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Artificial Intelligence in Healthcare: Data Protection and Liability Issues. An Italian Private Law Perspective*

Giorgia Vulpiani

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1. Introduction

The use of AI systems raises a lot of issues that demand careful consideration by jurists[1]; among these the protection of personality rights[2] and the liability for damages connected with the use of these systems are of utmost importance[3]. These issues become particularly problematic when

* Peer-reviewed article

1 C. Perlingieri, *L'incidenza dell'utilizzazione della tecnologia robotica nei rapporti civilistici*, in *Rass. dir. civ.*, 4, 2015, 1235; A. Pajno - M. Bassini - G. De Gregorio - M. Macchia - F.P. Patti - O. Pollicino - S. Quattrocolo - D. Simeoli - P. Sirena, *AI: profili giuridici. Intelligenza artificiale: criticità emergenti e sfide per il giurista*, in *BioLaw Journal*, 3, 2019, 205; A. Alpini, *Sull'approccio umanocentrico all'intelligenza artificiale. Riflessioni a margine del "progetto europeo di orientamenti etici per una IA affidabile"*, in *www.comparazioneediritto civile*, April 2019; P. Perlingieri - S. Giova - I. Prisco (eds.), *Rapporti civilistici e intelligenze artificiali: attività e responsabilità. Atti del 15° Convegno Nazionale della SISDiC*, Napoli, 2020; E. Caterini, *Intelligenza artificiale «sostenibile» e il processo di socializzazione del diritto civile*, Napoli, 2020, 32; S. Faro - T.E. Frosini - G. Peruginelli, *Dati e algoritmi. Diritto e diritti nella società digitale*, Bologna, 2020; G. Vulpiani (ed.), *Diritto, Intelligenza Artificiale e medicina. Un dialogo interdisciplinare*, Napoli, 2024.

2 P. Perlingieri, *La personalità umana nell'ordinamento giuridico*, Camerino-Napoli, 1972, 12; Id., *La persona e i suoi diritti. Problemi del diritto civile*, Napoli, 2005, 25; Id., *Il diritto civile nella legalità costituzionale secondo il sistema italo-europeo delle fonti*, III, Napoli, 2020, 23. Concerning AI, see, U. Ruffolo - A. Amidei, *Intelligenza Artificiale e diritti della persona: le frontiere del "transumanesimo"*, in *Giur. it.*, 7, 2019, 1658; M. Franzoni, *Lesione dei diritti della persona, tutela della privacy e intelligenza artificiale*, in *Jus civile*, 1, 2021, 4; F. Mollo, *Il trattamento dei dati genetici tra libera circolazione e tutela della persona*, in *Jus civile*, 1, 2022, 70; E. Fazio, *Intelligenza artificiale e diritti della persona*, Napoli, 2023, 267.

3 U. Ruffolo (ed.), *Intelligenza artificiale e responsabilità*, Milano, 2017; U. Ruffolo, *Intelligenza Artificiale, machine learning e responsabilità da algoritmo*, in *Giurisprudenza italiana,* 7, 2019, 1689; M. Costanza, *L'intelligenza artificiale e gli stilemi della responsabilità civile*, in *Giurisprudenza italiana*, 7, 2019, 1686; G. Finocchiaro, *Intelligenza artificiale e responsabilità*, in *Contratto e impresa*, 2, 2020,

it comes to applying AI in healthcare[4], given the delicate nature of the questions that this area raises[5].

There are now various uses of robotics and AI systems that can assist the physician in diagnosis, performing procedures, developing treatments and patient care: surgical robotics[6], rehabilitation and assistance robotics[7], clinical decision support systems[8], and even human enhancement prac-

713; M. Ratti, *Riflessioni in materia di responsabilità civile e danno cagionato da dispositivo intelligente alla luce dell'attuale scenario normativo*, in *Contratto e impresa*, 3, 2020, 1181; A. Fusaro, *Quale modello di responsabilità per la robotica avanzata? Riflessioni a margine del percorso europeo*, in *Nuova giurisprudenza civile commentata*, 6, 2020, 1344; F. Naddeo, *Intelligenza artificiale: profili di responsabilità*, in *Comp. dir. civ*., 3, 2020, 1141; M. Porcelli, *Tecnologie robotiche e responsabilità per danni tra prospettive reali e falsi miti*, in *Tecnologie e diritto*, 2, 2020, 506; C. Iorio, *Intelligenza Artificiale e responsabilità: spunti ricostruttivi*, in *Tecnologie e diritto*, 2, 2021, 51; M. Grondona, *Responsabilità civile e IA: tra paure e mitizzazioni, meglio un anything goes in salsa popperiana*, in *Danno e responsabilità*, 3, 2022, 277; A. Bertolini, *Artificial Intelligence does not exist! Defying the technology-neutraleity narrative in the regulation of civil liability for advanced technologies*, in *Europa e diritto privato*, 2, 2022, 369; Id., *Intelligenza artificiale e responsabilità civile. Problema, sistema, funzioni*, Bologna, 2024; C. Scognamiglio, *Responsabilità civile ed intelligenza artificiale: quali soluzioni per quali problemi?*, in *Responsabilità civile e previdenza*, 4, 2023, 1073; L. Arnaudo - R. Pardolesi, *Ecce robot. Sulla responsabilità dei sistemi adulti di intelligenza artificiale*, in *Danno e responsabilità*, 4, 2023, 409; A. Astone, *Sistemi intelligenti e regole di responsabilità*, in P*ersona e mercato*, 3, 2023, 496; M. Scotto di Carlo, *La responsabilità connessa all'utilizzo dei sistemi di intelligenza artificiale*, in *Danno e responsabilità*, 4, 2024, 21; E. Palmerini, *Il problema dei (nuovi) danni negli illeciti algoritmici*, in *Responsabilità civile e previdenza*, 2, 2025, 419; F. Cerea, *La responsabilità civile da sistemi intelligenti*, Torino, 2025.

[4] On the risks associated to the use of AI in healthcare, see European Commission: Directorate-General for Health and Food Safety, EEIG, Open Evidence and PwC, Study on the deployment of AI in healthcare – Final report, Publications Office of the European Union, 2025.

[5] C. Perlingieri, *Responsabilità civile e robotica medica*, in *Tecnologie e diritto*, 1, 2020, 165; Ead., *Intelligenza artificiale in ambito medico-sanitario: profili di ricostruzione normativa a seguito dell'AI Act*, in *Rassegna di diritto civile*, 3, 2024, 907; F. Vimercati, *L'intelligenza artificiale in sanità*, in *Rapporti civilistici e intelligenze artificiali: attività e responsabilità*, P. Perlingieri - S. Giova - I. Prisco (eds.), Napoli, 2020, 211; F. Cerea, *Intelligenza artificiale a servizio dei pazienti per il contrasto a COVID-19*, in *Nuova giurisprudenza civile commentata*, 3, 2020, 45; A. Fiorentini, Machine learning *e dispositivi medici: riflessioni in materia di responsabilità civile*, in *Corriere giuridico*, 10, 2021, 1260; A. D'Adda, *Danni da robot (specie in ambito sanitario) e pluralità di responsabili tra sistema della responsabilità civile e iniziative di diritto europeo*, in *Riv. dir. civ.*, 5, 2022, 805; G. Votano, *Intelligenza artificiale in ambito sanitario: il problema della responsabilità civile,* in *Danno e resp*., 6, 2022, 669; M. Faccioli (ed.) *Profili giuridici dell'utilizzo della robotica e dell'intelligenza artificiale in medicina*, Napoli, 2022; Id., *Intelligenza artificiale e responsabilità sanitaria*, in *Nuova giur. civ.*, 3, 2023, 732; A.G. Grasso, *Diagnosi algoritmica errata e responsabilità medica*, in *Riv. dir. civ.*, 2, 2023, 335.; E. Verona, *Errore diagnostico e intelligenza artificiale: profili di responsabilità nell'imaging medico*, in *Nuova giurisprudenza civile commentata*, 4, 2025, 1075.

[6] Y. Rivero - Moreno - S. Echevarria - C. Vidal-Valderrama, et al. (July 24, 2023), *Robotic Surgery: A Comprehensive Review of the Literature and Current Trends*, in *Cureus* 15(7): e42370.

[7] R.S. Calabrò - G. Morone - A. Naro - M. Gandolfi - V. Liotti - C. D'Aurizio - S. Straudi - A. Focacci - S. Pournajaf - I. Aprile, et al., *Robot-Assisted Training for Upper Limb in Stroke (ROBOTAS): An Observational, Multicenter Study to Identify Determinants of Efficacy*, in *J. Clin. Med.,* 10, 2021, 5245.

[8] A.T.M. Wasylewicz - A.M.J.W. Scheepers-Hoeks, *Clinical Decision Support Systems*, in P. Kubben - M. Dumontier - A. Dekken (eds.), *Fundamentals of Clinical Data Science*, Berlin, 2019, 153; S. Montani - M. Striani, *Artificial Intelligence in Clinical Decision Support: a Focused Literature Survey*, in *Yearb. Med. Inform*., 28(1), 2019, 120; R.T Sutton et al., *An overview of clinical decision support systems: benefits, risks, and strategies for success*, in *NPJ Digit Med*., 6 February 2020.

tices[9]. An AI system can process information faster and more accurately, but the associated risks should not be underestimated: uncritical acceptance of outputs, unreliable outputs due to the quality of the data used for training (human diagnostic errors, classification errors, insufficient data collection, presence of bias), failure to consider contextual aspects (fragility, extra-clinical conditions of distress, psychological, social and family factors) that are difficult to express in quantitative terms[10], and data security breaches[11].

Regarding the regulatory framework, it is necessary to first refer to the Regulation (EU) 2024/1689 (AI Act)[12], which emphasises in several passages the potential risks associated with the use of AI systems[13], also in the healthcare sector. The Regulation, using a risk-based approach, outlines preventive, precautionary, safety and transparency safeguards for artificial intelligence systems, but leaves open several issues regarding the protection of fundamental rights and liability for the use of AI tools[14].

There had been several European Union initiatives on AI[15], such as the 2017 European Parliament Resolution on civil law rules on robotics[16], the 2020 Commission Report on the safety and liability implications of artificial intelligence, the Internet of Things and robotics[17]; the 2020 Parliament

[9] P. Perlingieri, *Note sul «potenziamento cognitivo»*, in *Tecnologie e diritto*, 1, 2021, 214; L. D'Avack, *Per un uso umano dell'enhancement*; A. D'Aloia, *I diritti della persona alla prova dello human enhancement*; U. Ruffolo – A. Amidei, *Intelligenza artificiale, biotecnologie e potenziamento: verso nuovi diritti della persona?,* in *XXVI Lezioni di diritto dell'intelligenza artificiale*, U. Ruffolo (ed.), Torino, 2021, 79, 85, 101; U. Ruffolo – A. Amidei, *Diritto dell'Intelligenza artificiale*, vol. II, 2024, Roma, 193; E. Fazio, *Robotica Medica, Human Enhancement e tutela dei fragili*, in *Jus civile*, 2, 2023, 513; E. Palmerini, *Il potenziamento umano tra ideologia e mercato*, in *BioLaw Journal*, 1, 2024, 161.

[10] A. Di Martino, *Intelligenza artificiale e responsabilità civile in ambito sanitario*, Milano, 2022, 21.

[11] S.T. Argaw *et al.*, *The State of Research on Cyberattacks against Hospitals and Available Best Practice Recommendations: A Scoping Review*, in *BMC Medical Informatics and Decision Making*, 19, no. 1 (11 January 2019).

[12] Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence and amending Regulations (EC) No 300/2008, (EU) No 167/2013, (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1139 and (EU) 2019/2144 and Directives 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828 (Artificial Intelligence Act).

[13] Recital 47 AI Act: « in the health sector where the stakes for life and health are particularly high, increasingly sophisticated diagnostics systems and systems supporting human decisions should be reliable and accurate».

[14] O. Pollicino – F. Donati – G. Finocchiaro – F. Paolucci (eds.), *La disciplina dell'Intelligenza Artificiale*, Milano, 2025.

[15] A. Amidei*, Intelligenza Artificiale e product liability: sviluppi del diritto dell'Unione Europea*, in *Giurisprudenza italiana,* 7, 2019, 1715; A. Fusaro, *Quale modello di responsabilità per la robotica avanzata? Riflessioni a margine del percorso europeo*, cit., 1344; U. Salanitro, *Intelligenza artificiale e responsabilità: la strategia della Commissione europea*, in *Rivista di diritto civile*, 6, 2020, 1246; G. Alpa, *Quale modello normativo europeo per l'intelligenza artificiale?*, in *Contratto e impresa*, 4, 2021, 1003; v., M. Gambini, *Nuovi paradigmi della responsabilità civile per l'Intelligenza artificiale*, in *Rass. dir. civ.*, 4, 2023, 1314.

[16] European Parliament resolution of 16 February 2017 with recommendations to the Commission on Civil Law Rules on Robotics (2015/2103(INL).

[17] Report from the commission to the European Parliament, the council and the European Economic and Social Committee. Report on the safety and liability implications of artificial

Resolution with recommendations to the Commission on a civil liability regime for artificial intelligence[18].

Moreover, the EU enacted the Directive (EU) 2024/2853 on liability for defective products[19] and issued, and then withdrew, a proposal for a directive on non-contractual liability for AI on the disclosure of evidence relating to high-risk AI systems and the burden of proof in civil non-contractual liability actions for damage caused by AI[20].

In the context of AI in healthcare, with particular reference to health data, we should also consider the well-known Regulation EU 2016/679 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (GDPR) and the Regulation (EU) 2025/327 on the European Health Data Space (EHDS)[21], which aims at establishing a common framework for the use and exchange of electronic health data across the EU, enhancing individuals' access to and control over their personal electronic health data, while also enabling certain data to be reused for public interest, policy support, and scientific research purposes, and which establishes a harmonised legal and technical framework for electronic health record (EHR) systems, fostering interoperability, innovation, and the smooth functioning of the internal market.

Recently, Italy enacted the first Italian law on AI: law no. 132 of 23 September 2025, named "*Disposizioni e deleghe al Governo in materia di intelligenza artificiale*". This law sets out principles on research, testing, development, adoption and application of AI systems and models, focusing on personal data protection (art. 4) and the use of AI-based systems in healthcare (art. 7). In particular, art. 7 highlights that the use of artificial intelligence systems contributes to the improvement of the healthcare system, the prevention, diagnosis and treatment of diseases, while respecting the rights, freedoms and interests of individuals, including in relation to the protection of personal data, and that the introduction of artificial intelligence systems into the healthcare system cannot select and condition access to healthcare services according to discriminatory criteria.

The regulatory framework outlined above leaves room for uncertainty regarding the effective protection of individuals' rights. It is, therefore, necessary for jurists to carefully focus on the impact of the use of AI in healthcare on fundamental rights, on the remedies and on the liability connected.

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intelligence, the internet of Things and robotics [(COM (2020)64].

[18] European Parliament Resolution of 20 October 2020 with recommendations to the Commission on a civil liability regime for artificial intelligence (2020/2014(INL))

[19] Directive (EU) 2024/2853 of the European Parliament and of the Council of 23 October 2024 on liability for defective products and repealing Council Directive 85/374/EEC. See G. Ponzanelli, *Responsabilità da prodotto difettoso: dalla Dir. n. 374 del 25 luglio 1985 alla Dir. n. 2853 del 23 ottobre 2024*, in *Danno e Responsabilità*, 2, 2025, 153; A. Amidei, *La responsabilità del produttore tra novella e sistema. Contributo allo studio dei criteri di imputazione*, Napoli, 2025.

[20] Proposal for a Directive of the European Parliament and of the Council on adapting non-contractual civil liability rules to artificial intelligence (AI Liability Directive)COM (2022) 496 final, 2022/0303 (COD)].

[21] S. Corso, *Lo spazio europeo dei dati sanitari. Prime riflessioni sul regolamento UE 2025/327*, in *Nuove Leggi Civili Commentate*, 3, 2025, 565.

The identification of potentially liable parties and the criteria for imputation of liability for the physician's use of AI systems is, in fact, particularly important to ensure adequate and effective protection of the individual.
The issue is complex because several factors must be taken into account, such as the different levels of autonomy that an AI system may have[22], in terms of the possibility of control by users and the transparency of decision-making processes, and the plurality of actors involved in addition to the professional and the healthcare facility.
The difficulty in identifying who is liable is emphasised by the fact that AI systems are endowed with an intrinsic opacity, in a way that it is very difficult to establish on the basis of which criteria the machine processed the information and made certain decisions: it is the so-called black box problem[23]. In fact, it is necessary to distinguish the case of a system used as a mere executive tool of the doctor from that of a system that acts on the basis of a self-learning algorithm, whose decision-making processes are beyond the control of the humans involved.
Also, the issue of AI hallucinations should not be forgotten: some AI tools may, in fact, make stuff up in generating the output.
In this context another problem that needs to be addressed concerns informed consent and patient self-determination[24], focusing on the extent of the information obligations incumbent on the physician who uses an AI system to perform the healthcare service.

2. AI in healthcare: data protection

As outlined above, a particularly critical issue related to the use of artificial intelligence in healthcare concerns the protection of fundamental rights, such as the right to health, dignity, non-discrimination, self-determination and data protection. With particular reference to data protection and privacy[25], there is first of all a potential conflict between the right to privacy of individuals and the need for the circulation of health data for better patient health protection. For example, in order to develop an effective treatment strategy or to be able to identify a particular gene for the diagnosis

[22] S. Koosha – A. Mahyar, *Machine Learning and Deep Learning: A Review of Methods and Applications*, in *World Information Technology and Engineering Journal*, 10(7), 2023, 3897.

[23] J. Burrel, *How the Machine 'Thinks': Understanding Opacity in Machine Learning Algorithms*, in *Big Data & Society*, 6 January 2016; P. D. König - T. D. Krafft - W. Schulz - K. A. Zweig, *Essence of A.I.,* in *The Cambridge Handbook on Artificial intelligence. Global perspectives on Law and Ethics*, Cambridge, 2022, 17.

[24] V. Rotondo, *Responsabilità medica e autodeterminazione della persona*, Napoli, 2020, 113.

[25] A. Spina, *La medicina degli algoritmi: intelligenza artificiale, medicina digitale e regolazione dei dati personali*, in F. Pizzetti (ed.), *Intelligenza artificiale, protezione dei dati personali e regolazione*, Torino, 2018, 327; G. Finocchiaro*, Intelligenza artificiale e protezione dei dati personali*, in *Giurisprudenza italiana*, 7, 2019, 1670; M. Ciancimino, *Protezione e controllo dei dati in ambito sanitario e intelligenza artificiale. I dati relativi alla salute tra novità normative e innovazioni tecnologiche*, Napoli, 2020; P. Perlingieri, *Sul trattamento algoritmico dei dati*, in *Tecnologie e diritto*, 1, 2020, 181; Id., *Privacy digitale e protezione dei dati personali*, in *Foro napoletano*, 2, 2018, 481; C. Perlingieri, *eHealth and Data*, in R. Senigaglia - C. Irti - A. Bernes (eds.), *Privacy and Data Protection in Software services*, Berlin, 2021, 127.

of a rare disease, the AI system needs to process a huge amount of data. To this end, there is a need to share health data, while respecting the principle of data minimisation. Health data is particularly sensitive because it often constitutes intimate information, covered by medical confidentiality, whose disclosure to unauthorised third parties can cause serious violations of individuals' privacy; it is exposed to various risks of unauthorised access and possible cybersecurity incidents.

The risks to data protection and privacy associated with the use of AI are highlighted in the EU report on the use of AI in healthcare. In particular, it highlights how a primary concern is the uncertainty about where and how the data processed by AI solutions is stored. Many AI tools, particularly those relying on cloud-based platforms, may require data to be transferred and stored across different jurisdictions, potentially outside the EU. This raises concerns about compliance with the Regulation EU 2016/679 (GDPR) and the risk of unauthorised access, especially in regions with weaker data protection standards. As known, concerning health data[26], art. 9 GDPR provides for a general prohibition on processing this kind of data, but with some exceptions: a) consent of the data subject; b) necessity to protect a vital interest of the data subject; c) reasons of public interest; d) purposes of preventive medicine or occupational medicine; e) purposes of scientific research. So, the issue here is, how this rule shall be interpreted in the context of AI in healthcare. In general, data processing must be lawful, fair and transparent (art. 5(1)(a) GDPR), but transparency, in this context, may be difficult to achieve, given the aforementioned black box problem. Data must also be collected for specific, explicit and lawful purposes and processed in a manner compatible with those purposes, but it is not certain that these purposes will be fully explicit and that processing compatible with them could be guaranteed, again due to the possible opacity of the systems. It is also necessary to consider the principles of data minimisation, according to which personal data must be adequate, relevant and limited to what is necessary in relation to the purposes for which they are processed, and storage limitation. Here too, there may be a critical issue with regard to the processing of data by an AI that processes a huge amount of data, which may need to be stored in order to produce more accurate outputs. In addition, another concern involves the potential misuse of data collected by AI tools: sensitive health data, initially used for specific diagnostic or therapeutic purposes, could be repurposed for secondary uses, such as commercial profiling or research, without a proper legal basis. This is exacerbated by a lack of transparency in how some AI solutions handle data after deployment, creating challenges in maintaining patient trust.

The AI act deals with data protection in high-risk AI systems at art. 10, which states that high-risk AI systems that use techniques involving the

[26] C. Sartoris, *Sanità digitale e dati personali*, in A. Adinolfi - A. Simoncini (eds.), *Protezione dei dati personali e nuove tecnologie. Ricerca interdisciplinare sulle tecniche di profilazione e sulle loro conseguenze giuridiche*, Napoli, 2022, 347; G. Garofalo, *Trattamento e protezione dei dati personali: spunti rimediali in ambito sanitario*, in *Dir. fam. pers.*, 3, 2021, 1392; M. Gambini, *Principio di responsabilità e tutela aquiliana dei dati personali,* Napoli, 2018, 124; E. Tosi, *Responsabilità civile per illecito trattamento dei dati personali e danno non patrimoniale*, Milano, 2019, 49.

use of data for training AI models must be developed on the basis of training, validation and testing datasets that meet certain quality criteria whenever such datasets are used. Such datasets shall be subject to governance and management practices appropriate to the intended purpose of the high-risk AI system, which are relevant, sufficiently representative, possibly error-free and complete for the intended purpose, taking into account, to the extent necessary for the intended purpose, the particular characteristics or elements of the specific geographical, contextual, behavioural or functional environment in which the high-risk AI system is intended to be used. In this context, it must also be mentioned art. 14, which states that high-risk AI systems shall be designed and developed in such a way, including with appropriate human-machine interface tools, that they can be effectively overseen by natural persons during the period in which they are in use. This provision is aimed at preventing or minimising risks to health, safety or fundamental rights that may arise when a high-risk AI system is used in accordance with its intended purpose or under reasonably foreseeable conditions of misuse, in particular where such risks persist despite the application of other requirements under the AI Act. The subsequent article (art. 15), then states that: high-risk AI systems shall be designed and developed in such a way that they achieve an appropriate level of cybersecurity, and that they perform consistently in those respects throughout their lifecycle.

Also law no. 132/2025 deals with the processing of personal data and AI systems, stating first of all that the use of AI systems «ensures the lawful, fair and transparent processing of personal data and compatibility with the purposes for which they were collected, in accordance with European Union law on personal data and privacy protection» and that «information and communications relating to data processing must be provided in clear and simple language, so as to ensure that users are aware of the risks involved and have the right to object to the authorised processing of their personal data»[27] (art. 4). Law no. 132/2025 then states, at art. 9, that the treatment of data defined in art. 9 of the GDPR is governed by a decree of the Minister of Health to be issued within 120 days of the date of entry into force of law no. 132/2025, after consultation with the Data Protection Authority, research bodies, health authorities and the authorities and operators in the sector. Finally, art. 10 deals with electronic health records. Regulation (EU) 2025/327 on the European Health Data Space (EHDS) is also relevant here and, in particular, art. 53, which states that among the purposes for which access to electronic health data referred to in art. 51 is permitted for secondary use there is: (e) scientific research related to health or care sectors that contributes to public health or health technology assessments, or ensures high levels of quality and safety of healthcare, of medicinal products or of medical devices, with the aim of benefiting end-users, such as patients, health professionals and health administrators, including: (i) development and innovation activities for products or services; (ii) training, testing and evaluation of algorithms, including in medical devices, in vitro diagnostic medical devices, AI systems and digital health

[27] Author's translation.

applications. Here again the same concerns underlined before arising.
Now, in consideration of the aforementioned legal framework, it is necessary to address the issue concerning the remedies applicable in cases of data violation in the context of the use of AI system in healthcare. As provided by art. 82 GDPR, any person who has suffered material or non-material damage as a result of an infringement of Reg. shall have the right to receive compensation from the controller or processor for the damage suffered[28]. But a problem may arise when it comes to the proof of the damages suffered by the patient, especially in connection with AI systems. In this regard, to overcome some obstacles the possibility to apply the remedy outlined by art. 80 GDPR has been underlined[29].

3. Artificial Intelligence and medical liability

One of the most significant issues regarding the use of AI in healthcare concerns the liability of physicians and healthcare facilities for damages related to the use of such systems. As said, in fact, the identification of potentially liable parties and the criteria for imputation of liability for the physician's use of AI systems is particularly important to ensure adequate protection of the individual[30].
For years, in Italy, medical liability has been the subject of heated debate in legal theory and jurisprudence[31]. In fact, before the introduction of law no. 189/2012 [32] and law no. 24/2017, the rules governing the liability of

[28] On this topic, see E. Palmerini, *Responsabilità da trattamento illecito dei dati personali*, in E. Navarretta (ed.), *Codice della responsabilità civile,* Milano, 2021, 2466; C. Camardi, *Note critiche in tema di danno da illecito trattamento dei dati personali*, in *Jus civile*, 3, 2020, 786; S. Patti, *Il risarcimento del danno immateriale secondo la Corte di Giustizia*, in *Nuova giurisprudenza civile commentata*, 5, 2023, 1146; U. Salanitro, *Illecito trattamento dei dati personali e risarcimento del danno nel prisma della Corte di Giustizia*, in *Rivista di diritto civile*, 3, 2023, 426. See also CGEU, 4 May 2023, C-300/2021, in *Foro italiano*, 6, 2023, IV, 268, commented by A. Palmieri - R. Pardolesi, *Mai futile il danno non patrimoniale da violazione della privacy (purché lo si provi!)*, S. Pagliantini, *Un altro palcoscenico della "guerra" tra le corti: il danno (immateriale) bagatellare dell'art. 82 Gdpr*; and M. Federico, *"La tempesta perfetta": ultime dalla Corte di Lussemburgo su danno (non patrimoniale) da illecito trattamento dei dati personali e possibili risvolti in tema di tutela collettiva.*

[29] E. Palmerini, *Il problema dei (nuovi) danni negli illeciti algoritmici*, cit., 440.

[30] A. D'Adda, *Danni da robot (specie in ambito sanitario) e pluralità di responsabili tra sistema della responsabilità civile e iniziative di diritto europeo*, cit., 812.

[31] M. Zana, *Responsabilità medica e tutela del paziente*, Milano, 1993, 1; P. Stanzione - V. Zambrano, *Attività sanitaria e responsabilità civile*, Milano, 1998, 254; G. Canzio - P. Proto Pisani, *Evoluzione storica e linee di tendenza della giurisprudenza di legittimità in tema di colpa medica*, in *Corti Supreme e salute*, 1, 2019, 79.

[32] G. Alpa, *"Ars interpretandi" e responsabilità sanitaria nella nuova legge "Bianco-Gelli", Commento a l. 8 marzo 2017, n. 24*, in *Contr. impr.*, 3, 2017, 728; M. Franzoni, *La nuova responsabilità in ambito sanitario*, in *Resp. med.*, 1, 2017, 5; C. Granelli, *La riforma della disciplina della responsabilità sanitaria: chi vince e chi perde?*, in *Contratti*, 4, 2017, 377; V. Carbone, *Legge Gelli: inquadramento normativo e profili generali,* in *Corr. Giur.*, 6, 2017, 737; G. Ponzanelli, Medical malpractice: *la legge Bianco-Gelli. Una premessa*, in *Danno e resp.*, 3, 2017, 268; F. Carmini, Ars medica *e tutela del paziente*, Napoli, 2019, 82; F. Criscuolo, *La nuova disciplina del rapporto medico-paziente tra buone pratiche, natura dell'obbligazione e responsabilità del sanitario*, in *Rass. dir. civ.*, 3, 2019, 751; G. Iudica (ed.), *La tutela della persona nella nuova responsabilità sanitaria*, Milano, 2019, 3; E. Marchisio, *Evoluzione della responsabilità civile medica e medicina*

doctors and healthcare facilities were developed through the interpretation of case law, in a perspective of increasing patient protection. At first, court rulings included medical liability in the area of non-contractual liability, accompanied, in a system of dual liability, by the contractual liability of the healthcare facility. Subsequently, following the ruling of the Court of Cassation no. 589 of 1999[33], the liability of the doctor was qualified as contractual liability by virtue of the incorporation of the theory of qualified social contact between doctor and patient, established through the therapeutic relationship[34]. However, in response to this approach, the phenomenon of defensive medicine began to emerge[35], with the medical professionals adopting a highly cautious approach, which translated into a tendency to omit treatment in high-risk situations or to provide unnecessary treatment, with an exclusively defensive perspective[36].

Law no. 189/2012 (so-called Balduzzi Law) challenged the contractual nature of medical liability, with specific regard to the reference made by art. 3 to art. 2043 of the Italian Civil Code (from now on "c.c."). In particular art. 3 of the Balduzzi Law provided that healthcare professionals who, in performing their activities, comply with the guidelines and best practices of the scientific community, shall not be held criminally liable, except in cases of gross negligence or wilful misconduct, and that, in such cases, however, the liability referred to in art. 2043 c.c. remains unaffected and the judge, in determining the amount of the compensation of damages, takes into account the doctor's conduct in line with what was expressed before. Art. 3 was interpreted by some jurists as an expression of the legislator's intention to qualify medical liability as a non-contractual liability within the scope of art. 2043 c.c., thus disregarding the established orientation of case law. On the other hand, some Courts held that the Balduzzi Law had only decriminalised medical liability in cases of minor negligence, where the doctor had followed guidelines and good practices recognized by the scientific community, without, however, implying a change in the traditional approach to contact liability and its implications[37].

Law no. 24/2017 (Gelli-Bianco law) reintroduced the so-called "dual track of liability", stating that the healthcare facility is liable for the healthcare

"difensiva", in *Riv. dir. civ.*, 1, 2020, 189; C. Scognamiglio, *Ingiustizia del danno, contatto sociale, funzioni del risarcimento*, Torino, 2021, 193.

[33] Italian Supreme Court, 22 January 1999, no. 589, in *Foro italiano*, 1, 1999, 3322, commented by F. Di Ciommo, *Note critiche ai recenti orientamenti in tema di responsabilità del medico ospedaliero*, and A. La Notte, *L'obbligazione del medico dipendente è un'obbligazione senza prestazione o una prestazione senza obbligazione?*

[34] C. Castronovo, *Obblighi di protezione*, in *Enc. giur. Treccani*, XXI, Roma 1990, 1; F. Benatti, *Osservazioni in tema di "doveri di protezione"*, in *Riv. trim. dir. proc. civ.*, 1960, 1342.

[35] F. Introna, *Un paradosso: con il progresso della medicina aumentano i processi contro i medici*, in *Rivista italiana di medicina legale*, 6, 2001, 879; C. Granelli, *La medicina difensiva in Italia*, in *Resp. civ. prev.*, 1, 2016, 22.

[36] C. Granelli, *Il fenomeno della medicina difensiva e la legge di riforma della responsabilità sanitaria*, in *Resp. civ. prev.*, 2, 2018, 410.

[37] Italian Supreme Court, 17 April 2014, no. 8940, in *Resp. civ. prev.*, 2014, 803; Court of Milan, 17 July 2014, no. 14320, in *Resp. civ. prev.*, 1, 2015, 173, annotated by M. Gorgoni, *Colpa lieve per osservanza delle linee guida e delle pratiche accreditate dalla comunità scientifica e risarcimento del danno*.

professional's failure to perform their duties pursuant to art.s 1218 and 1228 c.c., while the doctor is liable on a non-contractual basis, unless they acted in fulfilment of a contractual obligation undertaken with the patient[38]. The 2017 law, therefore, overcomes the prevailing approach in case law up until then. The Gelli-Bianco law also provides for the quantification of damages based on the criteria referred to in arts. 138 and 139 D.Lgs. no. 209/2005 (private insurance code) and highlights the importance of guidelines in permeating the notion of diligence. Art. 5, para. 1, of law no. 24/2017 elevates the recommendations set out in the guidelines and best practices, to be used in the absence of the mentioned recommendations, to the status of criteria for verifying the existence of civil liability of the healthcare professional: therefore, the conduct required is that which is expected according to the standards of professional diligence applicable in the relevant socio-economic sector.

With particular regard to medical liability associated with the use of artificial intelligence systems, the following possible scenarios should be examined: a) the AI system malfunctioned and caused harm to the patient; b) the system functioned perfectly and the harm was caused exclusively by the doctor; c) it cannot be determined whether the harm is attributable to the AI system or to the actions of the professional. The issue is complex because several factors must be taken into account, such as the different levels of autonomy that an AI system may have in terms of user control and transparency of decision-making processes, and the plurality of parties involved, in addition to the professional and the healthcare facility (software manufacturer, hardware manufacturer, programmer)[39]. The difficulty in identifying those who are responsible is, in fact, emphasised by the fact that AI systems are intrinsically opaque, making it very difficult to determine the criteria used by the machine to process information and make certain decisions (black box problem).

Starting from the different levels of autonomy, in cases where the system is under the complete control of the professional, there do not seem to be any particular problems in applying the ordinary regime of medical liability: the professional may therefore be held liable for damage caused during the use of the machine, where this is attributable to their negligence. Here, the healthcare facility or the self-employed doctor is contractually liable and the facility's auxiliary doctor is liable under non contractual liability[40].

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[38] In arg. C. Scognamiglio, *Regole di condotta, modelli di responsabilità e risarcimento del danno nella nuova legge sulla responsabilità sanitaria*, in *Corr. Giur.*, 6, 2017, 740; Id., *Ingiustizia del danno, contatto sociale, funzioni del risarcimento*, Torino, 2021, 194; G. Ponzanelli, *Medical malpractice: la legge Bianco-Gelli. Una premessa*, cit., 356; G. Alpa, Ars interpretandi *e responsabilità sanitaria a seguito della nuova legge Bianco-Gelli*, cit., 728; N. De Luca - M. Ferrante - A. Napolitano, *La responsabilità civile in ambito sanitario*, in *Nuove leggi civ. comm.*, 4, 2017, 740; M. Zana, *Responsabilità medica: antiche e nuove criticità,* in E. Canterini - L. di Nella - A. Flamini - L. Mezzasoma - S. Polidori (eds.), *Scritti in onore di Vito Rizzo. Persona, mercato, contratto e rapporti di consumo* Napoli, 2017, 2527; F. Criscuolo, *La nuova disciplina del rapporto medico-paziente: tra buone pratiche, natura dell'obbligazione e responsabilità del sanitario*, cit., 751; E. Marchisio, *Evoluzione della responsabilità civile medica e medicina difensiva*, cit., 189; C. Ricci*, Profili problematici delle responsabilità in ambito sanitario*, Napoli, 2020, 71; V. Rotondo, *Responsabilità medica e autodeterminazione della persona*, Napoli, 2020, 84.

[39] G. Votano, *Intelligenza artificiale in ambito sanitario: il problema della responsabilità civile*, cit., 673.

[40] A. D'Adda, *Danni da robot*, cit., 813.

The problem becomes more delicate as the autonomy of the AI system intensifies, and it is in this context that a liability gap and the difficulty of applying traditional categories have been highlighted[41]. Consider the case of a malfunction of an AI tool that has been carefully chosen for the type of pathology and used with every possible diligence, skill and prudence, within a fully suitable structure, not susceptible to useful correction by the healthcare professional and, therefore, completely autonomous. Or consider the case where an autonomous AI system is used and its decision-making processes remain opaque, without it being possible to clearly establish whether there has been a malfunction of the machine or an error on the part of the professional. In these cases, as mentioned, the chain of individuals who, in various capacities, were involved in the creation of the "intelligent" machine whose malfunction caused the damage, such as the manufacturer, programmer, etc., also comes into play, together with the rules on product liability.

On liability and AI, various solutions have been proposed in legal theory. According to one thesis, based on the subjectification of intelligent machines, AI systems covered by insurance can be held liable for any damage they cause[42]. Although this interpretation was taken into account in the 2017 European Parliament Resolution, it does not appear in the most recent European initiatives. Part of the legal doctrine referred to special forms of non-contractual liability, such as art. 2048, para. 2, c.c. on the liability of teachers[43], art. 2049 c.c. on the liability of employers and principals, art. 2050 c.c.[44], assimilating the use of robots in activities involving human beings to the exercise of a dangerous activity, and art. 2051 c.c. on damage caused by objects in custody[45]. In this regard, with particular reference to the liability of doctors, it has been noted that art. 7, para. 3, law no. 24/2017 explicitly refers to art. 2043 c.c., which would preclude interpretations aimed at subjecting the liability of doctors to different regulatory provisions; interpretations that would conflict with the purpose of the law itself, introduced also to contrast the phenomenon of defensive medicine[46].

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[41] C. Perlingieri, *L'incidenza dell'utilizzazione della tecnologia robotica nei rapporti civilistici*, in *Rass. dir. civ.*, 4, 2015, 1235.

[42] G. Teubner, *Soggetti giuridici digitali? Sullo stato giuridico degli agenti software autonomi*, Napoli 2019; E. Palmerini, *Soggettività e agenti artificiali: una soluzione in cerca di un problema?,* in *Oss. dir. civ. comm.*, 2, 2020, 464.

[43] A. Santosuosso - C. Boscarato - F. Caroleo, *Robot e diritto: una prima ricognizione*, in *Nuova giur. civ. comm.*, 7-8, 2012, 494.

[44] C. Leanza, *Intelligenza artificiale e diritto: ipotesi di responsabilità civile nel terzo millennio*, in *Resp. civ. e prev.*, 3, 2021, 1023. *Contra*, C. Perlingieri, *Responsabilità civile e robotica medica*, cit., 170.

[45] U. Ruffolo, *Responsabilità da produzione e gestione di ai* self-learning, in P. Perlingieri - S. Giova - I. Prisco (eds.), *Rapporti civilistici e intelligenze artificiali: attività e responsabilità. Atti del 15° Convegno Nazionale della SISDiC*, cit., 233; Id., *Intelligenza artificiale*, machine learning *e responsabilità da algoritmo*, in *Giurisprudenza italiana*, 7, 2019, 1689. See also, M. Ratti, *Riflessioni in materia di responsabilità civile e danno cagionato da dispositivo intelligente alla luce dell'attuale scenario normativo*, *Contr. impr.*, 3, 2020, 1174; G. D'Alfonso, *Il regime di responsabilità da cose in custodia tra questioni tradizionali e "responsabilità da algoritmo"*, *EJPLT*, 1, 2022, 82.

[46] U. Ruffolo, *L'intelligenza artificiale in sanità*, cit., 504; G. Votano, *Intelligenza artificiale in ambito sanitario: il problema della responsabilità civile*, cit., 675; M. Faccioli, *Intelligenza artificiale e*

It is also necessary to consider the position of the healthcare facility, which may be liable not only indirectly for the conduct of the doctor, but also directly for organisational defects[47]. The healthcare facility may, in fact, have failed in its duty to provide an adequate organisational environment and to periodically control technical equipment, including the artificial intelligence systems provided[48]. According to one theory, the same liability would also apply in the event of a malfunction of the AI system due to a manufacturing defect[49]: the healthcare facility is liable under art. 1228 c.c. for the negligent conduct of human medical auxiliaries and the same could therefore be said in the case of machine auxiliaries. Also, following the same theory, the same should apply to private practitioners who choose to use an artificial intelligence system, the associated risks of which can only be attributed to the doctor using it. The benefit derived by the facility or the private practitioner from the use of the AI system would therefore justify the burden of responsibility in the user's sphere of risk, even when the damage results from autonomous and unpredictable choices made by the machine and no incompetence in the performance of the service has been established.

A different argument, however, considers that the healthcare facility should not be held liable if the damage is due to a malfunction of the AI system caused by a manufacturing defect that was unforeseeable and unavoidable by its users[50]; in this case, the breach is due to a cause not attributable to the physician or the facility, and therefore the chain of distinct activities that led to the creation and marketing of the AI system becomes relevant. However, in practice, it may be difficult to clearly establish whether the damage was caused by the doctor's actions or by a programming defect in, for example, the AI system. In this case, liability will lie with both the users (assistant doctor, healthcare facility, private practitioner) and the manufacturer of the AI system. Arts. 2055 of the Italian Civil Code and 121 of the Italian Civil Code come into play here[51]. All parties involved would be jointly and severally liable to the injured party. The injured party may therefore take action against a number of subjects.

In view of adequate patient protection, it seems correct to assume, therefore, that even in the event of a malfunction of the AI system, the patient still has action against the healthcare facility, which can then seek compensation from the manufacturer of the artificial intelligence system[52].

On the use of AI in the medical sector, law no. 132/2025 states that artificial intelligence systems in healthcare provide support in prevention, diagnosis, treatment and therapeutic choice processes, without prejudice to the decision, which is always left to medical professionals (art. 7, para.

responsabilità sanitaria, cit., 738.

47 M. Faccioli, *La responsabilità civile per difetto di organizzazione delle strutture sanitarie*, Bologna, 2018.

48 C. Perlingieri, *Responsabilità civile e robotica medica*, cit., 170.

49 A. D'Adda, *Danni da robot*, cit., 813.

50 M. Faccioli, *Intelligenza artificiale e responsabilità sanitaria*, cit., 739.

51 A. Di Martino, *Intelligenza artificiale e responsabilità civile in ambito sanitario*, cit., 91.

52 D'Adda, *Danni da robot*, cit., 829.

5). It is therefore emphasised that the AI system must act as a support to the doctor's actions, who retains the final decision on the patient's clinical condition. The law also highlights that AI systems used in healthcare and the related data employed must be reliable, periodically verified and updated in order to minimise the risk of errors and improve patient safety (Art. 7, para. 6), but it does not take an explicit position on the issue of liability. One of the most challenging issues regarding the use of artificial intelligence systems in healthcare concerns the determination of the causal link[53]; an issue that is already complex in itself in the field of medical liability[54]. The use of an autonomous AI system, characterised by the opacity that makes decision-making processes unfathomable and unpredictable, presents particular difficulties in establishing causality.

Causality is traditionally defined as the relationship between two events that identifies one as the consequence of the other[55] and constitutes a fundamental element for the assessment of liability. One issue that has long been the subject of legal debate concerns the relationship between civil causality and criminal causality. In the Italian legal system, based on the principles of legality, materiality and personality of criminal responsibility, in accordance with arts. 25 and 27 of the Italian Constitution, the causal link between conduct and event is an essential, though not sufficient, condition for attributing the criminal act to its author[56]. The debate on causality, which developed after the advent of the Constitution, led to a shift from liability for the actions of others to liability for one's own actions. In fact, the reading of arts. 25 and 27 of the Constitution and the provisions of the Italian Criminal Code (hereinafter, "c.p.") suggests that no one can be punished for an act they did not commit. The discussion of causality also precedes that concerning the *suitas* of conduct. It is, in fact, with the development of the principle of fault that a further step forward has been taken towards responsibility for one's own negligent acts. Starting from the regulatory framework, reference should be made to arts.

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[53] G. Gorla, *Sulla cosiddetta causalità giuridica: fatto dannoso e conseguenze*, in *Riv. dir. commerciale*, 11-12, 1951, 409; P. Forchielli, *Il rapporto di causalità nella responsabilità civile*, Padova, 1960; F. Realmonte, *Il problema del rapporto di causalità nel risarcimento del danno*, Milano, 1967; P. Trimarchi, *Causalità e danno*, Milano, 1967; R. Scognamiglio, *Responsabilità civile*, in *Noviss. Dig. it.*, Torino, XV, 1969, 628; C. Rossello, *Il danno evitabile*, Padova, 1990; M. Franzoni, *Dei fatti illeciti*, in F. Galgano (ed.) *Comm. cod. civ.*, Roma, 1993, 84. More recently, M. Taruffo, *La prova del nesso causale*, in *Riv. critica dir. privato*, 1, 2006, 101; F. Piraino, *Il nesso di causalità*, in *Europa e dir. privato*, 2, 2018, 399; L. Nonne, *Prova e giudizio di causalità*, in M. Maggiolo (ed.), *Il regime probatorio nel giudizio sulla responsabilità da inadempimento*, Milano, 2022, 631; N. Rizzo, *La causalità civile*, Torino, 2022; Id., *Dalla scomposizione del nesso causale alla causalità civile*, in *Contratti*, 3, 2023, 245.

[54] N. Rizzo, *Inadempimento e danno nella responsabilità medica: causa e conseguenze*, in *Nuova giur. civ. comm.*, 2, 2020, 327.

[55] F. Carnelutti, *Teoria generale del diritto*, Roma, 1951, rist. Camerino-Napoli, 1998, 192, 298.

[56] F. Mantovani, *Diritto penale*, Padova, 2015, 136. See also, F. Antolisei, *Il rapporto di causalità nel diritto penale*, Padova, 1934; G. Azzali, *Contributo alla teoria della causalità nel diritto penale*, Milano, 1954; G. Fiandaca, *Causalità (rapporto di)*, in *Dig. pen.*, II, Torino 1988, 119; F. Grispigni, *Il nesso causale nel diritto penale*, in *Riv. it. dir. pen.*, 1935, 39; E. Morselli, *Il problema della causalità nel diritto penale*, in *Ind. pen.*, 1998, 879; S. Ranieri, *La causalità nel diritto penale*, Milano, 1936; F. Stella, *Rapporto di causalità*, in *Enc. Giur.*, XV, 1991, 1. See also G. Fiandaca, *Riflessioni problematiche tra causalità e imputazione obiettiva*, in *Ind. pen.*, 2006, 946; A. Pagliaro, *Causalità e diritto penale*, in *Cass. pen.*, 2005, 1037; Id., *Causalità (rapporto di)*, in *Enc. dir.*, Annali, 2007, 153.

40 and 41 c.p. Over time, various doctrinal and jurisprudential interpretations have developed regarding these provisions. The traditional thesis is represented by the *condicio sine qua non* theory[57], according to which the cause of the event is every single condition of the event, every antecedent without which the event would not have occurred. Therefore, in order to verify whether the event is the consequence of a conduct, it is necessary to start from a so-called counterfactual assessment to verify whether, by mentally eliminating the conduct carried out by the agent, the event would have occurred or not[58]. The *condicio sine qua non* theory has been the subject of several critical observations with particular reference, in addition to its limited effectiveness, to the possibility of considering human conduct as the cause of an event even in the case of completely exceptional external conditions and to the possible infinite regression of the causal antecedents of a given event[59]. Furthermore, this theory would not be applicable either in cases of additional causality, where several conditions operate jointly and each of them would have been sufficient to cause the event, or in cases of hypothetical alternative causality, where it appears that a causal process other than the one that actually occurred would in any case have caused the event. Criminal law doctrine has thus sought to develop correctives to the *condicio sine qua non* theory: the thesis of human causality and the thesis of adequate causality. According to the latter reconstruction, an event can be attributed to a specific conduct when two circumstances occur: the conduct is *condicio sine qua non* of the event and the event constitutes, based on an *ex ante* judgement, a probable, normal and foreseeable development of the conduct itself. Therefore, human conduct is the cause only of those effects which, at the time it occurred, were to be considered probable according to the *id quod plerumque accidit* and not atypical, inadequate or abnormal consequences. According to the theory of human causality, on the other hand, human conduct is the cause of the event when it constitutes a *condicio sine qua non* and the event falls within the "sphere of human control" based on human cognitive and volitional powers and is therefore not due to exceptional factors. The search for a suitable method to explain the relationship between conduct and event has led doctrine and jurisprudence to develop the theory of scientific causality, according to which an action is the cause of an event when, according to the best science and experience of the historical moment and the outcome of a counterfactual prognostic judgement, the event is a certain or highly probable consequence of the action. More precisely, it is argued that an antecedent can be considered a necessary condition for an event only if it falls within the category of antecedents which, on the basis of a regular sequence conforming to a scientifically valid law, lead to events of the same type as the one that actually occurred. Moreover, jurisprudence has clarified that the covering laws that can be used by the judge are both universal and statistical laws. In addition, the need to rely on statistical laws

[57] M. Von Buri, *Uber Causalität und deren Verantwortung*, Leipzig, 1873.

[58] The thesis was initially followed by Italian case law, see M. Bonafede, *Il rapporto di causalità materiale*, in F. Bricola - V. Zagrebelsky (eds.), *Giurisprudenza sistematica di diritto penale*, Torino, 1984, 190; G. Fiandaca, *Causalità (rapporto di)*, cit., 119.

[59] F. Stella, *Rapporto di causalità*, cit.; F. Mantovani, *Diritto penale*, cit., 139.

means that the determination of causation is probabilistic in nature. Doctrine and jurisprudence debated how scientific-probabilistic laws should be applied, i.e. whether, in order to establish the existence of a causal link, it is sufficient for there to be a low probability that the event was the consequence of the conduct, or whether a probability close to certainty is required. The Italian Court of Cassation ruled on this point, drawing a distinction between statistical probability and logical probability[60]. The former concerns the identification of the frequency that characterises a given sequence of events, while the latter involves additional verification, based on the available evidence, of the reliability of the application of statistical law in the specific case. Therefore, in order to establish causality, it is necessary to identify the statistical law and carry out additional verification of the credibility of the application of scientific law to the specific case. As a consequence, the judge will have to make a double judgement: identify the scientific law that applies and verify its rational credibility in the specific case, based on the circumstances of the fact and the available evidence, so that, at the end of the evidentiary reasoning that has also excluded the interference of alternative causal factors, it appears that the agent's conduct was a necessary condition for the event with a high or very high degree of logical probability.

With regard to civil causality, according to established case law, the principles governing de factual causality in civil matters are those outlined in arts. 40 and 41 c.p.[61], tempered by the principle of efficient causality, which can be inferred from the second paragraph of art. 41 c.p., according to which the harmful event must be attributed exclusively to the perpetrator of the conduct that occurred, only if this is such as to render the other pre-existing causes irrelevant, placing itself outside the normal lines of development of the causal series already in place[62]. It should therefore be noted that, within the causal series considered, only those that, with reference to the moment in which the conduct occurs, do not appear entirely implausible, but present themselves as an effect that is not entirely unpredictable, according to the principle of adequate causality or the similar principle of causal regularity, should be emphasised. What changes substantially between criminal and civil proceedings is the standard of proof, since in the former the rule of "beyond reasonable doubt" applies, while in the latter the rule of preponderance of evidence or "more likely than not" applies, given the difference in the values at stake in criminal proceedings between the prosecution and the defence, and the equiva-

[60] Italian Supreme Court, 11 September 2002, no. 30328, in *Riv. it. dir. proc. pen.*, 2002, 767, commented by F. Stella, *Etica e razionalità del processo penale nella recente sentenza sulla causalità delle Sezioni unite della Suprema Corte di Cassazione*.

[61] F. Carnelutti, Perseverare diabolicum *(a proposito del limite della responsabilità per danni)*, in *Foro it.*, 75, 1952, sez. IV, 97; F. Realmonte, *Il problema del rapporto di causalità nel risarcimento del danno*, cit., 26.

[62] Italian Supreme Court, 11 January 2008, no. 576, in *Corr. Mer.*, 6, 2008, 694, commented by G. Travaglino, *Causalità civile e penale: modelli a confronto*; Italian Supreme Court, 11 January 2008, no. 581 in *Danno e resp.*, 10, 2008, 1011, annotated by R. Simone, *Equivoci della causalità adeguata e contaminazione dei modelli di spiegazione causale*; Italian Supreme Court, 11 January 2008, n. 582, in *Giust. civ.*, 11, 2009, 2532; Italian Supreme Court, 11 January 2008, no. 584, in *Foro it.*, 2008, 2, 451.

lence of those at stake in civil proceedings between the two contending parties. Furthermore, this "standard of probabilistic certainty" cannot be anchored exclusively to the "quantitative-statistical" determination of the frequencies of classes of events, which may also be lacking or irrelevant, but must be verified by tracing its degree of validity back to the scope of the confirming elements – and at the same time excluding other possible alternatives available in relation to the specific case[63].

It should be noted that the assessment of causality consists of two stages: the first concerns the relationship between conduct and event, known as material or factual causality; the second concerns the relationship between the event and the compensable harmful consequences, known as legal causality. It is to this type of causality that art. 1223 c.c. refers when limiting the compensability of damages to those that are the immediate and direct consequence of the breach, while there is no regulatory reference to the relationship between the conduct and the event.

As said before, various theories have been developed regarding the determination of causality: the thesis of *condicio sine qua non*; the purpose of the violated rule; causal adequacy and specific risk. In the first reconstruction, conduct is the cause of the event if it constitutes a necessary condition, i.e. if the counterfactual judgement shows that, by mentally eliminating that conduct, the event would not have occurred. This thesis, applied in civil law, raises the same concerns previously examined in the context of criminal causality. Legal doctrine and jurisprudence have therefore sought remedies for the rigidity of conditional theory. This has led to the development of the theory of adequate causality or causal regularity, which recognises the cause of an event in the fact normally capable of producing it. According to this theory, a person is only liable for the consequences of their conduct, whether active or passive, that appear sufficiently foreseeable at the time they acted. Liability for consequences that are completely atypical, implausible and unforeseeable is therefore excluded[64]. Moreover, the assessment of adequacy must be made *ex ante*, i.e. with reference to the time when the conduct took place.

Now, with regard to the question of causation in medical liability and the associated burden of proof[65], according to prevailing case law, which has been criticised by legal scholars, the patient is required to prove, even with presumptions, the material causal link between the doctor's conduct and the harmful event, consisting of damage to health, aggravation of the condition or the onset of a new disease, while it is the debtor's responsibility to prove that they have fulfilled their obligations or that the non-fulfilment was due to the impossibility of performance for reasons not attributable to them. If proof of the cause of exemption has been established, it means that the aggravation of the pathological condition or the occurrence of a new pathology is etiologically attributable to the medical intervention, but compliance with the leges artis has been lacking

[63] Italian Supreme Court, 11 January 2008, no. 581, cit.

[64] Italian Supreme Court, 19 July 2005, no. 15183; 6 April 2006, no. 8096; 6 July 2006, no. 15384; 1° March 2007, no. 4791; 11 January 2008, nos. 576 and 581; 8 July 2010, no. 16123; 23 December 2010, no. 26042; 17 September 2013, no. 21255.

[65] M. Taruffo, *La prova del nesso di causalità*, cit., 101.

in this case for reasons not attributable to the doctor. It follows that, if the cause of the damage remains unknown even through the use of presumptions, the unfavourable consequences for the purposes of the judgment fall on the creditor of the professional service; if, on the other hand, the cause of the supervening impossibility of professional diligence remains unknown, or the unpredictability and inevitability of that cause remains unproven, the unfavourable consequences fall on the debtor[66]. It has also been stated that the assessment of causality in healthcare liability is based on the rule of preponderance of evidence (or "more likely than not"), which, with regard to cases where there is a positive hypothesis and a complementary negative hypothesis regarding the same event, requires the judge to choose the one for which the probability that the conduct caused the event is greater than the opposite, and with regard, in the case where, with regard to the same event, there are several alternative hypotheses, requires the judge to first eliminate the least probable hypotheses from the list of those to be evaluated and then analyse the remaining hypotheses considered most probable, finally selecting the one that, according to inferential reasoning, has received the highest degree of confirmation from the factual circumstances acquired during the trial, in any case exercising his power of free assessment of the latter, taking into account the quality, quantity, reliability and consistency of the available evidence, from whose overall assessment he draws his probabilistic judgement[67].

In the event that there is a concurrence in the production of the harmful event between the conduct of the healthcare professional and an independent natural event, such as a pre-existing pathological condition of the injured party, the creditor of the professional service has the burden of proving the causal link between the healthcare professional's intervention and the damage event in terms of aggravation of the pathological condition and, once the contributory cause of the medical error has been estab-

[66] Italian Supreme Court, 11 November 2019, nos. 28991-28992, in *Resp. civ. e prev.*, 1, 2020, 193, commented by M. Franzoni, *Onere della prova e il processo* e C. Scognamiglio, *L'onere della prova circa il nesso di causa nella responsabilità contrattuale del sanitario*. Also in R. Pardolesi (ed.), *Responsabilità sanitaria in Cassazione: il nuovo corso tra razionalizzazione e* consolidamento, Foro *it*., *Gli speciali*, 1, 2020, 129, commented by R. Pardolesi- R. Simone, *Prova del nesso di causa e obbligazioni di facere professionale: paziente in castigo*; G. D'Amico, *L'onere della prova del nesso di causalità materiale nella responsabilità (contrattuale) medica. Una giurisprudenza in via di "assestamento"*; F. Macario, *Prova del nesso di causalità (materiale) e responsabilità medica: un pregevole chiarimento sistematico da parte della Cassazione*; F. Piraino, *Ancora sul nesso di causalità materiale nella responsabilità contrattuale*; U. Izzo, *In tema di tecnica e politica della responsabilità medica.* On this topic, see also N. Rizzo*, Inadempimento e danno nella responsabilità medica: causa e conseguenze*, cit., 327; Id., *La causalità civile*, cit., 72; F. Piraino, *Inadempimento e causalità nelle obbligazioni di fare professionale*, in *Danno e Resp*., 5, 2020, 559; R. Favale, *Causalità e ripartizione dell'onere della prova nella responsabilità sanitaria*, in *Comparazione e dir. civ*., 2, 2023, 425. See also, Italian Supreme Court, 26 July 2017, no. 18392, in *Foro it.,* 2017, I, 3358, and 2018, I, 1348, commented by G. D'Amico, *La prova del nesso di causalità «materiale» e il rischio della c.d. «causa ignota» nella responsabilità medica*, e *Danno e resp*., 2017, 696, commented by D. Zorzit, *La Cassazione e la prova del nesso causale: l'inizio di una nuova storia?. Sulla prova del nesso di causalità materiale*. See also, F. Piraino, *Il nesso di causalità materiale nella responsabilità contrattuale e la ripartizione dell'onere della prova*, in *Giur. it*., 3, 2019, 709; Id., *Causalità e responsabilità contrattuale (tenzone tra un giudice e un professore). Parte I: La causalità generale*, in *Foro it*., 10, 2022, V, 262; Id., *Causalità e responsabilità contrattuale (tenzone tra un giudice e un professore). Parte II: La causalità materiale e obbligazioni di facere professionale*, in *Foro it*., 11, 2022, V, 321.

[67] Italian Supreme Court, 5 March 2024, no. 5922, in *Ced Cass. civ*., 2024.

lished, it is up to the healthcare professional to demonstrate the absorbing and not merely concurrent nature of the external cause; if the extent of the natural contributory cause remains uncertain, the responsibility for all the consequences identified on the basis of legal causality must be attributed entirely to the author of the human conduct[68].
If the damage is caused by an AI system, proving the causal link could, in practice, be particularly difficult. As seen, autonomous systems are characterised by an opacity that makes it impossible to probe the machine's actions. In this regard, the mentioned Proposal for a Directive on adapting non-contractual liability to Artificial Intelligence established a relative presumption of causality in cases of fault. More specifically, art. 4 of the proposal provides that « Subject to the requirements laid down in this article, national courts shall presume, for the purposes of applying liability rules to a claim for damages, the causal link between the fault of the defendant and the output produced by the AI system or the failure of the AI system to produce an output, where all of the following conditions are met: (a) the claimant has demonstrated or the court has presumed pursuant to art. 3(5), the fault of the defendant, or of a person for whose behaviour the defendant is responsible, consisting in the non-compliance with a duty of care laid down in Union or national law directly intended to protect against the damage that occurred; (b) it can be considered reasonably likely, based on the circumstances of the case, that the fault has influenced the output produced by the AI system or the failure of the AI system to produce an output; (c) the claimant has demonstrated that the output produced by the AI system or the failure of the AI system to produce an output gave rise to the damage». At the moment, this proposal has been withdrawn[69].

4. Consent to the use of AI systems and the patient's right to self-determination

One further point that needs to be discussed concerns informed consent and patient self-determination. The key questions in this area relate to the scope of the information obligations incumbent on doctors who use AI systems to provide healthcare services and the technical accuracy of the information provided. Art. 1 of law no. 219/2017 establishes that no medical treatment may be initiated or continued without the freely given and informed consent of the person concerned – except in cases expressly provided for by law – and that every person has the right to know their health condition and to be informed in a comprehensive, up-to-date and understandable manner about the diagnosis, prognosis, the benefits and risks of the diagnostic tests and medical treatments indicated, as well as possible alternatives and the consequences of any refusal of medical treatment and diagnostic tests or of waiving them. Consent must be not only informed and explicit, but also conscious and complete, i.e. it must cover all foreseeable risks, including those that are statistically less likely,

[68] Italian Supreme Court, 23 February 2023, no. 5632.

[69] List of withdrawals, in *eur-lex.europa.eu.*

with the sole exception of those that are absolutely exceptional or highly improbable; furthermore, such consent must cover not only the intervention as a whole, but also each individual phase of it[70]. Case law has clarified that the acquisition of informed consent by the physician constitutes a performance that is separate and distinct from that of the medical assistance requested, assuming independent relevance for the purposes of possible liability for damages in the event of failure to perform. Ultimately, these are two distinct rights: informed consent relates to the fundamental right of the individual to express their informed consent to the medical treatment proposed by the doctor and therefore to the freely given and informed self-determination of the patient, given that no one can be forced to undergo a specific medical treatment except by law (and even then, the law cannot violate the limits imposed by respect for the human person under art. 32, para. 2, of the Constitution); medical treatment, on the other hand, concerns the protection of the (different) fundamental right to health (art. 32, para. 1, of the Constitution). The Court of Cassation has also clarified that compensation for damage resulting from a violation of the right to self-determination is applicable if and only if, due to a lack of information, the patient has suffered financial or non-financial damage (and, in the latter case, of appreciable severity), other than the violation of the right to health, in terms of subjective suffering and restriction of the freedom to dispose of oneself, psychologically and physically, to be specifically attached and proven in concrete terms, albeit by means of presumptions[71]. The patient must be compensated even if they cannot prove that they would have refused the operation had they been informed of the risks involved[72].

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[70] Italian Supreme Court, 27 November 2012, no. 20984, in *Riv. it. Medicina Legale*, 3, 2013, 1505, commented by S. Cacace, Medice, cura te ipsum? *Il diritto all'informazione del paziente-medico (e qualche altra questione sul consenso al trattamento)*; Italian Supreme Court, 4 February 2016, no. 2177, in *Resp. civ. prev.*, 4, 2016, 1359; Italian Supreme Court, 25 June 2021, no. 18283, in *Foro it.*, 2, 2022, I, 723.

[71] Italian Supreme Court, 12 June 2023, no. 16633, in *IUS Responsabilità Civile*, 4 Agust 2023, commented by A.B. Serpetti, *Violazione dell'obbligo informativo in relazione alla lesione del diritto all'autodeterminazione e alla salute.*

[72] Jurisprudence repeatedly ruled that patients always have the right to refuse medical treatment, even when such refusal could result in their death. However, in order for refusal of medical treatment to be valid and thus exempt the doctor from the power and duty to intervene, it must be expressed, unequivocal and current: it is not sufficient, therefore, to express a generic dissent ex ante and at a time when the patient was not in danger of death, but it is necessary that the dissent be expressed ex post, i.e. after the patient has been fully informed about the seriousness of their situation and the risks arising from the refusal of treatment (Italian Supreme Court, 15 September 2008, no. 23676, in *Resp. civ. prev.*, 1, 2009, 126, annotated by M. Gorgoni, *Libertà di coscienza v. salute; personalismo individualista v. paternalismo sanitario*. Jurisprudence also stated that, with regard to the refusal of certain therapies, in accordance with a right based on the combined provisions of art. 32 of the Constitution, art. 9 of Law no. 145 of 28 March 2001, and art. 40 of the Code of Medical Ethics, even in the presence of an express prior refusal, it cannot be ruled out that the doctor, faced with an unexpected and unpredictable worsening of the patient's condition and in the presence of circumstances preventing the effective verification of the persistence of such dissent, may consider it certain or highly probable that it is no longer valid and, consequently, may administer the treatment already refused, where it is essential to save the patient's life. (Italian Supreme Court, 23 February 2007, no. 4211, in *Foro it.*, 6, 2007, I, 1711).

With regard to data processing by algorithms, jurisprudence has also established that when personal data are intended to be "processed" by an algorithm (in this case, an algorithm for calculating the so-called reputation rating), in order to meet the requirements of a freely given and clear consent, for it to be legitimate and valid, the user must be able to understand the algorithm, understood as a reliable procedure for obtaining a certain result or solving a certain problem, which is described in an unambiguous and detailed manner, as capable of leading to the result in a finite time. In such cases, it is not the mathematical question that is relevant, except to the extent that it serves to understand whether the consent given by the subject can be said to be informed and aware[73].

The same principles should apply when using artificial intelligence systems. The physician must therefore provide the patient with all information relating to the AI system used, including the risks and benefits, the degree of autonomy and controllability, in order to ensure full awareness of the choices available[74]. On the other hand, however, it has been noted that law no. 219/2017 does not expressly require the doctor to inform the patient of the techniques and means that will be used in the course of the treatment and that the decision to include technical details in the information provided should therefore be left to the doctor's discretion, also taking into account the patient's emotional state[75].

On this subject, law no. 132/2025 states in para. 3 of art. 7 that the data subject has the right to be informed about the use of artificial intelligence technologies. Therefore, the doctor has a duty to provide adequate information to the patient, highlighting the benefits and risks of AI, including those related to the opacity of the systems, in order to fully implement the patient's right to self-determination.

[73] Italian Supreme Court, 10 October 2023, no. 28358, in *Resp. civ. prev.*, 6, 2023, 2005, commented by F. Cerea, *Trattamento algoritmico dei dati a fini reputazionali tra consenso dell'interessato e controllo ex ante di conformità al GDPR e all'AI Act.*

[74] M. Franzoni, *Lesione dei diritti della persona, tutela della privacy e intelligenza artificiale*, cit., 20; A.E. Tozzi - G. Cinelli, *Informed consent and artificial intelligence*, in, *BioLaw Journal*, Special Issue, 2, 2021, 106; R. Tuccillo, *Intelligenza artificiale e prestazioni sanitarie: impatto sulla relazione di cura e sullo statuto della responsabilità*, in *Dir. merc. tecn.*, 16 May 2022, 35. See also R. Messinetti, *La tutela della persona umana versus l'intelligenza artificiale. Potere decisionale dell'apparato tecnologico e diritto alla spiegazione della decisione automatizzata*, in *Contr. impr.*, 3, 2019, 861.

[75] C. De Menech, *Intelligenza artificiale e autodeterminazione in materia sanitaria*, in M. Faccioli (ed.), *Profili giuridici dell'utilizzo della robotica e dell'intelligenza artificiale in medicina*, Napoli, 2022, 16; Ead., *Intelligenza artificiale e autodeterminazione in materia sanitaria*, in *BioLaw Journal*, 1, 2022, 181; M. Faccioli, *Intelligenza artificiale e responsabilità sanitaria*, cit., 740.

Abstract

The use of AI systems raises many questions that require careful reflection for jurists, especially with reference to the application of AI in healthcare, given the delicate nature of the questions that this area raises. There are now several uses in healthcare of robotics and AI-based systems, which are capable of assisting the physician in all the steps of patient care. This can bring considerable advantages, but the associated risks should not be underestimated. It is therefore necessary to carefully focus on the impact of the use of AI in healthcare on personality rights, on the remedies and on the liability connected. The identification of potentially liable parties and the criteria for imputation of liability for the physician's use of AI systems is particularly important to ensure adequate protection of the individual and to ensure an effective exercise of the right to compensation.

Keywords

AI – healthcare – data protection – medical liability – right to self-determination

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