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LIABILITY ISSUES IN DATA-DRIVEN HEALTHCARE AND HARMONISATION EFFORTS IN EUROPE

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1. INNOVATIONS IN DATA-DRIVEN HEALTHCARE

Digital transformation in healthcare is increasingly relevant as more people have access to improved e-health services and better care and outcomes, including across borders.[2]

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[2] WHO, *Global strategy on digital health 2020-2025*, Geneva, World Health Organization, 2021. On this topic see: S. KRAUS, F. SCHIAVONE, A. PLUZHNIKOVA, A. C. INVERNIZZI, *Digital transformation in healthcare: Analyzing the current state-of-research*, in *Journal of Business Research*, no. 123/2021, 557 – 567. AI-based solutions are mostly deployed in: (i) diagnosis, prognosis and treatment using clinical data and image recognition; (ii) patient engagement

The integration of appropriate digital health technologies is widely recognised as a strategy to build stronger and more resilient health systems, stimulate innovative solutions, and facilitate economic recovery from the recent pandemic crisis.[3] Data and artificial intelligence (AI) are the key features of digital transformation in healthcare. AI and particularly 'machine learning' technologies hold enormous potential to improve clinical diagnostics, reduce errors, medical malpractice rates and costs and render citizens' rights to access health effectively.[4] Such technologies use algorithms to find patterns within vast amounts of data and elaborate patient-based solutions, perhaps more accurately than any clinician could understand or

and follow-up; (iii) clinical decision-making process, through predictive analytics, clinical risk interventions and population health information, public health, care services, self-care, and health systems. See recently: EU COMMISSION, Directorate-General for Health and Food Safety, Lupiáñez-Villanueva, F., Gunderson, L., Vitiello, S., et al., *Study on health data, digital health and artificial intelligence in healthcare*, 2022; T. NICHOLAS, *Of Regulating Healthcare AI and Robots*, in *Yale Journal of Health Policy, Law, and Ethics*, 18:3 (2019), 133 – 190.

[3] EU COUNCIL, *Council conclusions on COVID-19 lessons learned in health*, Brussels, 18 December 2020. See also: EU COMMISSION, *Communication from the Commission to the European Parliament, The Council, The European Economic and Social Committee and The Committee of The Regions on enabling the digital transformation of health and care in the Digital Single Market; empowering citizens and building a healthier society*, Brussels, 25.4.2018, COM(2018) 233 final.

[4] G. M. RACCA, *Salute*, in *Enc. dir., I tematici. Le funzioni amministrative*, Giuffrè, Milano, 2022, 995 – 1015.

evaluate.[5] Moving to data-driven medicine can improve diagnosis and treatment through personalised and value-based care.[6]

The use of AI offers scope for administrative improvements as well, reducing the overall costs and expenses of healthcare systems.[7] Administrative databases and in-patient data have evolved from their sole use of tracking hospital activity to being utilised by policymakers and researchers for conducting clinical, policy and economics-related research.[8] The pandemic further highlighted the importance of e-health data and new technological solutions in responding appropriately to health emergencies.[9] Integrated surveillance systems proved to be a necessary tool, providing information on the impact and

[5] W. N. PRICE II, *Artificial Intelligence in Health Care: Applications and Legal Implications*, 14 in *SCITECH LAW*, no. 10/2017. Examples of highly accurate AI-based solutions include an imaging system that uses algorithms to provide diagnostic information for skin cancer, or an intelligent electrocardiogram device that can estimate the likelihood of a heart attack. See on this topic: I. G. COHEN, T. MINSSEN, W. N. PRICE, C. T. ROBERTSON, C. SHACHAR (eds.), *Innovation and protection: the future of medical device regulation*, Cambridge University Press, Cambridge, 2022.

[6] EU COMMISSION'S EXPERT PANEL ON EFFECTIVE WAYS OF INVESTING IN HEALTH, *Opinion on Defining value in "value-based healthcare"*, 26 June 2019.

[7] J. FERNÁNDEZ GARCÍA, A. SPATHAROU, S. HIERONIMUS, J.-P. BECK, J. JENKINS, *Transforming healthcare with AI*, EIT Health and McKinsey & Company, 2020.

[8] Among the sources used by OECD countries to monitor their health systems, administrative data developed since the 1980s have been particularly important for health services research. See: OECD, *Ageing related disease study technical report using hospital administrative databases for a disease-based approach to studying health care systems*, August 2001.

[9] C. PAGLIARI, *Digital health and primary care: Past, pandemic and prospects*, in *J Glob Health*, no. 11/2021, 1 – 9.

evolution of the pandemic and helping authorities to make public health decisions, particularly in the countries most affected by COVID-19, such as Italy.[10]

Despite its potential as a tool for health monitoring and planning, fragmentation and legal barriers to access and use of e-health data can hinder effective administrative cooperation and the development of data-driven innovation in Europe.[11] Actions by Member States alone are not sufficient and may hamper innovation and the deployment of digital health products and services, including AI technologies.[12] Lessons learned from the pandemic crisis and the gradual development of a European Health Union aim to overcome the limited role of the EU in the protection of health, which still focuses predominantly on Member States.[13] The recent health crisis has strengthened administrative cooperation in the

[10] OECD, European Observatory on Health Systems and Policies, *Italy: Country Health Profile 2021*, State of Health in the EU, OECD-Publishing, Paris, 2021.

[11] R. CAVALLO PERIN, G. M. RACCA *Administrative Cooperation in the Public Contracts and Service Sectors for the Progress of European Integration*, in F. MERLONI, A. PIOGGIA (eds.), *European Democratic Institutions and Administrations*, Giappichelli, Torino, 2018, 265 – 296.

[12] G. M. RACCA, C. R. YUKINS (eds.), *Joint Public Procurement and Innovation: Lessons Across Borders*, in Droit Administratif/Administrative Law Collection (Directed by J. B. Auby), Bruxelles, Bruylant, 2019.

[13] Article 168 of the Treaty on the Functioning of the European Union identifies public health as a shared competence between the EU and the Member States. While Member States define and provide their national health services and care, the EU has competence to support, coordinate and complement national action to protect and improve human health (Article 6(a) of the Treaty on the Functioning of the European Union). Article 168(5) of the TFEU allows for the adoption of incentive measures to protect and improve human health, in particular to address serious cross-border threats. Under this provision, the EU response to the COVID-19 crisis envisaged various coordination measures between Member States, including the possibility of implementing forms of joint procurement of goods and medical devices, introduced by Decision No 1082/2013/EU, in relation to phenomena that may determine serious health risks of a cross-border nature, recently amended by Regulation (EU) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health and repealing Decision No 1082/2013/EU. See also Article 35 of the Charter of Fundamental Rights of the European Union on the protection of health which states the right of everyone to have access to health care; and secondly, a mandate for the EU in defining its policies

healthcare sector; procurement under the Joint Procurement Agreement (JPA), the RescEU scheme, and the Advanced Purchase Agreements (APAs) for the purchase of COVID-19 vaccines, while having significant flaws, are evidence of this.[14]

The level of public interest in data regulation is reflected in the numerous initiatives to promote a European-based digital transition, including the European Health Data Space (EHDS) proposal.[15] The EHDS, as part of the European Strategy for the Digital Decade[16], is a harmonised framework aimed at ensuring "*data for the public good*"[17], based on the free movement, sharing and reuse of health data for the benefit of European patients, industry, researchers, and public administrations. It will allow individuals greater control over their

and actions. See on this topic: M. GUY, *Towards a European Health Union: What Role for Member States?*, in *European Journal of Risk Regulation*, 11(4), 2020, 757 – 765.

[14] G.M. RACCA, C. R. YUKINS, *As the Fever Subsides: The Pandemic's Lessons in Corruption*, in S. WILLIAMS-ELEGBE & J. TILLIPMAN (eds.), *Routledge Handbook of Public Procurement Corruption*, Routledge, Forthcoming. See: S. ARROWSMITH, L.R. BUTLER, A. LA CHIMIA, C.R. YUKINS (eds.) *Public Procurement Regulation in (a) Crisis? Global Lessons from the COVID-19 Pandemic*, Oxford, Hart Publishing, 2021.

[15] EU COMMISSION, *Proposal for a Regulation of the European Parliament and of the Council on the European Health Data Space*, Strasbourg, 3.5.2022, COM(2022) 197 final. See also the *Communication from the Commission to the European Parliament and the Council, A European Health Data Space: harnessing the power of health data for people, patients and innovation*, Strasbourg, 3.5.2022 COM(2022) 196 final.

[16] On 19 February 2020, the EU Commission presented its 'European Strategy for Data' with the aim of encouraging data-driven innovation to achieve better and more transparent governance and public services. See: EU COMMISSION, *Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions. A European Strategy for Data*, Brussels, 19.2.2020, COM(2020) 66 final. On 30 May 2022, Regulation (EU) 2022/868 on European data governance ('Data Governance Act') was adopted as part of the European Strategy for Data. It is aimed at promoting the re-use of public sector data and reinforcing a European digital space for data sharing and strengthening of the open strategic autonomy of the Union.

[17] EU COMMISSION, *A European Strategy for Data*, 2020, cit., 6 ff.

data through digital access to health information (i.e. primary use of data) and enable the cross-border use of data for research, innovation, and policy making (i.e. secondary use of data).

Obviously, in order to function effectively and meet current regulatory requirements, EHDSs need to be coordinated and supported by a larger number of public and private entities. This coordination is necessary to ensure that the EHDS is integrated into existing ecosystems and is able to function seamlessly. The implementation of the EHDS aims to promote the 'right of access to data'[18] in the health sector by using new technologies and digitalisation-driven innovations. This initiative is expected to improve the protection of the health of European citizens by increasing the accessibility of health data.

2. THE REGULATORY CHALLENGES AND RISKS OF AI

Alongside the potential benefits, AI in healthcare raises new risks and a series of legal issues that require a clear regulatory framework to address the implications of its use. These challenges mainly relate to liability, safety and transparency of AI systems, as well as the risks of AI failures and their wider impact on businesses and citizens. Such legal challenges

[18] The right of access by the data subject is established by Article 15 of the General Data Protection Regulation (Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (), 4.5.2016, L 119/1) and includes: "*the right for data subjects to have access to data concerning their health, for example the data in their medical records containing information such as diagnoses, examination results, assessments by treating physicians and any treatment or interventions provided*" (Recital 63).

are identified as one of the potential barriers to the adoption of AI in healthcare[19], while liability is identified as one of the top three barriers to the use of AI by EU companies. [20]

The unpredictable 'self-learning' and 'black-box' nature of AI systems causes uncertainty and precludes full understanding and comprehension of their operations.[21] Concerns are emerging due to the opacity and complexity of so-called 'black-box medicine', which requires 'accountable' solutions.[22] The increasing opacity of clinical decision-making threatens trust and reliability between healthcare professionals and patients. In addition, the use of black-box medicine raises concerns about informed consent, as patients and clinicians may not understand AI-based solutions, jeopardising the therapeutic alliance and end-user trust.[23] To address this concern, the concept of 'explainable AI' is often posited, referring to

[19] EU PARLIAMENT, *Artificial intelligence in healthcare. Applications, risks, and ethical and societal impacts*, Study for the European Parliamentary Research Service, June 2022, 26 ff.. E. THELISSON, *AI Technologies and Accountability*, in *Digital Health*, *Cambridge Bioethics and the Law Series*, Cambridge University Press, 2021, forthcoming. See also: INTERNATIONAL COALITION OF MEDICINES REGULATORY AUTHORITIES - ICMRA, Informal Innovation Network, *Horizon Scanning Assessment Report – Artificial Intelligence*, 6 August 2021. See: J. ORDISH, *Legal liability for machine learning in healthcare*, PHG Foundation, University of Cambridge, 2018.

[20] EU COMMISSION, Directorate-General for Communications Networks, *Content and Technology, European enterprise survey on the use of technologies based on artificial intelligence: final report*, Publications Office, 2020, https://data.europa.eu/doi/10.2759/759368, 58 ff.

[21] S. J. SCHWEIKART, *Who Will Be Liable for Medical Malpractice in the Future? How the Use of Artificial Intelligence in Medicine Will Shape Medical Tort Law*, in *Minnesota Journal of Law, Science & Technology*, no. 22/2021, 1 – 23.

[22] J. A. KROLL, J. HUEY, S. BAROCAS, E. W. FELTEN, J. R. REIDENBERG, D. G. ROBINSON, H YU, *Accountable Algorithms*, in *U. PA. L. REV.*, 2017, 633 – 705.

[23] See, for example, in Italy, Law No. 217/2019 on informed consent in medicine (Article 1, para. 2) which is aimed at promoting and enhancing "*the relationship of care and trust between patient and doctor that is based on informed consent in which the patient's decision-making autonomy and the doctor's competence, professional autonomy and responsibility meet*".

the need for solutions proposed by AI systems to be understandable to human experts, particularly in the medical field. This requires careful consideration when establishing professional standards for the use of AI systems directly with patients.[24]

Transparency and opacity are closely linked to issues of accountability and liability for harm that may result from the use of AI systems. The opacity of 'black box medicine' could make it extremely difficult to identify who was in control of the risk associated with its use and which code, input or data have caused the damages or an incorrect clinical decision.[25]

AI systems pose significant legal challenges, as the more difficult it is to determine who is responsible for an error involving a patient or a medical decision, the more likely it is that liability will "*fall more heavily on the clinician who used a non-transparent medical AI tool and is unable to explain their medical decision or the error that occurred*".[26]

[24] EU COMMISSION, Directorate-General for Health and Food Safety, LUPIÁÑEZ-VILLANUEVA, F., GUNDERSON, L., VITIELLO, S., et al., *Study on health data, digital health and artificial intelligence in healthcare*, 2022, cit. See more recently: COUNCIL OF EUROPE, *The impact of artificial intelligence on the doctor-patient relationship*, report written by Brent Mittelstadt, Senior Research Fellow and Director of Research at the Oxford Internet Institute, University of Oxford, United Kingdom, 2022. See also: P. HUNT, G. BACKMAN, *Health Systems and the right to the highest attainable standard of health*, in *Health and Human Rights*, 10, 1, 2008, 81-92.

[25] M. MATHENY, S. THADANEY ISRANI, M. AHMED, A. WHICHER (eds.), *Artificial Intelligence in Health Care: The Hope, the Hype, the Promise, the Peril*, NAM Special Publication. Washington, DC: National Academy of Medicine, 2019, 200 ff. See also the European Parliament Resolution of 20 October 2020 with recommendations to the Commission on a civil liability regime for artificial intelligence (2020/2014(INL), Recital 3. These concerns have also been raised by the EU Parliament in its Resolution of 3 May 2022 on Artificial intelligence in a digital age, 2020/2266(INI).

[26] EU PARLIAMENT, *Artificial intelligence in healthcare. Applications, risks, and ethical and societal impacts*, 2022, cit., 27.

The existing legal framework at the Member State level primarily rests upon negligence-based liability (or *culpa aquiliana*) and contractual liability rules which do not seem to take into account the new risks posed by artificial intelligence. [27] Challenges in emerging AI applications push current regulations, policies, and laws to adapt traditional clinical negligence rules to the new reality of AI-assisted healthcare.[28] Addressing the complexity and opacity of AI is widely recognised as essential for ensuring efficiency and transparency but the goal of ensuring legal certainty and preventing gaps in compensation claims where AI systems are involved can best be achieved not through state-level

[27] Fault-based liability imposes a duty of compensation on the subject who has negligently breached a standard of behaviour and caused damage. Strict liability and vicarious liability regimes - the latter more commonly applied in common law systems - are forms of indirect liability rules, for things or animals in custody, or for the acts of children and auxiliaries, and could be applied to hold primarily owners and users of advanced technologies liable. Contractual liability, on the other hand, requires a legal relationship (contract or legal obligation) between the parties before the damage occurs. Contractual liability rules are generally considered to be more favourable to the claimant than fault-based rules, which may prove overly burdensome and difficult to access justice and obtain compensation. For a detailed assessment of the EU legal regime see: A. BERTOLINI, *Artificial Intelligence and Civil Liability Legal Affairs*, Study requested by the Policy Department for Citizens' Rights and Constitutional Affairs Directorate-General for Internal Policies of the EU Parliament, PE 621.926, July 2020, 10 ff.

[28] A particularly well-known AI-based system is IMB's Watson, a question-answering computer system used as a clinical decision support system in oncology. The system uses AI algorithms to evaluate information from patients' medical records to help doctors explore cancer treatment options for patients. However, it has recently come under criticism for reportedly making unsafe and incorrect cancer treatment recommendations (the reason for the problem was that the system was trained on a few 'synthetic' cancer cases rather than real patient data). Although the errors only occurred as part of the system's testing and research, and no incorrect treatment recommendation was given to a real patient, the development of such AI-based systems for commercial use in the medical sector is increasing and requires attention at a policy and legislative level. See on this topic: S. GERKE, T. MINSSEN, G. COHEN, *Ethical and legal challenges of artificial intelligence-driven healthcare*, in A. BOHR, K. MEMARZADEH (eds.), *Artificial Intelligence in Healthcare*, Elsevier, 2020, 302. See also: A. BERTOLINI, *Artificial Intelligence and Civil Liability Legal Affairs*, 2020, cit., 112. Recent medical AI projects (e.g. GE Healthcare's Edison and Google's DeepMind) aim to develop consumer-oriented products such as apps and smartwatches based on AI and even neural networks, which poses a number of challenges regarding the use of data, even if based on user consent. See: T. NICHOLAS, *Of Regulating Healthcare AI and Robots*, cit., 151.

interventions. There is therefore a need for further European and supranational harmonisation of principles and liability rules for the use of AI, particularly in healthcare.[29]

While a core set of general principles for the deployment of AI has progressively emerged at supranational and European level, those standards still require comprehensive regulation, particularly in a high-risk area such as healthcare. For example, organisations and individuals developing, implementing and using AI systems in OECD countries are expected to effectively manage the operation of such systems and fulfil their responsibilities according to their role and context.[30] The World Health Organization (WHO) has explicitly recognised the importance of protecting human well-being and safety as a key ethical principle for the deployment of AI in healthcare.[31] The International Coalition of Medicines Regulatory Authorities, which includes healthcare and pharmaceutical regulators from around the world, has made recommendations on the use of AI technologies in medicine, from the validation and analysis of clinical data in trials to pharmacovigilance and the optimisation of clinical use. It also highlighted a series of regulatory challenges, including transparency of

[29] EU COMMISSION, *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)*, Brussels, 28.9.2022, COM(2022) 496 final.

[30] OECD, *Principles on Artificial Intelligence, Accountability* (Principle 1.5). Where 'liability' generally refers to adverse legal implications arising from a person's (or an organisation's) actions or inaction, 'responsibility' can also have ethical or moral expectations and can be used in both legal and non-legal contexts. In the OECD AI framework, 'accountability' refers to the expectation that organisations or individuals will ensure the proper functioning throughout their lifecycle, of the AI systems that they design, develop, operate, or deploy.

[31] WHO, *Ethics and governance of artificial intelligence for health: WHO guidance*, Geneva, World Health Organization, 2021.

algorithms, the risks of AI failures, and the wider impact on pharmaceutical development and on patients' health. [32]

The need for the development of a risk-based approach to the assessment and regulation of AI and its use has become apparent, with more and more specific considerations at the EU level.[33] The first step in this process was the publication of a Resolution by the European Parliament in 2017 on 'civil law rules on robotics'.[34] It questions whether the current liability rules are sufficient and whether new rules are required to "*provide clarity on the legal liability of various actors concerning responsibility for the acts and omissions of robots*". It also highlights two possible approaches as follows: the 'strict liability' model, which "*requires only proof that damage has occurred and the establishment of a causal link between the harmful functioning of the robot and the damage suffered by the injured party*" and the 'risk management approach', which focuses not "*on the person 'who acted negligently' as individually liable*" but on the entity or subject "*who is able, under certain*

[32] The Informal Innovation Network for the Horizon Scanning Assessment Report – Artificial Intelligence includes: the Italian Medicines Agency (AIFA), the Danish Medicines Agency (DKMA), the European Medicines Agency (EMA) as working group lead, the USA's Food and Drug Administration (FDA) as an observer, Health Canada (HC), the Irish Health Products Regulatory Authority (HPRA), Swissmedic and the World Health Organisation (WHO).

[33] The EU Commission has proposed two legislative initiatives to upgrade rules governing digital services in the EU: the Digital Services Act (DSA) and the Digital Markets Act (DMA), aimed at creating a single set of rules applicable across the EU. The DMA has been approved by Regulation (EU) 2022/1925 of the European Parliament and of the Council of 14 September 2022 on contestable and fair markets in the digital sector and amending Directives (EU) 2019/1937 and (EU) 2020/1828 (*Digital Markets Act*); on 23 April 2022 a political agreement was reached on the Digital Services Act. See: EU COMMISSION, *Proposal for A Regulation of the European Parliament and of the Council on a Single Market for Digital Services (Digital Services Act) and amending Directive 2000/31/EC*, Brussels, 15.12.2020.

[34] EU PARLIAMENT, *Resolution of 16 February 2017 with recommendations to the Commission on Civil Law Rules on Robotics*, (2015/2103(INL), 18.7.2018.

circumstances, to minimize risks and deal with negative impacts".[35] In 2018, the European Commission adopted its AI strategy, which provides an initial map of liability challenges for emerging digital technologies.[36] A report on the safety and liability implications of artificial intelligence, the Internet of Things (IoT) and robotics was published by the Commission in February 2020. It highlights the importance of these technologies and the aim of making "*Europe a world leader in AI, IoT and robotics*".[37] In the same year, the European Parliament recommended the Commission to define a civil liability regime for AI.[38] Recently a clear-cut, risk-based regulatory framework has been proposed, differentiating between uses of AI that create (i) an unacceptable risk, (ii) a high risk and (iii) low or minimal risk, where health and safety are considered 'high risk' areas. [39] Under the proposed framework (i.e. the 'Artificial Intelligence Act'), AI systems are allowed on the European market provided they

[35] *Ibidem*, para. 54.

[36] EU COMMISSION, *Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions Artificial intelligence for Europe*, Brussels, 25.4.2018, COM(2018) 237 final.

[37] EU COMMISSION, *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 Intelligence, the Internet of Things and robotics*, Brussels, 19.2.2020 COM(2020) 64 final. See on this topic: S. GERKE, T. MINSSEN, G. COHEN, *Ethical and legal challenges of artificial intelligence-driven healthcare*, in A. BOHR, K. MEMARZADEH (eds.), *Artificial Intelligence in Healthcare*, Elsevier, 2020, 295 – 336.

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

[39] EU COMMISSION, *Proposal for a Regulation of the European Parliament and of the Council laying down harmonised rules on Artificial Intelligence (Artificial Intelligence Act)*, Brussels, 21.4.2021, COM(2021) 206 final, 2021/0106(COD). This category corresponds to AI tools which contradict EU values and hence should be prohibited, e.g. subliminal manipulation resulting in physical/psychological harm; exploitation of vulnerabilities resulting in physical/psychological harm; social scoring; real-time biometric identification in public spaces (with few exceptions).

meet mandatory requirements and pass an *ex-ante* conformity assessment. [40] On 28 September 2022, the Commission published a 'AI Liability Directive' proposal to harmonise certain aspects of non-contractual civil liability rules for damage in the use of AI systems. [41] The AI Liability Directive follows a 'minimum harmonisation approach'; it does not intend to harmonise general aspects of civil liability regulated at national level (such as the definition of fault or causality, the different types and the calculation of damages, the distribution of liability, etc.) but introduces a right to disclosure for high-risk AI systems (Article 3) and a lighter burden of proof with a presumption of non-compliance[42] (Article 3 para. 5) and a

[40] The Artificial Intelligence Act is in line with the recommendations of the EU Parliament of 2017 in which it called on the Commission to draw up a proposal for a Directive aimed at regulating the use of robotics in the healthcare sector (EU PARLIAMENT, *Resolution of 16 February 2017 with recommendations to the Commission on Civil Law Rules on Robotics*, cit.).

[41] EU COMMISSION, *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)*, 2022 cit. The proposal (which follows the recommendations of the EU Parliament of 20 October 2020 on a civil liability regime for artificial intelligence), aims to complement the Product Liability regime for an overall effective civil liability system, on which topic, see below.

[42] The "*presumption of non-compliance*" shall apply "*where a defendant fails to comply with an order by a national court in a claim for damages to disclose or to preserve evidence at its disposal*". In such cases "*The defendant shall have the right to rebut that presumption*". (Article 3, para. 5 of the AI Liability Directive).

presumption of causality in case of a breach of duty of care[43] set under Union or national laws (Article 4), so to establish broader protection and guarantees for victims.[44]

The EU's approach to digital transformation is consistent with the protection of fundamental rights and recognises that public administration and healthcare are increasingly taking place through digital means. This requires pursuing security and accountability, as embodied in the 'Declaration on European Digital Rights and Principles'[45] (January 26, 2022) and the 'Declaration for the Future of Internet' (April 28, 2022).[46] Inadequacies in a system of liability may "*compromise the expected benefits*" of such a technology, requiring the existing rules to be adjusted to ensure patients' right to receive compensation or recover

[43] Under Article 2(9) of the AI Liability Directive, "*duty of care refers*" to as "*a required standard of conduct, set by national or Union law, in order to avoid damage to legal interests recognised at national or Union law level, including life, physical integrity, property and the protection of fundamental rights*". The "*presumption of causal link*" shall apply where all the following conditions are met: a) the claimant has demonstrated or the court has presumed pursuant to Article 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" (Article 4, para. 1). Stricter requirements apply to providers of a "*high-risk AI system*" according to Article 4, para. 2.

[44] Member States may always "*adopt or maintain national rules that are more favourable for claimants to substantiate a non-contractual civil law claim for damages caused by an AI system, provided such rules are compatible with Union law*" (Article 1, para. 4 of the AI Liability Directive).

[45] EU COMMISSION, *European Declaration on Digital Rights and Principles for the Digital Decade*, Brussels, 26.1.2022 COM(2022) 28 final.

[46] See the Declaration for the Future of the Internet, signed by the European Union, the United States, and several international partners on April 28, 2022, to promote a shared vision and principles in the digital age.

losses.[47] By guaranteeing effective compensation, these rules may contribute to the protection of the right to an effective remedy and a fair trial (Article 47 of the EU Charter of Fundamental Rights) while also giving potentially liable persons an incentive to prevent damage, in order to avoid such liability.[48]

The introduction of AI tools in medicine and healthcare adds a new layer within the traditional patient–clinician dynamic and to the medical decision-making process which include not only the patients, clinicians, and healthcare facilities but now also AI developers and manufacturers.[49] The complexity of the medical and scientific field entails the risk that the costs will not be shared equally between the patient and the producer of the AI and that the burden of proof will be particularly complex.[50] Even when applying strict liability or similar fault-based liability systems, it may be difficult to prove that the product is defective, that damage has occurred and that there is a causal link between the two.[51] Possible difficulties in assigning liability related to foreseeability or product control must be

[47] EU COMMISSION'S EXPERT GROUP ON LIABILITY AND NEW TECHNOLOGIES, *Liability for Artificial Intelligence and Other Emerging Digital Technologies*, 2019. See recently: EU COMMISSION, Directorate-General for Justice and Consumers, Karner, E., Koch, B., Geistfeld, M., *Comparative law study on civil liability for artificial intelligence*, Publications Office of the European Union, 2021, https://data.europa.eu/doi/10.2838/77360.

[48] EU COMMISSION, *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)*, 2022, cit., 9 ss,

[49] EU PARLIAMENT, *Artificial intelligence in healthcare. Applications, risks, and ethical and societal impacts*, 2022, cit., 27 ss.

[50] EU COMMISSION, *Report from the Commission to the European Parliament, the Council and the European Economic and Social Committee on the Application of the Council Directive on the approximation of the laws, regulations, and administrative provisions of the Member States concerning liability for defective products* (85/374/EEC), Brussels, 7.5.2018 COM(2018) 246 final.

[51] See: EU COMMISSION, *Evaluation of Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products*, Brussels, 7.5.2018 SWD(2018) 157 final.

considered; for instance, a recent report by the UK's Office for Product Safety and Standards noted that where software is controlled by a third party – the care provider or hospital – they could be held liable rather than the AI manufacturer.[52] A widespread awareness has emerged about the need to revise the 'Product Liability Directive' (PLD) to include aspects of AI that are related to algorithm transparency and liability.[53] Under the current PLD, producers can be held liable for any damage caused by a defect in their product according to a 'strict liability' model.[54] Medical devices, as products or equipment intended for medical use, fall

[52] Government of the United Kingdom, Office for Product Safety and Standards, *Study on the impact of artificial intelligence on product safety*, study commissioned from the UK Centre for Strategy and Evaluation Services (CSES), 23 May 2022. See also: Central Digital & Data Office, Office for Artificial Intelligence, A guide to using artificial intelligence in the public sector, UK, 10 June 2019.

[53] See EU COMMISSION, *White Paper on Artificial Intelligence - A European approach to excellence and trust*, Brussels, 19.2.2020 COM(2020) 65 final. Interestingly, industry representatives believe that the Product Liability Directive ensures satisfactory liability for defective products and contributes to a reasonable balance between protecting and ensuring fair competition. See: MedTech Europe, Position Paper, *Product Liability rules and the Medical Technology Sector. MedTech Europe views on the revision of the Product Liability Directive*, 7 July 2022.

[54] Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products. According to the no-fault liability scheme introduced by the PLD, it is not the fault of the producer but a defect of the product that is decisive for triggering the liability of a producer. A product is defective "*when it does not provide the safety which a person is entitled to expect, taking all circumstances into account, including: (a) the presentation of the product; (b) the use to which it could reasonably be expected that the product would be put; (c) the time when the product was put into circulation*" (Article 6(1). The PLD also provides that "*A product shall not be considered defective for the sole reason that a better product is subsequently put into circulation*" (Article 6(2). The general presumption of liability for a defective product is subject to a list of derogations provided in Article 7. See more recently: D. ROSENBERG, A. ADEDIRAN, *Strengthening the Power of Health Care Insurers to Regulate Medical Device Risks*, in I. G. COHEN, T. MINSSEN, W. N. PRICE, C. T. ROBERTSON, C. SHACHAR (eds.), *Innovation and protection: the future of medical device regulation*, Cambridge University Press, Cambridge, 2022, 273 ss.

under the EU general product liability rules.[55] The Medical Devices Regulation (MDR) also applies to software and is supposed to cover e-health and digital products.[56] This view is confirmed by several decisions of the European Court of Justice (ECJ), which have significantly broadened the concept of a 'product defect' concerning implantable medical devices.[57] More recently, the ECJ has recognised that algorithm-based software specifically intended for medical purposes constitutes a medical device, even if not acting directly in or on the human body.[58] In this area, the European Commission has recently proposed a clearer

[55] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (MDR). In light of the overriding need to address the public health crisis associated with the COVID-19 outbreak, the entry into force of the Regulation was postponed from May 26, 2020 to May 26, 2021 by the Regulation (Eu) 2020/561.

[56] See: EU COMMISSION, Directorate-General for Health and Food Safety, LUPIÁÑEZ-VILLANUEVA, F., GUNDERSON, L., VITIELLO, S., et al., *Study on health data, digital health and artificial intelligence in healthcare*, 2022, cit.

[57] ECJ, Judgment of the Court (Fourth Chamber) of 5 March 2015, Joined Cases C-503/13 and C-504/13, *Boston Scientific Medizintechnik GmbH*. The extent to which medical devices should be considered as a special kind of consumer product, with a realignment of the responsibilities of regulation and product liability framework is explored by: S. BARTLETT FOOTE, *Product Liability and Medical Device Regulation: Proposal for Reform*, In K. B. EKELMAN, *New Medical Devices: Invention, Development, and Use*, National Academy of Engineering (US); Institute of Medicine (US), Washington (DC), National Academies Press (US), 1988, 73 – 92.

[58] ECJ, Judgment of the Court (Fourth Chamber) of 7 December 2017, Case C-329/16, *Syndicat national de l'industrie des technologies médicales (Snitem) and Philips France v Premier ministre and Ministre des Affaires sociales et de la Santé*. See also the Opinion of Advocate General Campos Sánchez-Bordona delivered on 28 June 2017 (case c-329/16) which recalls examples and features of software and algorithm classified as a medical device from the MEDical DEVices Documents (MEDDEV) provided by the European Commission as "*computer-based tools which combine medical knowledge databases and algorithms with patient specific data. They are intended to provide healthcare professionals and/or users with recommendations for diagnosis, prognosis, monitoring and treatment of individual patient*" and thus "*they are qualified as medical device*". In the US, AI systems with a medical purpose have been subjected to specific regulation by the competent authority, the Food and Drug Administration. As of today, 343 medical devices based on AI systems have been approved. See: U.S. FOOD & DRUG

mechanism for seeking compensation for damage caused by a defective AI product, as well as an adjustment of the burden of proof to reflect the complexity of technological and digital products.[59]

3. RETHINKING THE ROLE AND LIABILITY OF PUBLIC SERVICES IN THE HEALTHCARE SECTOR

The increasing use of AI for medical purposes adds an additional layer of complexity to the issue of healthcare liability. In this area, there are several differences in the way national healthcare systems implement liability rules. One important difference concerns the subject of the claim, i.e. whether it is the clinician (who made the error) or the organisation (in which they are embedded). Despite the diversity of medical malpractice liability regimes in different EU and non-EU jurisdictions, a common feature is the protection of patient safety, which is the responsibility of both healthcare providers and professionals, and which can

ADMINISTRATION, *Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD) Action Plan*, January 2021.

[59] The EU Commission opened a public consultation to address the specific challenges that circular economy and artificial intelligence pose for product liability rules. The consultation ran from 18 October 2021 to 10 January 2022. On 28 September 2022, the Commission published a proposal for a directive on liability for defective product (EU COMMISSION, *Proposal for a Directive of the European Parliament and of the Council on liability for defective products Brussels*, 28.9.2022 COM(2022). This proposal confirms that AI systems and AI-enabled goods are 'products' and therefore fall within the PLD's scope (Article 2). It also introduces rebuttable presumptions, in specific cases, to alleviate the burden of proof of the injured person (Article 9). This proposal will also need to consider the recently proposed Artificial Intelligence Act introducing additional obligations on providers and users of high-risk AI applications and proposing to apply strict liability or similar faultless responsibility schemes together with mandatory insurance as possible solution to the problem of distributed liability and AI. See: EU COMMISSION, *Proposal for a Regulation of the European Parliament and of the Council laying down harmonised rules on Artificial Intelligence (Artificial Intelligence Act) and amending certain union legislative acts*, 2021, cit.

result in significant compensation costs if these parties are negligent. Negligence may be the responsibility of a single individual. On the other hand, it may also arise under the healthcare organisation and system within which the clinician and the healthcare professionals work. Defining medical liability is typically problematic, as clinical errors are often the result of multiple flaws within the healthcare organisation.[60] Various studies and research have recalled the notion of 'system failure' by analysing compliance with care standards in public care and welfare services. A well-known study in the UK, for example, identified a number of organisational shortcomings in the National Health Service (NHS).[61] Based on observations at a paediatric care centre in Bristol, the study analysed the fragmented nature of care, the lack of a systematic way of monitoring clinical standards, staff shortages and the standardised treatment of patients despite their differing clinical needs. The combination of these factors and circumstances is estimated to have led to the deaths of between thirty and thirty-five more children than would be expected in other NHS paediatric units. This suggests a more accurate picture of the institutional dimension of negligence, where hospitals, health authorities and the wider health service may all be responsible. [62]

To address this inner complexity, Floridi's point that "*the effects of decisions or actions based on AI are often the result of countless interactions among many actors, including designers, developers, users, software and hardware*" is particularly accurate when applied to healthcare. Referring to this issue as 'distributed agency', Floridi also points out

[60] A. BERTOLINI, *Artificial Intelligence and Civil Liability Legal Affairs*, 2020, cit.

[61] G.M. TEASDALE, Council of the Society of British Neurological Surgeons, *Learning from Bristol: report of the public inquiry into children's heart surgery at Bristol Royal Infirmary 1984-1995*, in *British journal of neurosurgery*, vol. 16,3, 2002, 211-6, doi:10.1080/02688690220148815. See also: C. NEWDICK, *Who Should We Treat? Rights, Rationing, and Resources in the NHS*, Oxford University Press, 2006.

[62] C. NEWDICK, *Liability of Health Authorities and Government*, in C. NEWDICK (ed.), *Who Should We Treat? Rights, Rationing, and Resources in the NHS*, 2nd edn., Oxford, 2005.

that "*With distributed agency comes distributed responsibility*".[63] However, a solution involving the allocation of responsibilities among different actors in the value chain, although theoretically appealing, could prove to be a very problematic and complex operation in practice. In addition, due to the novelty of medical AI and the lack of legal precedents, there is currently considerable uncertainty regarding the definition of liability for AI-related medical errors that may cause harm to patients. It should also be considered, as Floridi points out, that "*too often 'distributed' turns into 'diffused': everybody's problem becomes nobody's responsibility*".[64] Accordingly, he suggests a 'faultless liability' solution. A possible solution for the 'multi-actor problem' in medical AI could reinforce the case for a model of 'enterprise liability', calling for the responsibility of the institution with the clearest involvement in healthcare delivery, rather than on individual clinicians.

The option for 'enterprise liability' or 'organisational liability' has been explored for several years and lies in the traditional doctrine of *respondeat superior*, which makes the enterprise (as the best risk avoider) liable for the torts of its workers.[65] A widely debated option involves the model of 'Enterprise Medical Liability' (EML), which refers to a system in which healthcare organisations bear responsibility for medical malpractice instead of individual health professionals.[66] Underlying this rationale is a view of modern healthcare as an entrepreneurial organisation, as opposed to the traditional image of a 'charitable' institution

[63] M. TADDEO, L. FLORIDI, *How AI can be a force for good*, in *Science*, Vol 361, Issue no. 6404/2018, 751 – 752.

[64] L. FLORIDI, *Faultless responsibility: on the nature and allocation of moral responsibility for distributed moral actions*, in *Phil. Trans. R. Soc*., 2016, A 374: 2016011.

[65] See: P. C. WEILER, *Medical Malpractice on Trial*, Harvard University Press, 1991. See also the noteworthy works of: P. TRIMARCHI, *Rischio e responsabilità oggettiva*, Giuffrè, Milano, 1961 and G. CALABRESI, *The Costs of Accidents: A Legal and Economic Analysis*, Yale University Press, New Haven and London, 1970.

[66] W. M. SAGE, *Enterprise Liability and the Emerging Managed Health Care System, in Law and Contemporary Problems*, no. 2/1997, 159 – 210.

that could often be absolved of responsibility.[67] In the United States, where clinicians are typically the most involved in medical malpractice claims, proposals to apply the EML model have emerged in the malpractice insurance debate over the past three decades.[68] The rationale behind enterprise liability is to hold networks of providers, hospitals and insurance companies accountable for injuries caused by clinician negligence, while reducing the high costs of defensive medicine.[69] Although the proposal was not eventually enforced in the US, some managed care organisations have allegedly voluntarily agreed to use this scheme, thereby creating *de facto* enterprise liability.[70]

Nevertheless, such 'market-oriented' approach must consider the specific features of this sector, given that healthcare in numerous countries, notably the UK and Italy, is a public

[67] In the US, hospitals enjoyed 'charitable immunity' from tort suits, being immune from malpractice liability, until the I940s. See: K. S. ABRAHAM, P. C. WEILER, *Enterprise Medical Liability and the Evolution of the American Health Care System, Harvard Law Review*, no. 2/1994, 381 – 436.

[68] The concept of enterprise medical liability was embodied in the U.S. Health Security Act Proposal (1993), aimed at transferring the liability in malpractice cases from individual physicians to the patient's healthcare plan (thus eliminating the need for doctors to purchase high-priced malpractice insurance) and to establish no-fault malpractice insurance. The original proposal, partly due to opposition from the American Medical Association, turned to a different premium-limiting proposal for malpractice. See: W. M. SAGE, *Enterprise Liability and the Emerging Managed Health Care System, in Law and Contemporary Problems*, cit., 159 – 210.

[69] See: K. S. ABRAHAM, P. C. WEILER, *Enterprise Medical Liability and the Evolution of the American Health Care System*, cit., 381-436; T. BAKER, *Medical Malpractice Insurance Reform: "Enterprise Insurance" and Some Alternatives*, in W. M. SAGE, R. KERSH (eds.), *Medical Malpractice and the U.S. Health Care System*, Cambridge University Press, 2006, 267 – 290; P. G. PETERS JR., *Resuscitating Hospital Enterprise Liability*, *in Mo. L. Rev.*, 2008, 369 – 397.

[70] P. FENN, A. GRAY, N. RICKMAN, D. VENCAPPA, O. RIVERO, E. LOTTI, *Enterprise Liability, Risk Pooling, and Diagnostic Care*, in *Journal of Public Administration Research and Theory*, No. 2/2010, 225 – 242.

service and not strictly comparable to a market service provider.[71] To address 'systemic failure' in the UK healthcare system, a model of 'organisational' liability has been in place in England and Wales since 1990 through the application of the 'Indemnity Arrangements for clinical negligence claims in the NHS' (NHS Indemnity), which makes NHS bodies vicariously liable for the negligent acts and omissions of their employees.[72] In particular, the NHS Indemnity applies where: (i) the negligent healthcare professional was working under a contract of employment or (ii) contracted to an NHS body to provide services to persons to whom that NHS body owed a duty of care. This requires NHS bodies to accept full financial liability for negligent harm. In addition, NHS trusts are prevented from recovering all or part of their costs from the healthcare professional concerned or from any compensation they may receive. Thus, NHS entities can carry this risk entirely or spread it through membership in the 'NHS Clinical Negligence Scheme for Trusts', an insurance scheme administered by the NHS Litigation Authority whereby individual NHS organisations pay an annual premium to mitigate against the cost of clinical negligence claims.[73]

[71] Italy's National Health Service (*Servizio Sanitario Nazionale*) is publicly financed by general tax revenues (about 74% of health spending was publicly funded in 2019) and regionally based: each region is responsible for organisation and delivery of health services through local health units and via public and accredited private hospitals. In response to the COVID-19 pandemic, the Italian government allocated additional funding of EUR 3.7 billion in 2020 and EUR 1.7 billion in 2021 to the health system, an increase of 3.3% and 1.7% over the original funding plan. Data provided by: OECD/EUROPEAN OBSERVATORY ON HEALTH SYSTEMS AND POLICIES, *Italy: Country Health Profile 2021*, State of Health in the EU, OECD Publishing, Paris, 2021. See: L. GARATTINI, M. BADINELLA MARTINI, M. ZANETTI, *The Italian NHS at regional level: same in theory, different in practice*, in *Eur J Health Econ* 23, 2022, 1 – 5.

[72] NHS Indemnity Arrangements for clinical negligence claims in the NHS, issued under cover of HSG 96/48.

[73] To address the high costs of clinical negligence claims, the NHS Litigation Authority (NHSLA) was established in 1995 as a Special Health Authority to manage an 'insurance policy' (i.e. the 'Clinical Negligence Scheme for Trusts) for NHS organisations to fund the cost of clinical negligence claims. Although the participation in this scheme is voluntary all the trusts in England are enrolled in the CNST. See also V. NAIR, E. CHANDRAHARAN,

In Italy, the courts have stressed the liability of the Italian NHS for organisational failures and deficiencies. The lack of a recovery service in a hospital where highly specialised surgery is often carried out, the inadequate distance between departments in a hospital, and the under-allocation of specialists capable of intervening in urgent cases were all factors that led to the organisation, rather than the individual doctor, being held responsible.[74] Organisation and risk management have been given a strong emphasis in the recent reform of medical liability in Italy. These new rules focus on the contractual responsibility of healthcare facilities for the safety of care.[75] Safety of care is the result of all activities aimed at preventing and managing health risks and the appropriate use of structural, technological and organisational resources.[76] These examples of possible systemic failures underline the difficulty of apportioning blame when structural complexity is high, especially when health is at stake (is it the fault of the doctors, the care units, the health administration, or all three?). Digital transformation will require more precise rules on liability for failures in the national health system. Failure to adequately prepare for this transformation could exacerbate such failures and jeopardise the quality of care.

The liability of the health care institution, linked to the organisation of the service, therefore seems to be the most appropriate legal regime to reduce or even eliminate the liability of doctors and health care workers in the case of an AI medical solution. In the event of an adverse clinical event following the use of such technology, it is the lack of adequate organisation that would result in the healthcare organisation being liable for damages. This

Clinical Negligence Scheme for Trusts (CNST), in *Obstetrics, Gynaecology & Reproductive Medicine*, no. 4/2010, 125 – 128.

[74] See, e.g.: Italian Supreme Court, decision of 18 May 2018, n. 22007 decision of 11 May 2009, n. 10743; decision of 1 July 2002, n. 9556.

[75] Art. 7, Law No. 24 of March 8, 2017.

[76] Art. 1, para. 2, Law No. 24 of March 8, 2017.

may also mean a greater regulatory focus on the organisation providing healthcare, rather than on individual providers or specific tools, and could therefore stimulate demand for liability regimes that shift towards product or organisational liability, with an erosion of individual professional liability.[77]

Moreover, with the pandemic putting additional strain on healthcare systems, AI is feared to further increase medical negligence claims in complex and challenging situations. This further strengthens the case for a reconsideration of the 'systemi' liability of healthcare organisations, in order to address systemic risks in healthcare.[78] Rethinking the role and liability of public services in the healthcare sector could pave the way for a gradual shift from the application of traditional civil liability rules to a more 'distributed' liability regime within healthcare organisations, based on precautionary measures.[79] This would create strong incentives to manage potential errors arising from the use of AI systems in healthcare, as managed care organisations arguably have the most influence over the type of technology used, how it is used and by whom.[80]

[77] E. PARASIDIS, D. B. KRAMER, *Compulsory Medical Device Registries. Legal and Regulatory Issues*, in I. G. COHEN, T. MINSSEN, W. N. PRICE, C. T. ROBERTSON, C. SHACHAR (eds.), *Innovation and protection: the future of medical device regulation*, Cambridge University Press, Cambridge, 2022, 254.

[78] R. HEYWOOD, *Systemic Negligence and NHS Hospitals: An Underutilised Argument*, in *King's Law Journal*, 2021.

[79] A recent book proposes three liability regimes to address the wide liability gaps created by AI systems: vicarious liability for autonomous software agents, enterprise liability for inseparable human-AI interactions, and collective fund liability for interconnected AI systems. See: A. BECKERS, G. TEUBNER, *Three liability regimes for artificial intelligence: Algorithmic actants, hybrids, crowds*, Hart Publishing, Oxford, 2022.

[80] B. CHAN, *Applying a Common Enterprise Theory of Liability to Clinical AI Systems*, in *American Journal of Law & Medicine*, no. 47/2021, 351 – 385.

4. TOWARDS A PRECAUTIONARY APPROACH FOR DIGITAL HEALTHCARE LIABILITY

The emergence of new risks and legal issues due to the disruptive innovation of artificial intelligence in healthcare highlights the need for regulatory change in digital healthcare. EU-wide regulation is crucial to identify the unique characteristics of AI-based products and services in healthcare, clarify the role of clinicians, consider the best interests of patients in data-driven healthcare, and establish clear responsibilities for all parties involved in the care process. The choice of liability regime will affect innovation in healthcare, and how regulators address liability issues will affect the cost and uptake of new technologies and AI in healthcare.[81]

At EU level, the new approaches to the debate on liability and AI described above are consistent with the precautionary principle, enshrined in Article 191(2) of the Treaty on the Functioning of the EU, to act to prevent damage and protect human health.[82] The precautionary approach captures the idea that regulatory intervention is legitimate for addressing new risks, e.g. biological, chemical, or environmental risks to health,[83] even if the supporting evidence is incomplete and the economic costs of regulation are high.[84] In the

[81] J. ORDISH, *Legal liability for machine learning in healthcare*, 2018, cit.

[82] M. MARTUZZI, J. A. TICKNER, *The precautionary principle: protecting public health, the environment and the future of our children*, World Health Organization, 2004.

[83] A common definition of the precautionary principle can be found in the Rio Declaration on Environment and Development of 1992: "*Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation*". See more recently: A. DONATI, *Le principe de précaution en droit de l'Union européenne*, Brussels, Bruylant, 2021.

[84] The precautionary principle is a core principle of European Union (EU) law and is enshrined in Article 191(2) of the Treaty on the Functioning of the EU to act to prevent damage and protect human health. See: EU COMMISSION,

modern 'risk society',[85] the precautionary principle is observed as more complex and dynamic than the prevention principle, which addresses already known and better-understood risks.[86] While traditionally conceived and applied in environmental law, the precautionary principle is gaining new ground and application at the national level[87] and in the context of the 'Europeanisation'[88] of health issues and the COVID-19 crisis.[89] As an example, during the pandemic outbreak, mandatory vaccination was held to fall within the application of the precautionary principle to protect public health and ensure safe conditions for care services.

Communication on the precautionary principle, Brussels, 2 February 2000. See: M. MARTUZZI, J. A. TICKNER, *The precautionary principle: protecting public health, the environment and the future of our children*, 2004, cit.

[85] U. BECK, *La société du risque. Sur la voie d'une autre modernité*, Paris, Aubier, 2001; C. R. SUNSTEIN, *Risk and reason: safety, law and the environment*, Cambridge University Press, 2002; J. B. AUBY, *Le droit administratif dans la société du risque: quelques réflexions, Rapport public 2005: jurisprudence et avis de 2004. Responsabilité et socialisation du risqué*, 2005, *La Documentation Française* 351 – 357.

[86] S. EL BABIDI, *The precautionary principle in civil liability: a contribution to the development of traditional rules*, in https://www.future-globalist.org/, 29 January 2021.

[87] The precautionary principle was introduced into Article 5 of the French Constitution by the amendment of 1 March 2005 (LOI constitutionnelle n° 2005-205 du 1er mars 2005 relative à la Charte de l'environnement). See: D. MARRANI, *Human rights and environmental protection: the pressure of the Charter for the Environment on the French Administrative Courts*, 2009, *Sustainable Development Law & Policy*, 2009, 52-57. In Italy, see the Legislative Decree No. 152/2006 (Environment Code), Article 301 ('Implementation of the Precautionary Principle').

[88] S. GEVERS, *Health law in Europe: from the present to the future*, 15(3) *European Journal of Health Law*, 2008, 261 – 272.

[89] E. FREDIANI, *The administrative precautionary approach at the time of Covid-19: the law of uncertain science and the Italian answer to emergency*, 17 *Utrecht Law Review*, 2021, 6-17; I. GOLDNER LANG, *'Laws of Fear' in the EU: the precautionary principle and public health restrictions to free movement of persons in the time of COVID-19*, European *Journal of Risk Regulation*, 2021, 1 – 24.

Claims that vaccines were unsafe, ineffective, or experimental have been dismissed by national courts.

A significant case was also brought to the attention of the Italian Council of State, which, in the key decision no. 7045 of 20 October 2021, rejected the appeal of a group of health professionals who had challenged the compulsory vaccination against COVID-19 for the medical profession.[90] The Council of State has determined that, in compliance with the precautionary principle and the principle of solidarity enshrined in Article 2 of the Italian Constitution, the legislative authority can mandate compulsory vaccination to prevent the spread of infection or disease. This decision has been followed in subsequent judgements which have held that vaccination, as an instrument of public health,[91] is neither disproportionate nor negatively affects the fundamental rights of care providers.[92] The Court held that precautionary measures such as the vaccination campaign serve the fundamental right to health, enshrined in Article 32 of the Italian Constitution, and the fundamental

[90] The appeal was brought by a group of healthcare professionals against the measures adopted by Friuli-Venezia Giulia Region implementing Decree Law no. 44 of 2021, converted into Law no. 76 of 2021, which imposes mandatory vaccination on health professions and healthcare operators who carry out their activities in public and private health, social and welfare structures, pharmacies, and professional offices, for the prevention of SARS-CoV-2 infection. After the Regional Administrative Court had rejected the claim for procedural reasons, the applicants appealed to the Council of State, arguing that mandatory vaccination violates fundamental principles, including the right to self-determination, freedom of therapeutic choice, and the right to work, and that vaccination therapy is disproportionate, unreasonable, and insufficiently safe and effective.

[91] A. SANTOS RUTSCHMAN, *Vaccines as Technology: Innovation, Barriers, and the Public Health*, Cambridge University Press, doi:10.1017/9781009129169.

[92] See more recently: Regional Administrative Court of Calabria Region, Decision no. 7 of January 13, 2022, on mandatory vaccination for nurses and Regional Administrative Court of Sicily Region, Decision no. 182 of April 7, 2022, on mandatory vaccination for pharmacists. In a similar decision, the Council of State held that mandatory vaccination can be justified in view of protecting public health and healthcare users (Italian State Council, Decision no. 583 of February 4, 2022).

principles of human dignity and solidarity, enshrined in Article 2 of the Constitution,[93] which recognises freedom but at the same time demands responsibility from the individual, thus representing *"the basis of social coexistence normatively prefigured by the Constitution"*.[94] Mandatory vaccination aims to protect not only clinicians themselves, but more importantly, patients and end-users of healthcare services who require ongoing care and support.[95] This anticipatory approach aims to avoid vaccine hesitancy, which has been identified by WHO, especially among doctors and health workers.[96] It remains to be seen whether the national courts will adopt the same approach in future cases in which the fundamental right to health is explicitly invoked as an application of the precautionary principle.

As the world continues to respond to the pandemic, other risks, such as the climate crisis and cybersecurity, must also be addressed. Lessons from the health crisis include the importance

[93] Article 32 of the Italian Constitution protects health as both an individual fundamental right and a collective interest and requires mandatory medical treatments to be provided by the Law. See more recently: G. M. RACCA, *Salute*, cit., 995 – 1015.

[94] See: Italian Constitutional Court, Decision no. 75 of February 13, 1992, which defined solidarity as the principle by which the person is called to act not by utilitarian calculation or by imposition of authority, but by free and spontaneous expression of the deep sociality that characterises the person himself.

[95] See: G. SDANGANELLI, *The Italian Council of State's ruling on mandatory COVID-19 vaccination for healthcare professionals*, in *Public Law*, Oct. 2022, 691 – 694.

[96] F. UBERTI, *The unwitting contribution of vaccine regulation to vaccine scepticism*, LSE Legal Studies Working Paper 14, 2021. In the pivotal Decision no. 5/2018, the Italian Constitutional Court declared mandatory vaccination to be a medical treatment compatible with Article 32 of the Italian Constitution, if adverse effects are in a scientifically low range, and if indemnities are provided for potential damage. The Constitutional Court also stressed the legislator's discretion in assessing the necessity of introducing incentive or mandatory measures to address health threats, based on the most advanced and reliable scientific evidence, according to the precautionary principle. Italian Constitutional Court, Decision no. 5 of January 18, 2018, on the compulsory vaccinations (re)introduced by Law Decree no. 73 of 2017. See also Judgments no. 258/1994 and no. 307/1990.

of risk-based analyses and a functioning liability system, all of which contribute to effective precautionary approaches.[97]

Abstract. *The article examines the process of digital transformation in healthcare and the implications for liability rules and compensation. Digitalisation in healthcare is leading to improved eHealth services and better patient care and outcomes, including across borders. While data and AI are undoubtedly transforming healthcare, they also raise legal and liability issues for manufacturers, care providers, healthcare professionals and insurers. The need to adapt liability rules to the digital age has been recognised. Emerging concerns about 'black box medicine' due to the opacity and complexity of AI have been addressed in the recent Artificial Intelligence Act, and two new proposed Directives also aim to cover compensation for damage caused by AI systems (AI Liability Directive) and to extend the Product Liability Directive to AI-based medical devices. Protecting patients' right to health and adequate compensation requires health authorities to adopt a 'best risk avoidance' and precautionary approach to liability rules.*

[97] B. D. GOLDSTEIN, *The precautionary principle also applies to public health actions*, in *American journal of public health*, no. 9/2001, 1358 – 1361.