective ways to overcome the lack of trust, low self-esteem and exaggerated dependence that often characterize the patient in psychiatric hospital»².

This experience, which was continued in Trieste, was the starting point for the so-called 'deinstitutionalisation' of psychiatric care³ which would lead, sixteen years later, to law no. 180 of 13 May 1978, known as the Basaglia law, which definitively set aside the constrictive model of psychiatric hospitals⁴.

Compulsory health treatment through hospitalisation becomes, in fact, the exception (art. 2 paragraph 2) to be implemented, in any case, not in 'ghetto' facilities, but with the establishment of specific psychiatric diagnostic and treatment services in general hospitals (art. 6 paragraph 2), respecting the dignity of the person and the constitutionally guaranteed civil and political rights, for which a special reserve of jurisdiction is introduced retained by the office of the tutelary judge which has the right to validate the measure whereby the mayor, as government official⁵, may order compulsory medical treatment (Article 3 paragraphs 1 and 2)⁶.

Basic treatment, for all cases that are not to be hospitalised, is entrusted to a network of widespread territorial public health centres (Article 1(2)) called upon to operate by ensuring the consent and participation of the person obliged to health care for mental illness⁷. This new approach proposes to bring the health system closer to the mentally ill person, considering the continuity of need that characterises his or her frailty.

Public authorities are asked to assume the responsibility of not limiting themselves to providing therapeutic services, but of having a constant and dialectical attention to the

² M. JONES, *Ideology and practice of social psychiatry*, Milan, 1981, p. 91.

³ A valuable account of this experimentation is in F. BASAGLIA, *L'istituzione negata*, Milan, 2018.

⁴ Although the path to the effective closure of asylums lasted for thirty years.

⁵ Supreme Court of Cassation, sec. I, 13 February 2020, no. 3660 in *Civil Justice Maximum 2020*

⁶ By means of an overall assessment of the compatibility of the indicated coercive measure with the protection and security needs of potential victims of violence and the possible indication of a different, less restraining, and more appropriate solution chosen from among those falling within the articulated system of security measures. See Italian Constitutional Court, 27/01/2022, no. 22 in *Law & Justice 2022*, Court of Bari sez. Sorveglianza, 18 July 2011 in *Giurisprudenzabarese.it* 2011 EDU Court judgment of 24 January 2022, (Sy v. Italy) regarding residences for the execution of security measures (REMS).

⁷ «In the formulation of the Basaglia law, psychiatric treatment presupposes that the patient's adherence to the therapeutic project and the submission to psychiatric treatment is, therefore, ordinarily conditioned, in an almost absolute manner, to the existence of the latter's consent: on the one hand, recourse to compulsory medical treatment is considered exceptional and subject to strict time limits (a maximum of seven days, unless extended); on the other hand, the very rationale of the endo-therapeutic purposes and, in any case, centred on the person of the patient, underlying the provisions of Law 833/1978, require the doctor to seek, in any case, albeit following a temporary coercive imposition, the patient's adherence and consent to treatment». Court Reggio Emilia, 15 March 2012, in *De Jure*, edited by Giuffrè 2012.

vulnerable ‘person’, protected by Article 2 of the Constitution individually and in his or her social projection, which is then the foundation of ‘care’ in the legal sense, highlighted by the most attentive legal doctrine on the subject⁸.

The model is also aimed, to the integration of the sick person into the community and, through public intervention, at rendering effective, pursuant to Article 3, paragraph 2 of the Constitution, the right to care for the indigent, until then effectively marginalised by the system, overcoming the obvious differences that characterised the treatment of mental distress depending on economic possibilities and the cultural and social context of the family of origin⁹.

Subsequently, Article 34 of Law No. 833 of 1978, instituting the National Health Service, transposed the Basaglia law, providing for a special Department of Mental Health, later organised on a regional basis and consisting of a set of structures to which the function of prevention and treatment of mental disorders is attributed, aimed at avoiding, as far as possible, the hospitalisation of patients and guaranteeing the rehabilitation of stabilised disorders¹⁰.

Basaglia’s thesis that treatment cannot occur without free communication between the doctor and the patient has been taken up by new experimental directions around the world and applied to models of care, also at home care, for disabled persons, including those with psychiatric disorders.

Such models can be traced more generally to the systemic-relational approach, to which Basaglia’s own method is connected. According to this theory, individual behavior is the

⁸ On this subject, A. PIOGGIA, *La cura nella costituzione*, in G. ARENA, M. BOMBARDELLI (eds.) *L'amministrazione condizionalista*, Naples, 2022, p. 57, G. ARENA, *La società della cura, un progetto fondato sull'empatia*, in <https://www.labsus.org/2018/01/la-societa-della-cura-un-progetto-fondato-sull-empatia>.

⁹ It has been pointed out that the marginalisation of economically unproductive subjects, including the mentally ill, has been a postulate of a bourgeois and industrial society since the end of the 16th century as a practical measure to rationalise production by relieving workers and their families of burdensome tasks to be employed for the benefit of the economy. While economically sound families were able to resort to home care or private clinics not based on restraint, the approach to illness for the destitute was predominantly oriented towards protecting the community of healthy and productive individuals from the patient, who, deemed unproductive and presumptively dangerous to themselves and others, were interned in psychiatric hospitals or, in the most serious cases, imprisoned in prisons as a consequence of their own conduct and treated with alienating therapies aimed at rendering them harmless rather than curing them or identifying the factors to be corrected even in their context of origin in order to avoid or manage their dangerousness so as to allow their social integration, deemed impossible and in any case anti-economic. In this sense the regulation of the sector and the role assigned to public institutions seems to be based on ‘protection from the patient’ rather than of the patient. On the subject P. GRITTI, S. GAGLIARDI, *Stigma and social exclusion in mental illness: an unresolved problem* in L. CHIEFFI (ed. by) *Bioethics practice and causes of social exclusion*, Milan, 2020 pp. 253-269.

¹⁰ The articulation of DSMs was envisioned by the Goal Projects of the 1990s. Each DSM is made up of three basic structures: the Mental Health Centre (CSM), the Psychiatric Diagnosis and Treatment Service (SPDC) and the intermediate structures of a semi residential (day centre) and residential nature (community, residential home, group flat). Most SRPs (Psychiatric Residential Facilities), i.e., so-called intermediate facilities, are accredited private facilities that the DSM uses, often without real integration of services and treatment teams. To consult the Presidential Decrees reciting the target projects, https://www.salute.gov.it/imgs/C_17_pubblicazioni_558_allegato.pdf. For a reconstruction P. MASCARO, *I servizi per la salute mentale in Italia: considerazioni critiche sulla riforma Basaglia e in merito alla sua tenuta al tempo della pandemia da COVID-19* in *Amministrazione in cammino*, 19 February 2021.

result of complex interactions within the system of belonging so that the therapeutic focus should not be limited to the identification and treatment of a person's internal symptoms, but requires understanding and modifying the relational dynamics that contribute to those symptoms. In therapy, this means working not only with the individual, but often involving family members or other significant members of his or her social system¹¹.

Among these approaches, particular interest has been aroused by the so-called 'open dialogue' therapeutic practice initiated in Finland and Lapland by Jaakko Seikkula at the beginning of the 1980s and now also experimented in Italy on the initiative of the C.N.R., which has an ongoing project on the subject funded by the Ministry of Health¹².

This method is characterised by the fact that all treatment decisions are taken and discussed openly, in the presence of the patient and those close to him (mainly his family members), and the institutional intervention is carried out in a social network perspective, oriented to operate as much as possible in the context to which the person undergoing treatment belongs, so as to favour understanding on the part of the practitioners and to place the recipient of care in a more open and collaborative attitude¹³.

This demanding form of care is based on very strong proximity pillars, such as flexibility, understood as «selection of the most effective therapeutic methods in each situation»¹⁴ which can change not only for different patients but also over time for the same subject, or continuity, understood as «unique and cohesive treatment»¹⁵ within which several specialists of the public administration operate in a complementary manner, with the active participation of the patient and his social network, in a dialogue on the choice to be made among several feasible options, through a shared and inclusive analysis of the needs to be met.

¹¹ The systemic-relational approach has focused on interactions and relationships within systems, such as families or social groups. Gregory Bateson, one of the pillars of this approach, contributed significantly with his double-bond theory, exploring how paradoxical communication within a system can contribute to psychological disorders. According to Bateson, "double-binding" occurs when a person receives contradictory messages on two different levels of communication, such as a verbal command being contradicted by nonverbal signals. This view ties in closely with the Palo Alto School, of which Bateson was an influential member. The school, active in the 1950s and 1960s, explored how communication patterns affect mental health and behavior within groups. Studies by this group emphasized the importance of considering social and interpersonal context in the treatment and analysis of behavioral disorders. On the subject G. BATESON, *Steps to an Ecology of Mind*, Chicago, 1972, in which the author sets out his vision of the ecology of mind and introduces the concept of double-binding. P. WATZLAWICK, J. BEAVIN BAVELAS, & D.D. JACKSON, *Pragmatics of Human Communication: A Study of Interactional Patterns, Pathologies, and Paradoxes*. New York, 1967 which contains the views of members of the Palo Alto School on how communication affects family relationships and structures. S. MINUCHIN, *Families and Family Therapy*. Harvard, 1974. in which systemic family therapy is described.

¹² Available at <https://www.istc.cnr.it/project/il-%E2%80%9Cdialogo-aperto%E2%80%9D-un-approccio-innovativo-nel-trattamento-delle-crisi-psichiatriche-desord>.

¹³ For an in-depth look at this therapeutic approach J. SEIKKULA, *The open dialogue, the Finnish approach to severe psychiatric crises*, Rome, Giovanni Fioriti Ed., 2014.

¹⁴ J. SEIKKULA, cit., p. 14

¹⁵ J. SEIKKULA, cit., p. 16

In this sense, the model referred to which will be briefly described below, may be considered an application of the democratic method in the administration of care, in which the relationship between private individuals and the administration changes, being ‘at the same time collaborators of each other’¹⁶, without attributing any *munus* to the former, but allowing them to express their needs and participate in the formation of the choices that affect them¹⁷, through instruments of dialogue with the users of the services that the public administration is required to provide¹⁸.

This approach is not easy to implement, and is characterised by a given technical complexity with an organisational and professional nature, since it does not follow a standardised and protocol-based model¹⁹, but requires an effort aimed at constructing a therapeutic pathway for each case and at guaranteeing assistance to the social network involved, composed mainly of family members who bear the burden of the patient’s daily management. If in fact this problem emerges in general for any form of care provided by the public health or social service to dependent patients living at home with relatives²⁰, in the case at hand it takes on greater significance in relation to the impact that the type of distress under consideration has on families as well as the preparation required to deal with it adequately²¹.

Within this framework, this paper questions the possibility if a valid support in overcoming application difficulties and effectively addressing the described therapeutic approach could come from the use of artificial intelligence (AI) systems, whose use in psychiatry is growing²².

In particular, having examined the proximity therapy model and the general framework of the legislation on artificial intelligence in the psychiatric field, we will reflect on the potential and limits of the use of artificial intelligence (AI) to support ‘open dialogue’ both in terms of the organisational aspects of this model, which is strongly marked by the home-based nature of care, and with respect to the method used, which emphasises the impor-

¹⁶ *Ibid.*

¹⁷ F. BENVENUTI, *Il nuovo cittadino*, Padua, p. 93.

¹⁸ On this subject, for a reconstruction of the notion of deliberative democracy in the administrative sphere, see B. MERCURIO, *Società e decisioni amministrative. Processi evolutivi verso una democrazia deliberativa*, Naples, 2021.

¹⁹ And in 2020, the use of restraining methods by psychiatric service workers was reported, see R. BOMBACE, A. CIOFFI, *Mental health, the complaint: ‘Coercive practices are still widespread in psychiatric services’*, in www.dire.it, 2020.

²⁰ Thus, A. PIOGGIA, *La cura*, cit. p. 62.

²¹ In March 2024, the magazine VITA dedicated a special issue to the hundredth anniversary of Basaglia’s birth on the state of the art of the system for taking charge of mental suffering from which it emerged how public mental health services are often in distress so that patients find themselves stuck in a chronic cycle of hospitalisations and pharmacological treatment, between public and private facilities, such as to configure a more sophisticated system of asylum characterised by alternating periods at home and stays in different health facilities where the pharmacological approach is prevalent. See <https://www.vita.it/rivista/basaglia-dove-sei/>.

²² C.A. CLERICI, A. FERRARI, C. ALBASI, Cesare *First considerations on clinical applications of chatgpt. artificial intelligence*, in *Psychiatry and Psychotherapy*, 2023, Vol 42, Issue 2, p. 53 et seq.

tance of communication and interaction within a support network, such as family, friends and health professionals, to help a person who is facing psychiatric difficulties. These are activities in which technology can certainly facilitate the work, but which require a big investment in terms of expenditure to implement the systems and train the operators, and a careful balancing with other relevant interests, such as that of confidentiality, which cannot be neglected and which strongly affect the feasibility and timing of testing, evaluation and widespread application of this emerging therapeutic model.

2. The ‘open dialogue’ as an alternative organisational and therapeutic model in the health service

By ‘open dialogue’ we mean a therapeutic approach involving the whole family and relationship network, preferably at home, leaving drug treatment on the back burner. This therapeutic approach was developed in a region of Finland (Lapland), in a large but sparsely populated area (around 80,000 inhabitants), and now forms the basis of an integrated network of mental health services in a Scandinavian country at the forefront of integrated social and health care systems²³.

The path that has led to the establishment of this model as *mainstream* in the treatment of mental distress has taken place over the last twenty-five years, in a constant connection between practice, research, academia and public services that has produced multiple clinical evidences from which a high percentage of psychopathological and social cures have emerged together with a decrease in the rate of chronicity²⁴.

The concept of ‘openness’ refers, as mentioned in the introduction, to the transparency of planning and decision-making processes that take place in the presence of all stakeholders: health professionals, the patient and the social network that relates with the latter on a daily basis.

It therefore takes the form of an integrated community-based care system involving family members and social networks from the first moment help is sought and a defined ‘dialogic practice’ of therapeutic interview within the ‘treatment meeting’²⁵.

The treatment method consists of a special type of interaction, the basic characteristic of which is that each participant feels listened to and finds adequate answers in a dialogue that is nourished by the coexistence of multiple, separate and equally valid ‘voices’ within a *setting*, consisting of the so-called ‘treatment meeting’, in which the patient is the cen-

²³ The Finnish approach to severe psychiatric crises is part of a psycho-pathological tradition that has always favoured the possibility of understanding psychotic onset in relation to the subject’s life events and any traumatic experiences.

²⁴ M. BALTER, *Returning to Madness*, in *Science*, Vol. 343, No. 6176 pp. 1190-1193, 2014.

²⁵ M. OLSON, J. SEIKKULA, D. ZIEDONIS, *The key elements of dialogic practice in open dialogue: fidelity criteria*, in *New Review of Psychiatric Studies*, vol. 4, 2017.

tre, but is not the focus of attention, being placed in a comfortable position, given by the preference for the home context that allows him or her to participate in the confrontation from a calming, non-subjugating position.

Dialogue is developed according to the principle of co-evolution, which promotes the open sharing of information between the patient and the treatment team regarding diagnosis, proposed treatment, therapeutic goals and care plans. This transparency aims at building trust and actively involving the patient in the decision-making process regarding his or her treatment.

The multidisciplinary healthcare *team* of mental health professionals, which includes psychiatrists, psychologists, nurses, social workers and occupational therapists, works exclusively in a synchronous manner, so that each element is examined contextually both among the professionals and with the other parties involved (the patient and members of the social network) in a collaborative manner²⁶.

The system is based on five organisational principles and two principles guiding treatment. The first principle, ‘immediate help’, provides for intervention within the first twenty-four hours of the psychotic event and has been found to be a decisive factor in reducing hospitalisations²⁷.

The second principle, ‘social network perspective’, involves the participation from the outset of the social network surrounding the patient, which is considered relevant «in the very definition of the problem»²⁸ and in understanding the context in which it may have arisen or otherwise manifested itself.

The third principle of ‘flexibility and mobility’, which has already been referred to, is that of personalised treatment methods and the preference of the patient’s home as a meeting place²⁹.

The fourth principle of ‘responsibility’ is indicative of the person-oriented approach of the model, as it basically refers to the ‘care’ given by the first person to whom the need arising from the patient’s behaviour is manifested or reported to, and to the commitment to following up either directly or by activating those with the competence to assist.

The last principle, that of ‘psychological continuity’, which has also been mentioned, is that «the team assumes responsibility for treatment for as long as necessary for recovery and in any setting, whether hospital or outpatient»³⁰.

Instead, the two principles that guide the meetings are “tolerance of uncertainty” whereby the entire group of experts and non-experts attending the meetings do not follow a standardized protocol but are guided by what emerges from the meeting which, in turn is

²⁶ J. CILIBERTO, M. PICCININ, *Le pratiche collaborative nei servizi di cura e tutela*, Carocci, 2022.

²⁷ J. SEIKKULA, cit., p. 13.

²⁸ J. SEIKKULA, cit., p. 14.

²⁹ J. SEIKKULA, cit., p. 15.

³⁰ J. SEIKKULA, cit., p. 16

conducted according to the last principle namely that of dialogism whereby every decision is formed through direct and participatory confrontation³¹.

It is, therefore, a highly innovative approach, which is currently being tested and adopted in many Western countries, both for its high effectiveness in containing and resolving the symptoms of the patient, who presents to the services with a severe psychiatric crisis, and for maintaining long-term therapeutic effectiveness³².

In Italy, open dialogue has been gradually adopted by several healthcare facilities. In particular, a project funded by the Ministry of Health within the framework of the CCM call for proposals (2014), aimed at assessing the applicability of the approach to the Italian context, through testing and evaluating the outcomes of the open dialogue method in several Mental Health Departments (DSM).

As a result, in 2014, some Departments of Mental Health and social services started to organise training courses aimed at a reorganisation of services and practices in a dialogic sense.

Moreover, in response to the 2014-2018 National Plan for Prevention, which included mental health among its priority objectives, assigning healthcare facilities the task of intervening early on the first symptoms of a psychiatric crisis, ASL TO1 submitted to the Ministry of Health a two-year trial project aimed at assessing the transferability (operational and organisational practice) of the open dialogue in Italian mental health departments³³.

The results of the experiment revealed that although a partial adherence to the open dialogue paradigm was found at the clinical level, the greatest difficulties encountered by practitioners and the greatest obstacle to the transferability/applicability of the dialogue approach were identified at the organisational level, i.e. in relation to the context of the service that had to adopt and implement the model in question.

These elements, related to the service adopting and delivering the clinical interventions, are also those that most hindered the possibility of faithful adherence to the protocol.

Then, in 2015, the Italian Ministry of Health funded a national project - still ongoing - to assess the transferability of the open dialogue in the context of seven Italian mental health departments: Turin, Savona, Trieste, Rome (two departments), Modena, Catania. In particular, it is worth mentioning that the Department of Mental Health (DSM) of Modena began its clinical work by engaging not only in training but also in a specific research activity aimed at assessing the feasibility and effectiveness of applying DA in a Mental Health Centre (CSM) and in the Psychiatric diagnosis and Treatment Department (SPDC)³⁴.

³¹ J. SEIKKULA, cit., p. 17 - 19.

³² More than 80% of the patients actively returned to their social and working lives.

³³ The regions involved were Piedmont, Liguria, Marche, Lazio, Sicily

³⁴ R. POCOBELLO, G. SALAMINA, C. ROSSI, C. ALONZI, 'Open Dialogue in Italy: From project to programme. The UK Peer-Supported Open Dialogue Bulletin', Rome, 2016.

3. Legal perspectives on the use of A.I. in the psychiatric public health service

It is undoubtedly a phenomenon of legal significance that artificial intelligence tools are increasingly being used to achieve specific goals faster and more accurately than the use of human intelligence³⁵.

In healthcare, the interaction between complex machines and medical specialists makes it possible, in particular, to strengthen the sustainability of a working hypothesis formulated by the latter, facilitating the performance of both diagnostic and therapeutic activities based on timely, as well as potentially better, decisions, since they are endorsed on the basis of more reliable predictions of their favourable outcome³⁶ and customised to the individual needs of patients.

In recent years, following the health emergency caused by the Covid-19 pandemic, the need to use technological support for clinical knowledge to improve the quality of service and healthcare provision is even more evident.

In fact, on the one hand, the pandemic event, especially in the first phase, imposed rules of behaviour, such as the so-called social distancing, which put operators in serious diffi-

³⁵ Artificial intelligence was first mentioned by J. McCarthy at a conference at Dartmouth. On this subject see J. MCCARTHY, M. L. MINSKY, N. ROCHESTER, C.E. SHANNON, “A proposal for the Dartmouth Summer Research Project”, August 1955. Also, for an initial reconstruction of the evolution of artificial intelligence, see A. D’ALOIA (ed. by), *Intelligenza artificiale e diritto. Come regolare un nuovo mondo*, Milan, 2020; A. VITERBO and A. CODIGNOLA, *Intelligenza artificiale e le sue origini*, in *Giur. It.*, no. 7/ 2004; G. SARTOR, *L’intelligenza artificiale*, in Id., *L’informatica giuridica e le tecnologie dell’informazione. Corso di informatica giuridica*, Turin, 2016, p. 279 et seq.; V. NERI, *Administrative law, and artificial intelligence: a possible love*, in *Urb. App.*, n. 5/2021, p. 581 et seq., to which we also refer for an examination of the first pronouncements of administrative jurisprudence on the modalities and application limits of such technologies in public administration.

³⁶ As for experiences in which the use of AI tools has proved to have had a favourable impact on the search for and identification of diagnoses, there are numerous initiatives already under way to improve the efficiency of the health service and simplify the exercise of the citizen’s right to health at every stage of the health and socio-health care process with a view to developing a citizen-centred healthcare system. During the pandemic, for example, the use of so-called chatbots or virtual assistants was used alongside call centres, i.e. *machine learning* systems that learn from the data already accumulated to respond to patients, who indicated their symptoms on the basis of which the virtual assistant either reassured them or decided to pass the call on to a doctor. A positive experience to be reported is IBM’s Watson system, see in this regard A. BIANCARDO, *Le problematiche etico giuridiche relative all’utilizzo dell’intelligenza artificiale in ambito sanitario*, in *Jus online*, n. 3/2021, where the author, describing it, states that ‘it is able to recognise sounds and images of the environment, dialogue with people, perform predictive calculations, and make decisions autonomously, under the control of the user. In the medical field, Watson has reached very advanced levels of development: to date, it is one of the most advanced artificial intelligence systems, with complex algorithms that can learn from interaction with the environment and learn from mistakes and experience. Its use in the field of medical diagnosis and therapy enables doctor-patient interaction, constant monitoring of the latter’s state of health, and direct administration of treatment plans. Specifically, the system processes a set of data, such as the patient’s symptoms, clinical and hereditary history, examines scientific information including clinical studies, medical articles, and guidelines, and finally formulates hypotheses providing a set of recommendations and personalised therapies, classified by level of evidence. The IBM DeepQA architecture on which it is based also makes it possible to calculate the probability of success of treatments and expected recovery times. The first commercial application of IBM Watson, dating back to 2013, concerns the diagnosis and treatment of lung cancer, and has achieved encouraging results.’

culty in the activity of treating and monitoring patients³⁷ and, on the other hand, once it was over, it entailed an increase in the need for care, which was difficult for a health system that had been severely downsized by the spending cuts that affected it. The pandemic not only adversely affected prevention activity, due to a distortion for many of the real health priorities, but also had a serious impact on people's mental health and the development of new mental disorders, even among the business community³⁸.

This scenario has accelerated the debate that had already been going on for some time concerning the advisability of resorting to telemedicine and AI support in the identification and reconstruction of the origin, course, and recovery of psychopathological conditions through tools that are capable of supporting medical *teams*³⁹ not only in diagnosis, but also in the personalisation of psychiatric treatments, real-time monitoring of patients, and evaluation of the results obtained⁴⁰.

In this sense, case law distinguishes telemedicine, which uses the algorithm⁴¹ by applying it to technological systems in order to achieve an automation effect, i.e., action and control systems suitable for reducing human intervention, from artificial intelligence in which, on the other hand, the algorithm contemplates machine learning mechanisms and creates

³⁷ At this stage, the first application of AI was undoubtedly to assist researchers in designing a vaccine that would protect healthcare workers and contain the pandemic. However, such tools were also used in the continued care of patients not infected with the coronavirus, who were unable or unwilling to be seen regularly and who risked aggravating themselves or failing to detect the risk of relapse in time. It was also on this occasion that awareness was raised of the very poor digital training of the human resources deputed to provide healthcare in various capacities. On this point, see: <https://www.coe.int/en/web/artificial-intelligence/ia-e-lotta-contro-il-coronavirus-covid-19>, where we find an overview, albeit not exhaustive, of the research carried out worldwide on the various implications of AI in the fight against Covid-19. As well as, in doctrine A. PAJNO and L. VIOLANTE (eds. by), *Biopolitica, pandemia e democrazia- Il ruolo del diritto nella società digitale*, Bologna, 2021; L. FERRARO, *La telemedicina quale nuova (e problematica) frontiera del diritto alla salute*, in *Dir. dell'informazione e dell'informatica*, no. 4-5/2022, p. 837 et seq.

³⁸ On this subject, see <https://www.nbst.it/1307-lockdown-e-salute-mentale-in-toscana-uso-antidepressivi.html>; <https://www.nbst.it/1306-suicidi-durante-pandemia-confronto-dati-germania-italia.html>; <https://www.nbst.it/996-salute-mentale-e-covid-19-fra-tante-variabili-ansia-e-depressione-restano-purtroppo due elementrici.html>; [https://www.nbst.it/746-coronavirus-segni-non-fisici-operatori-sanitari-stress-ansia-disordini posttraumatici depressione insonnia burnout.html#:~:text=Between%20the%2011%20and%20health%20and%20anxiety%20in%2045%25](https://www.nbst.it/746-coronavirus-segni-non-fisici-operatori-sanitari-stress-ansia-disordini posttraumatici depressione insonnia burnout.html#:~:text=Between%20the%2011%20and%20health%20and%20anxiety%20in%2045%25;); https://www.who.int/publications/i/item/WHO-2019-nCoV-Sci_Brief-Mental_health-2022.1; <https://www.who.int/news/item/02-03-2022-covid-19-pandemic-triggers-25-increase-in-prevalence-of-anxiety-and-depression-worldwide#:~:text=Wake%20Dup%20call%20to%20all,mental%20health%20services%20and%20support&text=In%20the%20first%20year%20of,Health%20Orga>.

³⁹ The aim is not to replace the doctor who alone is in charge of the decision and the related responsibility, as pointed out by M. DAVERIO and F. MACIOCE, *Artificial Intelligence and the Right to Health in European Regulation: Emerging Aspects Concerning the Doctor-Patient Relationship*, in *Teoria e critica della Regolazione Sociale*, n. 1/2023, p. 11. where the authors affirm that "On the physician's side, an excessive reliance on AI technologies may in fact generate, as highlighted by the *soft law* documents on the subject, risks of de-empowerment of those who use such systems and the relative tendency to trust the systems' outputs on the basis of their objectivity, accuracy or perceived complexity rather than on their clinical efficacy, and *deskilling* risks, linked to the excessive reliance on AI systems as an inhibitor of health professionals' clinical competences"; K. GODDARD and A. ROBERT, in the same direction are also expressed. GODDARD and A. ROUDSARI and J.C. WYATT, *Automation bias: a systematic review of frequency, effect mediators, and mitigators*, in *Journ. American Medical Inf. Ass.*, 2011, p. 311-347.

⁴⁰ G. COLLECCHIA and R. DE GOBBI, *Artificial intelligence, and digital medicine: a critical guide*, Cambridge, 2023.

⁴¹ understood as a finite sequence of instructions, well-defined and unambiguous, such that they can be executed mechanically and such that they produce a given result.

a system that does not merely apply software rules and preset parameters but, on the contrary, constantly processes new criteria of inference between data and makes efficient decisions on the basis of such processing, according to a process of machine learning⁴². The latter application is the one that raises the greatest concern and on which the attention of the various sciences, including human and social sciences, is, therefore, focusing on the limits necessary for its use.

The ‘admissibility and limits of the use of so-called advanced algorithmic decision-making, in fact, is an issue that has been addressed by administrative doctrine⁴³ and jurisprudence for some years now, due to the increasingly frequent recourse to the algorithmic tool within administrative proceedings, especially if characterised by serial or standardised procedures where a considerable number of requests must be handled, for the processing of which the use of the algorithmic tool allows for greater speed, efficiency and in abstract terms greater impartiality⁴⁴.

However, the opposite need has emerged to counterbalance the simplifying and acceleratory pressures, ensuring continuous human control within the procedure, as a guarantee function (the so-called human in the loop) especially *ex ante*, during the design of the *software* when the identification of the data and the definition of the algorithmic rule takes place, which acquires fundamental importance since the automated decision consisting of the *output* produced by the machine depends on the *input* with which it is trained, when the administration is called upon to carry out continuous tests and updates to guarantee the rights of citizens⁴⁵.

The control must then be kept constant over time, allowing the administration to intervene to carry out interlocutions with the private individual to verify upstream the accuracy of the data⁴⁶ and the private individual to have full knowledge of the mechanisms that led to the decision, supplemented or even created by artificial intelligence, in compliance with the principles governing the administrative procedure.

Hence, the use of the algorithm, in a supplementary and subservient function to the human decision, or even in a partially decisional function, must never entail a lowering of the

⁴² Thus, Council of State sect. III, Nov. 25, 2021, no.7891, in *Rass. dir. farmaceutico* 2022, 1, 95.

⁴³ with also quite various positions which, for reasons of economy, cannot be accounted for here. For an open approach is that of M.G. PELUSO *Artificial intelligence and quality data. La tecnologia come valido alleato*, in *Astrid*, 2, 2022, et sew. 322 A doubtful reading is instead that of M. INTERLANDI, *Ma siamo davvero sicuri che l'intelligenza artificiale sia più efficiente di quella umana? Spunti di riflessione sulla decisione amministrativa algoritmica rispetto alle garanzie personali e ai rischi di possibili discriminazioni (cd. bias) e di minacce per la democrazia*, in *irpa.eu*, 20 November 2021.

⁴⁴ This is because, «applied to administrative choice, indeed, the algorithm always leads to an impartial result, without any subjective element intervening to alter or change the result. A merit is therefore the invariability of the outcome: the “terms” of the algorithm, combined in the manner assumed by the same, always and invariably lead to the same result». In this sense, T.A.R. Napoli, sec. III, 14 November 2022, no. 7003, in *Diritto dell'Informazione e dell'Informatica* (II) 2023, 1, II, 91.

⁴⁵ Council of State sez. VI, 8 April 2019, no.2270, in *Foro it.* 2019, 11, III, 606

⁴⁶ In this sense see Council of State, 13 December 2019, Judgments Nos. 8472, 8473, 8474 in *giustiaamministrativa.it*.

level of protection guaranteed by the law on administrative procedure, and in particular those on the identification of the person responsible for the procedure, on the obligation to state reasons, on participatory guarantees, and on the so-called non-exclusivity of the algorithmic decision⁴⁷.

Nor can the imputability of the decision to the competent authority be waived, which is always obliged and must be able to carry out the necessary verification of the logicity and legitimacy of the choice and outcome entrusted to the algorithm⁴⁸.

The now prevailing orientation thus tends to overcome the perplexities, rightly expressed by the initial positions of international and domestic jurisprudence on the full fungibility of human choice with automated choice⁴⁹, calibrating it with the principle of verifiability and non-exclusivity of the algorithmic decision taken up by the European Parliament Resolution of 16 February 2017⁵⁰ and by the European Regulation on the protection of personal data (2016/679, the so-called GDPR)⁵¹, which expressly provides, in Article 22, that in the event in which an automated decision «produces legal effects concerning or significantly affecting a person» the same cannot be entrusted exclusively or otherwise imputed, as to liability to the machine⁵².

Having ensured these guarantees, the use of the algorithmic function within the administrative procedure is not only not prohibited, not even in relation to proceedings characterised by discretion, including technical discretion, but it is even encouraged, since it meets the standards of efficiency and economy of administrative action laid down in Article 1 of

⁴⁷ Tar Napoli no. 7003/2022, cited above.

⁴⁸ Council of State, Section VI, Judgment No. 8472 cit., In doctrine G. GALLONE, *Riserva di umanità e funzioni amministrative*, Milan, 2023, pp. 41 et seq.: in this regard, authoritative doctrine had already pointed out at the dawn of legal informatics that the administrative act, even if computerised, is in any case an 'act attributable to the authority' in all its aspects. The referability of the computer act to the authority is proven by the circumstance that the will of the computer is, as to its genesis, still the will of the authority. Cf. A. MASUCCI *L'atto amministrativo informatico. Primi lineamenti di una ricostruzione*, Naples, 1993, 19 et seq., pp. 83 et seq. On the inconceivability of an artificial intelligence system as an employer, see European Patent Office, 27 January 2020 in *Giur. annotata dir. ind.* 2020, 1, 1241.

⁴⁹ In *Loomis v. Wisconsin* in *SCOTUSblog*. Retrieved May 5, 2017 concerning a case in which the judge in determining the sentence for a person found guilty of fleeing a public official referred to a score assigned by a robotic instrument that had given the defendant a high index of risk of recidivism. Council of State sec. III, 28/12/2020, (hearing 11/12/2020, dep. 28/12/2020), no.8435; T.A.R. Lazio, Rome, 22 March 2017, no. 376, in which Section III-bis of the showed strong perplexity in the use of computer programmes executing predetermined algorithmic rules, in *giustiziaamministrativa.it*.

⁵⁰ Available at <https://eur-lex.europa.eu/legal-content/IT/TXT/PDF/?uri=CELEX:52017IP0051&from.de>.

⁵¹ Available at <https://www.garanteprivacy.it/documents/10160/0/Regolamento+EU+2016+679>. For an in-depth study on the topic, G. LO FARO, *Health data and European e-Health: between personal data processing and algorithmic administrative decision-making*, in *www.astrod-online* no. 2/2023.

⁵² Particularly in the healthcare sector the issue concerns the difficult identification of the criterion for allocating liability where, for instance, the jointly formulated diagnosis turns out to be incorrect or where, due to technical errors in the AI instrument, elements that should have led to changes in the treatment or, in any case, to a different approach from the one taken, are not detected in time during patient monitoring. On the issue of liability for the use of AI, see, among others, M. SAVINI NICCI and G. VETRUGNO, *Intelligenza artificiale e responsabilità nel settore sanitario*, in U. RUFFOLO (ed. by), *Intelligenza Artificiale - Il diritto, i diritti, l'etica*, Milan, 2020.

Law 241/90 on administrative proceedings, which, in turn, is linked to the constitutional principle of good administrative behaviour, enshrined in Article 97 of the Constitution⁵³.

From a regulatory point of view, we are still far from having a specific discipline for applications of artificial intelligence in healthcare⁵⁴.

Recently, in fact, a general notion of artificial intelligence, including the different definitions provided over time in the resolutions and regulations referred to in part, was introduced into the European legal system by the *Artificial Intelligence Act*⁵⁵, which defines it in Article 3 as “a machine-based system, designed to operate with different levels of autonomy, which can show adaptability after implementation and which, for explicit or implicit purposes, deduces from the *input* it receives how to generate *output* such as predictions, content, recommendations or decisions that can influence physical environments”.

The standard therefore includes all those mechanisms that can make autonomous determinations based on information provided to them⁵⁶, bringing benefits in the areas in which they are used because they are able to speed up and make human activity more precise. At the same time, however, in the wake of the jurisprudential orientations produced at international level and in the Member States, which have just been mentioned, the European legislator is aware that these instruments, especially when used by public authorities, entail a number of risks, the marginalisation of which is far from simple⁵⁷.

In this sense, in line with the regulatory development and the recalled jurisprudential formulation, which are substantially transposed in this new framework source on I.A. in Europe, the approach is primarily focused on risk, being oriented in the sense of ‘not hin-

⁵³ Consiglio di Stato sez. VI, 4 February 2020 n. 881 in giustizia amministrativa.it.

⁵⁴ For a reconstruction of the European regulatory framework on artificial intelligence in the medical field, see M. DAVERIO and F. MACIOCE, *Intelligenza Artificiale e diritto alla salute*, cit.

⁵⁵ This is the Regulation of the European Parliament and of the Council laying down harmonised rules on artificial intelligence, which has not yet entered into force, but was approved by the European Council and lastly by the European Parliament on 13 March 2024. In addition to formulating a definition of artificial intelligence, it sets itself the ambitious goal of providing an organic framework for the use of the relevant technologies while respecting the rights potentially affected by them. For the text, <https://digital-strategy.ec.europa.eu/it/policies/regulatory-framework-ai>.

⁵⁶ In this sense, it has been pointed out that it is possible to distinguish between weak and strong AI and that only the latter includes so-called *machine learning*, i.e. those machines that are able to modify their behaviour based on their experience. On this point, see: L. VIOLA, *Attività amministrativa e intelligenza artificiale*, in *Cyberspazio e diritto*, n. 1-2/2019, p. 78; A.F. URICCHIO, *La sfida della strategia europea dell'Intelligenza Artificiale tra regolazione e tassazione*, in ID. (ed. by), *Intelligenza Artificiale tra etica e diritti, Prime riflessioni a seguito del libro bianco dell'Unione europea*, Bari, 2020.

⁵⁷ These risks underlie an attitude of mistrust that is still widespread in public opinion, which is divided on the subject into two categories, that of the apocalyptic and that of the integrated. The words are by U. Eco, *Apocalyptic and integrated*, Milan, 1964, and emerge in the *White Paper on Artificial Intelligence at the Service of the Citizen*, drawn up by the Agenzia per l'Italia Digitale in 2018. More specifically, the former are against the inclusion of AI in public administration, highlighting a series of criticalities that could only produce negative effects not only on the efficiency and effectiveness of the administration but also on citizens' rights. The latter, on the other hand, take a diametrically opposed position, believing that the implementation of these technologies would significantly improve both administrative activity and citizens' quality of life.

dering' innovations in public administration <<which would benefit from a wider use of compliant and secure AI systems, provided that such systems do not entail a high risk>>⁵⁸. The measure of risk, in turn, is predetermined, having been identified in appropriate lists annexed to the Regulation the uses of AI that involve unacceptable risks, therefore to be prohibited; those with a high risk, for which clear requirements must be established by defining specific obligations borne by those who develop, distribute and supply the relevant applications; those with a low risk, for which specific transparency obligations are introduced to encourage full information and thus promote user confidence; and those with a low or no risk, for which no specific guidelines are taken.

Health care is among the activities configured as high risk, first and foremost as an essential service and, therefore, in relation to the possibility of access to services, which, in the particular context of the treatment of psychiatric disorders we are dealing with, has been seen to be an element of constant criticality.

In particular, the social rights to protection, non-discrimination and human dignity, which should be guaranteed by the universal nature of the health service, have historically been and still are measured against the organisational and economic difficulties of the system in achieving and maintaining the particularly high standards of continuity and flexibility in care that holistic approaches to mental illness, such as the one analysed in the open dialogue, would require⁵⁹.

This leads to a poor redistribution of public assistance⁶⁰, as occurred in the therapeutic practice examined, in which the inadequacy of the public health system to guarantee services inspired by approaches other than those based on pharmacological treatment alternating with hospitalisation, has led to the aforementioned situation of 'widespread asylum' in all those cases in which families are economically and culturally unable to provide the patient with additional specialist care or even substitutes for public care at home or in facilities.

In this context, the safe use of A.I., understood as a non-discriminatory use⁶¹, to the extent that it is able to facilitate the intervention of health professionals in the care pathway,

⁵⁸ See Recital 58 of Regulation, cit.

⁵⁹ It is no coincidence that one of the Sustainable Development Goals, part of the 2030 Agenda, agreed upon by UN member states is precisely that of ensuring adequate health coverage for the poor. See *Universal health coverage (UHC)*, in [https://www.who.int/news-room/fact-sheets/detail/universal-health-coverage-\(uhc\)](https://www.who.int/news-room/fact-sheets/detail/universal-health-coverage-(uhc)).

⁶⁰ It has been observed that, although funded by a progressive contribution system, the universal health system based on a compulsory, contributory insurance model, accompanied by transfers of public resources and the simultaneous existence of private services, presents a substantial disparity according to the total income of users, contradicting the very sense of universality. S. A. GLIED, *Health Care Financing, Efficiency and Equity*, in NBER Working Paper n. 13881, March 2008, DOI:10.3386/w13881, available in chrome extension: //efaidnbmnbicajpcgclcfndmkaj/https://www.nber.org/system/files/working_papers/w13881/w13881.pdf.

⁶¹ In fact, the use of AI to profile access to essential services is prohibited. In particular, Recital 68 states that «as far as health is concerned, the European Health Data Space will facilitate non-discriminatory access to health data and the training of AI algorithms from such data sets in a secure manner».

represents a facilitator of access to adequate services, capable of reducing in the long term the critical issues that lead to a denial or at any rate a reduction in the protection of vulnerable persons⁶², such as the scarcity of human resources, the costs of home visits and the difficulty of ensuring adequate continuity of care.

However, there are critical aspects, especially in the short to medium term perspective in which such systems should be created and implemented, primarily the limited available economic resources.

In this sense, a specific contribution should have come from the use of the funds specifically allocated in measure 6 of the National Recovery and Resilience Plan for structural investments in health, including the objective of ‘home as the first place of care’ aimed at creating the prerequisites for increasing home care services also by strengthening the technological infrastructure and tools for data collection, processing, analysis and simulation (ESF)⁶³.

Although there are no direct references to the implementation of artificial intelligence models in the guidelines issued to implement the aforementioned measure⁶⁴, it does not seem to be excluded that they could be included among the tools that use telemedicine to better support patients, especially those suffering from chronic pathologies, among which psychiatric disorders fall into the category of ‘major pathologies’⁶⁵.

However, the expenditure dedicated to mental health, even within the framework of the National Recovery and Resilience Plan, is still very low, and it is therefore presumable that it will not be sufficient to give a strong boost to complex models such as the one examined in this paper, which would have needed instead an injection of extraordinary funds, since they could not rely on ordinary ones⁶⁶.

⁶² The concept of vulnerability is multifactorial and, as has been keenly observed, constantly changing; it encompasses both those who are chronically or for long periods in one or more objective situations of weakness (European Court of Human Rights judgment of 24 January 2022 - Appeal no. 11791/20 - Sy against Italy Constitutional Court judgment no. 22 of 2022) and each individual, at certain times in their lives. On the subject. M. LUCIANI, *Le persone vulnerabili e la Costituzione*, in https://www.cortecostituzionale.it/documenti/convegni_seminari/roma_2022-persone_vulnerabili_-_massimo_luciani_20220503170920.pdf.

⁶³ The reference is to Component: C1 of the Mission under the heading Neighbourhood networks, facilities and telemedicine for territorial health care under which Investment Line: M6C1 I1.2 - Home as first place of care and telemedicine.

⁶⁴ See the Organisational Guidelines containing the digital model for the implementation of home care at https://www.pnr.salute.gov.it/imgs/C_17_pagineAree_5874_0_file.pdf.

⁶⁵ For which telepsychiatry and telepsychology services are provided. Thus, the national guidelines on telemedicine issued by the Ministry of Health https://www.salute.gov.it/imgs/C_17_pubblicazioni_2129_allegato.pdf

⁶⁶ According to a recent study by the ITACA Foundation, Italy ranks last in Europe in terms of the share of health expenditure devoted to mental health, allocating approximately 3,4% of total health expenditure to it, while the main high-income countries allocate more than 10%. See https://www.sanita24.ilsole24ore.com/art/aziende-e-regioni/2023-10-04/salute-mentale-italia-servono-almeno-19-miliardi-e-47percento-operatori-scommessa-territorio-e-chance-telemedicina-195220.php?uuid=AFhsxn6&refresh_ce=1_

The impact of the possible fragmentation of the Regional Health Services – resulting from the so-called differentiated regionalism project⁶⁷ – which could further increase disparity of inequalities in a multi-level healthcare system such as ours⁶⁸ should be pointed out. Regarding the impact that the use of *machine learning* in this particular area of healthcare may have on fundamental rights, the European Parliament's guidelines incorporate the results of the most open jurisprudential formulation that has been reported in the Italian context, but which has been paralleled worldwide.

In particular, it is expected that the interference of I.A on fundamental rights must be assessed during the development of the systems themselves, before making them operational, so as to put in place adequate risk mitigation systems; guarantee a high quality of the data that feed the system, to minimise discriminatory results; allow the traceability of the results for control by the authorities in charge of verifying the work of public health facilities to protect patients; provide clear and adequate information to the operator, so that the level of safety and accuracy in the operation of the machine can be monitored⁶⁹. These are aspects that must necessarily be taken into account, which also raise ethical issues of no small importance⁷⁰, such as the vulnerability of digital data in health care, the protection of which is crucial since we are dealing with sensitive data, the handling of which requires the prior informed consent of the patient and the regulation of the consequences of errors in the training of algorithms.

More precisely, the issue of the protection of privacy and confidentiality of health data⁷¹ whose discipline is dictated by the aforementioned EU Regulation No. 679/2016 is connected both to the risk of such data being stolen (through hacking activities) and then subsequently tampered with, and to the difficulty of considering explicit consent to the

⁶⁷ On this topic, see D-U. GALETTA and J.G. CORVOLAN, *Artificial intelligence for a Public Administration 4.0*, in *Federalismi*, no. 3/ 2019; M. OROFINO, *The question of the under-use of artificial intelligence in the health field: hints of constitutional relevance*, in *These Institutions*, n. 4/2022.

⁶⁸ According to the data provided by the National Agency for Regional Health Services, by the fourth quarter of 2023 all the European deadlines of the NRP's Health Mission had been met, but the Centre-South is worryingly lagging behind in home care and the whole country. See https://www.agenas.gov.it/images/2023/primo-piano/monitoraggio-dm77/Monitoraggio_DM_77_sintesi_fase_2_v2__finale.pdf. A gap that, according to the Gimbe Foundation, risks worsening with the Calderoli Bill. Cf. *Independent monitoring of the progress status of the Pnrr Health Mission* at <https://coronavirus.gimbe.org/press/comu>. On organisational complexity and territorial prluralism M. D'ARIENZO, *Contributo allo studio dei modelli organizzativi in sanità*, Torino, 2022, p. 84 et seq.

⁶⁹ According to Recital 96 of the Regulation «The objective of the fundamental rights impact assessment is to enable the deployer to identify the specific risks to the rights of persons or groups of persons likely to be affected and to identify the measures to be taken when those risks materialise. The impact assessment should apply to the first use of the high-risk AI system and should be updated when the deployer considers that any of the relevant factors have changed».

⁷⁰ A. BIANCARDO, *Le problematiche etico giuridiche relative all'utilizzo dell'intelligenza artificiale in ambito sanitario*, in *Jus online*, no. 3/2021, p. 102 et seq.

⁷¹ F. PIZZETTI, *Artificial intelligence, personal data protection and regulation*, Turin, 2018. They are defined as, according to Article 4(15) of Reg. (EU) No. 679/2016, 'personal data relating to the physical or mental health of a natural person, including the provision of health care services, revealing information relating to his or her state of health'.

processing of data for the so-called secondary use, i.e. their use for research, not knowing all the possible potentialities and capabilities of the AI that collects and uses them. In this sense, the aforementioned *Artificial Intelligence Act* seems to go in the direction of balancing the need to protect sensitive data with the public interest in developing tools that can improve the quality of citizens' health.

In particular, Article 59(1)(a) of the European Regulation provides that personal data lawfully collected for other purposes may be processed in the regulatory testing space for AI for the purpose of developing, training and testing AI systems to safeguard a substantial public interest, inter alia in the fields of «public health, including the detection, diagnosis, prevention, control and treatment of diseases and the improvement of health systems». This also applies to biometric data, which are generally afforded particularly stringent protection, and for which it is considered appropriate to prohibit their use to develop AI systems, with the exclusion of applications used for medical or security reasons, such as systems intended for therapeutic use⁷².

Such data, when usable, are rightly classified as 'high risk' both if they are intended for biometric categorisation, based on sensitive attributes or characteristics protected under Article 9(1) of Regulation (EU) 2016/679, and if they are processed for emotion recognition⁷³, both possible uses to implement sharing platforms and chatbots for use in psychiatry, in support of proximity models, such as the open dialogue under consideration.

4. Potentialities and limits of the “open dialogue” in the Italian DSM and the role of the A.I. in its implementation. Concluding remarks

In the framework outlined so far, we see a preference of the system towards care services centred on proximity and of a holistic type, i.e. marked by framing all the healthcare services provided within a broader scheme of responsibility for the overall well-being of the patient and, therefore, of taking charge of his or her needs and understanding and supporting the context in which he or she lives⁷⁴.

⁷² See Recital 44 of the Regulation of the European Parliament and of the Council laying down harmonised rules on artificial intelligence.

⁷³ Recital 132 of the Regulation states «Natural persons should, in particular, be notified when interacting with an AI system, unless such interaction is apparent from the perspective of a reasonably well-informed, observant and circumspect natural person, considering the circumstances and context of use. In implementing this obligation, the characteristics of persons belonging to groups of persons who are vulnerable due to their age or disability should be considered to the extent that the AI system is also intended to interact with such groups. Individuals should also be notified when they are exposed to systems that, in processing their biometric data, may identify or infer the emotions or intentions of such persons or assign them to specific categories.

⁷⁴ In this perspective, as has been acutely observed, «the provision of goods and services is but one aspect, not even the most important, of caring» A. PIOGGIA, *La cura nella Costituzione*, cit., p. 62.

With respect to this trend, which is enunciated but far from being reality, the guideline given is not to hinder the implementation of artificial intelligence systems that can support such therapeutic approaches and foster their development.

The practice of open dialogue used in psychiatry, as we have seen, fully corresponds to this model, both from the organisational point of view, being centred on the mobility of the health care *team*, tending towards the patient's home, and from the point of view of the method based on the flexibility of the treatment that is constructed and modified through the dialogue of all the participants in the group that constitutes the setting of the 'care meeting'.

In particular, from an organisational point of view, AI could be used to provide communication platforms for the management of open dialogue meetings, facilitating participation even at a distance by the patient, as well as members of the social network who may not live close to the patient's home.

Remote participation, in this sense, would make the service more accessible, making it possible to increase the number of sessions, without changing the assumption that the patient remains at home or at any rate in an environment that constitutes a *comfort zone* for them, which is, as we have seen, a peculiarity of this practice.

Obviously, the use of these tools could not be a substitute for the essential the direct relationship between doctor and patient on which the analyzed approach is based, but it could be useful, to intensify the contacts between team and context, which otherwise would not be possible to carry out as frequently, perhaps to discuss the progress of therapy or to support the network in the management of psychotic events that require immediate contact.

This would make it possible to reduce the number of professionals to be permanently dedicated to the aforementioned activities, while at the same time making it possible to follow a larger number of patients and to facilitate access to this approach also for individuals from logistically or culturally disadvantaged backgrounds, who are less inclined, for example, to accept home visits from health professionals, especially in the case of family members of individuals with less obvious disorders, for fear of the social stigma associated with mental health problems.

Moreover, by processing the data collected in the framework of the open dialogue, it would contribute to the dissemination and sharing of clinical knowledge, which would be useful for specific purposes, i.e. within the framework of the treatment of the individual case, as it would be suitable for facilitating the rapid training of health professionals in the event of the turnover of one or more members in the health care team, which, as we have seen, constitutes one of the inevitable limits in the treatment pathway in question, which should normally be followed by the same specialists from whom it was initiated and with whom both the patient and the social network establish a relationship of trust.

Such knowledge would also help to form a useful case history for the specialisation of new therapists in what is, at present, still an experimental method in Italy.

A.I. can also be useful in forming and supporting the social network made up of family members, but also of volunteers from the third sector, neighbours, friends, etc. that sur-

rounds the patient who, as we have seen, participates in the treatment in all its phases and constitutes an essential support for the patient in the periods between meetings with health professionals.

On the level of method, the participation of the A.I. itself in the dialogue could constitute an element of correction and improvement of the practice which, as pointed out, is based on contextuality and on the sharing of therapeutic choices both between the various professionals who make up the health care *team* and between the latter and the social network.

This could be done by feeding features such as A.I.-based *chatbots* capable of analysing conversations during meetings and elaborating autonomous conclusions, useful for therapists to compare them with those reached by the working group operating according to the described principle of ‘tolerance of uncertainties’ and, thus, accepting that the outcomes of the session may be influenced by a number of internal factors (e.g. even humour) of the professionals themselves, as well as of the patient and the social network taking part in the session.

Also in modulating and monitoring progress and in adapting treatment strategies, especially in the intermediate period between meetings, the support of real time wellbeing detection systems and therapy management tools that are able to provide the healthcare professional, even remotely, may be useful, objective elements, deriving from the processing of biometric data, to take decisions, perhaps solicited by the family or in any case by members of the social network, so as to potentially reduce the margin of error derivable from the mere evaluation of information provided by these subjects, who lack specialist skills, and to reassure them.

AI algorithms can, in fact, help healthcare professionals integrate and analyse information from various sources, including clinical data, patient preferences, and scientific research findings, to formulate personalised treatment recommendations. The set of data collected can be discussed with patients and their families in the context of the first useful open dialogue meeting or at a dedicated one, promoting shared decision-making.

In terms of method training, AI could be used to develop customised training programmes for healthcare professionals, improving their communication skills and their ability to facilitate open dialogue. This includes training on how to interpret and act on AI-generated insights into patients’ needs and preferences.

Finally, in terms of evaluating the entire therapeutic process, through the continuous analysis of interaction data and patient feedback, AI can help assess the effectiveness of open dialogue strategies, identifying areas of success and aspects to be improved, enabling health services to adapt their practices to better meet patients’ needs.

In the face of this potential, the barriers to be broken to make the system effective appear quite high at present.

Indeed, the limitations already highlighted in the previous section concerning the use of A.I. systems in the health sector, and in the psychiatric field in particular, become even more stringent in relation to this peculiar therapeutic approach.

In spite of the fact that the open dialogue is fully traceable to the objectives of Measure 6 of the National Recovery and Resilience Plan concerning investments to bring care closer to the patient according to the principle of the ‘home as a place of care’ it is sufficient to glance at the reference legislation to realise that in reality most of the relevant investments have been aimed at the creation of physical places of proximity and easy identification that constitute forms of decentralisation of the classic health, social and health care system⁷⁵.

The story is the same with reference to telemedicine, which although, as already mentioned, may include computer systems for use in the psychiatric field, it is also conceived primarily as a support to the healthcare structure to speed up procedures (as in the case of the planned territorial operating centres) and improve the quality of public services, through remote assistance by regional healthcare systems.

Important objectives with respect to which, however, the requirements for the implementation of open dialogue do not coincide, except incidentally.

It is, in fact, a home-based approach strongly inspired by the democracy of care, which requires co-participation in choices and which, therefore, is unlikely to benefit even indirectly from investments geared, instead, to improving the efficiency of the public apparatus alone. All the more so since, as we have already seen, psychiatric care has been allocated a truly residual share of the available sums.

In this sense, since it is still an experimental approach in our country, the described treatment model could not reasonably have aspired to specific funds, but if the political direction to the distribution of the *recovery fund* funds, of which the National Recovery and Resilience Plan is the implementation, had been more far-sighted in the definition of home-based care and proximity, perhaps we could have at least hypothesised early interventions on the level of training and the development of platforms dedicated to this type of horizontal approach to care.

Finally, while the risk profiles connected to the substitution of A.I. for man are not of particular concern in the practice of open dialogue, since no other function for the technology is conceivable in the therapeutic practice described other than that of serving the work of the medical team, the issue of the protection of fundamental rights affected by the use of artificial intelligence systems is more delicate.

In fact, in addition to the general profiles of delicacy already described above with regard to the handling of sensitive data and the processing of biometric data, there are also those specific to this particular method, which concerns diseases in which the understanding of biological mechanisms and the determination of reliable biometric *markers* is difficult⁷⁶

⁷⁵ In fact, the financed project «consists of the establishment and operation of 1,350 Community Health Houses, through the activation, development and aggregation of primary care services and the construction of energy-efficient care centres for an integrated response to care needs» <https://www.italiadomani.gov.it/it/Interventi/investimenti/case-della-comunita-e-presenza-in-carico-della-persona.html>.

⁷⁶ C. TARANTINO, *Preface* in J. SEIKKULA, cit. p. IX.

and consequently, it also becomes more complex for the jurist to establish the limits of the secure implementation of applications that make use of these data⁷⁷.

In this respect, the question remains whether human and machine intelligence can speak the same language, and in particular whether A.I. can reach a level of emotion processing that can be translated into robotic semantics⁷⁸.

In particular, the conditions of prior and constant human control and vigilance identified over time by jurisprudence to favour full fungibility between human and artificial intelligence, may not be sufficient to guarantee the ability for robotics to penetrate the sphere so intimate and difficult to codify of emotions linked to mental distress, returning data that can be considered fully reliable and that protect the vulnerable subject from making inappropriate but reassuring therapeutic choices, for instance for family members who have to manage a crisis (from the administration of a drug to the assessment of a hospitalisation)⁷⁹. However, this risk should be reasonably contained since, in any case, open dialogue presupposes direct intervention and discussion in the 'care meeting' on every occasion when therapeutic choices must be made, thus even and especially if they were suggested by the A.I.

Ultimately, 'open dialogue', while representing an ideal model in the process of bringing care closer to the patient and while it could receive a valuable contribution from the implementation of A.I. technologies, at a time in history when both sectors are the subject of attention and funding, is most likely destined to remain relegated to the sphere of experimentation in which it is practised today, despite its obvious potential.

In this sense, it would be desirable, as part of the corrective measures to the spending of funds for measure 6 of the NRP that are still in progress⁸⁰ and given the time frame of the two-year period 2024 - 2026 still available to achieve the objectives, for the Ministry of Health to direct part of the sums to the development of telemedicine applications also intended for horizontal approaches and not only for the decentralisation of care.

Moreover, the development of A.I. in the psychiatric field requires a more incisive intervention of the European legislator. If, in fact, it can be argued, on the basis of the analysis carried out, that technological innovation is considered a central element in the reorgani-

⁷⁷ The use of biometric data in clearly identified cases must be justified, also in the light of the balancing in a reasonable manner of the impact that such use may have on other rights, considering the purposes and context in which they are processed. In this regard, EU Court of Justice, Grand Chamber, 30 January 2024, no. 118.

⁷⁸ In this sense, Cf. A. SIMONCINI, *The Unconstitutional Algorithm: Artificial Intelligence and the Future of Freedoms*, in *BioLaw Journal*, 1, 2019, 69 et seq., where it is pointed out that predictive accuracy does not only depend on the technical reliability of the automatism, but on ontological factors to the two different languages (human and artificial). In the same vein, L. ALEXANDRE, *The War of Intelligences. Artificial versus human intelligence*, EDT, Turin, 2018, 29 et seq. A. CASSATELLA, *La discrezionalità amministrativa nell'età digitale*, in AA.VV. (ed.), *Diritto amministrativo: scritti per Franco Gaetano Scoca*, vol. 1, Naples. Edizioni Scientifiche Italiane, 2021, 675 et seq.

⁷⁹ In case law, there is no lack of sceptical orientations even after 2019. See Tar Lazio, Rome, section III, judgment no. 4409 of 15 April 2021.

⁸⁰ The latest change in the allocation of funds by the Ministry of Health came with the Decree of 28 September 2023.

sation of proximity healthcare, as support for de-institutionalised models of assistance and care, centred on the ‘person’ and aimed at ensuring equity in access to care. However, there are many gaps highlighted in the course of the work, given that the recent European Regulation, which currently constitutes the only regulatory reference on the subject, declaredly aims to regulate the heterogeneity of artificial intelligence models in a comprehensive manner, without taking into account the specific features of the sectors in which these tools can be used⁸¹ which, on the other hand, need to be regulated, so that the path undertaken can be made effective.

⁸¹ On this subject, see M. INTERLANDI and L. TOMASSI, *La decisione amministrativa algoritmica*, in A. CONTIERI (ed. by) *Argomenti di diritto amministrativo*, Naples, Editoriale Scientifica 2022, p. 133 et seq. where the authors dwell on the main aspects of the proposed regulation; and C. CASONATO and B. MARCHETTI, *First observations on the proposed European Union Regulation on Artificial Intelligence*, in *BioLaw Journal*, no. 3/2021; F. PIZZETTI, *The European Commission’s proposal for a regulation on AI presented on 21.4.2021 between the Single Market and global digital competition*, in *Internet Law*, 2021.

