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a cura di P. Ricci e L. Ricci

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Social Medicine in an Era of Epochal Transformation: Between Science and Biolaw

Pasquale Ricci, Lidia Ricci

Social Medicine is now one of the most effective tools for interpreting and addressing the global health challenges of the 21st century. The United Nations 2030 Agenda and WHO strategies highlight the need for healthcare that is not only technologically advanced, but also equitable, inclusive and socially oriented.

This editorial project brings together original, multidisciplinary contributions on socially relevant health issues, biomedical innovations, gender inequalities and disabilities, offering a systemic vision that links public health, bioethics, digital transformation and social justice.

The topics covered in this special editorial, proposed by professors who have long been involved in the field of social medicine, are inspired by the evolution of social and health policies that have emerged in recent years, both nationally and internationally.

The achievements in the areas of “care”, “social security”, “protection and defence against disease”, “social and health security and health promotion”, although evolving towards “*human enhancement*”, leave open many concerns regarding global assistance for the protection of fundamental human rights.

Therefore, scientific progress and unconditional trust in technological advancement require immediate and urgent moral reflection to establish the boundaries of legal research and the limits of the application of its results.

The selection of contributions by distinguished scholars in the *Special Issue*, on topics of doctrinal value and great topicality, sets the focus of the discussion on emerging issues of a new (and one might say futuristic) nature for Social Medicine at a global level, with the aim of emphasising issues that require profound consideration in order to translate the results obtained by science and technology into the most appropriate practical applications.

The selected articles propose integrated models and bio-legal reflections that combine prevention, treatment and the protection of rights. Although the *Special Issue* is presented in the form of “*original articles*”, it is systematically structured as a sequence of doctrinal reflections on a sustainable future for global health protection in a planetary context marked by a serious crisis.

Health, technological innovations, climate and social justice are the topics addressed. Adherence to the principle of shared responsibility for the protection of the fundamental right to health has led Social Medicine to follow paths aligned with the times.

Its scientific uniqueness and doctrinal profile place it today more than ever in a leading position in the protection of “health” in its most current sense, promoting all those rights attached to the “person” which, in the varied scenario of contemporary globalised society where the most diverse ideologies, cultures and religions intersect, makes the recognition of the dignity of the person is the real reason for reaffirming individual freedom.

The genetic makeup of humans, selected over millions of years of evolution, has adapted us to various environmental changes. Despite this, the human matrix has remained virtually unchanged, while cultural, scientific and technological evolution has had an enormous impact on human life.

Health, although unanimously recognised as a fundamental human right, is still not sufficiently pursued, protected and guaranteed for all people in the world. Known issues, together with emerging ones connected to health to a greater or lesser extent, must now be assessed in a dimension that transcends national borders.

The development of technology, means of communication and transport, and the growing phenomenon of migration have made “global” social issues definitively interdependent.

The possibility of making a useful contribution in this regard, starting from different doctrinal perspectives, has inspired us to carry out this project.

This work brings together contributions from scholars from different disciplines, who analyse in an integrated manner the scientific, cultural, legal, environmental and social determinants of global human health as something that goes beyond disease. It is divided into four sections, structured in an orderly manner in relation to the topics discussed. It is introduced by an editorial (by invitation) that outlines the goals pursued by the discipline (social medicine) and focuses on the objectives for the future with forward-looking considerations. The first section addresses the issues of “health as a human right and global justice” from an ethical, bioethical, bio-legal and clinical perspective. The second section focuses on aspects of social vulnerability: disability, social hardship and growing inequalities, with reflections on the pursuit of inclusiveness. The third section highlights the numerous issues related to technological innovations and the applicability of scientific results and manipulations, the protection of the ecosystem, and aspects of translational and predictive medicine. The final section analyses, in summary form, the protection of rights in relation to the applicability of biomedical research and advances in artificial intelligence and robotics.

The articles are presented by the authors individually or in collaboration. The latter are the result of the integrated contribution to the research undertaken by several scholars, scientists, jurists and ethicists.

There is no shortage of essays that clearly illustrate the historical evolution of awareness of human values which, as such, form the basis of the principles of modern Global Social Medicine.

Social Medicine for Global Health Equity

Serafino Ricci

For some time now, health has been recognized not only as an individual asset but also as a social one, and its protection as both a right and a duty of the individual.

Rapid scientific and technological progress-particularly in the last thirty years-has generated unprecedented scenarios in the field of healthcare. This continuous evolution has raised complex organizational, ethical, moral, deontological, and medico-legal issues, broadening the horizons of knowledge within a multidisciplinary context.[1]

Social Medicine explores, analyses, and studies the features and dynamics of social phenomena in their constant evolution, particularly those with medical relevance or repercussions on human health. Its work in the service of social life is vast and necessarily draws on profound scientific understanding of biological, pathophysiological, physical, and chemical processes inherent to medicine. At the same time, it must remain an attentive observer of those events that can be traced back to sociological dynamics and the social sciences.

In practice, Social Medicine seeks to adapt medical-scientific advances to the evolving needs of society, moving away from the traditional individualistic approach of clinical medicine: the individual exists only as a person integrated within the community-family, workplace, association, and so on and as such is both a holder of rights and a bearer of duties. This concept is enshrined in the social pact underlying our society, namely the Constitutional Charter, which in Article 32 states: *"*The Republic safeguards health as a fundamental right of the individual and as an interest of the community*"*.[2]

No other right except the right to health protection is defined as *fundamental* by our Constitution.[3] Through Article 32, it clearly expresses four foundational principles: a. universality of beneficiaries; b. comprehensiveness of services; c. equality of treatment; d. respect for human dignity.

Health, as an inviolable human right of paramount importance among all rights guaranteed by the legal system, has what may be called a *transversal nature*. This means that all other rights must be regulated and realized in ways that do not harm or conflict with the needs that arise from it. It follows that, in its broadest sense, the right to health cannot be fulfilled solely through the healthcare system or through medical acts. Every social, environmental, or legal phenomenon that may affect human health must be governed in such a way that health is safeguarded and promoted.

For example, since 1987 the Italian Constitutional Court[4] has interpreted the right to health as encompassing the right to a healthy environment an understanding that today, more

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[1] S. Ricci, *Social Medicine between science and biolaw,* in *PanMinerva Medica*, 2014, 56, 1-12.

[2] S. Ricci, *Atto Medico. Evoluzione e Valore sociale*, Rome, 2000, 1-169.

[3] Right to health is the only right explicitly defined as "fundamental" by the Constitution. The judiciary, in order to emphasize its importance, has also characterized it as a "primary" ("primario") right. Cfr. Italian Constitutional Court, 26 July 1979, n.° 88, in *Foro It.*, I, 1979, 2542 and 18 December 1987, n.° 559, in *Riv It Med Leg*, 1990, 227.

[4] In Decision no. 617/1987, with regard to provisions aimed at protecting the environment and at preventing situations of environmental harm, the Court acknowledged the special nature of the interest at stake, defining it as «a primary good of absolute value, constitutionally guaranteed to the community» («un bene primario e di un valore assoluto costituzionalmente garantito alla collettività»).

than ever, is perceived as requiring greater protection.[5] It is clear that the right to health takes precedence over other rights because it pertains to the right to life, the quality of life, and public well-being.[6]

The possibility of inducing changes in the natural processes of life and even of death calls for profound reflection on the limits of lawful human intervention. Such limits cannot be defined solely in biological or medical terms. The *legal phenomenon* must also be considered, since it represents the instrument through which the needs of collective life are addressed and regulated.[7],

It was not so long ago that Jules Guérin (1848) urged physicians to assume "the role of intermediaries" between divided interests and conflicting social elements between medicine and legislation.[8] Over time, Social Medicine has evolved along multiple paths, yet always in harmony with its foundational aims and attuned to the social realities of each era.[9]

There are areas within the biomedical sciences that are especially delicate and of pressing relevance, which cannot be left to individual initiative or to market forces. Consider, for instance, the control or modification of the beginning and end of life through interventions in natural generative processes; the potential of genetic engineering to alter the chromosomal makeup and thus the biological identity of present and future individuals; the protection of privacy and human dignity in the face of automated data processing; and, finally, the globalizing impact of new technologies. What, then, are the limits of lawful human intervention in life?[10]

In daily practice, healthcare professionals frequently face situations that inevitably involve ethical dilemmas. Even when the law prescribes specific conduct, the fact remains that legal

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[5] B. Pezzini, *One Health e Corti supreme: le coordinate di un paradigma,* in *Corti supreme e salute*, 1, 2025, 191-216.

[6] S. Ricci, A. Miglino, *Medicina e Società. Dalla tutela dell'integrità fisica al diritto alla salute,* Rome, 2005, 1-97; M.V. Rosati, A. Sancini, F. Tomei, C. Sacco, V. Traversini, A. De Vita, D.P. De Cesare, G. Giammichele, F. De Marco, F. Pagliara, F. Massoni, L. Ricci, G. Tomei, S. Ricci, *Correlation between benzene and testosterone in workers exposed to urban pollution,* in *Clinica terapeutica*, 168, 6, 2017, e380-87; T. Archer, S. Ricci, F. Massoni, L. Ricci, M. Rapp-Ricciardi, *Cognitive benefits of exercise intervention,* in *Clinica Terapeutica*, 167, 6, 2016, 180-85; F. Tomei, M.V. Rosati, C. Di Pastena, G.F. Tomei, G. Giammichele, F. De Marco, S. Corsale, A. Suppi, P. Ricci, C. Sacco, S. Ricci, C. Monti, *Urinary Nichel and Progesterone in Workers Exposed to Urban Pollutants,* in *Journal of occupational and environmental medicine*, 63, 10, 2021, e660-e666; M.V. Rosati, C. Sacco, A. Mastrantonio, *et al.*, *Prevalence of chronic venous pathology in healthcare workers and the role of upright standing,* in *International Angiology*, 38, 3, 2019, 201-10.

[7] M. Gulino, M. Martelli, P. Ricci, S. Marinelli, G. Montanari Vergallo, *How can euthanasia and assisted suicide regulation guarantee patient health and autonomy? Lesson from nine European countries,* in *Ethics, Medicine and Public Health*, 33, 2025, article 101131; F.M. Damato, P. Ricci, R. Rinaldi, *Informed consent and compulsory treatment on individuals with severe eating disorders: a bio-ethical and juridical problem*, in *Clinica Terapeutica*, 174, 4, 2023, 365-69.

[8] W.E. Nicoletti, *Argomenti di Medicina Sociale,* Rome, 1991, 1-380.

[9] A. Beretta Anguissola, *Medicina Individuale e Medicina Sociale,* Rome, 2, 1982, editoriale; Id, *Le ragioni storiche della Medicina Sociale, principi ed obiettivi. La Medicina Sociale e le Politiche sociali e sanitarie in Italia,* Rome, 1995, 15-20.

[10] E. Sgreccia, *La bioetica, nuova disciplina: limiti e prospettive. La medicina sociale e le politiche sociali e sanitarie in Italia*, Rome, 1995, 33-39; G. Montanari Vergallo, M. Gulino, P. Ricci, A. Pastorini, G. Bersani, R. Rinaldi, *Psychiatric advance directives (Ulysses Contract): the need for a specific law and a criteria proposal for its introduction,* in *Rivista di Psichiatria*, 58, 5, 2023, 241-48; L. Ricci, B. Di Nicolò, P. Ricci, F. Massoni, S. Ricci, *The exercise of rights beyond therapy: on Human Enhancement,* in *BioLaw Journal*, 1, 2019, 497-512.

norms should never override ethical norms. Hence the need for an educational project that profoundly shapes professional identity one in which ethics, legal objectives, and deontological principles are harmonized through the practice of moral virtue.

Ethics and morality, when compared with the administrative, civil, and criminal frameworks of the State, give rise to the codes of ethics, which establish rules of conduct drawn up by professionals themselves and to which each practitioner must adhere. Yet when deontological conduct alone fails to adequately protect certain fundamental human values, it becomes the legislator's duty to intervene. The State must act to safeguard everyone from judicial distortions that could undermine the legal institutions on which civil coexistence is founded.[11]

Professional categories and especially those in healthcare require clear and equitable laws that explicitly define what is permissible and what is not. Nevertheless, legislation can never encompass the entire moral dimension of human behavior. Ethics must therefore complement the legal system. Fulfilling one's legally defined duties does not exhaust professional responsibility: acts may be performed that, though not punishable by law, still merit an ethically grounded judgment of illegitimacy.

For these reasons both scientific and practical Social Medicine has risen to the status of a full medical discipline, with a distinct scientific framework and clear practical aims.[12]

Going through the centuries, we can already find in the works of Hippocrates clear evidence of the social dimension of medicine, just as the *Regimen Sanitatis Salernitanum* unmistakably promotes the defense of public health.

The stages of medicine's social evolution over time are numerous and irrefutable. The examples could extend across many centuries, with a long list of works that confirm this distinctive feature.

The need to provide free care for the poor and to combat infectious diseases such as cholera, plague, and smallpox that devastated entire populations, generated the first efforts to establish organized healthcare systems. Within this framework shaped by the State's growing interest in the health of its people the seed of Social Medicine was sown in seventeenth-century Italy through the works of two great physicians: *Quaestiones medico-legales* by Paolo Zacchia and *De morbis artificum diatriba* by Bernardino Ramazzini.

Zacchia's work marked a decisive step forward, affirming the community dimension of medicine. Thanks to this eminent scholar, the social character of medicine found its first concrete expression one that was then deepened and systematized by Ramazzini. Indeed, Ramazzini can be considered not only the founder of Occupational Medicine, but also a pioneer of the medico-social interpretation of public health problems. His thought was pervaded by a remarkable social sensibility, exceptional for his time, and extended to the entire community without distinction of social class.[13]

The eighteenth century was dominated by the figure and work of Peter Frank, a great physician–politician. In the following century, the social mission of medicine was reaffirmed by other enlightened physicians such as Giacomo Barzellotti, Francesco Puccinotti, Guido Baccelli, and Angelo Celli.[14]

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[11] A. MIGLINO, L. RICCI, S. RICCI, *The right to hearth as a liberty of self-determination,* in *Panminerva medica*, 56, 2014, 13-24.

[12] F. ANTONIOTTI, *Corso di Cultura in Medicina Sociale,* Rome, 1971, 1-481.

[13] *Ibidem*.

[14] W.E. NICOLETTI, *op. cit.*

The twentieth century, however, proved especially fertile ground for the development of discipline. Three main factors contributed to its growth: the rise of industrialization, scientific and technological advances in medicine, and the emergence of social insurance systems.

Although the inherently social nature of medicine is beyond dispute, the profound economic, social, and structural transformations of the modern era and especially the rise of welfare systems and organized public assistance made it clear that medicine required its own specific instrument. This instrument, on both the scientific and educational levels, was to serve as a link between medicine and society, addressing the new and evolving relationship between the doctor and the citizen.

From a historical perspective, therefore, Social Medicine represents the *modus agendi* of medicine its way of acting as both science and practice in response to the deep social transformations of the past two centuries and to the needs arising from the protection of public health in a community undergoing continuous social and cultural evolution.[15]

As an academic discipline, Social Medicine was first introduced in 1963 at the University of Sassari (under the chairmanship of a professor from the Roman School) and was subsequently established in many other Italian universities, including Rome from 1968 to the present (professors C. Gerin, F. Antoniotti, W.E. Nicoletti, S. Ricci). For over forty years, it has also been taught in the Faculty of Law. It has always held an autonomous position within the University Competition Sector of *Legal and Occupational Medicine*.

Its unique scientific and doctrinal identity now places it at the forefront of efforts to safeguard *good health* understood in its most modern and comprehensive sense and as a promoter of all the rights inherently connected to the human person. Over time, these rights have acquired peremptory and universally recognized status.

Given its doctrinal, historical, cultural, and methodological foundations, Social Medicine, as a discipline within the broader area of Public Health, rightfully stands as Global Social Medicine, a fully autonomous field equipped with its own specific research methods and theoretical framework.

The arguments elaborated underline how it must now be admitted that the "right to health" must interface with the awareness that there is also a "duty to health", which is revealed as an individual responsibility towards society.[16] In truth, the relationship between the protection of citizens' health and the economic interests of organized communities have generated social needs and discrepancies in response such that the doctor before any other professional must face on a daily basis. This can only be calmly addressed if, on the one hand, the professional has a holistic view of the problem, but on the other hand, the user has sufficient education to understand its meaning[17]. Adherence to the principle of collective responsibility to protect social and health safety is the only way in which the objective of promoting health in the sense of a positive meaning of the concept can be achieved.[18]

The experience of recent years has shown the existence of a worrying trend towards growing

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[15] F. Antoniotti, *op. cit.*

[16] G. Lombardi, *Contributo allo studio dei doveri costituzionali,* Milan, 1967; F. Polacchini, *Doveri costituzionali e principio di solidarietà,* Bologna, 2016, 1-353.

[17] Art. 4.2. of the Principles of European Medical Ethics, approved in Paris on 6 January 1987 by the European Conference of Medical Associations and Bodies with Similar Functions.

[18] S. Ricci, A. Miglino, *Persona e Diritti*, Roma, 2009, 1-57.

international instability with an incipient request for help coming from many parts of the planet, which risks becoming a serious problem for the near future. The problem is to identify the most effective way to provide the life of international relations with adequate centers (references) of universally recognized authority and power, which can peacefully manage this request for aid in the health field. The principle of humanitarian intervention, which is increasingly pressing, in our opinion must be institutionalized not according to the logic of emergencies, but according to that of development, for a correct and useful humanitarian policy.

Clearly, the rapid changes in society of our time are also reflected in the cultural and institutional environment within which health services are provided and make us feel the need to operate new theoretical and systematic options, which can coherently organize the continuous acquisition of knowledge. Paradoxically, while the progress of science and technology offers new tools for the protection of health, the resources necessary for everyone to benefit from the best medical activity are becoming scarce.[19] Today's society marginalizes many groups of people, the so-called weaker groups, who are often marginalized because they have health problems that involve the entire family unit (think, for example, of autism).[20] It is therefore natural to ask whether the right to health can be interpreted in such a way as to derive indisputable criteria for the acquisition and rational management of financial resources intended for the health sector. This is clearly not possible. Nevertheless, in practice, the content of health legislation, even when it is endowed with an intrinsic logical rigor, finds its legitimacy in the principle of the balancing of interests, on the basis of which a constitutionally protected right can be limited to protect a right of equal degree.[21]

Today, social medicine must, on the one hand, be able to bring out the salient aspects of this dynamic phenomenon and, on the other, make the appropriate evaluations so that objectives are pursued that protect the personality and rights of the citizen to the highest degree. This gives rise to the need to highlight two essential elements in the operational system: reaffirming a global vision of the behavioral frameworks of medical activity; seeking to recompose the mental process of synthesis in the face of circumstances that simultaneously require technical and scientific skills and therapeutic performance tempered by the legitimacy and humanity of the act performed. The defect of our times to break everything down analytically, sometimes to excess, often translates into cultural by-products of confusion and intellectual

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[19] N. Diridin, E. Caruso, C. Rivoiro, *Universalism and budgetary constraints in health protection: a political issue, even before a financial one,* in *Social Policies*, 3, 2014, 387 ff.

[20] R. Ferrara, L. Iovino, M. Di Renzo, P. Ricci, *Babies under 1 year with atypical development: Perspectives for preventive individuation and treatment,* in *Frontiers in Psychology*, 13, 2022. 1016886; R. Ferrara, L. Ricci, P. Ricci, L. Iovino, S. Ricci, F.M. Damato, G. Cicinelli, R. Keller, *How autistic women are aware of their body and take care of their health? Focus on menstruation cycles and gynaecological care*, in *Clinica Terapeutica*, 175, 3, 2024, 168-175; G.M. Troili, R. Businaro, F. Massoni, L. Ricci, L. Petrone, P. Ricci, S. Ricci, *Investigation on a group of autistic children: Risk factors and medical social considerations*, in *Clinica terapeutica*, 164, 4, 2013, e273-e278; R. Ferrara, F.M. Damato, L. Ricci, L. Iovino, S. Ricci, P. Ricci, M.C. Laznik, G. Cicinelli, *Parents-children coregulation as therapeutic variable and target in autism spectrum disorders. From observation of drive to need of cooperative parent-mediated therapy.*, in *Clinica Terapeutica*, 174, 6, 2023, 537-44.

[21] H. Rebscher, *Social medicine and healthcare economics. The framework for future forms of healthcare,* in *Bundesgesundheitsblatt Gesundheitsforschung Gesundheitsschutz*, 51, 5, 2008, 552-7.

uncertainties, which in our environment unfortunately turn into the suffering of interpersonal relationships.

The risks of such a delicate profession, the achievements attributable to current scientific achievements (think of genomics, predictive medicine, translational approaches, etc.) and technological capabilities (Artificial Intelligence, Robotics, etc.) and the responsibilities arising from them and connected to them, highlight today more than ever the need for a relational alliance between doctor and patient supported by institutions.[22] An underestimation of the past was perhaps that (particularly in our country) of setting up university education by favoring a model of care with purely specialist-hospital characteristics.[23] It is therefore essential that a powerful reorganization of territorial social and health care is carried out with the aim of enhancing resources in respect of the quality of life and making the figure of the general practitioner central

Global Social Medicine can now exert catalytic action to raise awareness of the healthcare needs of the community and also stimulate a new approach to university teaching based on medicine that is practiced outside hospitals but coordinated with them. Let us consider the growing interest in unconventional medicine (traditional Chinese medicine: acupuncture, herbal medicine, etc.).[24]

To achieve concrete results, responsibility, self-sacrifice and a real willingness to measure oneself in an equal role with other countries (including intercontinental ones) are needed, COVID has taught us this.[25]

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[22] S. Ricci, F. Massoni, *Privacy e professione sanitaria*, Roma, 2014, 0-47; G. Montanari Vergallo, L.L. Campanozzi, M. Gulino, L. Bassis, P. Ricci, S. Zaami, S. Marinelli, V. Tambone, P. Frati, *How Could Artificial Intelligence Change the Doctor–Patient Relationship? A Medical Ethics Perspective,* in *Healthcare*, 13, 18, 2025, 2340.

[23] C. Calvaruso, *Quali bisogni informativi e formativi in medicina sociale*. *La Medicina sociale e le politiche sociali e sanitarie in Italia,* Roma, 1995, 181-186; E. Garaci, *Il ruolo dell'università nei processi di formazione di medicina sociale. La medicina sociale e le politiche sociali e sanitarie in Italia,* Roma, 1995, 187-189; S. Ricci, W.E. Nicoletti, *Docenza universitaria e servizio sanitario nazionale nell'evoluzione dei sistemi: rapporti, compatibilità ed incompatibilità,* in *Difesa Sociale*, 4, 1996, 1-8.

[24] S. Ricci, A.Miglino, E.Onofri, *Aspetti medico legali dell'agopuntura,* in *Annali di Medicina Sociale*, Roma, 2000, 103-12.

[25] P. Ricci, M. Pallocci, M. Treglia, S. Ricci, R. Ferrara, C. Zanovello, Pl. Passalacqua, F.M. Damato, *The Effect of Physical Exercise during COVID-19 Lockdown.* Healthcare, 11, 11, 2023, article 1618 open access; G. Montanari Vergallo, P. Ricci, M. Gulino, *Palliative care and covid-19 pandemic between hospital-centric based approach and decentralization of health services: a valuable opportunity to turn the corner?*, in *EuroMediterranean Biomedical Journal*, 18, 7, 2023, 34-39.

Medicina sociale e bioetica

Laura Palazzani*[*]

SOCIAL MEDICINE AND BIOETHICS
ABSTRACT: This article analyzes the role of bioethics within the context of social medicine and public health, with a particular focus on the social determinants of health, as framed within the bio-psycho-social model of health and illness. Special attention is given to situational vulnerability and inequities in access to healthcare. The analysis also considers behavioral and environmental determinants, as they relate to social determinants, and highlights the necessary transformations in public policy, especially regarding the need for health literacy and education.

KEYWORDS: Bioethics; social determinants of health; situational vulnerability; health inequities; health literacy and education

ABSTRACT: Il contributo analizza il ruolo della bioetica nel contesto della medicina sociale e della salute pubblica con particolare attenzione ai determinanti sociali della salute nell'ambito della concezione bio-psico-sociale della salute e malattia, alla vulnerabilità situazionale e alle iniquità di accesso alla salute. Sono analizzati anche i determinanti comportamentali e ambientali, connessi ai determinanti sociali, e le trasformazioni necessarie delle politiche pubbliche con particolare attenzione alle esigenze di alfabetizzazione sanitaria ed educazione.

PAROLE CHIAVE: Bioetica; determinanti sociali della salute; vulnerabilità situazionale; iniquità di accesso alla salute; alfabetizzazione sanitaria e educazione

1. Medicina sociale e salute pubblica: il contributo della bioetica

La medicina sociale è una branca della medicina che studia il rapporto tra salute, malattia e società in generale, partendo dalla considerazione che la salute è il benessere fisico-psichico e so-

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ciale e che dunque la malattia è la patologia fisica e mentale, strettamente connessa al disagio sociale. Con l'ampliamento del concetto di salute e malattia mediante l'introduzione del paradigma bio-psico-sociale (dell'Organizzazione Mondiale della Sanità, 1948)[11] sono divenuti rilevanti i fattori sociali nella medicina, come le condizioni di vita, il lavoro, l'istruzione, la povertà e le disuguaglianze. La medicina sociale cerca di capire l'impatto dei fattori sociali sulla salute e come la società influisce sulla salute delle persone e promuove interventi che migliorino il benessere collettivo, non solo attraverso cure mediche (terapie), ma anche attraverso politiche sociali, che mirano a cambiare le condizioni sociali per migliorare la salute. La medicina sociale amplia il concetto di salute, riconoscendo che non basta curare il singolo individuo, ma bisogna anche trasformare le condizioni sociali che causano malattie o impediscono il benessere[2].

La medicina sociale è una dimensione della medicina strettamente legata a igiene, medicina preventiva, medicina legale, medicina del lavoro, medicina interna, epidemiologia, ma anche alle scienze sociali, quali la psicologia sociale, la sociologia, l'antropologia. La medicina sociale ha pertanto basi interdisciplinari per l'identificazione dei bisogni sanitari sociali o socio-sanitari, l'identificazione delle malattie sociali al fine di identificare i percorsi di prevenzione, protezione, educazione. In questo ambito si potrebbe identificare la medicina sociale con la salute pubblica, tema divenuto sempre più centrale anche a seguito della pandemia, in cui è emerso in modo molto evidente il legame tra comportamenti sociali e salute individuale. Al punto che diventa oggi quasi difficile parlare di medicina individuale senza anche parlare di medicina sociale o medicina di comunità, essendo l'individuo un essere relazionale.

La salute pubblica pone particolare attenzione all'analisi delle cause sociali della malattia (es. povertà, esclusione, discriminazione), promuove la prevenzione (e non solo curare le conseguenze), al fine di ridurre le diseguaglianze sanitarie e assicurare la giustizia sanitaria. Ne sono esempi le politiche sociali che mirano a migliorare le condizioni igienico-sanitarie in quartieri svantaggiati, campagne contro il fumo, l'alcool e la tossicodipendenza nelle scuole o nei luoghi pubblici, politiche per facilitare l'accesso ai servizi sanitari per i migranti in una società multietnica o per chi ha redditi bassi (nel contesto del Sistema Sanitario Nazionale), analisi del legame tra disoccupazione e depressione.

Il rapporto tra medicina sociale e bioetica è profondo e complementare[3]. Entrambe si occupano della salute e del benessere umano, ma da prospettive diverse che si arricchiscono a vicenda. I temi che si intersecano sono: l'analisi delle nuove vulnerabilità "situazionali" dovute a condizioni socio-economiche e culturali[4]; la riflessione sulla responsabilità collettiva quale dovere delle politiche pubbliche di creare condizioni per la salute degli individui nel rispetto della dignità umana e del bene comune[5]; l'analisi della giustizia e della equità come indispensabile valore nella distribuzione delle risorse scarse per la garanzia dell'accesso alla salute per tutti; la promozione dell'informazione, della comunicazione, dell'educazione per la comprensione dei comportamenti che facilitano buone condizioni di salute individuali e collettive; l'elaborazione di politiche sociali, nel contesto delle politiche sanitarie, per prevenire, mitigare e supera-

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[1] WORLD HEALTH ORGANIZATION, *Constitution of the World Health Organization*, 7 April 1948.

[2] G. LA TORRE, *Medicina sociale*, in E. SGRECCIA, A. TARANTINO (a cura di), *Enciclopedia di Bioetica e Scienza Giuridica*, Napoli, 2015, 439-445.

[3] R.J. DOUGHERTY, J. J. FINS, *Toward a Social Bioethics Through Interpretivism: A Framework for Healthcare Ethics*, in *Cambridge Quarterly of Healthcare Ethics*, 33, 2024, 6-16.

[4] R. PEGORARO, L. SANDONÀ (a cura di), *Vulnerabilità, una sfida per la bioetica*, Milano, 2024.

[5] M. SERIO, *Lineamenti di bioetica e public health. La salute come bene comune,* Soveria Mannelli, 2024.

re condizioni sociali che compromettono la salute (es. la definizione di politiche per la produzione, il commercio, la pubblicizzazione, la distribuzione o la tassazione di prodotti nocivi per la salute).

2. I determinanti sociali della salute e nuove vulnerabilità

Nel contesto del concetto bio-psico-sociale di salute/malattia emerge sempre più la consapevolezza del rilievo delle condizioni esistenziali, da un lato, e socio-culturali, dall'altro lato, nell'identificazione dei bisogni di salute. Emerge in modo sempre più evidente che la salute dipende dalle condizioni fisiche e psichiche individuali (età, sesso) e dalle condizioni socio-culturali (luogo, periodo storico, condizioni economiche e politiche, contesto sociale e culturale).

Circostanze interne ed esterne possono influenzare la manifestazione dei bisogni e la condizione di salute: ciò si evidenzia nella trasformazione dei concetti di bisogno e di vulnerabilità, declinati in relazione all'età (persona di minore età, adulta, anziana) e al sesso (maschi, femmine), oltre che in relazione all'esposizione ai fattori esterni, quali possono essere circostanze storiche, sociali, culturali, economiche, politiche. Persone che vivono in luoghi, tempi, contesti diversi – a parità di condizioni fisiche – possono avere bisogni diversi e livelli di salute differenti. Si parla di "vulnerabilità esistenziale" e "vulnerabilità situazionale", in relazione ai diversi fattori interni e/o esterni che possono intrecciarsi[6].

Sul piano esistenziale, la ricerca evidenzia in modo sempre più chiaro come i bisogni di salute vanno declinati in modo specifico in base alla differenza di età e alle differenze sessuali. Persone di minore età, adulte, anziane, hanno condizioni fisiologiche diverse, variabili da individuo a individuo, ma emerge in modo permanente che la condizione di assimilazione di farmaci (farmacocinetica e farmacodinamica) è correlata alla fase di vita vissuta: le persone di minore età non sono "piccoli adulti" e gli anziani non sono "adulti in età avanzata", ma minori e anziani necessitano di una sperimentazioni di farmaci "ad hoc", non solo la riduzione o l'aumento di dosaggi rispetto ai farmaci sperimentati su adulti, ma calcolato in base allo stadio di vita raggiunto[7]. Analogo argomento riguarda la differenza sessuale: la cosiddetta "medicina di genere" indica l'esigenza di una declinazione della salute e della cura specifica in base alla sessualità maschile e femminile, in quanto il modo di reagire ai farmaci e assimilare i farmaci è differente, in particolare per le donne a causa delle variazioni delle condizioni fisiologiche[8].

Sul piano situazionale, socio-economico, i livelli di reddito e la distribuzione della ricchezza nella popolazione influenzano i bisogni e l'esposizione al rischio per la salute. La scarsità di risorse economiche può condizionare l'accesso alle cure e all'assistenza, e al tempo stesso può influire sul comportamento sociale del soggetto. Con precarie condizioni economiche, individui possono essere costretti a vivere in alloggi inadeguati, con condizioni igieniche inappropriate o situazioni di affollamento: tutti fattori che au-

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[6] Cfr. F. Macioce, *The Politics of Vulnerable Groups. Implications for Philosophy, Law, and Political Theory*, Cham, 2022; O. Giolo, B. Pastore (a cura di), *Vulnerabilità. Analisi multidisciplinare di un* concetto, Roma, 2015; G. Zanetti, *Filosofia della vulnerabilità. Percezione, discriminazione, diritto*, Roma, 2019; B. Pastore, *Semantica della vulnerabilità, soggetto, cultura giuridica*, Torino, 2021.

[7] Comitato Nazionale per la Bioetica, *Bioetica con l'infanzia*, 22 gennaio 1994; Comitato Nazionale per la Bioetica, *Bioetica e diritti degli anziani*, 20 gennaio 2006.

[8] S. Garattini, R. Banzi, *La medicina che penalizza le donne*, Torino, 2022.

mentano il rischio di malattie[9]. Condizioni socio-economiche sfavorevoli si intrecciano con altri fattori nel determinare condizioni di vulnerabilità per particolari gruppi sociali, come ad esempio le minoranze etniche[10]. Fattori di vulnerabilità sono legati anche alla "alfabetizzazione sanitaria" (la c.d. *health literacy*). Il grado di competenza o di consapevolezza con il quale le persone ottengono, recepiscono e valutano le informazioni, al fine di prendere decisioni rispetto alla propria salute, è legato sia al livello generale di educazione ricevuta sia alla capacità di utilizzare le tecnologie dell'informazione. L'educazione è generalmente scarsa nelle persone con condizioni socio-economiche inferiori e spesso è molto deficitaria in gruppi quali le minoranze etniche, le persone migranti in condizioni di irregolarità rispetto alla legislazione vigente, in ragione di barriere linguistiche, scarsa conoscenza delle procedure e dei meccanismi burocratici, della mancanza di reti relazionali di supporto. In questo contesto va ricordata la diversa declinazione della salute e dei bisogni nell'ambito delle diverse culture, tra "multiculturalismo" che le ritiene relativisticamente equivalenti[11] e "interculturalismo" che declina la salute in base alla specifica cultura, ritenendo che alcune richieste o bisogni emergenti da una cultura possano essere accolti nei limiti del rispetto dell'integrità del corpo, intesa in senso psico-fisico, inteso come diritto fondamentale[12].

In questo contesto, le tradizionali e le nuove condizioni di vulnerabilità esigono strumenti di mitigazione. È necessario tenere in considerazione quei bisogni specifici che i gruppi vulnerabili manifestano in un dato contesto. Questa dimensione sottolinea la necessità di ripensare il sistema di welfare nelle politiche pubbliche, declinato rispetto alla specificità delle esigenze di salute, esistenziali e situazionali[13].

3. Le diseguaglianze e l'accesso alla salute

Il tema delle vulnerabilità situazionali in bioetica è strettamente connesso al tema della distribuzione delle risorse sanitarie e delle garanzie di accesso alla salute. La medicina sociale evidenzia la rilevanza dei fattori sociali sulla salute degli individui e abbraccia, in contrapposizione alla visione libertaria individualistica (che punta l'attenzione sull'autodeterminazione individuale) e alla visione utilitarista (che su basa sul calcolo costi/benefici e sulla qualità di vita), una visione bioetica che riconosce la centralità dell'uguaglianza tra gli esseri umani nell'accesso alle cure. L'intervento dello Stato (o Stato del benessere) è considerato rilevante per evitare gli inconvenienti del libero mercato. Secondo la visione dell'egualitarismo sociale, la società si deve fare carico delle disuguaglianze derivanti dalla "lotteria naturale" e dalla "lotteria sociale": le disuguaglianze naturali e sociali vanno corrette e riparate in quanto ritenute ingiuste, nel continuo sforzo di compensazione delle differenze. Cura ed assistenza sanitaria sono considerati bisogni fondamentali che vanno garantiti al cittadino, "massimizzando il minimo", ossia

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[9] M. Gensabella, *Vulnerabilità e cura: bioetica ed esperienza del limite*, Soveria Mannelli (CZ), 2008; T. Ten Have, *Respect for Human Vulnerability: the Emergence of a New Principle in Bioethics*, in *Bioethical Inquiry*, 12, 2015, 400.

[10] G.E. Henderson, *What Bioethicists Need to Know About the Social Determinants of Health - and Why*, in *Perspectives in Biology and Medicine*, 65, 2022, 664-671.

[11] Aa.Vv., *Medicina e multiculturalismo: dilemmi epistemologici ed etici nelle politiche sanitarie*, Bologna, 2000.

[12] I. Quaranta, M. Ricca, *Malati fuori luogo: medicina interculturale*, Milano, 2012; G. Boniolo, E. Martinelli (a cura di), *La cura del paziente e la diversità spirituale: per una medicina interculturale*, Milano, 2024.

[13] UNESCO, International Bioethics Committee (IBC), *The Principle of Respect for Human Vulnerability and Personal Integrity*, 2013.

aumentando la possibilità e l'opportunità di accesso alle cure e all'assistenza per i meno avvantaggiati, considerando tali condizioni "immeritate limitazioni di opportunità" che vanno ristabilite.

Sulla stessa linea, la teoria personalista che pone al centro il riconoscimento della dignità intrinseca dell'essere umano, intende la giustizia nel significato di "non danneggiare alcuno", come proteggere (in senso negativo) e rispettare (in senso positivo) la vita di ogni essere umano e nel significato di "dare a ciascuno il suo", come riconoscere ad ogni essere umano ciò che gli "spetta" ontologicamente, in forza della stessa natura umana. Secondo questo modo di intendere la giustizia, ogni essere umano ha sostanzialmente gli stessi diritti di qualsiasi altro essere umano pur nella diversità di condizioni. In questo ambito si riconosce il dovere diretto della società di salvaguardare il bene comune, come l'insieme delle condizioni che promuovono e difendono la dignità umana: in tal senso le disuguaglianze naturali e sociali sono considerate inique, e alla società spetta il compito di ristabilire, per quanto possibile, un equilibrio sociale, operando attraverso il bene delle singole persone.

Pur nella diversità argomentativa, tali teorie, applicate alla selezione dei pazienti per l'accesso alle cure, riconoscono come unico criterio applicabile quello della valutazione medica oggettiva, caso per caso, della condizione clinica del paziente, dell'urgenza e della gravità della condizione (considerando la condizione della malattia o l'eventuale presenza di altre malattie) e della presumibile efficacia prognostica del trattamento in termini di probabile guarigione, secondo i criteri di proporzionalità ed appropriatezza. Qualsiasi deviazione dalla logica della uguaglianza e dell'equità (come giustizia del caso singolo), introduce elementi arbitrari di discriminazione. Il criterio dell'età o della preferenza della vita meno vissuta e aperta al futuro rispetto alla vita più vissuta, della qualità di vita probabile, della disponibilità finanziaria, del ruolo sociale, della disabilità o dipendenza, della capacità o efficienza produttiva, del costo sociale, della responsabilità rispetto alla patologia contratta, della nazionalità, dell'etnia, sono tutti criteri ritenuti inaccettabili in quanto extra-medici, che stabiliscono arbitrariamente ed estrinsecamente disuguaglianze tra gli individui umani.

Il punto di partenza è il riconoscimento "di principio" che tutti devono essere curati. Se "di fatto" le circostanze (quali la scarsità di risorse) costringono inevitabilmente a non potere curare tutti, ma a curare alcuni e non altri, il criterio non può essere definito su basi soggettive o sociali (non mediche), ma dovrebbe essere definito solo su basi oggettive (mediche), ossia sulla base delle condizioni cliniche del paziente[14]. È evidente che le risorse scarse non possono essere usate male e sprecate, ma devono essere efficaci, ossia usate per salvare vite umane. Ma non bisogna dimenticare che al centro vanno posti i bisogni di ogni persona malata. Proprio coloro che sono più vulnerabili, come le persone anziane o con disabilità, le persone povere, non devono essere emarginate da logiche selettive ispirate all'individualismo o alla convenienza sociale. Questo non significa comunque trattare "ad ogni costo" o attuare pratiche di accanimento clinico, che devono essere sempre doverosamente sospese quando sproporzionate, inefficaci e gravose, così come va rispettata l'autonomia del paziente di rifiuto o rinuncia a trattamenti, con la verifica della consapevolezza e della piena informazione delle conseguenze (secondo la Legge 219/2017).

Il Comitato Nazionale per la Bioetica in Italia nel parere *Covid-19: la decisione clinica in condizioni di carenza di risorse e il criterio del "triage in emergenza pandemica"* (8 aprile 2020) partendo dai principi Co-

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[14] S. Ricci, *Atto Medico. Evoluzione e Valore Sociale*, Roma, 2000.

stituzionali (in particolare l'art. 32 sulla tutela della salute, l'art. 2 sui doveri di solidarietà e l'art. 3 sull'uguaglianza) e dalla Legge 833 (1978), istitutiva del Servizio Sanitario Nazionale, ribadisce che «è doveroso fare sempre tutto il possibile per garantire a tutti, nessuno escluso», rispettando «i principi di giustizia, equità e solidarietà, per offrire a tutte le persone eguali opportunità di raggiungere il massimo potenziale di salute consentito». Il criterio clinico è considerato il più adeguato punto di riferimento per l'allocazione delle risorse, sottolineando che «ogni altro criterio di selezione definito aprioristicamente, quale ad esempio l'età anagrafica, il sesso, la condizione e il ruolo sociale, l'appartenenza etnica, la disabilità, la responsabilità rispetto a comportamenti che hanno indotto la patologia, i costi, è ritenuto dal Comitato eticamente inaccettabile». Con riferimento al triage in emergenza pandemica, il documento esplicita i criteri di "appropriatezza clinica", intesa come valutazione medica dell'efficacia del trattamento rispetto al bisogno clinico di ogni singolo paziente, con riferimento all'urgenza e alla gravità del manifestarsi della patologia e alla possibilità prognostica di guarigione e il criterio di "attualità", che include, oltre ai pazienti "fisicamente presenti", anche la "comunità dei pazienti" (non solo ammalati di Covid-19), ammettendo la revisione di liste di attesa includendo anche i pazienti che sono stati valutati e osservati da un punto di vista clinico, collocati temporaneamente in reparti subintensivi o a domicilio, ma che si aggravano improvvisamente. Una decisione e programmazione, quella del triage, che deve sempre «evitare la formazione di categorie di persone che poi risultino svantaggiate e discriminate»[15].

4. I determinanti comportamentali della salute: verso una salute "sartoriale"

Non solo le condizioni sociali sono fattori che determinano la salute, ma anche i comportamenti dei singoli e il c.d. stile di vita. È questo un elemento che emerge nel contesto della medicina di precisione, nata a seguito della rapida accelerazione delle tecnologie genetiche di sequenziamento genomico. L'obiettivo della medicina di precisione è quello di definire l'ereditarietà genetica delle malattie e di comprendere la modulazione dell'ambiente sul genoma nei diversi individui: ciò consentirebbe di "personalizzare" la medicina e le terapie, misurando in modo preciso la suscettibilità e la resistenza di ogni persona nei confronti delle malattie comuni. Il sequenziamento genetico su vasta scala e l'analisi bioinformatica consentono l'analisi massiva di dati (i c.d. *big data*) correlati alle informazioni sugli stili di vita delle persone e i determinanti socio-ambientali, mediante algoritmi. Tali tecniche stanno avendo un crescente utilizzo nell'ambito della ricerca e in ambito clinico, che si inserisce in qualche misura anche nella medicina sociale.

Si parla della "medicina della 4P", ossia medicina preventiva, predittiva, personalizzata, partecipativa[16]. Una medicina rivolta al cittadino, che identifica precocemente le malattie e la suscettibilità a determinate malattie, con un coinvolgimento diretto e attivo nelle conoscenze e nell'adozione di stili di vita. L'obiettivo è quello di analizzare la variabilità individuale nel rapporto fra genetica, società e ambiente, con riferimento alla biografia dell'individuo, allo stile di vita, ai fattori esterni, al fine di identifica-

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[15] COMITATO NAZIONALE PER LA BIOETICA, *Covid-19: la decisione clinica in condizioni di carenza di risorse e il criterio del "triage in emergenza pandemica"*, 8 aprile 2020.

[16] M. FLORES, G. GLUSMAN, K. BROGAARD, N.D. PRICE, L. HOOD, *P4 Medicine: how Systems Medicine will Transform the Healthcare Sector and Society*, in *Personalized Medicine*, 10, 2013, 565–576.

re il giusto trattamento per il giusto paziente nel momento opportuno, contro la generalizzazione per categorie e protocolli[17].

L’obiettivo della medicina di precisione delinea scenari nuovi, con vantaggi e limiti: vantaggi per quanto riguarda la prevenzione e la diagnosi di patologie, perché una precoce informazione in merito al rischio di contrarre una specifica patologia può portare importanti benefici in termini di prevenzione e controllo, con la possibilità di una terapia personalizzata in base alle specifiche esigenze; i limiti sono dati dal fatto che dalla consapevolezza del rischio presente e futuro possono derivare effetti negativi dal punto di vista psicologico, in specie per patologie incurabili allo stato attuale delle conoscenze scientifiche.

Questa trasformazione della medicina spinge verso un cambiamento delle politiche pubbliche, da un lato con un rafforzamento della prevenzione mediante l’educazione a stili di vita adeguati, anche mediante *nudging*, ossia la “spintarella gentile” che agevoli scelte favorevoli per la salute, e dall’altro lato con la responsabilizzazione dei cittadini rispetto alle proprie condizioni di salute, che non sia una limitazione della libertà individuale, ma l’acquisizione di una maggiore consapevolezza delle condizioni individuali per migliorare la propria vita e salute. In questo contesto è in atto una revisione anche delle politiche pubbliche relative alla privacy, che consentano di proteggere i dati personali degli individui (mediante codificazione e pseudonimizzazione) per evitare abusi in particolare da assicurazioni sanitarie e datori di lavoro, ma al tempo stesso di condividere campioni biologici e dati con una *governance* che non ostacoli la ricerca, basata sulla raccolta e confronto di dati personali (genetici e ambientali)[18].

5. I determinanti ambientali della salute: la salute globale e *one-health*

Il concetto di *one health* allarga ulteriormente la medicina sociale includendo anche la medicina ambientale[19]. È il concetto di “salute globale”, che si è progressivamente diffuso nella consapevolezza che la salute sia un bene comune di tutti, oltre le barriere geografiche e i confini politici. Alla salute globale, *one health* aggiunge anche la presa di coscienza della stretta connessione tra la salute umana, la salute degli animali, la salute dell’ambiente. Si parla infatti di *planetary health* per indicare l’estensione della salute a tutti gli organismi viventi umani e non umani. *One health* è dunque una concezione di salute allargata, basata su un approccio integrato che mira ad equilibrare in modo sostenibile la salute di persone, animali (domestici e selvatici) ed ecosistemi (piante e ambiente in generale) collegati tra loro. È un approccio che spinge molteplici settori, discipline e comunità a vari livelli della società a lavorare insieme per promuovere il benessere e affrontare le minacce per la salute dei cittadini e degli ecosistemi, contrastando il cambiamento climatico e contribuendo allo sviluppo sostenibile[20].

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[17] The US National Academy of Sciences, *Report Toward Precision Medicine*, 2011; The US National Institutes of Health, *All of US Research Program*, 20 January 2015; EU, *1 + Million Genomes (1+MG) Initiative,* 2018.

[18] UNESCO, International Bioethics Committee (IBC), *Report of the IBC on Updating Its Reflection on the Human Genome and Human Rights*, 2 October 2015; Comitato Nazionale per la Bioetica, *Gestione degli “incidental findings” nelle indagini genomiche con le nuove piattaforme tecnologiche*, 17 marzo 2016.

[19] F. Lirussi, E. Ziglio, *One Health: un approccio e un metodo non più rinviabili*, in *Scienza in rete*, pubblicato online l’8 febbraio 2021; F. Lirussi, D. Curbelo Pérez, E. Ziglio, *One Health and New Tools to Promote Health from a Holistic and Environmental Perspective*, in *Revista Iberoamericana de Bioética*, 16, 2021, 1–15.

[20] Con l’inclusione formale del “*Programma Ambientale*” delle Nazioni Unite nella condivisione con World Health Organization, Food and Agriculture Organization e World Organization for Animal Health nel 2022, è stato lanciato *il* ”Global One Health Joint Plan of Action*” (2022-26) ove “*one Health” coincide con «approccio integrato e unifi-

Stiamo acquisendo consapevolezza che il cambiamento climatico, l'inquinamento, lo sfruttamento indebito delle risorse naturali incidono sulla nostra salute; stiamo acquisendo consapevolezza delle relazioni che intercorrono tra i bisogni dei singoli e della popolazione mondiale, i bisogni di salute umani e non umani che includono animali e ambiente, sia in relazione alla diffusione delle malattie (e dunque al dovere di contrastarle) che alla distribuzione delle risorse volte alla ricerca e alla prevenzione/cura[21].
Ciò che emerge da questa concezione ampia di salute è l'esigenza di una ricerca transdisciplinare che includa nel confronto e nel dialogo medicina, psicologia, sociologia, antropologia, economia, diritto, etica, veterinaria, competenza ambientale. Anche l'organizzazione sanitaria delle politiche va ripensata: *health in all policies* indica l'esigenza che la salute sia oggetto non solo nelle politiche sanitarie, ma anche nelle politiche sociali, economiche, veterinarie e ambientali. Nella ricerca i medici dovrebbero collaborare con psicologi, sociologi, ma anche veterinari e studiosi dell'ambiente, per comprendere le cause delle malattie e i fattori che incidono sulla salute per cercare percorsi terapeutici. L'informazione e l'educazione dei cittadini alla salute dovrebbero consentire l'acquisizione della consapevolezza dell'interazione delle diverse componenti, per comprendere come modificare i comportamenti (ad es. lo stile di vita, che include la salute individuale e i comportamenti 'sostenibili' nei confronti degli animali e dell'ambiente).

6. Quali politiche pubbliche di fronte alle trasformazioni della salute?

Il quadro sintetico delle trasformazioni in atto della nozione di salute e dell'identificazione dei bisogni di salute mostra l'ampiezza e dinamicità dei concetti, nel contesto pluralistico. Probabilmente la parola "determinanti", di fatto usata nel dibattito oggi, può essere un'espressione troppo forte, in quanto pretende di identificare "il fattore" o "i fattori" che causano la modificazione della salute. A ben vedere, la complessità, incertezza e dinamicità degli scenari ci portano in modo più prudente a intuire o definire correlazioni e non causazioni deterministiche. Ne emerge, al di là dell'uso dei termini, una nozione sempre più complessa di salute e certamente una nozione che ha o può avere molteplici significati, che rimandano a visioni dell'uomo e della relazione tra umano e non umano.
Ciò che emerge, in modo trasversale, nell'ambito dei diversi percorsi delineati, è la necessità di un approccio interdisciplinare e pluralista alla nozione di salute e all'identificazione dei bisogni di salute. Bisogna partire dal confronto delle diverse discipline e delle diverse visioni di salute, per acquisire pur negli scenari complessi, incerti, in evoluzione a causa dello sviluppo tecno-scientifico e delle trasformazioni sociali e ambientali, la consapevolezza individuale e collettiva dei problemi emergenti. Su tali basi potranno essere sollecitate e svilupparsi politiche pubbliche che sappiano adeguarsi, in modo integrato e collaborativo, ai bisogni di salute.

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cante che mira ad equilibrare e ottimizzare in modo sostenibile la salute di persone, animali ed ecosistemi. Riconosce che la salute dell'uomo, degli animali domestici e selvatici, delle piante e dell'ambiente in generale (ecosistemi inclusi) sono strettamente collegati e interdipendenti. L'approccio One Health spinge molteplici settori, discipline e comunità a vari livelli della società a lavorare insieme per promuovere il benessere e affrontare le minacce per la salute e gli ecosistemi, affrontando al tempo stesso la necessità comune di acqua pulita, energia e aria, alimenti sicuri e nutrienti, contrastando il cambiamento climatico e contribuendo allo sviluppo sostenibile» (*One Health High-Level Expert Panel, Annual Report*, 2021).

[21] W. ANDERSON ET AL., *Bioethics for the planet*, in *The Lancet*, 406, 2025, 881-884.

L'identificazione dei bisogni e la prioritizzazione dei bisogni di salute, non potrà essere individuata in modo univoco, unilaterale e rigido, ma dovrà essere oggetto di una continua discussione tra discipline e tra teorie a confronto, alla luce di dati emergenti dalla prassi (livello raggiunto dalle conoscenze scientifiche e dalle applicazioni tecnologiche, trasformazioni sociali e ambientali), nella consapevolezza della loro costante modificazione.

In questo contesto possono avere una rilevanza i Comitati e le Commissioni di bioetica, a livello locale, nazionale e internazionale, di esperti sui temi connessi alla salute quale luogo di confronto interdisciplinare e pluralista, anche costituiti "ad hoc" rispetto a problemi specifici, che possano contribuire all'elaborazione di politiche pubbliche, partendo dallo stato dell'arte ed elaborando raccomandazioni che sappiano orientare i decisori politici[22]. Indispensabile è che chi fa parte di questi comitati e commissioni abbia una competenza adeguata e una disponibilità dialogica, in grado di confrontarsi con metodologie ed epistemologie diverse oltre che differenti visioni dell'uomo e della società, al fine di individuare percorsi condivisi, frutto di mediazioni sagge, prudenti e responsabili che sappiano aprirsi al dibattito pubblico[23].

7. Il ruolo dell'informazione, dell'alfabetizzazione sanitaria e dell'educazione

Un obiettivo delle politiche pubbliche è dunque anche quello di accrescere la capacità delle persone di gestire la propria salute, scegliendo di far leva sulla soggettività e consapevolezza dei cittadini. È questa una strategia che nella storia è stata vincente per debellare molte malattie e salvare molte vite, grazie alla responsabile adozione di norme di igiene da parte della grande maggioranza dei cittadini.

In questo campo, il ruolo dell'informazione, da parte delle istituzioni, dei comitati tecnico-scientifici, dei media, è cruciale. La completezza e la trasparenza dell'informazione rafforzano la fiducia dei cittadini: fiducia tanto più preziosa in un momento di scelte difficili. I media, i giornalisti professionisti, le emittenti pubbliche hanno un ruolo chiave nel fare da tramite tra le notizie che provengono dagli organismi governativi e dai comitati tecnico-scientifici e la cittadinanza. Spetta alla loro competenza e alla loro etica professionale dare informazioni corrette, accurate, aderenti alla verità dei fatti, evitando sensazionalismi, né eccessivamente allarmanti né falsamente rassicuranti, cercando di prevenire il panico o la rassegnazione, e di suscitare presa di coscienza dei problemi, senso di responsabilità e sentimenti di cooperazione.

In questo senso il diritto-dovere di informazione dei professionisti della comunicazione, diritto fondamentale in ogni democrazia, può, se correttamente realizzato, essere un prezioso strumento per la valutazione libera e responsabile da parte dei cittadini delle norme restrittive stabilite dalle autorità preposte per la tutela della salute individuale e collettiva, e ciò sia in merito alla loro finalità e proporzionalità che alla loro durata ed efficacia. Tutti i temi relativi alla salute e malattia, nel contesto sociale, compor-

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[22] L. PALAZZANI, *Dalla bio-etica alla tecno-etica. Nuove sfide al diritto*, Torino, 2017.

[23] COMITATO NAZIONALE PER LA BIOETICA, *Vulnerabilità e cura nel welfare di comunità. Il ruolo dello spazio etico per un dibattito pubblico*, 10 dicembre 2021; COUNCIL OF EUROPE, STEERING COMMITTEE FOR HUMAN RIGHTS IN THE FIELDS OF BIOMEDICINE AND HEALTH (CDBIO), *Guide to Public Debate on Human Rights and Biomedicine,* 19-21 November 2019; *Guide to Health Literacy. Contributing to Trust Building and Equitable Access to Healthcare,* January 2023; European Group on Ethics in Science and New Technologies (EGE), *Opinion on the ethical implications of new health technologies and citizen participation*, 13 October 2015.

tamentale e ambientale devono essere oggetto di divulgazione alla società. I cittadini devono essere informati, per potere acquisire consapevolezza critica e partecipare alla discussione. I media, i giornalisti professionisti, le emittenti pubbliche hanno un ruolo chiave nel trasmettere le notizie che provengono dagli esperti di medicina. Spetta alla loro competenza e alla loro etica e deontologia professionale dare informazioni corrette, accurate, autentiche, evitando sensazionalismi che producono eccessivi e ingiustificati allarmi o false rassicurazioni, cercando di prevenire il panico e la rassegnazione, di suscitare presa di coscienza dei problemi, senso di responsabilità. In questo modo il diritto-dovere di informazione dei professionisti della comunicazione, diritto fondamentale in ogni democrazia, può essere un prezioso strumento per l'acquisizione di consapevolezza da parte dei cittadini. Esiste un'etica intrinseca alla comunicazione che esplicita i valori interni alla stessa comunicazione, in relazione a chi comunica (istituzioni, scienziati, medici, ricercatori, giornalisti scientifici) e a fronte di chi riceve la comunicazione (i cittadini). Una "buona" comunicazione relativamente alla salute e ai temi di bioetica deve seguire i criteri, orientati al "bene" di chi riceve la comunicazione: evidenza scientifica e documentazione (se i dati non ci sono, l'informazione deve essere onesta sulle incertezze scientifiche); trasparenza e correttezza; consistenza e coerenza nella spiegazione e argomentazione, che consenta un'adeguata comprensione delle ragioni di certe scelte o comportamenti; chiarezza ed adeguazione alla capacità di comprensione di chi riceve la comunicazione, con semplificazione del linguaggio per raggiungere tutti; inclusività e giustizia, comunicazione che si rivolga a tutti e non escluda alcuno (es. persone immigrate, persone con disabilità, i gruppi particolarmente vulnerabili); affidabilità, con una comunicazione che consenta di costruire un rapporto di fiducia, basato su rigore e responsabilità. La comunicazione sui temi di bioetica ai cittadini deve avere la finalità di coniugare informazione ed educazione: l'obiettivo dovrebbe essere consentire ai cittadini di acquisire una consapevolezza critica e una responsabilità individuale e sociale verso la salute, la c.d. alfabetizzazione sanitaria, che è anche alfabetizzazione bioetica (c.d. *health literacy, bioethics literacy*). La pandemia è un ambito in cui questo elemento è emerso in modo evidente. La comunicazione sulla salute può anche avere, contestualmente, l'obiettivo, sulla base della informazione e formazione dei cittadini, di coinvolgerli nel "dibattito pubblico" o discussione pubblica sulla salute anche in vista della regolazione. Nell'ambito della medicina sociale diviene di particolare rilievo offrire gli strumenti ai cittadini per discernere informazioni corrette ed errate, nell'ambito dello sviluppo delle nuove tecnologie della informazione e della comunicazione. Le informazioni inventate, ingannevoli o distorte (*fake news*), rese pubbliche su internet con l'intenzione di disinformare sono estremamente pericolose, ancora più in mancanza di un filtro di selezione critica. L'informazione non veritiera può provocare nel cittadino fraintendimenti che lo portano a comportarsi in modo scorretto ed inadeguato. Emerge l'esigenza di correttezza e autenticazione dell'informazione, per garantire un diritto ad accedere ad informazioni veritiere in generale, soprattutto nell'ambito della salute. Mancano, ad oggi, misure di "certificazione di qualità", siti accreditati da istituzioni sanitarie che attestino al cittadino l'autenticità dei contenuti.

Towards a Systemic Social Medicine:
Epistemological Foundations and Operational Perspectives

Vittoradolfo Tambone, Francesco De Micco*

WELL-BEING AND DISEASE IN THE FIELD OF AESTHETIC SURGERY. OVERCOMING THE DICHOTOMY AND THE ROLE OF THE PHYSICIAN

ABSTRACT: In recent years, renewed attention has been devoted to the epistemological and operational foundations of Social Medicine. Building on contributions to Global Social Medicine and critical analyses of the political economy of healthcare, this article advances the notion of Systemic Social Medicine. Grounded in complexity theory and systemic epistemology, this framework transcends reductionist paradigms and repositions health as an emergent property of interrelated biological, social, and political determinants. Four epistemic axes are proposed relationality, conscious and cooperative reduction, transcendence of knowledge, and global relationality aiming to reconfigure both clinical reasoning and public health practice within a genuinely systemic perspective.

KEYWORDS: Systemic social medicine; epistemology of complexity; relationality; global health; evidence-based medicine

1. Introduction

In recent years, scholarship has increasingly sought to reconsider the theoretical and practical foundations of Social Medicine. Pentecost and colleagues[1] have advanced the notion of *Global Social Medicine* as a framework that reasserts, at the international level, an agenda oriented to-

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[1] M. PENTECOST, V. ADAMS, R. BARU, C. CADUFF, J.A.GREENE, H.HANSEN, *Revitalising global social medicine*, in *The Lancet*, 398, 10300, 2021, 573-574.

ward the promotion of human rights and social justice. This perspective forms part of a broader movement toward the decolonization and democratization of knowledge production and circulation in public health, building on earlier contributions by Adams et al.[2] (2019) and later by Abimbola and Pai.[3]

Concurrently, Anderson and Smith,[4] through a critical analysis of the political–economic trajectory of Western medicine progressively governed by "market rationality" have articulated a model of Social Medicine attentive to three structural dimensions: (a) the decisive impact of socio-economic conditions on medical practice; (b) the recognition of collective health as a matter of social relevance; and (c) society's responsibility to promote well-being at both individual and community levels.

The concept of social determinants of health, long regarded as the backbone of Social Medicine, is itself undergoing critical reassessment. This reappraisal responds to their increasing stratification and to the challenge of adapting them to contemporary geopolitical diversity.[5] Within this context, the political dimension of Social Medicine has assumed growing significance, particularly with respect to the active role of health professionals in medical intelligence[6] and in safeguarding or reinforcing democratic processes.[7]

We argue that attention to the political dimension of medicine in general, and of Social Medicine in particular, represents a theoretical and operational concern of crucial importance. As we have underscored elsewhere,[8] the practice of science and medicine, if it is to be genuinely meaningful and transformative, requires direct engagement with social life through observation, listening, and continuous encounter with pressing issues such as violence, poverty, corruption, addiction, and the many forms of social pathology that shape everyday existence.

For this reason, science and Social Medicine cannot be confined within an abstract, pre-systemic logic detached from lived reality. Real problems are inherently complex and multilayered; understanding and addressing them requires a medical paradigm capable of integrating such complexity. It is precisely in this domain that Social Medicine may assume a pivotal role in facilitating the transition of clinical reasoning from a pre-systemic mode to one that is genuinely systemic.

Within this perspective, the present contribution seeks to outline several elements for the theoretical and operational constitution of Systemic *Social Medicine*. The discussion unfolds as follows: we begin by providing a conceptual framework, followed by an epistemological proposal consistent with the current model of Evidence-Based Medicine (EBM). We then present four epistemic directions that we consider

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[2] V. Adams, D. Behague, C. Caduff, *et al.*, *Re-imaging globl health trough social medicine,* in *Glob Public Health*, 14, 10, 2019, 1383-1400.

[3] S. Abimbola, M. Pai, *Will global health survive its decolonization?,* in *The Lancet*, 396, 10263, 2019, 1627-1628.

[4] M. Anderson, L. Smith, V.W. Sidel, *What is social medicine?*, in *Monthly Review*, jan 01, 2005.

[5] E. Borde, M. Hernandez, *Revisiting the social determinants of health agenda from the global South*, in *Glob Public Health*, 2019, 14, 6-7, 847-862; Q. Eichbaum, S. Reid, A. Coly, *et al.*, *Conceptualizing medical humanities program in low-resource settings in Africa*, in *Acad Med*, 94, 8, 2019, 1108-1114.

[6] A.C. Vilasi, *Medical Intelligence and Public Health in the complexities of contemporary societies. The role of FBI in The United States*, Security Science Journal, 5, 2, 2024.

[7] V. Tambone, P. Frati, F. De Micco, G. Ghilardi, V. Fineschi, *How to fix democracy to fix health care*, in *The Lancet*, 399, 10323, 2022, 433-434.

[8] G. Ghilardi, L.L. Campanozzi, M. Ciccozzi, G. Ricci, V. Tambone, *The political nature of medicine*, in *The Lancet*, 395, 10233, 2020, 1340-1341.

fundamental to the development of systemic Social Medicine and conclude with a brief reflection intended as an open invitation to critical debate.

2. An Ethical Rationality for a Medicine of Complexity

When Baruch Spinoza entitled his major work *Ethica ordine geometrico demonstrate,*[9] he explicitly declared already on the title page his intention to construct a rigorous philosophical system modeled on the axiomatic structure of Euclidean geometry. The entire architecture of the work unfolds according to a stringent logical sequence: definitions, axioms, propositions, demonstrations, corollaries, and scholia. What might appear as a purely formal exercise is, in fact, the coherent expression of an ontological premise in which reality is conceived as a unified, rational, and necessary system. The universe is neither fragmented nor ruled by chance or arbitrariness; it constitutes an interconnected whole, intelligible through the use of reason.

From this standpoint, the *Ethics* is not to be understood as a set of subjective moral prescriptions, but as the outcome of an adequate comprehension of being. A good life coincides with a rational life: the ethical subject is one who recognizes their position within the order of truth, including their relation to the web of necessities that structures nature. Ethics and ontology thus converge inseparably; to understand what is, simultaneously means to understand how one ought to act. This is a form of thought that does not merely describe the world but immerses itself within it, seeking to transform it through awareness and the coherence of action.

In this light, the so-called naturalistic fallacy identified by G.E. Moore[10] may be read, on the one hand, as a logical fracture between knowing and acting, and on the other, as one of the theoretical roots of modern anti-ecological attitudes, which deprive nature and its laws of any normative force.

Despite the historical distance, this approach retains a striking relevance today. It can be traced, in renewed form, within contemporary medicine, particularly in those strands most attuned to complexity. In this respect, a medicine that seeks to define itself as social and systemic appears to recover precisely that demand for order, rationality, and interconnectedness that Spinoza ascribed to reality. The idea of a systemic Social Medicine emerges from the need to overcome specialist and technicist reductionism, in order to construct a form of knowledge capable of reassembling what has been fragmented, integrating rather than separating, and inquiring beneath the surface of phenomena into the deeper conditions that generate them.

Research that aspires to a systemic knowledge of reality can, and indeed has, followed two very different paths. On the one hand, it seeks a “theory of everything” capable of formalizing existence through axiomatization. On the other, it advances through an open dynamic, aware of the limitations inherent in knowing a multidimensional reality and, for this very reason, open to the cooperation of multiple forms of knowledge.

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[9] B. SPINOZA, *Ethica* ordine geometrico demonstrata, 1677.

[10] G.E. MOORE, *Principia ethica*, 1903.

3. From Formalization to Complexity: An Epistemological Turn

Over the course of the twentieth century, the project of a fully formalized science founded on a few first principles and capable of deducing every truth axiomatically reached its apex in David Hilbert's program.[11] The aim was to reduce the entire corpus of mathematical, and ideally scientific, knowledge to a coherent, complete, and logically grounded system. Yet this ambition encountered a radical limit in Kurt Gödel's incompleteness theorem,[12] which demonstrated that within any sufficiently powerful formal system there exist propositions that, while true, cannot be demonstrated within the system itself.

From this turning point onward, science has been compelled to acknowledge the constitutive limit of immanence: no system of knowledge can ever be entirely closed, exhaustive, or self-sufficient. Rationality, therefore, is not negated but transformed from a foundational and immanent logos into an open, dialogical, and, in a certain sense, transcendent process.

Concurrently, the emergence of systems theory[13] and the rise of the sciences of complexity[14] introduced new epistemological paradigms, which challenged classical notions of linear causality, explanatory reductionism, and predictive determinism. These developments suggest a new approach: circular and open causality, a conscious and cooperative reduction, and a prognostic capacity only partially amenable to formalization.

Within this new horizon, knowledge is no longer constructed through the analysis of isolated parts but tends toward the comprehension of open, dynamic, and interconnected systems. Phenomena can no longer be interpreted through mere analytical decomposition, as they arise from complex relations, unstable equilibria, feedback processes, and mechanisms of self-organization. Reality thus takes shape as *emergent reality*, a totality qualitatively distinct from the simple sum of its components.

From this perspective, medicine may evolve toward increasing specialization in the search for deep biological evidence, while interpreting such evidence clinically through a systemic paradigm. The growing availability of data and their processing through advanced algorithms does not mark the end of interpretation; on the contrary, it constitutes its point of departure. These data must be read through a systemic and personalized lens, capable of restoring complexity and clinical meaning. This dual interpretation personalized and systemic could form the epistemological foundation both of future clinical medicine and of systemic Social Medicine.

The foundational element of this transition is represented by the dynamic interplay between correlation and interpretation. The former, supported by Artificial Intelligence, enables a semantic refinement of data; the latter, acting upon this same product, reintegrates it within a systemic context of meaning, thereby arriving at increasingly veridical and thus effective formulations, both at the individual and collective levels.

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[11] G. Israel, A. Millan Gasca, *The World as a Mathematical Game: John Von Neumann and Twentieth Century Science*, Science networks Historical Studies, Birkhäuser, Basel, 38, 2009, 219.

[12] Gödel first presented the incompleteness theorem at a roundtable following the Second Conference on the Epistemology of the Exact Sciences in Königsberg in 1930. The theorem states that any consistent formal system of mathematics, sufficiently expressive to represent the structure of the natural numbers with addition and multiplication, admits the construction of a well-formed statement that is true but neither provable nor refutable within that system itself.

[13] L. Von Bertalanffy, *General System Theory. Foundations, Development, Applications*, New York, 1968.

[14] I. Prigogine, *Introduction to thermodynamics of irreversible processes*, 1955.

This dynamic is not merely cooperative; it possesses a complex and circular nature in itself: it simultaneously becomes a site for the fine-tuning of Artificial Intelligence and an epistemic space in which the constitutive dynamic relations of reality unfold. In this perspective, the social medicine of the future must be conceived as systemic medicine, engaged not only in understanding biological physiology and pathophysiology but also and perhaps more importantly the physiology and pathophysiology of relationships.

4. Reductionism and Complexity: Towards a Systemic Evidence-Based Medicine

Such an epistemological shift carries significant implications for the life sciences and, in particular, for medicine. Linear, deterministic, and predictive models have undoubtedly yielded important results in the diagnosis and treatment of diseases. However, they today exhibit clear structural limitations, especially when confronted with phenomena such as chronic conditions, multimorbidity, psychosocial suffering, or when approached from the integrated perspectives of One Health and Global Health.

Every clinical condition is embedded within a dynamic and transformative context biological, psychological, cultural, environmental, relational, political, that cannot be dissociated from the other dimensions with which it constantly interacts. Moreover, these interconnections are subject to temporal changes that elude representation through linear statistical models or classical probabilistic logic.

In light of this, it appears inadequate to continue defining medicine as a merely probabilistic science. It is, in our view, more appropriate to conceive of it as a systemic science, akin to other practical sciences—and, one might add, even theoretical sciences. This does not imply the adoption of a single scientific method across all disciplines, as already noted by Popper.[15] Each science must retain its methodological specificity, while acknowledging that every form of knowledge represents, at best, a reduction of reality: a partial truth within a broader network of meaning.

Consequently, there arises the need for conscious and cooperative reduction:[16] an epistemological stance that recognizes the partiality of knowledge and actively seeks interdisciplinary collaboration to construct a systemic and shared vision of the object of study. Such a vision maintains structural openness, both in terms of epistemic completeness and operational applicability.

Adhering to a linear framework entails perpetuating a partial and potentially misleading understanding. An authentically scientific medicine today must integrate ontological and epistemic transcendence into its method, transitioning from traditional Evidence-Based Medicine (EBM) to what we might term Systemic Evidence-Based Medicine (SEBM), which is more faithful to the complexity of reality.

This implies that every act of knowledge must transcend mere empirical evidence, interrogating the deep causal relationships, emergent levels, and latent dynamics that structure phenomena not only in space and time, but also within multiparametric configurations, as suggested by chaos theory.

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[15] D. ANTISERI, K. POPPER, *Protagonista del secolo XX*, 2002.

[16] V. TAMBONE, G. GHILARDI, *Aware and cooperative reduction*, in *La Clinica Terapeutica*, 163, 3, May 2012, e133-e143; G. GHILARDI, V. TAMBONE, *Per una fondazione ontologica della riduzione consapevole e cooperante*, in *Medicina e Morale*, 64, 5, 2015; G. GHILARDI, V. TAMBONE, *Per una fondazione ontologica della riduzione consapevole e cooperante*, in *Medicina e Morale*, 2015; 64, 5.

An exemplary reference in this context is provided by the dimensional ontology developed by Viktor Frankl[17]. According to the first law of this theory, "a single and identical phenomenon, projected onto lower dimensions than its own, gives rise to different and mutually contrasting figures." The example of the cylinder is emblematic: projected onto a horizontal plane, it generates a circle, whereas on a vertical plane, it produces a rectangle. Two irreconcilable figures yet arising from the same object.

Applying this concept to the human being, if one observes a person solely in their biological dimension, somatic phenomena will emerge; if seen only in the psychological dimension, psychic aspects will surface. Although both perspectives concern the same reality, they may appear irreconcilable or in conflict.

Frankl's second law states that "different phenomena, projected onto the same lower dimension, may appear similar or ambiguous." Here too, the geometric analogy is illuminating multidimensional phenomena, observed through a single reductive perspective, lose their specificity and risk being misinterpreted or confused.

Numerous thinkers have anticipated or developed a similar multidimensional vision: from Edwin A. Abbott with *Flatland,*[18] to Ken Wilber with his Integral Theory; from classical psychoanalysis (Freud, Jung, Hillman) to the theories of Carl Friedrich von Weizsäcker, according to whom the world is constituted not by objects but by informational structures articulated across ontological levels. In the physical sciences, one can recall Michio Kaku's extra-dimensional theories, or the quantum perspective advanced by Niels Bohr, Werner Heisenberg, and David Bohm, for whom the very behavior of matter depends on the observer (principle of complementarity), with non-local and interconnected levels of reality (entanglement), so that the universe can be viewed as interconnected, holistic, and composed of overlapping layers of reality—much like Frankl's dimensional ontology.

This leads naturally to systems thinking (Systems Theory and Cybernetics) with authors such as Ludwig von Bertalanffy, Gregory Bateson, Edgar Morin, Humberto Maturana, Fritjof Capra, and Joanna Macy. Within this framework, existing phenomena including human beings are open complex systems composed of hierarchical and interdependent levels. Each system possesses emergent properties that cannot be reduced to the sum of its parts (for example, consciousness). The human being is seen as a node within a network of biological, social, cultural, and ecological relationships, which can be progressively understood, but whose main characteristic is to serve as an ontological and transcendent interpretive key, possessing its own dialectic with a persistent level (which may be termed substance, self, or otherwise) that actualizes its potential in a becoming already present as a project (sometimes described as passive potentiality). This predefines the acting subject even before its development and thus enables the relationship, which becomes a prerequisite for any co-relation.

"Relationship" must therefore be observed at a multiparametric level: an immanent dimension (relation to oneself), a horizontal dimension (relation to peers), a global dimension (relation to the mineral, vegetal, and animal worlds), a vertical dimension (relation to one's formal and ultimate cause), a historical dimension (relation to memory), and additional dimensions such as the technological (relation of reinforcing alteration). The subject and their relationships thus constitute the genetics of a systemic interpretation of reality.

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[17] V. FRANKL, *Man's Search for Meaning: The classic tribute to hope from the Holocaust*, Vintage Pub, 2004.

[18] E.A. ABBOTT FLATLAND, *A Romance of Many Dimensions*, Independently published, 2025.

It is in this direction that the proposal for systemic social medicine develops, grounded on four constitutive axes: relationship, conscious and cooperative reduction, transcendence of knowledge, and global relationship as an operational guide.

5. Four Epistemic Axes for Systemic Social Medicine

5.1. Relationship

The concept of relationship that we aim to propose goes far beyond its traditional applicative forms, such as the physician-patient, physician-society, physician-politics, or physician-economy relationships. While these manifestations are important, they represent partial expressions of a more radical truth: every individual reality is intrinsically relational. Relationship, therefore, is not a mere accessory to existence but constitutes a foundational, existential, and dynamic element.

In human beings, relationality manifests in forms that are partially involuntary and partially voluntary; it may be comprehensible in its effects or elusive and unpredictable; sometimes physiological, sometimes pathological; it can present as reception or as offering. Beyond these forms, however, relationship is primarily the means through which the human subject constructs both self and world. Here, we will focus particularly on the voluntary dimension of relationships, the one that implies awareness and responsibility.

Voluntary acts, in fact, do not merely modify the environment; they primarily transform the actor. According to the ancient principle that “man becomes what he does”, the one who steals progressively constitutes himself as a thief, the one who writes as a writer, and so on. This phenomenon signals the presence of a primary immanent relationship, internal to the subject, articulated in the dynamic between intellect, will, and passions. If the will chooses to act in accordance with the judgment of the intellect, which has recognized the good to be done, action will be rational (*kata logon*), and over time the subject will strengthen their capacity for rational action. Conversely, if the will is drawn toward what contradicts the intellect’s directive, behavior will be irrational and, over time, will tend to weaken rational faculties.

The structure of this immanent relationship profoundly influences the quality of transcendent relationships: these may be rational and constructive, or irrational and destructive. In the first case, one speaks of physiological relationality; in the second, of pathological relationality.

Without delving further here, we can affirm that systemic social medicine should adopt as its primary objective the study, promotion, and support of physiological relationality, as well as the diagnosis and treatment of its pathological forms. In this sense, it must address risk behaviors, interpersonal violence, ecological challenges, social responsibilities, and many other areas central to public health, all starting from and through the foundational category of relationship.

In line with the thought of Ivan Cavicchi, who defined medicine as an “incomparable science”[19] due to its irreducible complexity, we consider it urgent to move beyond an approach based solely on biological facts toward a relational paradigm, capable of integrating the biological dimension with the social, systemic, and global dimensions, while recognizing that “biological facts” are themselves relational.

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[19] I. CAVICCHI, *La Scienza impareggiabile*, 2022.

Applied examples of relationality in systemic social medicine

1. Human-technology relationship (bio-techno-relational domain):
    - Biological effects of new technologies on the central and peripheral nervous system.
    - De-skilling phenomena, particularly the loss of critical and reflective thinking.
    - Use of personalization algorithms and implications for freedom of choice.
    - Mental health in relation to the use of conversational interfaces (chatbots).
2. Relationship with political-economic dynamics (socio-political-relational domain):
    - Impacts of public health within the context of surveillance capitalism.
    - Psychopolitics and forms of behavioral modulation.
    - Distorted meritocracy and unequal access to education.
    - Longtermism and the crisis of democratic participation.
3. Pathological abusive relationships (deviant-relational domain):
    - Bullying and gratuitous violence;
    - Gender-based violence;
    - Institutional violence and latent states of war.
    - Sexual violence and extremes of bondage.
4. Relationship with nature (One Health and beyond):
    - Overcoming G.E. Moore’s naturalistic fallacy.
    - Science for humanity vs. transhumanism.
    - Ecological urban planning and environmental sustainability.
    - Human ecology as a critical development beyond deep ecology.

These examples far from exhaustive demonstrate how systemic and social medicine must address relationship in a transversal, multidimensional, and interdisciplinary manner.

5.2. Conscious and Cooperative Reduction

In contemporary scientific thought, method is often considered the cornerstone of rationality. However, this methodological emphasis can easily degenerate into a form of epistemological reductionism, in which only the scientific method is deemed legitimate for producing valid knowledge of reality.

This stance found its most complete expression in the twentieth-century formalism of David Hilbert, who sought to ground mathematics on perfectly coherent and complete axiomatic foundations. His second problem proving the internal consistency of the real number system represents the apex of this vision. However, Hilbert’s dream was shattered by Kurt Gödel’s incompleteness theorems (1931), which established the impossibility for any sufficiently complex formal system to prove its own consistency from within. This failure sparked a profound crisis in scientific reductionism.

In the second half of the twentieth century, an alternative epistemological orientation emerged, aimed at reaffirming the irreducible complexity of reality. Holism was its first expression, supported by authors such as Fritjof Capra and David Bohm, who promoted an interconnected view of phenomena. However, even holism can degenerate into a mirror form of reductionism, in which parts are absorbed into the whole, losing their specificity.

A genuine overcoming of this polarization was offered by complexity theory, which rejects both reductionist simplification and holistic universalism. It recognizes the existence of multiple levels of reality, each of which cannot be reduced to the others. The concept of emergence is central here: the properties of a complex system such as a symphony or a culinary dish cannot be deduced from its individual parts but emerge from nonlinear relationships and higher-order organization.

The science of complexity therefore proposes a new epistemology: interconnected, transdisciplinary, and cooperative. The interaction between different bodies of knowledge is no longer optional but an epistemic necessity. Every phenomenon, to be adequately understood, requires the contribution of multiple disciplines, each carrying a fragment of truth.

However, it is equally necessary to recognize that every act of knowledge entails a reduction. To observe, analyze, or interpret inevitably involves selecting, simplifying, and cutting through the complexity of reality. The epistemic error does not lie in reduction per se, but in the failure to recognize it as such. Reduction is legitimate only if it is conscious, provisional, purpose-driven, and open to revision.

From this perspective emerges an epistemology of conscious and cooperative reduction, grounded in the dialogical integration of different forms of knowledge. Scientific knowledge thus becomes a collective, self-critical, and asymptotic endeavor: never definitive, always revisable. The multidimensional approach, also theorized by Viktor Frankl, restores the complexity of the person and the world, honoring the diverse dimensions of human suffering.

Applied to medicine, this principle translates into clinical practice based on temporary and directed reductions, capable of integrating into a systemic reading of the human condition. The clinician, from this perspective, is not an isolated technician but an actor within a dialogical and collaborative network. Every diagnosis becomes an interpretative hypothesis to be verified, integrated, and, if necessary, reformulated.

A systemic social medicine founded on this epistemology will therefore have the courage to recognize the limits of its own reductions and the wisdom to embrace interdisciplinary cooperation as the primary path toward a more humane, more accurate, and more effective understanding of health and care.

5.3. Knowledge as Necessarily Transcendent

As previously observed, Gödel’s incompleteness theorems indicate the impossibility for any sufficiently complex formal system to exhaustively encompass the totality of truth it claims to represent. Authentic knowledge, therefore, can never be fully contained within a closed system; it always requires reference to dimensions that transcend it. This transcendence should not be understood merely in hierarchical or organizational terms, but as an openness to a further systemic level that allows phenomena to be interpreted in their circular dynamics, according to both top-down and bottom-up causality.

In the medical field, this need for transcendence is particularly evident in the approach to clinical complexity. For instance, understanding an oncological pathology requires integrating molecular biochemistry with the patient’s immunological profile, individual genetics, existing comorbidities, expected therapeutic responses, and much more. However, to fully comprehend the immune profile itself, one must consider the subject’s nutritional status, possible substance abuse, quality of habitat, presence of domestic animals or environmental pathogens, and so on. Furthermore, to adequately assess nutritional status, one must examine the socio-economic and geopolitical context in which the patient lives, as well as potential psychopathological conditions such as an eating disorder which, in turn, point to an additional causal level, namely familial, affective, social, and friendship relationships.

In each of these articulations, a central principle becomes evident: the cause can never be entirely immanent to the phenomenon but must necessarily transcend it, as only what is external can determine it. From this perspective, scientific knowledge recovers its etymological root: *scire per causas*. To know is to investigate the deep causes, not to remain at the surface of the data. In medicine, this entails recognizing that the object of knowledge health, disease, body, mind can never be reduced to the observable but always lies beyond the symptom, the lesion, and the parameter.

The recovery of the Aristotelian causal model which includes material, formal, efficient, and final causes—allows medicine to reclaim its authentic therapeutic status: not merely treating effects but interrogating the deep causal structures of clinical phenomena. Systemic medicine thus constitutes a critical and reflective knowledge, capable of transcending the specialist and sectoral perspective to address suffering in all its existential and contextual density.

Even dysfunctional behaviors individual or collective must be read as systemic symptoms, indicators of relational or environmental dysfunction rather than mere anomalies to be corrected. Authentic diagnosis thus becomes an hermeneutics of complexity and therapy an act of reconnection and rebalancing.

5.4. Global Relationship as Operational Evidence

In a famous passage from his essay *Physics and Reality* (1936), Albert Einstein states that “the theory determines what we can observe.” This observation both overturns and complements the classical empiricist view: it is not observation alone that generates theory, but theory itself that guides, selects, and structures what is observed. Data, therefore, is never neutral, but mediated by a pre-existing theoretical horizon.

From this follows a fundamental implication for medicine: the necessity of adopting a global theoretical horizon capable of guiding clinical observation in a broad, contextual, and systemic manner. Medicine has always been an integrative knowledge: anamnesis, semiotics, and epidemiology are tools that seek connections among phenomena, not mere mechanical correlations.

From a systemic perspective, this integrative vocation must be carried to its extreme consequences: the patient is not an isolated organism but a person-in-relationship, embedded in complex networks—familial, social, cultural, environmental, economic. The patient is not a static being but a historical subject, in whom past experiences, memory, and current choices contribute to defining both the present and the intentional direction of existence. For reasons we will not elaborate here, we understand the historicity of the human being as a combination of permanence and dialectic. It seems incorrect to reduce it solely to the dialectical dimension, as this would strip it of meaning in the same way that, in nihilism, ideas detached from generative ideas lose significance. The permanence of relationship resides in the person and manifests at linguistic, legal, historical, ethical, clinical, and even biological levels.

For this reason, the dialectic and dynamic to which we refer is not a dialectic of negation and overcoming, as seen in contemporary deconstruction à la Derrida,[20] which proves fallacious and unsustainable. Rather, we refer to a dialectic or dynamic of construction when oriented toward the purpose of the per-

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[20] AA.VV., *Su Jacques Derrida: Scrittura filosofica e pratica di decostruzione*, in *LED*, 2012.

son, or to a dynamic of deconstruction when contrary to the purpose of the subject. Indeed, dynamics or dialectics are not inherently positive or negative; they are characterized according to their relation to the goal of the acting subject. Here, the material dimension must be combined with the psychological and spiritual dimensions in a dynamic of personal construction. This combination represents the deepest multiparametric dimension.

This historicity is also reflected on the biological level. The intellectual-volitional dimension of the human being as vividly illustrated by Viktor Frankl affects not only existential capacity but also personal biochemistry. Spiritual interiority is not reducible to a psychological epiphenomenon; rather, it constitutes a multiparametric openness capable of generating powerful existential attractors that orient choices, behaviors, and bodily states.

Within this framework, relationships are not a mere corollary of clinical practice but a primary operational evidence. Every medical intervention, treatment pathway, and public health strategy must be conceived and implemented within a relational logic. Systemic social medicine thus postulates that only a theory capable of embracing complexity as a structure of reality can underpin a clinical practice adequate to contemporary human and social realities.

6. Conclusion: Dwelling in Complexity, Living Relationship

Systemic social medicine does not propose itself as a new specialization, nor as an ideological alternative to existing medical knowledge. Rather, it represents an epistemic transformation: a shift in the very way of conceiving knowledge, observation, diagnosis, and care.

Far from rejecting science, it radicalizes its demand for truth, assuming complexity not as an obstacle to knowledge but as an original condition to inhabit. Medical knowledge, in this view, becomes reflective, dialogical, and open: it rejects the linear paradigm, exposes itself to the encounter of multiple levels of reality, and is nourished by disciplinary plurality and epistemic cooperation.

Ultimately, systemic social medicine is also ethics: not in the normative sense of a behavioral code, but as an ethics of epistemic and clinical responsibility. It is an ethics of well-executed work, of embodied rationality, of cooperative awareness. It is a practice that recognizes the value of relationships as a structural condition of care.

In a world marked by fragmentation of competencies, knowledge, and relationships systemic social medicine reminds us that to know is to correlate and interpret, and to care is also to heal relationships. Health is not merely the absence of disease but a fully realized form of lived relationality. Dwelling in complexity and living relationship: this is the horizon of the medicine we envision.

Efficiency and Equity: Assessing the Relationship Between Health System Efficiency and Social Inclusion in Europe

Maria Alessandra Antonelli, Alessia Marrocco, Angelo Castaldo, Andrea Salustri, Filippo Reganati*

ABSTRACT: This paper investigates the relationship between health system efficiency and social inclusion in Europe. Using a two-stage empirical strategy on a panel of 25 countries over the period 2009 – 2019, we first estimate health system efficiency scores through Stochastic Frontier Analysis (SFA), where per capita health expenditure is related to a composite health index including infant mortality, life expectancy, and hospital discharges. In the second stage, these efficiency scores are introduced into pooled OLS and panel mixed-effects models to assess their association with social outcomes, measured by both the Gini index and a multidimensional index of social inclusion. The results reveal wide cross-country differences in efficiency, with Germany, Austria, and Italy among the most efficient, while Romania, Latvia, and Bulgaria rank lowest. More importantly, the analysis demonstrates that greater efficiency in health systems is systematically associated with lower inequality and higher social inclusion. These findings suggest that efficiency in health resource allocation extends beyond improved health outcomes to broader societal benefits, reinforcing the case for policies that integrate fiscal sustainability, equity, and social cohesion within the European Social Model and the UN 2030 Agenda for Sustainable Development.

KEYWORDS: Social inclusion; health system efficiency; stochastic frontier analysis; panel data; social cohesion

1. Introduction

Understanding the relationship between health system efficiency and social inclusion is essential for advancing equitable and sustainable development in Europe. In the context of rising socio-economic disparities, demographic aging, and increasing fiscal pressures, the effi-

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cient allocation of health resources has become a central concern for policymakers. When health systems are able to achieve strong health outcomes while minimizing input use, they are not only more financially sustainable but also possess the potential to reduce inequality and enhance social cohesion.

The pursuit of more efficient health care systems has long been a key policy objective. This imperative was intensified following the 2007–2008 global financial crisis and, in Europe, the subsequent sovereign debt crisis of 2011–2012. These crises necessitated widespread fiscal consolidation and reinforced the need to rationalize public expenditure across all sectors, including health care, through spending review policies. Over the past four decades, health care expenditure as a share of GDP has increased substantially reaching 13.3% in OECD countries by 2016 underscoring the urgency of improving efficiency to ensure long-term financial sustainability.

An extensive body of empirical research has examined health system performance across various contexts, including OECD countries (e.g., Mobley and Magnussen, 1998[1]; Hollingsworth, 2003[2]; Osterkamp, 2004[3]; Retzlaff-Roberts et al., 2004[4]; Bhat, 2005[5]; Afonso et al., 2005[6]; Grosskopf et al., 2006[7]; Siciliani, 2006[8]; Hollingsworth, 2008[9]; Spinks and Hollingsworth, 2009[10]; Adam et al., 2011[11]; Mirmirani and Lippmann, 2011[12]; Sinimole, 2012[13]; Cetin and Bahce, 2016[14]; Carrillo and Jorge, 2017[15]; Ozcan and Khushalani, 2017[16]; Gavurova et al., 2021[17]), European Union member states (Afonso et al., 2010[18]; Jer-

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emic et al., 2012[19]; del Rocio Moreno-Enguix et al., 2018[20]; Lupu and Tiganasu, 2022[21]), and emerging economies (Herrera and Pang, 2005[22]; Afonso et al., 2010[23]; Moses et al., 2022[24]), employing a diverse set of socio-economic indicators.

Methodologically, much of this literature utilizes nonparametric production frontier techniques such as Free Disposable Hull (FDH-Deprins et al.,1984[25]) and Data Envelopment Analysis (DEA-Farrell, 1957[26]; Charnes et al.,1978[27]), which impose minimal restrictions on the data. More recent studies complement or replace these approaches with parametric methods, notably Stochastic Frontier Analysis (SFA) (e.g., Greene, 2004[28]; Greene, 2010[29]; Kumbhakar, 2010[30]; Varabyova and Schreyögg, 2013[31]; de Cos and Moral-Benito, 2014[32]; Hamidi and Akinci, 2016[33]).

Within this context, the present study has two primary objectives: (a) to estimate the efficiency scores identifying the efficiency degree of European health systems; and (b) to examine the potential role of health system efficiency on social inclusion, while controlling for socio-economic, demographic and in-

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[23] A. Afonso *et al.*, *op. cit.*

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stitutional variables. The empirical analysis covers 25 European countries over the period 2009-2019. Social exclusion/inclusion is assessed using two complementary measures: the Gini index, which is in fact a proxy for social exclusion, and a multidimensional index that captures various aspects of social participation and inclusion.

This research is situated within prominent international and regional policy frameworks, notably Sustainable Development Goal 3 ("Ensure healthy lives and promote well-being for all at all ages") and Goal 10 ("Reduce inequality within and among countries") of the United Nations 2030 Agenda, as well as the European Pillar of Social Rights, which underscores timely access to affordable, preventive, and curative health care alongside the right to social protection and inclusion.

The empirical strategy employs a two-stage approach. In the first stage, Stochastic Frontier Analysis (SFA) is used to estimate country-level health system efficiency scores by modelling the production of health outcomes as a function of relevant inputs. In the second stage, these efficiency scores serve as explanatory variables within a panel data framework using pooled Ordinary Least Squares (OLS) and panel mixed-effects models to investigate their association with social inclusion. The models incorporate a comprehensive set of socio-economic, demographic and policy control variables.

By empirically exploring the relationship between health system efficiency and wider measures of social inclusion and inequality, this study contributes to ongoing discussions on the societal benefits of health policy. The findings aim to inform evidence-based policymaking at both national and European levels, thereby supporting efforts to reinforce the social dimension of health systems consistent with the 2030 Agenda for Sustainable Development and the core values of the European Social Model.

2. Methodology and Data

The empirical analysis presented relies on a panel dataset covering 25 European countries over the period 2009–2019. The methodological approach follows a two-step strategy. In the first step, we estimate health system efficiency scores, using a parametric Stochastic Frontier Analysis (SFA). In the second these estimates are used as the central explanatory variable in the analysis of broader social outcomes through Ordinary Least Squares (OLS) and panel mixed-effects models. This sequential framework allows us not only to measure the performance of health systems in transforming resources into health outcomes but also to investigate the extent to which efficiency is associated with distributive dynamics and patterns of social inclusion.

In the first step, the efficiency of national health systems is assessed through a production frontier model that compares health outcomes with the resources employed to achieve them. We adopt a stochastic frontier approach, which is particularly suitable for distinguishing between inefficiency and random shocks or measurement errors. This step requires the definition of inputs and outputs in the health production process. Following the literature (e.g., Afonso and St. Aubyn, 2011[34]), we use per capita health expenditure as the input and a composite, multidimensional index of population health as the output.

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[34] A. Afonso, M. St. Aubyn, *Assessing health efficiency across countries with a two-step and bootstrap analysis*, in *Applied Economics Letters*, 18, 15, 2011, 1427-1430.

This Health Index (HI) is constructed using literature-based indicators (Mbau et al., 2023[35]). Specifically, it incorporates two health status indicators—infant mortality rate (IMR) and life expectancy (LE)—and a treatment-related indicator, hospital discharges (HD), which serves as a proxy for inpatient care provision (Castaldo et al., 2020[36]). Table 1 provides further details on the variables included.

Table 1. Basic Indicators for Health Index

Variables	Description	Source
Infant Mortality Rate (IMR)	Number of deaths under one year of age occurring among the live births in a given geographical area during a given year, per 1,000 live births occurring among the population of the given geographical area during the same year. In other terms, IMR is equal to (Number of children who died before 12 months) / (Number of born children) x 1,000	OECD
Life expectancy (LE)	Life expectancy at birth (how long, on average, a newborn can expect to live, if current death rates do not change)	OECD
Hospital discharges (HD)	Number of patients who leave a hospital after receiving care. Hospital discharge is defined as the release of a patient who has stayed at least one night in hospital. It includes deaths in hospital following inpatient care. Same-day discharges are usually excluded. This indicator is measured per 100,000 inhabitants	OECD

To ensure that all variables are positively oriented such that higher values indicate better outcomes—we transform the Infant Mortality Rate (IMR) by calculating 1000 – IMR, which reflects the number of children surviving their first year of life per 1,000 live births.

To enable comparability across indicators, we normalize each output variable by subtracting its minimum value and dividing by the range (maximum minus minimum)[37], following the methodology adopted in the construction of the Human Development Index (HDI), Afonso et al. (2005)[38] and Antonelli and De Bonis (2017[39]; 2019[40]) obtaining the following normalized variables ($V_{i,j,t}$) for each output:

$$0 \le V_{i,j,t} = \frac{x_{i,j,t} - x_{minj}}{x_{maxj} - x_{minj}} \le 1 \qquad (1)$$

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[35] R. Mbau, A. Musiega, L. Nyawira, B. Tsofa, A. Mulwa, S. Molyneux, E. Barasa, *Analysing the efficiency of health systems: a systematic review of the literature*, in *Applied health economics and health policy*, 21, 2, 2023, 205-224.

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[37] Where the minimum and maximum are computed over the entire panel.

[38] A. Afonso *et al.*, *op. cit.*

[39] M. A. Antonelli, V. De Bonis, *Social Spending, Welfare and Redistribution: A Comparative Analysis of 22 European Countries*, in *Modern Economy* 8, 2017, 1291-1313.

[40] M.A. Antonelli, V. De Bonis, *The efficiency of social public expenditure in European countries: a two-stage analysis*, in *Applied Economics*, 51, 2019, 47-60.

Where *i= 1, 2, 3….29* (countries); *j =1, 2, 3* (*IMR, LE, HD* output variables); *t = years*

The overall health output indicator (HI) for country *i* and time *t* is computed as follows:

$$HI_{i,t} = \sum_{j=1}^{3} V_{i,j,t} \qquad (2)$$

Table 2 presents the variables employed in the estimation of the efficiency scores, while Table 3 reports the ranking of countries according to the efficiency scores obtained.

Table 2. SFA-Based Input, Output, and Technical Efficiency Scores

Variables	**Description**	**Source**	**Unit of Measure**
Health indicator	Composite multidimensional index of overall health outcomes	Our elaboration on OECD and Eurostat data	Index
Health_Exp_pc	Per capita Health expenditure	Eurostat	Euro per inhabitant (at constant 2010 prices)
Efficiency scores	Health sector technical efficiency indicator	Our elaboration on OECD and Eurostat data	Index

At the top of the distribution, we find Germany, Austria, and Italy, which emerge as the most efficient systems in Europe. At the opposite end, Romania, Latvia, and Bulgaria display the lowest scores, highlighting the substantial heterogeneity that characterizes the continent.

Table 3. Efficiency scores (average value) and country rankings

Rank	Country	Efficiency score
1	Germany	0,964
2	Austria	0,947
3	Italy	0,925
4	Finland	0,916
5	Spain	0,915
6	Slovenia	0,910
7	Sweden	0,901
8	Norway	0,900
9	France	0,880
10	Greece	0,868
11	Czechia	0,861
12	Belgium	0,835
13	Denmark	0,777
14	Portugal	0,764
15	Estonia	0,764
16	Ireland	0,763

17	Luxembourg	0,750
18	Netherlands	0,675
19	Lithuania	0,630
20	Poland	0,610
21	Hungary	0,590
22	Slovakia	0,561
23	Bulgaria	0,546
24	Latvia	0,488
25	Romania	0,402

The variability in efficiency scores suggests that differences may also reflect contextual social and institutional factors, in addition to expenditures.

In the second step, our study explores whether the efficiency of the health sector exerts an influence beyond health itself, shaping social and distributive outcomes. To his purpose, we use the efficiency scores, obtained in the first step, as a key covariate to investigate their relationship with the social inclusion phenomenon across European countries, while controlling for socio-economic variables. Our empirical investigation is based on the following equation:

$$SO = \alpha_0 + \alpha_1 EFF_{HS_{i,t}} + \alpha_2 X_{i,t} + \alpha_3 Y_{i,t} + \alpha_4 Z_{i,t} + \alpha_5 Age\_Dep_{i,t} + T_t + \varepsilon_{i,t} \qquad (3)$$

Where the subscripts *i* and *t* respectively represent countries and time. Initially, we estimate a pooled OLS model with robust standard errors, followed by the application of a panel mixed-effects model that incorporates unobserved heterogeneity across countries and accounts for both intra- and inter-country variation. As dependent variables representing social outcomes (*SO*) capturing different aspects of inequality and inclusion. we employ two alternative measures: the Gini index (*GNI*), measured on a 0–100 scale, and a composite multidimensional index (*SOC_INC*) that reflects broader dimensions of social inclusion.

However, there is no single, universally accepted definition of social inclusion, more recent interpretations – such as that of Bellani and D'Ambrosio (2011)[41]; Giambona and Vassallo (2014)[42] – conceptualize it as an individual's capacity to participate meaningfully in the social, economic, and political spheres of society. Similarly, the European Commission (2004)[43] defines social inclusion as a process that ensures individuals at risk of poverty and exclusion have the necessary resources and opportunities to fully engage in economic, social, and cultural life, to attain an adequate standard of living, and to exercise their fundamental rights. In this vein, our composite indicator (*SOC_INC*) captures dimensions of economic marginalization and limited access to essential goods and services by aggregating the following varia-

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[41] L. BELLANI, C. D'AMBROSIO, *Deprivation, social exclusion and subjective well-being*, in *Social Indicators Research*, 104, 2011, 67–86.

[42] F. GIAMBONA, E. VASSALLO, *Composite indicator of social inclusion for European countries*, in *Social indicators research*, 116, 1, 2014, 269-293.

[43] EUROPEAN COMMISSION, *Joint report on social inclusion 2004*, Luxembourg, Office for Official Publications of the European Communities, 2004.

bles: the average of male, female, and youth unemployment rates, the poverty rate, and the housing cost overburden rate. All data are obtained from Eurostat[44].

Unemployment is included in the index, as employment serves not only as a fundamental source of income but also as an essential mechanism for social integration. It facilitates access to financial resources, social relationships, and active participation in society. Consequently, unemployment can contribute to social isolation and a diminished sense of self-worth.

Poverty often results in insufficient income to secure access to basic needs such as food, healthcare, education, and adequate housing, which are essential for maintaining minimum living standards.

The housing cost overburden rate – measuring the proportion of individuals living in households where total housing costs exceed 40% of disposable income – reveals less visible forms of poverty, capturing situations in which individuals may not fall below the poverty threshold yet still face substantial financial strain. High values may indicate housing insecurity and exclusion from adequate living conditions. Since all the previous variables are negatively oriented, they are transformed to have a positive orientation[45] and subsequently normalized using the same methodology described for the health indicator $HI_{i,t}$ in equations (1) and (2). As regressors, we include a set of control variables covering key dimensions of social inclusion: the health system efficiency (EFF_{HS}); socio-economic factors (X) such as GDP per capita and education population level; policy variables (Y) including social protection expenditure per capita and net replacement rate for the unemployed; labour market indicators (Z) as maternal employment rate and overall unemployment rate; and a demographic variable reflecting the population composition, measured by the age dependency ratio (Age_Dep). Finally, in eq. (3) T represents years fixed effects and ε is a well-behaved error term distributed IID (0, σ2). All variables are described in the following Table 4.

Table 4. Variables description

Variables	**Description**	**Source**	**Unit of Measure**
Health indicator (HI)	Composite multidimensional index of overall health outcomes	Our elaboration on OECD and Eurostat data	Index
Health_Exp_pc	Per capita Health expenditure	Eurostat	Euro per inhabitant (at constant 2010 prices)
EFF_{HS} *(Efficiency scores)*	Health sector technical efficiency indicator	Our elaboration on OECD and Eurostat data	Index
SOC_INC	Composite multidimensional index of social inclusion	Our elaboration on Eurostat data	Index
GNI	Gini index	Eurostat	Index (scale 0-100)

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[44] A detailed description of the variables is provided in Appendix (table A1).

[45] In this case all the variables (x_i) are expressed in percentages. Then, to give them a positive orientation we use the transformation 100- x_i.

GDPpc	The indicator is calculated as the ratio of real GDP to the average population of a specific year	Eurostat	Euro per capita, Chain Linked Volumes (2010)
Unemployment	Unemployment rate per population 15-74 years	Eurostat	Percentage
SOC_Exp_pc	Expenditure on social protection per capita	Eurostat	Euro per inhabitant (at constant 2010 prices)
NRR	Net replacement rate in unemployment: net unemployment benefits as a percentage of previous net earnings, indicating the income support level for unemployed individuals (calculated for a single person without children, earning 67% of the average wage)	OECD	Percentage
MTE	Maternal employment rate: employment rate for women (15-64 years old) by the presence of at least one child (aged 0-14)	Eurostat	Percentage
Age_Dep	Age dependency ratio: ratio of people older 64 to working age population (15-64)	World Bank, World Development Indicators	Percentage
Edu	Percentage of population from 15 to 74 years with upper secondary, post-secondary non-tertiary and tertiary education (levels 3-8)	Eurostat	Percentage

In conducting the second-stage analysis, we rely on two complementary estimation strategies: a pooled Ordinary Least Squares (OLS) model and a panel mixed-effects model. The use of pooled OLS provides a straightforward benchmark, offering an overall picture of the association between efficiency and social outcomes by pooling all country-year observations together. However, this approach does not fully account for the fact that countries differ in persistent ways that cannot be directly observed. For this reason, we also employ a mixed-effects panel model, which explicitly incorporates unobserved heterogeneity across countries while still allowing us to exploit the time variation in the data. By combining the two methods, we strengthen the robustness of the findings: if the results hold under both specifications, we can be more confident that they are not simply driven by country-specific characteristics or short-term fluctuations but rather reflect a systematic relationship between health system efficiency and social inclusion.

3. Descriptive Statistics

Table 5 presents the descriptive statistics—number of observations, mean, standard deviation, minimum, and maximum—for the variables included in the analysis. The Health Indicator (*HI*) ranges from 0.785 to 2.402, with a mean value of 1.83, while health expenditure per capita exhibits considerable variation, ranging from €183 to over €5,200. This highlights significant disparities in health resource allocation across countries. The efficiency score (EFF_{HS}) for national health systems averages 0.77, with a range from 0.30 to 0.99, indicating varying degrees of system performance.

Table 5. Descriptive Statistics

Variable	Obs	Mean	Std. Dev.	Min	Max
HI	275	1.834	0.356	0.785	2.402
Health_Exp_pc	275	1917.728	1380.252	182.62	5236.31
EFF_{HS}	275	0.766	0.169	0.299	0.987
SOC_INC	275	0.715	0.143	0.107	0.944
GNI	275	29.621	4.095	20.9	40.8
GDPpc	275	27930.51	18882.96	4970	84750
Unemployment	275	8.945	4.804	2	27.5
SOC_Exp_pc	275	7176.732	5154.078	825.56	18641.75
NRR	275	70.284	11.954	35	97
MTE	262	70.097	8.939	50.729	86.57
Age_Dep	275	27.165	4.24	16.244	36.173
Edu	275	72.256	11.484	27.8	88.9

Social inclusion (*SOC_INC*) shows a mean of 0.72, but values as low as 0.11 point to marked disparities in levels of inclusion. Similarly, the Gini index, ranging from 20.9 to 40.8, and GDP per capita, spanning from €4,970 to €84,750, reflect diverse income distributions and levels of economic development.

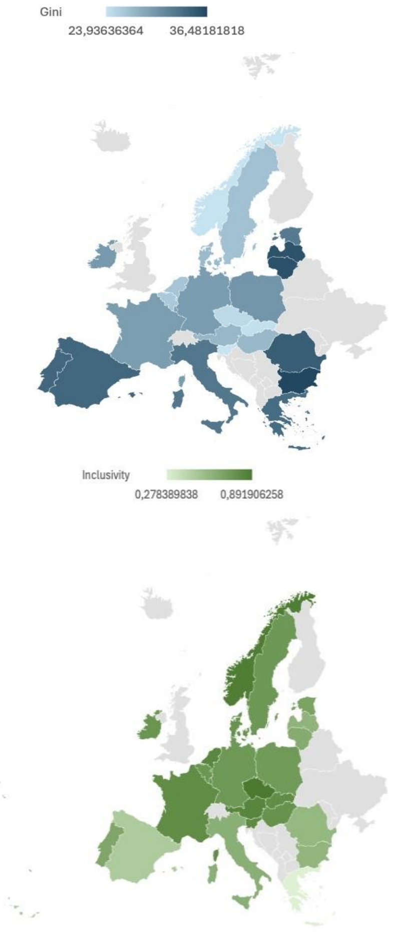
On average, 72% of individuals aged 15–74 have attained education levels ranging from upper secondary to tertiary education.

Social policy indicators also display substantial variation: social expenditure per capita ranges from €826 to over €18,600, and the net replacement rate for the unemployed averages 70.3%.

The average maternal employment rate is relatively high (mean = 70.1%, SD = 8.9) and exhibits greater variability across countries compared to the unemployment rate, which has a mean of 8.95% and a standard deviation of 4.8. Finally, the age dependency ratio averages 27.2%, reflecting differences in demographic pressures across national contexts.

To visualize the geographical distribution of income inequality and social inclusion, Figures 1 presents the maps of the Gini index and the Social Inclusion Indicator index across Europe.

Figure 1. Geographical distribution of the Gini Index and the Social Inclusion Indicator



The comparison shows that Northern and Western European countries generally perform better in terms of inclusivity, while higher inequality levels are observed in several Southern and Eastern member states. These patterns confirm well-known divides within Europe but also offer a spatial dimension that is useful for interpreting the statistical results.

The relationship between efficiency of national health systems and social outcomes is then illustrated by means of scatter plots. Figure 2 relates the efficiency scores to the Gini index, displaying a negative association: countries with more efficient health systems tend to record lower levels of income inequality.

Figure 2. Relationship between Income Inequality and Efficiency of the Health Systems

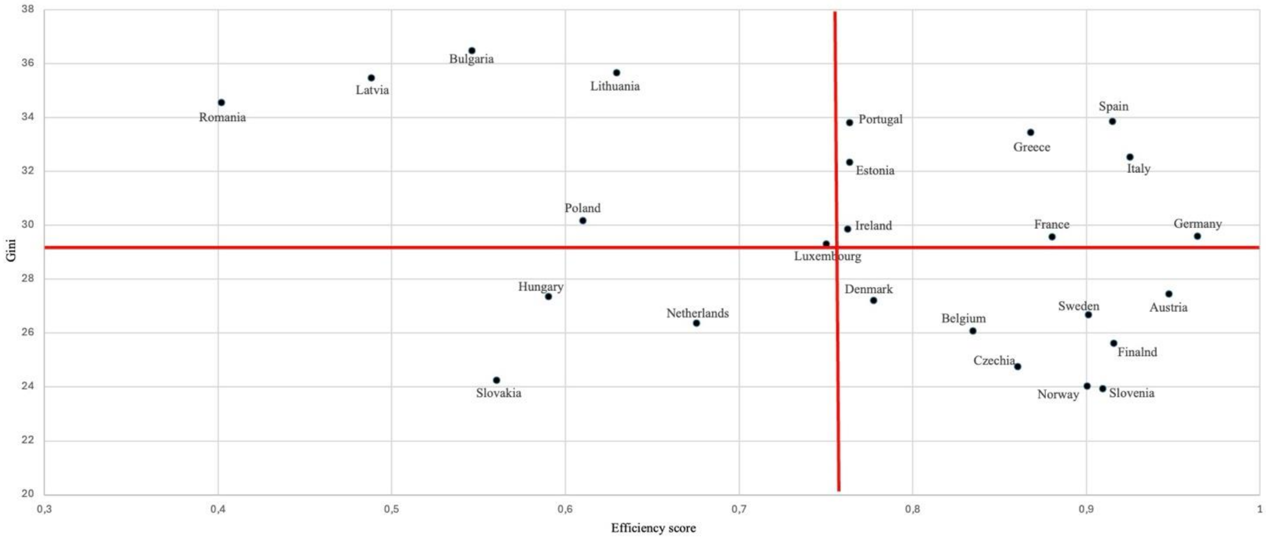
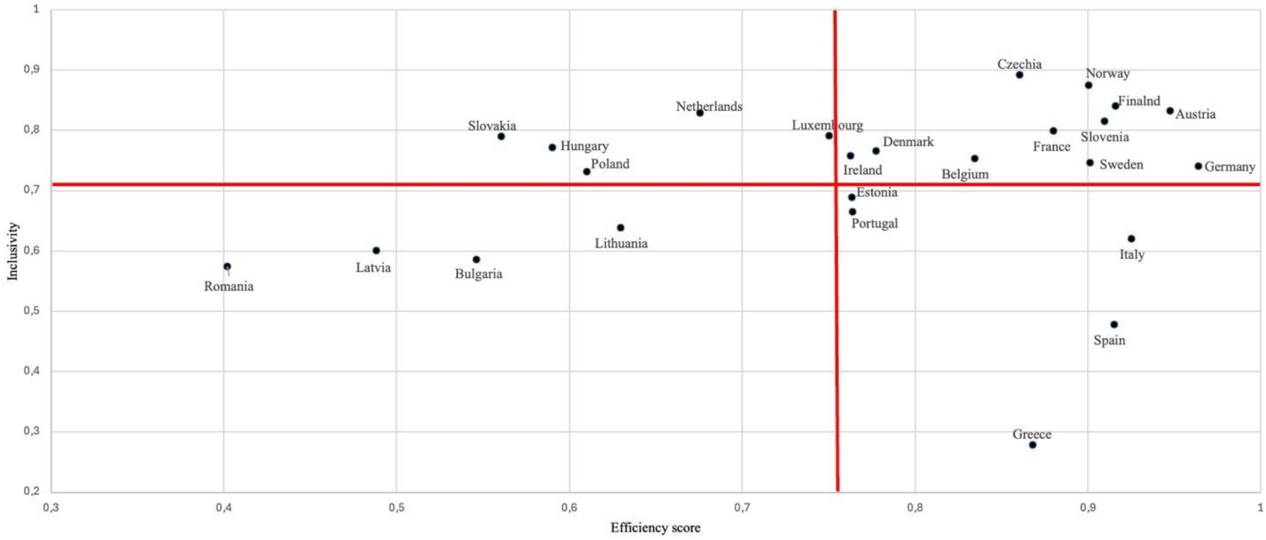


Figure 3 shows the connection between efficiency scores and the Social Inclusion index, highlighting instead a positive association: higher efficiency correlates with more inclusive societies.

Figure 3. Relationship between the Social Inclusion Indicator and the Efficiency of the Health Systems



While these relationships do not establish causality in a strict sense, they provide robust evidence of a systematic link between the way health resources are employed and the quality of social and distributive outcomes.

In summary, the two-step methodology adopted here makes it possible to move from the measurement of efficiency within health systems to the evaluation of its potential societal implications. By combining frontier analysis with panel econometrics, the study contributes to a better understanding of how health policy performance and resource allocation are connected with broader goals of social cohesion and equity. This approach situates the debate within the European policy context, where the challenge of ensuring sustainable health systems is increasingly intertwined with the pursuit of inclusive and balanced development.

4. Estimation Results

The results of the econometric analysis are summarized in Table 6, which reports both pooled OLS estimates and linear mixed-effects models for the two alternative dependent variables, the Inclusivity index and the Gini coefficient. Overall, the findings indicate a robust and consistent relationship between health system efficiency and social outcomes across specifications, confirming the central role of efficiency as identified in the first step of the empirical strategy.

Table 6. Estimation Results

Variables	OLS Dependent variable: Social Inclusion	MIXED Dependent variable: Social Inclusion	OLS Dependent variable: Gini index	MIXED Dependent variable: Gini index
EFF_{HS}	0.0687*** (0.0159)	0.0626*** (0.0155)	-0.141*** (0.0345)	-0.140*** (0.0330)
GDPpc	-0.107*** (0.0298)	-0.129*** (0.0273)	0.378*** (0.0518)	0.367*** (0.0495)
Unemployment	-0.132*** (0.0123)	-0.127*** (0.0116)	0.0758*** (0.0144)	0.0785*** (0.0140)
SOC_Exp_pc	0.0878*** (0.0234)	0.107*** (0.0205)	-0.336*** (0.0382)	-0.328*** (0.0369)
NRR	0.00174*** (0.000301)	0.00176*** (0.000303)	-0.00155*** (0.000449)	-0.00153*** (0.000426)
MTE	0.00103** (0.000435)	0.000930** (0.000418)	0.000993 (0.000708)	0.000949 (0.000658)
Age_Dep	-0.195*** (0.0266)	-0.223*** (0.0278)	0.410*** (0.0615)	0.401*** (0.0514)
Edu	0.0746*** (0.0243)	0.0715*** (0.0244)	-0.241*** (0.0276)	-0.239*** (0.0266)
Time	YES	YES	YES	YES
Constant	1.291*** (0.228)	1.441*** (0.239)	2.001*** (0.414)	2.049*** (0.375)
Countries	25	25	25	25
Observations	239	239	239	239
F.stat or Wald chi2	27.26***	461.71***	37.49***	651.51***
R-squared	0.730	-	0.587	-

When considering social inclusion as the dependent variable, the coefficient of the efficiency score is positive and statistically significant in both models. This suggests that countries whose health systems use resources more efficiently also tend to achieve higher levels of social inclusion. The result is in line with the idea that efficiency in the allocation of health expenditure does not merely translate into better health outcomes but also contributes to creating more inclusive societies, where access to opportunities and participation is more equally distributed. The effect remains stable across estimation techniques, further strengthening its robustness. The positive association identified in the estimates is visually consistent with the pattern already highlighted in Figure 4, where higher efficiency scores are correlated with stronger inclusivity.

Turning to the regressions with the Gini index as the dependent variable, the estimated coefficient of the efficiency score is negative and highly significant. This implies that more efficient health systems are associated with lower levels of income inequality. In other words, efficiency in the health sector appears to play a redistributive role, narrowing the gap between higher- and lower-income groups. The consistency of this finding across both pooled OLS and mixed-effects models provides compelling evidence that the link between efficiency and inequality is not driven by model specification or country-specific unobservable. Once again, the statistical results confirm the descriptive evidence shown in Figure 3, where countries with higher efficiency tend to cluster at lower levels of inequality.

Beyond efficiency, the estimates for the control variables also offer important insights. Social protection expenditure per capita exerts the expected effect, being positively associated with inclusivity and negatively with inequality, thereby highlighting the relevance of welfare transfers in shaping distributive outcomes. The net replacement rate (NRR) and maternal employment (MTE) are positively correlated with inclusivity and negatively with inequality, underlining the role of income support and gender-related factors in fostering more equitable societies. Conversely, GDP per capita displays a negative association with inclusivity and a positive one with inequality, suggesting that economic growth alone does not automatically guarantee cohesive social outcomes. Education contributes positively to inclusivity and reduces inequality, in line with its role in enhancing human capital and opportunities. Finally, unemployment and age dependency ratios are negatively associated with inclusivity and positively with inequality, reflecting their impact on vulnerability and social fragmentation.

Taken together, these findings provide a coherent picture of the channels through which health system efficiency interacts with broader social dynamics. Efficient health systems not only succeed in transforming spending into better health outcomes but also contribute to reducing income disparities and strengthening social participation. The stability of the results across alternative specifications and dependent variables reinforces the validity of these conclusions, while the graphical evidence provided by the scatter plots further illustrates the systematic nature of these relationships. This supports the hypothesis that efficiency in the health sector has a significant and beneficial impact on social cohesion in Europe.

5. Conclusions

This paper has explored the relationship between health system efficiency and broader social outcomes in Europe over the decade 2009–2019. By combining a two-step empirical strategy with a rich panel of 25 countries, the analysis has shown that efficiency in the health sector is not only a matter of internal performance but also a factor with far-reaching social consequences. The results provide consistent evidence that health systems capable of generating good health outcomes efficiently, are also those more likely to sustain higher levels of social inclusivity and to reduce income inequality.

The first step of the analysis provide a measure of the health systems efficiency by estimating how effectively per capita health expenditure is transformed into a multidimensional health outcome indicator. The resulting scores revealed striking cross-country differences: while Germany, Austria and Italy emerged among the most efficient health systems, countries such as Romania, Latvia and Bulgaria lagged behind. These gaps underscore the relevance of institutional capacity and governance quality in shaping how resources are converted into tangible results, beyond the sheer level of spending.

The second step demonstrated that efficiency has a significant bearing on distributive outcomes. Regression results indicated a positive and robust association between efficiency scores and social inclusivity, as well as a negative and equally strong relationship with the Gini coefficient of inequality. In practical terms, this means that efficiency in health care is not only fiscally desirable, but it also promotes a fairer and more cohesive society. Scatter plots provided additional visual confirmation of these relationships, making clear that more efficient countries are systematically better positioned in terms of both inclusion and equality.

From a policy perspective, these findings carry important implications. First, they suggest that efforts to improve efficiency in health systems through better management of resources, evidence-based allocation, and innovation in service delivery can generate benefits that extend well beyond the health sector itself. A more efficient health system reinforces social cohesion, contributes to reducing inequality, and strengthens the inclusiveness of economic growth. Second, the results highlight the importance of complementing efficiency improvements with broader social policies. Investments in education, gender equality, and employment opportunities emerge as critical complements that amplify the redistributive potential of efficient health systems. Finally, public policies matter: social expenditure and income support measures foster social inclusion, underscoring the importance of redistributive public intervention.

In conclusion, health system efficiency should be seen as a cornerstone of a broader development strategy in Europe. Far from being a purely technical issue, it is intrinsically linked to the social dimension of growth and to the ability of societies to ensure equal opportunities for all citizens. Policymakers aiming to reconcile fiscal sustainability with social cohesion would therefore do well to treat efficiency not as an end in itself but as a key driver of inclusive and equitable development.

6. Appendix

Table A1. Basic indicators for the Social Inclusion indicator

Variables	Description	Source
Unemployment rate (average value)	Male unemployment rate: number of unemployed males, expressed as a percentage of the male labour force (aged 15–74)	Eurostat
	Female unemployment rate: number of unemployed females, expressed as a percentage of the female labour force (aged 15–74)	Eurostat

	Youth unemployment rate: share of unemployed individuals aged 15 to 24 expressed as a percentage of the labor force in that same age group	Eurostat
Poverty rate	At-risk-of-poverty-rate (AROP): share of persons with an equivalised disposable income below the risk-of-poverty threshold (60% median income)	Eurostat
Housing cost overburden rate	Percentage of the population living in households where the total housing costs ('net' of housing allowances) represent more than 40 % of disposable income	Eurostat

Ethical, Deontological and Regulatory Challenges in Contemporary Clinical Trials: Implications for Scientific Research Institutions in the EU

Francesco Rossi, Mario Gaio, Annamaria Mascolo, Rosanna Ruggiero*

ABSTRACT: Clinical trials are fundamental to biomedical research, enabling the systematic evaluation of new drugs, devices, and interventions for safety and efficacy. Conducted in progressive phases, they follow rigorous ethical, scientific, and regulatory standards to ensure participant protection and data reliability. Despite their pivotal role in medical innovation, trials are resource-intensive and financially demanding. Ethical frameworks such as the Declaration of Helsinki and Good Clinical Practice guide their conduct, while post-marketing surveillance ensures ongoing safety monitoring. The role of clinical trials, together with their ethical and institutional aspects, is examined with particular attention to current challenges and regulatory developments.

KEYWORDS: Clinical trials; drug development; regulatory compliance; good clinical practice; ethics; deontology

1. Clinical Trials: Definition and Characteristics

Clinical trials are a type of research designed to investigates novel treatments and tests, assessing their impact on human health outcomes.[1] According to the definition provided by the National Institutes of Health (NIH), a study can be classified as a clinical trial if it meets the following four criteria:

- The study involves human participants,
- The participants are prospectively assigned to an intervention,
- The study is designed to evaluate the effect of the intervention on the participants,
- The effect is being evaluated on a health-related biomedical or behavioural outcome.

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[1] https://www.who.int/health-topics/clinical-trials/#tab=tab_1 (last visited 15/10/2025).

Importantly, the NIH definition of a clinical trial still applies even if the study includes healthy participants, lacks a comparison group (e.g., placebo or active control), is focused solely on assessing pharmacokinetics, safety, and/or maximum tolerated dose of an investigational drug, involves a behavioural intervention, or measures intent to change behaviour, as long as at least one aim or sub-aim of the study qualifies as a clinical trial.[2]

Clinical trials are conducted after preclinical investigations, which include animal studies and assessments of drug production and purity. These preclinical phases focus on evaluating the drug's safety in doses approximating human exposures, as well as its pharmacodynamics and pharmacokinetics. After these stages, clinical trials are carried out in four phases, each with a distinct purpose. Researchers actively recruit new participants for each phase.

Phase I trials (also referred as "dose escalation" or "human pharmacology" studies) are the first trials testing the experimental drug in humans, typically in a small group of healthy or diseased volunteers. The aim of Phase I is to assess the safety and determined the maximum tolerated dose of the drug, but also its pharmacokinetics.

Phase II trials (also referred as "therapeutic exploratory" trials) are performed in a small group of participants who have the disease of interest. This phase is designed to test safety, pharmacokinetics and pharmacodynamics, and may also gather data to inform the design of Phase III trials (such as determining optimal doses, dosing frequencies, administration routes, and endpoints). Phase II trials may also offer preliminary evidence of drug efficacy; however, the small number of participants limit supports the necessity of a subsequent Phase III trials.

Based on prior studies, Phase III trial (also referred as "therapeutic confirmatory", "comparative efficacy", or "pivotal trial") involve a larger and often more diverse population. Their main aim is to confirm or refute the drug's efficacy and identify common adverse reactions. Phase III trials are most commonly "superiority" trials, where the experimental drug is compared to a standard therapy or a placebo. Another type of Phase III trial is the "equivalence" or "positive-control" trial, designed to verify if the experimental treatment is similar to the chosen comparator. A variation of the equivalence trial is the "non-inferiority" study, which seeks to prove that the experimental treatment is not less effective than the standard by a pre-specified margin.

A hallmark of Phase III trials is treatment allocation balance, achieved through randomization. This method helps to eliminate confounders and any biases between treatment groups. Additionally, Phase III trials are often "blinded" (or masked) to minimize assessment bias. Blinding strategies can include single blinding (subject only), double blinding (both subject and investigator), or triple blinding (data analyst, subject, and investigator).

All clinical trials for marketing authorization of human medicines in the European Union must comply with EU clinical trial regulations, while trials conducted outside the EU must adhere to ethical standards equivalent to those in the European Economic Area, including international good clinical practice and the Declaration of Helsinki.[3]

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[2] https://grants.nih.gov/policy-and-compliance/policy-topics/clinical-trials/definition (last visited 15/10/2025).

[3] J.I. Halonen, M. Erhola, E. Furman, *et al., The Helsinki Declaration 2020: Europe that protects*, 4, 11, 2020, e503-e505.

Once a drug is approved, regulatory agencies may require Phase IV (post-marketing) studies. These observational studies evaluate the long-term effects of the drug, including less common adverse reactions, and assess its cost-effectiveness or effectiveness in populations or conditions different from those in the original trials. Post-marketing studies are essential because pre-marketing (Phase III) trials often do not capture rare side effects or long-term outcomes. Approximately 20% of drugs receive new black box warnings after marketing approval, and most post-marketing drug withdrawals are due to previously unanticipated adverse reactions.

The structured progression of clinical trial phases ensures methodological rigor but also reveals increasing complexity: each phase adds ethical, logistical, and financial burdens. This tension between scientific robustness and operational feasibility highlights the need for updated governance models capable of integrating ethical, regulatory, and technological dimensions.

This sets the stage for understanding why clinical trials are not only scientific tools but also ethical and institutional challenges.

2. The Importance of Clinical Trials in Drug Development

Clinical trials constitute a cornerstone for advancing biomedical knowledge and improving clinical outcomes in patients. They provide robust evidence on disease pathophysiology, treatment efficacy and safety, and interindividual variability in therapeutic response. These studies deepen scientific understanding, inform future research directions, and support regulatory decision-making processes. The evidence generated serves as the foundation for marketing authorization of medicinal products and fosters the development of innovative therapeutic interventions for the benefit of public health and patients worldwide. However, approximately 90% of clinical trials fail to obtain regulatory approval.[4] Beyond the substantial economic losses associated with unsuccessful studies, such failures delay patient access to potentially life-saving therapies and raise important ethical concerns, as participants may be exposed to risks without deriving direct therapeutic benefits.[5]

Clinical trials constitute an indispensable scientific mechanism but also expose profound challenges: high failure rates, escalating costs, and ethical tensions related to risk–benefit balance. These issues demonstrate the need for not only methodological improvement but also institutional strategies that reconcile innovation with ethical responsibility. This leads naturally to the ethical-deontological questions examined in the next section.

3. Ethical and Deontological Aspects of Clinical Trials

Although the ethical conduct of medicine had been a central concern since antiquity, it was only in 1947 that ethical principles to guide medical research were first codified.[6] The Nuremberg Code, born from the homonymous International Military Tribunal, established ethical principles for biomedical experi-

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[4] D. SUN, W. GAO, H. HU, S. ZHOU, *Why 90% of clinical drug development fails and how to improve it?*, in *Acta pharmaceutica Sinica B*, 12, 7, 2022, 3049-3062.

[5] D.A. ZARIN, S.N. GOODMAN, J. KIMMELMAN, *Harms From Uninformative Clinical Trials, in Journal of the American Medical Association*, 322, 9, 2019, 813–814.

[6] E. SHUSTER, *Fifty years later: the significance of the Nuremberg Code,* 337, 20, 1997, 1436–1440.

mentation. This Code was further developed by the World Medical Association's Declaration of Helsinki in 1964.[7] In 1996, the International Conference on Harmonization of Good Clinical Practice (GCP) achieved an international standard for the design, conduct, recording and reporting of clinical trials involving humans. GCP was later endorsed by the EU Clinical Trials Directive 2001/20/EC, which has been replaced by the EU Clinical Trials Regulations 536/2014 (CTR 2014).[8]

Specifically, prior to the trial, the foreseeable risks and inconveniences must be weighed against the potential benefits for the individual subjects and future patients, ensuring that the risks are justified. The safety, rights, and well-being of participants must be the primary consideration, taking precedence over scientific and societal interests. Sufficient non-clinical and clinical data must be available to support the trial, which should follow a clear, detailed protocol approved by an ethics committee. Medical care and decisions regarding the trial subjects are the responsibility of qualified healthcare professionals, and all individuals involved in the trial must have the appropriate qualifications and experience for their assigned tasks.

Freely given informed consent must be obtained from all participants before enrolling in the trial, and all clinical trial data must be recorded, managed, and stored in a way that ensures subject confidentiality in compliance with data protection laws. Investigational medicinal products used in the trial must be manufactured, imported, handled, and stored according to the Good Manufacturing Practice (GMP) guidelines and used according to the approved protocol. Systems and procedures must be in place to assure the quality of all aspects of the trial.

In the context of clinical trials, the Code of Ethics represents an additional layer of assurance, ensuring that researchers and healthcare professionals involved are committed to protecting the rights and well-being of participants. It defines a set of ethical and behavioral principles that guide the conduct of healthcare professionals, emphasizing the importance of personal and collective responsibility in carrying out clinical research. Key principles include respect for human dignity, which requires treating every participant fairly and without discrimination, and the duty to act always in the patient's best interest, avoiding conflicts of interest that could compromise the integrity of the study. Furthermore, the Code of Ethics highlights the need to maintain professional competence through continuous education and specific training on trial protocols, in order to guarantee high standards of quality and safety. Another fundamental aspect concerns the protection of privacy and confidentiality, which implies careful management of personal and sensitive data collected during the trial, in compliance with current data protection regulations. Finally, the Code of Ethics serves as a guide in managing the difficult ethical situations that may arise during research, promoting an attitude of transparency, honesty, and responsibility towards participants and the scientific community.

Recent research is bringing to light a series of new ethical challenges that traditional frameworks were not fully designed to address. For instance, decentralized clinical trials (DCTs) redistribute responsibilities across clinical sites and digital platforms, making it less clear who is accountable for ensuring participant safety and data integrity. Moreover, the use of artificial intelligence in patient recruitment and automated monitoring adds further complexity. It raises concerns about the transparency of algorithmic

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[7] WORLD MEDICAL ASSOCIATION, *World Medical Association Declaration of Helsinki: ethical principles for medical research involving human subjects*, 310, 20, 2013, 2191–2194.

[8] https://eur-lex.europa.eu/eli/reg/2014/536/oj/eng (last visited 15/10/2025).

decisions and the possibility of bias influencing who gets selected for a study or how their data is interpreted. At the same time, continuous data collection through wearable devices pushes the boundaries of conventional informed consent. Participation is no longer confined to specific research encounters but involves an ongoing flow of potentially sensitive information. Finally, the integration of real-world data complicates efforts to protect privacy and forces researchers to confront difficult questions about long-term data governance, including how information should be stored, who can access it, and for what purposes.

Foundational ethical principles remain essential, yet they require reinterpretation in the context of digitalization and decentralization. The evolving ecosystem demands dynamic ethical governance that goes beyond static regulatory frameworks and actively addresses new technological risks. These ethical tensions intersect with the equally challenging economic landscape of modern clinical trials.

4. Economic Aspects of Clinical Trials

Clinical trials represent one of the most expensive aspects of drug development. Trial costs vary widely across phases, ranging from approximately $1-4 million for Phase I studies to over $100 million for Phase III.[9] High costs stem from several core components: study design and regulatory submissions, patient recruitment and retention, site operations, laboratory and imaging assessments, investigational product manufacturing, and data management systems that ensure compliance with Good Clinical Practice (GCP) and international standards. Moreover, qualified personnel, such as investigators, coordinators, statisticians, and regulatory experts, represent a significant share of total expenditures. Regional differences are also substantial. The United States remains the most expensive location for clinical research due to high labor and infrastructure costs and rigorous regulatory expectations. Western Europe offers a balance between cost and quality, while Eastern Europe, Asia-Pacific, and Latin America provide more cost-efficient environments, albeit with additional challenges related to regulatory harmonization, logistics, and oversight.

To address rising expenses, sponsors increasingly adopt adaptive trial designs, decentralized and hybrid models, and artificial intelligence (AI)-driven tools for patient recruitment and data analysis. Strategic partnerships with Contract Research Organizations (CROs) and academic institutions further enhance operational efficiency.

5. Post-Marketing Evaluation Methods

Post-market surveillance (PMS) allows manufacturers to monitor the performance of pharmacological therapies by gathering and analyzing real-world usage data. The Commission Delegated Regulation (EU) No. 357/2014 establishes that competent authorities may impose obligations to confirm the efficacy of human medicinal products through post-authorization efficacy studies (PAES) and post-authorization

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[9] A. Sertkaya, T. Beleche, A. Jessup, B.D. Sommers, *Costs of Drug Development and Research and Development Intensity in the US, 2000-2018*, in *JAMA Network Open*, 7, 6, 2024; M. Schlander, K. Hernandez-Villafuerte, C.Y. Cheng, J. Mestre-Ferrandiz, M. Baumann, *How Much Does It Cost to Research and Develop a New Drug? A Systematic Review and Assessment,* in *PharmacoEconomics*, 39, 11, 2021, 1243–1269.

safety studies (PASS). The results from PAES complement existing efficacy data and could potentially influence the benefit-risk balance of a medicinal product or its accompanying product information. A PAES may be mandated either at the time of marketing authorization (when efficacy concerns can only be addressed post-marketing) or after authorization, if new insights into the disease, clinical methodology, or real-world product usage indicate that previous efficacy evaluations need substantial revision. PASS studies focus on assessing the safety and benefit-risk profile of a medicine, assisting in regulatory decision-making. These studies aim to identify, characterize, or quantify safety risks, confirm the safety profile of a medicine, or evaluate the effectiveness of risk management strategies. PASS studies can be either clinical trials or non-interventional studies.[10]

Additionally, the European Medicines Agency (EMA) oversees Pharmacovigilance within the EU.[11] Pharmacovigilance involves the detection, assessment, understanding, and prevention of adverse effects or other medicine-related problems. The EU's pharmacovigilance system is a collaborative effort between EU Member States, the EMA, and the European Commission. The Pharmacovigilance Risk Assessment Committee (PRAC), part of the EMA, is tasked with assessing and monitoring the safety of human medicines. PRAC prioritizes and evaluates safety signals (i.e., an information suggesting a potential adverse effect caused by a medicine) and issues recommendations based on its findings. These recommendations may include the need for further investigation (e.g., conducting a PASS study), no further action, or regulatory actions such as updating product information.

Post-marketing evaluation highlights the limitations of pre-approval evidence and reinforces the continuity of ethical responsibility beyond authorization. Real-world data introduce new methodological opportunities but also new governance and privacy challenges. This ongoing monitoring underscores the critical role of scientific institutions in managing the complexity of modern clinical research.

6. Scientific Institutions and Their Role in Clinical Trials

Clinical research within the European Union is undergoing a profound transformation following the full application of Regulation (EU) No. 536/2014 on 31 January 2022, which replaces Directive 2001/20/EC[12]. This regulation, known as the EU Clinical Trials Regulation (CTR), introduces a harmonized framework for the assessment and supervision of clinical trials across Member States, aiming to enhance efficiency, promote innovation, and reduce duplication of effort.

The CTR seeks to create a research environment that is both competitive and transparent. Its objectives include facilitating multinational trials, ensuring high standards of participant safety, and promoting public accessibility of clinical trial information. To this end, the European Medicines Agency (EMA) has implemented the Clinical Trials Information System (CTIS), a centralized digital platform designed to manage the submission, assessment, and supervision of all clinical trials conducted within the EU[13]. The

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[10] B.M. Cesana, E.M. Biganzoli, *Phase IV Studies: Some Insights, Clarifications, and Issues*, in *Current Clinical Pharmacology*, 13, 1, 2018, 14-20.

[11] P. Beninger, *Pharmacovigilance: An Overview*, Clinical Therapeutics, 40, 12, 2018, 1991–2004.

[12] C. Petrini, *Regulation (EU) No 536/2014 on clinical trials on medicinal products for human use: an overview*, in *Annali dell'Istituto Superiore di Sanità*, 50, 4, 2014, 317-21.

[13] Z. Zemla-Pacud, G. Lenarczyk, *Clinical Trial Data Transparency in the EU: Is the New Clinical Trials Regulation a Game-Changer?*, in *IIC - International Review of Intellectual Property and Competition Law*, 54, 5, 2023, 732–763.

CTIS enhances coordination, supports decision-making among Member States, and ensures the publication of comprehensive trial information for both professionals and the public.

While the EMA manages the CTIS and oversees publication of trial data, the authorization and supervision of individual studies remain the responsibility of national competent authorities. In Italy, these responsibilities are coordinated by the Italian Medicines Agency (AIFA), which serves as the competent authority for clinical trials of medicinal products. Other national stakeholders include the Italian National Institute of Health (ISS), which provides advisory opinions for Phase I studies, the Ethics Committees, responsible for ethical review and approval, and the hospital Directorates General, which manage contractual agreements.

As part of the European network of clinical trial authorities, AIFA plays a central role in aligning Italian procedures with European standards. To support the consistent application of the CTR, AIFA publishes national guidelines and training materials, supplementing resources issued by the European Commission and EMA.

In August 2024, AIFA released new Guidelines on the Simplification and Decentralization of Clinical Trials, published in the Gazzetta Ufficiale on 20 August 2024. Developed by a technical working group established by the Ministry of Health (Decree of 11 January 2024), these guidelines aimed to modernize clinical research processes for medicinal products by simplifying procedures, promoting digitalization, and integrating decentralized elements in line with the European ACT EU (Accelerating Clinical Trials in the EU) initiative. The guidelines address several key areas: the use of third-party service providers in activities related to clinical studies, the reimbursement and compensation for trial participants, the home delivery of investigational medicinal products, and the allocation of costs associated with investigational and auxiliary products.

The National Observatory on Clinical Trials (OsSC) represents another pillar of Italy’s research infrastructure. The OsSC manages the authorization process for Phases I–IV clinical trials, provides real-time data on national research activity, and interfaces with the European EudraCT database. It facilitates electronic submissions of clinical trial applications and substantial amendments, ensuring simultaneous transmission to AIFA and the relevant Ethics Committees. At the European level, the OsSC serves as a model for digital workflow integration, promoting transparency, efficiency, and harmonization in clinical research governance.

Through these coordinated institutional efforts (at both the European and national levels) the EU continues to strengthen its position as a global leader in clinical research, combining scientific rigor, regulatory transparency, and patient-centered innovation.

Scientific institutions operate in an increasingly complex governance ecosystem that requires coordination across European and national levels. Their role is no longer limited to administrative oversight but involves strategic adaptation to digitalization, decentralization, and new regulatory paradigms.

A meaningful comparative perspective emerges when considering the different regulatory approaches adopted in the European Union and the United States. While the EU CTR establishes a centralized, cooperation-based governance model through the CTIS and coordinated assessment among Member States, the U.S. Food and Drug Administration (FDA) maintains a more unilateral, agency-driven framework that places stronger emphasis on rapid trial activation and early industry-regulator dialogue (e.g., IND meetings, Fast Track and Breakthrough Therapy designations). Furthermore, unlike the EU system, which requires ethics review to be integrated at national and regional levels, the U.S. model relies primarily on Institutional Review Boards (IRBs), resulting in more localized ethical oversight. These structural differences shape operational practices: the EU prioritizes harmonization, transparency, and cross-country consistency, whereas the FDA system emphasizes flexibility, speed of development, and earlier regulatory engagement. For scientific institutions, understanding these divergent regulatory cultures is essential, as they influence protocol design, timelines, the integration of decentralized and digital elements, and the overall governance of clinical trial networks[14].

7. Conclusion

In light of the considerations discussed above, it becomes clear that scientific institutions need a comprehensive and balanced approach to manage the growing complexity of contemporary clinical trials. Four interconnected dimensions appear particularly useful in guiding this effort:

- First, scientific integrity remains essential. Institutions must rely on robust study designs, strategies capable of reducing bias, transparent data handling, and validated AI-based tools, where appropriated. Flexibility in methodology, including hybrid and decentralized trial models, has also become increasingly important.
- Equally crucial is ethical and participant protection. As digital technologies, remote monitoring, and algorithmic tools become more common, informed consent procedures must evolve to reflect these realities. Ensuring transparency in algorithmic processes, monitoring for potential bias, and promoting equitable access to participation (especially in decentralized settings) are now fundamental responsibilities.
- A further dimension concerns economic sustainability. Rising costs and logistical demands require institutions to use resources proportionally to the level of risk and complexity involved. Adaptive designs, as well as well-structured collaborations with CROs and academic partners, can help maintain efficiency without compromising scientific rigor.
- Finally, multi-level governance plays a decisive role. Effective alignment between the EU Clinical Trials Regulation, national authorities, and local institutional policies is essential, along with the efficient use of digital platforms such as CTIS and related national systems.

Taken together, these dimensions form a coherent framework that can help institutions navigate the intersection of scientific, ethical, regulatory, and operational challenges.

Clinical trials remain the foundation of biomedical innovation, yet they are increasingly influenced by digital transformation, decentralized approaches, economic pressures, and evolving European legislation. The traditional ethical and deontological principles that have long guided clinical research continue to be relevant, but they must be reinterpreted to align with new technological and methodological contexts.

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[14] M. KASHOKI, Z. HANAIZI, S. YORDANOVA, R. VESELY, C. BOUYGUES, J. LLINARES, S.L. KWEDER, *A Comparison of EMA and FDA Decisions for New Drug Marketing Applications 2014–2016: Concordance, Discordance, and Why*, in *Clinical pharmacology and therapeutics*, 107, 1, 2019, 195-202.

The New Frontiers of Socialised Medicine: AI, Bio-Legal and Clinical-Legal Liability Between EU Law and the Italian Legal System

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ABSTRACT: Socialised medicine in Europe is entering an algorithmic era. The Artificial Intelligence (AI) Act (Regulation (EU) 2024/1689) introduces horizontal, risk-based rules that coexist with sectoral regimes for medical devices-Medical Device Regulation (MDR) / In Vitro Diagnostic Medical Device Regulation (IVDR). In Italy, Law 24/2017 (Gelli Bianco) structures professional and organisational liability. We examined how these regimes interact in clinical practice and which governance, auditing and insurance tools make AI both safe and equitable. We conducted a multidisciplinary doctrinal and policy analysis of EU instruments (AI Act, MDR/IVDR, Medical Device Coordination Group-MDCG 2019 11 rev.1 and MDCG 2025 6), European Medicines Agency (EMA)'s 2024 Reflection Paper on the medicinal product lifecycle, World Health Organization (WHO) ethics guidance and Organisation for Economic Co-operation and Development (OECD) reports, complemented by a focused scoping of peer reviewed literature on algorithmic auditing, fairness and medico legal accountability. We mapped obligations along the AI lifecycle, built role responsibility matrices and derived an operational co regulation cycle. We identify a dual track compliance architecture: MDR/IVDR ensure clinical safety and performance; the AI Act adds data governance, logging, human oversight, fairness and post market monitoring, with staged application (2025-2027). We specify responsibilities for manufacturers, physicians and facilities and formalise algorithmic audits (pre market/post market/extraordinary) with transparent reporting. We link these to adaptive Health Technology Assessment (HTA) and product liability reform (Directive (EU) 2024/2853). We conclude that dynamic co regulation-living guidelines, lifecycle auditing, transparent logs and risk-based insurance-can align innovation with equity, safety and accountability.

KEYWORDS: Artificial Intelligence; social medicine; medical liability; digital therapeutics; bioethics

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1. Introduction

Artificial intelligence (AI) is reshaping European health systems across prevention, diagnosis, treatment and rehabilitation. It also tests the normative foundations of socialised medicine—equity, safety, accountability and distributive justice by demanding that technical reliability be translated into social reliability. Foundational bio-ethical debates on autonomy, non-maleficence, justice and accountability are now expressed as operational requirements for data governance, measurable fairness and explainability in clinical workflows.[1] As evidence of this clinical footprint across specialties, AI is increasingly used in gastrointestinal oncology, ophthalmology and urology, illustrating the breadth of high-stakes applications that socialised systems must govern.[2]

Within the European multilevel legal order, the Artificial Intelligence Act (AI Act) establishes horizontal, risk-based rules for AI, including definitions, prohibited practices and obligations for high-risk systems. Health software that qualifies as medical device software (MDSW) will typically be high risk and must comply both with the sectoral Medical Device Regulation (MDR, Regulation (EU) 2017/745) or the In Vitro Diagnostic Medical Device Regulation (IVDR, Regulation (EU) 2017/746), and with the AI Act's additional lifecycle duties.[3] Application is phased: prohibitions and general provisions begin in 2025, general application in 2026, and certain classification-linked duties in 2027 (see §3.1).[4]

At national level, Italy's Law 24/2017 ("Gelli-Bianco") centres patient safety and risk management, promoting guideline-concordant practice and organisational learning. Integrating AI reframes duties for

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[1] L. Floridi, J. Cowls, M. Beltrametti, *et al.*, *AI4People—An ethical framework for a good AI society: opportunities, risks, principles and recommendations,* in *Minds Mach*, 28, 2018, 689–707; B. Mittelstadt, *Principles alone cannot guarantee ethical AI*, in *Nature Machine Intelligence*, 1, 11, 2019, 501-507; W. Nicholson Price Ii, S. Gerke, I. G. Cohen, *Liability for Use of Artificial Intelligence in Medicine*, in B. Solaiman, I.G. Cohen (eds.), *Research Handbook on Health, AI and the Law*, 2024; 123-140; World Health Organization, *Ethics and governance of artificial intelligence for health*, Geneva, 2021; High Level Expert Group on Artificial Intelligence, *Ethics guidelines for trustworthy AI*, Brussels, European Commission, 2019.

[2] A. Fulga, D. Iancu, O. M. Dragostin, *et al.*, *Artificial Intelligence Revolutionizes Oesophageal Squamous-Cell Carcinoma Management*, in *BRAIN – Broad Research in Artificial Intelligence and Neuroscience*, 15, 3, 2024, 135-144; A. C. Rusu, R. O. Chistol, *et al.*, *Potential Screening, Grading and Follow-Up of Diabetic Retinopathy in Primary Care Using Artificial Intelligence—How Hard Would It Be to Implement? An Ophthalmologist's Perspective*, in *BRAIN – Broad Research in Artificial Intelligence and Neuroscience,* 15, 2, 2024; B. Novac, R. Zara, A. Ciobica, *Artificial Intelligence in Urology: New Technologies with Major Potential*, in *BRAIN – Broad Research in Artificial Intelligence and Neuroscience,* 15, 4, 2024.

[3] European Parliament and Council, *Regulation (EU) 2024/1689 (Artificial Intelligence Act)*, in *Official Journal of the European Union*, 2024, 1-120; Id, *Regulation (EU) 2017/745 on medical devices (MDR)*, cit., 2017, 1-175; Id*, Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR)*, cit., 2017; 176-332; Medical Device Coordination Group (MDCG), AI Board, *MDCG 2025-6 / AIB 2025-1: Interplay between MDR/IVDR and the AI Act*. 19 June 2025; European Medicines Agency (EMA). *Reflection paper on the use of Artificial Intelligence (AI) in the medicinal product lifecycle*, Amsterdam, 30 September 2024.

[4] European Parliament and Council, *Regulation (EU) 2024/1689 (Artificial Intelligence Act)*, cit., 2024, 1-120.

physicians and facilities from selection and validation of tools, to documentation of AI-assisted decisions and justification when overriding algorithmic outputs.[5]

Two aims guide this article. First, to map dual-track obligations when AI is deployed in clinical devices, showing how the AI Act and MDR/IVDR converge and where they diverge. Second, to translate those obligations into an implementable co-regulatory cycle linking living clinical guidelines, algorithmic audits and adaptive insurance/HTA capable of sustaining equity and accountability at scale. We test the hypothesis that harmonising AI Act lifecycle controls with MDR/IVDR processes reduces medico-legal ambiguity and improves insurability and sustainability of digital therapeutics without undermining professional autonomy, while supporting distributive justice.[6]

AI promises earlier diagnoses, personalised decisions and less administrative burden, but it reconfigures epistemic authority in the clinic. Decision support may appear precise even under high uncertainty, driving automation bias; conversely, blanket rejection forfeits benefits. Without documentation of model scope, training-data limits and intended populations, neither equity nor safety can be guaranteed. A solidarity-driven system must ask not whether AI beats a benchmark, but whether it improves outcomes fairly across diverse populations and care settings, consistent with WHO's rights-based approach.[7]

Regulatory fragmentation has impeded adoption. MDR/IVDR require clinical evidence, risk management, cybersecurity and post-market surveillance. The AI Act adds horizontal controls dataset governance, traceability (logs), robustness, human oversight across sectors. Coordination is now supported by guidance clarifying interplay, encouraging a single integrated technical file covering both clinical evidence and AI governance.[8]

The conceptual framing adopted in this study reflects how legal, clinical and ethical dimensions intersect across the AI lifecycle. Each element analyzed in the results section—regulatory architecture, professional responsibility, auditing, insurance, equity and governance—was therefore selected to illustrate a continuous operational chain from legal norm to clinical practice, allowing the mapping of AI's transformation from a technical artefact into a socially accountable system.

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[5] ITALIAN PARLIAMENT, *Legge 8 marzo 2017, n. 24 (Gelli-Bianco): Disposizioni in materia di sicurezza delle cure e responsabilità professionale*, in *Gazzetta Ufficiale della Repubblica Italiana*, 64, 17 March 2017.

[6] L. FLORIDI, J. COWLS, M. BELTRAMETTI, *et al., op.cit.,* 689–707; B. MITTELSTADT, *op.cit.,* 501-507; W. NICHOLSON PRICE II, S. GERKE, I. G. COHEN, *op.cit.*, in B. SOLAIMAN AND I. G. COHEN (eds.), *op.cit.*, 123-140; WORLD HEALTH ORGANIZATION, *Ethics and governance of artificial intelligence for health*, Geneva, 2021; HIGH LEVEL EXPERT GROUP ON ARTIFICIAL INTELLIGENCE, *Ethics guidelines for trustworthy AI*, Brussels, European Commission, 2019; ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT (OECD), *AI in Health: Huge potential, huge risks*, Paris, 2024; M. EBERS, *AI robotics in healthcare between the EU MDR and the AI Act*, in *Oslo Law Rev*, 11, 1, 2024, 1–12; E. BIASIN, E. KAMENJASEVIĆ, *Regulatory Approaches Towards AI-Based Medical Device Cybersecurity: A Transatlantic Perspective*, in *European Journal of Risk Regulation*, 15, 4, 2024; M. VEALE, F. ZUIDERVEEN BORGESIUS, *Demystifying the Draft EU Artificial Intelligence Act*. Computer Law Review International, 22, 4, 2021.

[7] WORLD HEALTH ORGANIZATION, *Ethics and governance of artificial intelligence for health*, Geneva, 2021; HIGH LEVEL EXPERT GROUP ON ARTIFICIAL INTELLIGENCE, *Ethics guidelines for trustworthy AI*, Brussels, European Commission, 2019; ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT (OECD), *AI in Health: Huge potential, huge risks*, Paris, 2024.

[8] MEDICAL DEVICE COORDINATION GROUP (MDCG), *Guidance on Qualification and Classification of Software under MDR/IVDR*, Brussels, European Commission, June 2025; MEDICAL DEVICE COORDINATION GROUP (MDCG), AI BOARD, *MDCG 2025-6 / AIB 2025-1: Interplay between MDR/IVDR and the AI Act*, 19 June 2025; EUROPEAN MEDICINES AGENCY (EMA), *Reflection paper on the use of Artificial Intelligence (AI) in the medicinal product lifecycle*, Amsterdam, 30 September 2024.

2. Materials and Methods

We designed a multidisciplinary, comparative analysis at the intersection of European public law, medical device regulation, bioethics and health policy.

Primary legal sources. We analysed the AI Act (Regulation (EU) 2024/1689), focusing on definitions, classification, governance and obligations (Chs. III–V), market surveillance (Ch. VII), governance (Ch. XII) and staged application dates. Sectoral instruments included MDR and IVDR. We used MDCG software qualification/classification guidance (MDCG 2019-11 rev.1, June 2025) and the 2025 interplay Q&A (MDCG 2025-6/AIB (Artificial Intelligence Board) 2025-1).[9]

Medicines guidance. Because many products bridge medicines, devices and data, we examined the EMA 2024 Reflection Paper on AI in the medicinal product lifecycle to align lifecycle controls (data integrity, validation, monitoring, documentation).[10]

Ethics and policy frameworks. We drew on WHO's 2021 guidance on ethics and governance of AI for health, the European Commission's High-Level Expert Group on Artificial Intelligence (HLEG) Ethics Guidelines for Trustworthy AI (2019), and OECD's 2024 report AI in Health to ground equity, transparency and accountability requirements.[11]

Focused literature scoping. We surveyed peer-reviewed work on algorithmic auditing and fairness in healthcare, medico-legal accountability and risk pooling for digital therapeutics. Inclusion criteria privileged conceptual clarity and operationalisable methods; purely technical articles without governance implications were excluded.[12]

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[9] European Parliament and Council, *Regulation (EU) 2024/1689 (Artificial Intelligence Act)*, in *Official Journal of the European Union*, 2024, 1725-2555; Id, *Regulation (EU) 2017/745 on medical devices (MDR)*, cit., 2017, 1-175; Id, *Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR)*, cit., 2017, 176-332; Medical Device Coordination Group (MDCG), *MDCG 2019-11 rev.1: Guidance on Qualification and Classification of Software under MDR/IVDR*, Brussels, European Commission, June 2025; Medical Device Coordination Group (MDCG), AI Board, *MDCG 2025-6 / AIB 2025-1: Interplay between MDR/IVDR and the AI Act*. 19 June 2025; European Medicines Agency (EMA). *Reflection paper on the use of Artificial Intelligence (AI) in the medicinal product lifecycle*. Amsterdam: EMA, 30 September 2024.

[10] European Medicines Agency (EMA), *Reflection paper on the use of Artificial Intelligence (AI) in the medicinal product lifecycle*, Amsterdam, 30 September 2024.

[11] World Health Organization, *Ethics and governance of artificial intelligence for health*, Geneva, 2021; High Level Expert Group on Artificial Intelligence, *Ethics guidelines for trustworthy AI*, Brussels, European Commission, 2019; Organisation for Economic Co-operation and Development (OECD), *AI in Health: Huge potential, huge risks*, Paris, 2024.

[12] M. Ebers, *op.cit*, 1–12; E. Biasin, E. Kamenjasević, *op.cit.*, 876-886; M. Veale, F. Zuiderveen Borgesius, *op.cit.*, 97-112; N.A. Smuha, *The EU Approach to Ethics Guidelines for Trustworthy Artificial Intelligence*, in *Computer Law Review International*, 2019; 20, 4, 97-106; N.A.K. Lekadir, A.F. Frangi, A.R. Porras, B. Glocker, C. Cintas, C.P. Langlotz, *et al.*, *FUTURE-AI: international consensus guideline for trustworthy and deployable artificial intelligence* in *Healthcare BMJ*, 388, 2025; E. Topol, *Deep Medicine: How Artificial Intelligence Can Make Healthcare Human Again*, PSNet Book/Report Classic, 2019; L. Gondara, J. Simkin, *A clinical-trial design approach to auditing language models in healthcare settings*. arXiv preprint, 2024; X. Liu, B. Glocker, M.M. Mccradden, M. Ghassemi, A.K. Denniston, L. Oakden-Rayner, *The medical algorithmic audit*, in *The Lancet Digital Health*, 4, 5, 2022, e384–e397; X.J.L. Cross, M. A. Choma, J.A. Onofrey, *Bias in medical AI: Implications for clinical decision-making*, in *PLOS Digital Health*, 3, 11, 2024; S.C. Nouis, V. Uren, S. Jariwala, *Evaluating accountability, transparency, and bias in AI-assisted healthcare decision-making: A qualitative study of healthcare professionals' perspectives in the UK*, in *BMC Medical Ethics*, 26, 89, 2025; Z. Obermeyer, E.J. Topol, *Artificial intelligence, bias, and patients' perspectives*, in *The Lancet*, 397, 10289,

Analytic strategy. We (a) constructed a matrix aligning AI Act lifecycle duties with MDR/IVDR processes; (b) mapped role responsibility across manufacturers, physicians, facilities and insurers; (c) specified an audit taxonomy (pre-market, post-market, extraordinary) with traceable KPIs and fairness metrics; and (d) derived clauses for adaptive HTA and insurance reflective of model updates, drift and bias.[13]

Search/synthesis and reproducibility. Sources were identified on EUR-Lex, Commission/MDCG and EMA sites, and international bodies (WHO/OECD). We independently extracted duties, dates and definitions, mapped them to lifecycle phases and actors, and iteratively refined tables/checklists with legal and clinical reviewers for implementability.

3. Results

The results are organised to reflect the logical progression from regulatory structure to operational implementation. Starting from the dual-track regulatory model, the analysis moves through the redefinition of professional and organisational responsibilities, the function of algorithmic auditing, and the integration of these mechanisms into insurance, health technology assessment and equity frameworks.

3.1. Risk-Based Regulation and the Dual-Track AI Act/MDR Model

The AI Act introduces lifecycle controls-risk management, data governance, technical documentation, logging, robustness, accuracy, resilience, human oversight and transparency-for high-risk systems. AI medical software typically falls in scope as high risk and must satisfy this horizontal layer while conforming to MDR/IVDR. The result is a dual track: clinical safety/performance (MDR/IVDR) plus algorithmic governance (AI Act).[14] In practice, representative high-risk deployments include endoscopic decision

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2021, 2038; J. ZHANG, Z. ZHANG, *Ethics and governance of trustworthy medical artificial intelligence*, in *BMC Medical Informatics and Decision Making*, 23, 7, 2023.

[13] EUROPEAN PARLIAMENT AND COUNCIL, *Regulation (EU) 2024/1689 (Artificial Intelligence Act)*, in *Official Journal of the European Union,* 2024, 1-120. ID, *Regulation (EU) 2017/745 on medical devices (MDR)*, cit., 2017, 1-175; ID*, Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR)*, cit., 2017; L 117, 176-332; MEDICAL DEVICE COORDINATION GROUP (MDCG), *MDCG 2019-11 rev.1: Guidance on Qualification and Classification of Software under MDR/IVDR*, Brussels, European Commission, June 2025; MEDICAL DEVICE COORDINATION GROUP (MDCG), AI BOARD, *MDCG 2025-6 / AIB 2025-1: Interplay between MDR/IVDR and the AI Act*. 19 June 2025; EUROPEAN MEDICINES AGENCY (EMA), *Reflection paper on the use of Artificial Intelligence (AI) in the medicinal product lifecycle*, Amsterdam, 30 September 2024; WORLD HEALTH ORGANIZATION, *Ethics and governance of artificial intelligence for health*, Geneva, 2021; HIGH LEVEL EXPERT GROUP ON ARTIFICIAL INTELLIGENCE, *Ethics guidelines for trustworthy AI*, Brussels, European Commission, 2019; ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT (OECD), *AI in Health: Huge potential, huge risks*, Paris, 2024; EUROPEAN PARLIAMENT AND COUNCIL, *Directive (EU) 2024/2853 on liability for defective products (revised Product Liability Directive)*, in *Official Journal of the European Union*, 2024, 1-41; EURACTIV, *Commission withdraws AI liability directive*, 2025, available at: https://www.euractiv.com.

[14] EUROPEAN PARLIAMENT AND COUNCIL, *Regulation (EU) 2024/1689 (Artificial Intelligence Act)*, cit., 2024, 1-120; ID, *Regulation (EU) 2017/745 on medical devices (MDR)*, cit., 2017; 1-175; ID, *Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR)*, cit., 2017, 176-332; MEDICAL DEVICE COORDINATION GROUP (MDCG), AI BOARD, *MDCG 2025-6 / AIB 2025-1: Interplay between MDR/IVDR and the AI Act*, 19 June 2025; EUROPEAN MEDICINES AGENCY (EMA), *Reflection paper on the use of Artificial Intelligence (AI) in the medicinal product lifecycle*, Amsterdam, 30 September 2024.

support in oesophageal squamous-cell carcinoma, AI-assisted diabetic-retinopathy screening and urologic decision support.[15]

Application timeline (AI Act). Prohibitions and general provisions apply from 2 Feb 2025; selected governance provisions from 2 Aug 2025; general application from 2 Aug 2026; and certain classification-linked obligations from 2 Aug 2027. Transitional arrangements address systems already on the market and general-purpose models.[16]

Table 1. Dual-track compliance for AI-enabled clinical software

Lifecycle phase	**AI Act (examples)**	**MDR/IVDR (examples)**
Scoping & intended use	Risk management; data governance; human oversight; transparency	Classification; intended purpose; CE marking; Unique Device Identification (UDI)
Validation & performance	Accuracy; robustness; bias/fairness analysis; logging for auditability	Clinical evaluation; usability; cybersecurity/safety
Post-market	Drift monitoring; periodic audit; Corrective and Preventive Action (CAPA); incident reporting; logs	Post-Market Surveillance/ Post-Market Clinical Follow-up (PMS/PMCF); vigilance; documented Corrective and Preventive Action (CAPA)

Coordination note: Interplay guidance clarifies that sectoral conformity procedures are not duplicated but coordinated via the device route. Manufacturers should build a single integrated technical file covering MDR/IVDR clinical evidence and AI Act data/logging/fairness controls.[17]

This dual-track model reveals a persistent tension between regulatory completeness and practical coherence: while the AI Act expands accountability through lifecycle governance, aligning its risk logic with the clinically grounded MDR/IVDR framework remains a delicate exercise in legal and technical synchronization.

3.2. Professional and Organisational Responsibility

Italian liability remains anchored in clinicians' fault (negligence, imprudence, inexperience) and the facility's contractual responsibility, with guideline-informed practice central. With AI, duties evolve: appropriate tool selection; competence and training; awareness of model limitations and indications; recording AI outputs in the patient record; justification of divergences; and participation in post-market monitoring. Facilities bear organisational duties: procurement and ex-ante compliance assessment; integra-

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[15] A. Fulga, D. Iancu, O.M. Dragostin, *et al.*, *op.cit.,* 135-144; B. Novac, R. Zara, A. Ciobica, *op.cit.,* 319-324; A.C. Rusu, R.O. Chistol, *et al.*, *op.cit.,* 280-303; M. Veale, F. Zuiderveen Borgesius, *op.cit.,* 97-112.

[16] European Parliament and Council, *Regulation (EU) 2024/1689 (Artificial Intelligence Act)*, in *Official Journal of the European Union*, 2024, 1-120.

[17] Medical Device Coordination Group (MDCG), *MDCG 2019-11 rev.1: Guidance on Qualification and Classification of Software under MDR/IVDR*, Brussels, European Commission, June 2025; Medical Device Coordination Group (MDCG), AI Board, *MDCG 2025-6 / AIB 2025-1: Interplay between MDR/IVDR and the AI Act*, 19 June 2025; European Medicines Agency (EMA), *Reflection paper on the use of Artificial Intelligence (AI) in the medicinal product lifecycle*, Amsterdam, 30 September 2024.

tion into care pathways; incident handling; and periodic audits.[18] The rapid integration of collaborative/robotic AI into clinical environments underscores these redistributed duties for human oversight and organisational governance.[19]

The redistribution of duties between physicians and facilities strengthens accountability but also exposes unresolved ambiguities regarding the threshold of human oversight and the limits of deference to algorithmic recommendations.

Table 2. Accountability across the digital-health chain

Actor	**Primary responsibility**	**Key notes**
Manufacturer	Technical compliance; updates; risk management; reporting; logs	Strict/product liability for defects and updates; duties under Product Liability Directive (PLD) 2024/2853.
Physician	Appropriate use; human oversight; documentation; rationale for divergence	Training/continuing education; chart annotation of AI use.
Healthcare facility	Protocols; team qualification; risk management; incident response	Organisational/contractual liability; governance and PMS interfaces.
Insurer	AI-specific cover; claims monitoring; retroactivity for updates	Incentives tied to audit KPIs; exclusions for lack of vigilance.

3.3. Algorithmic Audit

Auditing connects lifecycle controls with accountability. We distinguish pre-market audits (dataset review, representativeness and bias testing, stress tests, generalisation checks), post-market audits (real-world performance, drift monitoring, incident linkage) and extraordinary audits (triggered by anomalies, updates or incidents). Reports should publish abstracts and selected KPIs/fairness metrics to enable contestability without disclosing trade secrets.[20] Concrete examples reinforce why audits must document data provenance/augmentation and robustness/generalisation testing: data-augmentation pipelines (e.g., Conditional Generative Adversarial Network (CGAN) for early Parkinson's voice signals) raise traceability and bias questions, while Brain–Computer Interface/ Magnetoencephalography (BCI/MEG) pipelines illustrate robustness and interference-handling challenges in safety-critical contexts.[21]

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[18] W. Nicholson Price II, S. Gerke, I.G. Cohen, *op. cit.*, in B. Solaiman, I.G. Cohen (eds.), *op.cit.*, 123-140; Italian Parliament, *Legge 8 marzo 2017, n. 24 (Gelli-Bianco): Disposizioni in materia di sicurezza delle cure e responsabilità professionale*, in *Gazzetta Ufficiale della Repubblica Italiana*, 64, 17 March 2017; M. Ebers, *op.cit*, 1–12; E. Biasin, E. Kamenjasević, *op.cit.,* 876-886.

[19] I. Ienina, O. Ovcharenko, N. Opushko, M. Chumak, T. Zahorodnia, O. Dorofieiev, *Major trends in today's intelligent robotics in light of the creation of collaborative artificial intelligence*, in *BRAIN – Broad Research in Artificial Intelligence and Neuroscience*, 14, 3, 314–329, 2023.

[20] European Medicines Agency (EMA), *Reflection paper on the use of Artificial Intelligence (AI) in the medicinal product lifecycle*, Amsterdam, 30 September 2024; Organisation for Economic Co-operation and Development (OECD), *AI in Health: Huge potential, huge risks*, Paris, 2024; A.J.L. Cross, M.A. Choma, J.A. Onofrey, *op.cit.*, 1-19; X. Liu, B. Glocker, M. M. Mccradden, M. Ghassemi, A. K. Denniston, L. Oakden-Rayner, *op.cit.*, e384–e397; S.C. Nouis, V. Uren, S. Jariwala, *op.cit*.

[21] S. Chandrabhanu, S. Hemalatha, *CGAN-Facilitated Data Augmentation of Voice and Speech Parameters for Detecting Parkinson's Disease in the Prodromal Phase*, in *BRAIN – Broad Research in Artificial Intelligence and Neurosci-*

Algorithmic auditing enhances transparency and learning, yet it also confronts the structural dilemma of reconciling openness with intellectual-property protection and the operational burden of continuous verification.

Table 3. Key elements of algorithmic auditing

Phase	**Main activities**	**Objectives**
Pre-market	Dataset evaluation; simulation; robustness stress tests	Identify risk, bias, failure modes before release
Post-market	Drift monitoring; real-world KPIs; user feedback	Ensure stability and safety over time
Extraordinary	Root-cause analysis after anomalies/incidents/major updates	Prevent recurrence; improve model and process
Reporting	Summaries with KPIs and fairness metrics	Transparency and multi-actor learning

3.4. Insurance, Risk Pooling and Adaptive HTA

The revised Product Liability Directive (EU) 2024/2853 modernises strict liability, expressly covering software and updates and introducing disclosure/burden-of-proof presumptions relevant to AI-related harm; transposition is due by 9 December 2026.[22] Insurance contracts should recognise software-specific risks: versioning/updates, model drift, data-quality defects and latent bias. Clauses can align premiums to evidence of lifecycle controls—presence of logs, third-party audits, documented datasets and CAPA plans. Adaptive HTA for digital therapeutics should combine pre-market evidence and real-world outcomes, with registry-based agreements and periodic reassessment triggered by substantial updates.[23] Health-system efficiency and sustainability levers include AI-supported simulations for patient flow/cost optimisation and evaluable, outcomes-based digital therapy models (e.g., VR-assisted rehabilitation Randomised Controlled Trial (RCTs), both of which dovetail with risk-based insurance incentives.[24]

Integrating insurance and adaptive HTA introduces economic accountability into the governance chain, but the proportional calibration of premiums and evidentiary thresholds for software risk remains an open challenge for both regulators and markets.

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ence, 15, 3, 2024; B.S. Philip, D.A. Iordan, *et al.*, *Estimation of Interferences in Magnetoencephalography (MEG) Brain Data Using Intelligent Methods for BCI-Based Neurorehabilitation Applications*, in BRAIN. Broad Research in Artificial Intelligence and Neuroscience, 15, 3, 2024.

[22] European Parliament And Council, *Directive (EU) 2024/2853 on liability for defective products (revised Product Liability Directive)*, in *Official Journal of the European Union*, 2024, 1-41.

[23] W. Nicholson Price Ii, S. Gerke, I.G. Cohen, *op.cit.*, in B. Solaiman, I.G. Cohen (eds.), *op.cit.,* 123-140; Organisation for Economic Co-operation and Development (OECD), *AI in Health: Huge potential, huge risks*, Paris, 2024; L. Gondara, J. Simkin, *A clinical-trial design approach to auditing language models in healthcare settings*, 2024.

[24] K. Cincar, A.A. Minda, M. Varga, *A Simulation-Based Analysis Using Machine-Learning Models to Optimise Patient Flow and Treatment Costs*, in *BRAIN – Broad Research in Artificial Intelligence and Neuroscience*, 15, 3, 2024; R. Dumitrescu, *Medical liability between clinical practice and litigation: a bibliometric thematic analysis*, in *Romanian Journal of Legal Medicine*, 33, 2, 2025, 171-178.

3.5. Bioethical Profiles and Equitable Access

Socialised medicine requires that AI improve safety and dignity without entrenching disadvantage. This implies context-appropriate transparency, meaningful informed consent (including the role of AI in decisions), and user/patient participation in evaluation. Distributional metrics subgroup performance, calibration, error balance-should be part of routine evaluation and reported in plain language. WHO and HLEG guidance reinforce continuous governance as model capabilities evolve.[25] Related literatures on autism spectrum disorders, maternal health in autistic women, dementia, very-early developmental risk, and patient-centred lifestyle approaches highlight consent, communication and equity needs in vulnerable groups that digital tools must respect.[26] Complementary evidence on exercise and occupational/environmental determinants further underlines the importance of proportionate safeguards and accessible explanations when deploying digital health technologies.[27]

Ethical safeguards ensure legitimacy and fairness, yet operationalising equity metrics and meaningful consent across diverse populations requires sustained institutional commitment beyond regulatory compliance.

3.6. General-Purpose and Generative AI (GPAI/LLMs) in Care

Clinicians increasingly interact with general-purpose AI (GPAI) and large language models (LLMs) to draft notes, summarise literature or assist triage. Under the AI Act, GPAI model providers have duties (technical documentation and, for systemic-risk models, model evaluation/reporting). Deployers remain re-

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[25] WORLD HEALTH ORGANIZATION, *Ethics and governance of artificial intelligence for health*, Geneva, 2021. HIGH LEVEL EXPERT GROUP ON ARTIFICIAL INTELLIGENCE, *Ethics guidelines for trustworthy AI*, Brussels, European Commission, 2019; ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT (OECD), *AI in Health: Huge potential, huge risks*, Paris, 2024; X. LIU, B. GLOCKER, M.M. MCCRADDEN, M. GHASSEMI, A. K. DENNISTON, L. OAKDEN-RAYNER, *op.cit.*, e384–e397; Z. OBERMEYER, E.J. TOPOL, *op.cit.*, 2038; J. ZHANG, Z. ZHANG, *op.cit*.

[26] R. FERRARA, R. NAPPO, F. ANSERMET, P. RICCI, F. MASSONI, G. CARBONE, A. SPARACI, E. NONNIS, L. RICCI, S. RICCI, *The impact of DSM-5 on the diagnosis of autism spectrum disorder*, in *Psychiatric Annals*, 51, 1, 2020, 38-46; G.M. TROILI, R. BUSINARO, F. MASSONI, L. RICCI, L. PETRONE, P. RICCI, *et al.*, *Investigation on a group of autistic children: Risk factors and medical-social considerations*, in *Clinica Terapeutica*, 164, 4, 2013, e273-e278; P. RICCI, F. MASSONI, L. RICCI, E. ONOFRI, G. DONATO, S. RICCI, *Quality of life in dementia sufferers: The role of diet and exercise*, in *Current Alzheimer Research*, 15, 5, 2018, 400-407; R. FERRARA, L. RICCI, P. RICCI, L. IOVINO, S. RICCI, F.M. DAMATO, G. CICINELLI, R. KELLER, *How autistic women are aware of their body and take care of their health? Focus on menstruation cycles and gynaecological care*, in *Clinica Terapeutica*, 175, 3, 2024, 168-175; F.M. DAMATO, P. RICCI, R. RINALDI, *Informed consent and compulsory treatment on individuals with severe eating disorders: a bio-ethical and juridical problem*, in *Clinica Terapeutica*, 174, 4, 2023, 365-369; R. FERRARA, L. IOVINO, R. LATINA, A. AVALLONE, E. GRECO, G. MONTANARI VERGALLO, M. CALDARARO, P. RICCI, *Adolescent mothers and postpartum depression: a possible connection? A Scoping review*, in *Clinica Terapeutica*, 176, 1, 2025, 81-90; R. FERRARA, L. IOVINO, M. DI RENZO, P. RICCI, *Babies under 1 year with atypical development: perspectives for preventive individuation and treatment*, in *Frontiers in Psychology*, 13, 2022; M. V. ROSATI, C. SACCO, A. MASTRANTONIO, G. GIAMMICHELE, G. BUONPRISCO, P. RICCI, G. F. TOMEI, F. TOMEI, S. RICCI, *Prevalence of chronic venous pathology in healthcare workers and the role of upright standing*, in *International Angiology*, 38, 3, 2019, 201-210; P. RICCI, M. PALLOCCI, M. TREGLIA, S. RICCI, R. FERRARA, C. ZANOVELLO, P. L. PASSALACQUA, F. M. DAMATO, *The Effect of Physical Exercise during COVID-19 Lockdown*, in *Healthcare*, 11, 11, 2023, 1618.

[27] T. ARCHER, S. RICCI, F. MASSONI, L. RICCI, M. RAPP-RICCIARDI, *Cognitive benefits of exercise intervention*, in *Clinica Terapeutica*, 167, 6, 2016, 180-185; M. V. ROSATI, A. SANCINI, F. TOMEI, C. SACCO, V. TRAVERSINI, A. DE VITA, D. P. DE CESARE, G. GIAMMICHELE, F. DE MARCO, F. PAGLIARA, F. MASSONI, L. RICCI, G. TOMEI, S. RICCI, *Correlazione tra benzene e testosterone nei lavoratori esposti ad inquinamento urbano*, in *Clinica Terapeutica*, 168, 6, 2017.

sponsible for context-appropriate use in healthcare. Codes of practice are envisaged to operationalise these duties. In clinical settings, deployers should add domain-specific guardrails: constrain prompts to verified sources; require human sign-off; prohibit unsupervised diagnostic/therapeutic recommendations; log prompts/outputs; disclose use to patients in plain language; and route hallucination/unsafe-advice incidents to audit channels. When an LLM is embedded within a device/Clinical Decision Support (CDS), the integrated product must satisfy MDR/IVDR and AI Act logging/oversight duties. Contemporary governance debates around GPAI and superintelligence provide useful risk framings for clinical adoption.[28] WHO guidance on large multimodal models adds safeguards relevant to clinical contexts.[29]

The emergence of general-purpose and generative models blurs the traditional boundaries of medical liability, raising unresolved questions about attribution of error, data provenance and the enforceability of human oversight in hybrid decision processes.

3.7. Data Governance, Privacy and Documentation

Data governance is central to both regimes. Manufacturers and deployers should document provenance, curation, label quality and representativeness of training/validation/test sets; rationales for inclusion/exclusion; handling of missing data and augmentation; and link each dataset to intended use and clinical claims, with subgroup analyses where bias is plausible. Logs should capture inputs, salient context and outputs to enable traceability, incident reconstruction and learning. AI Act obligations complement, not replace, data-protection law; deployers must ensure a lawful basis, purpose limitation, minimisation and security by design.[30]

Despite robust documentation frameworks, the reconciliation of data minimisation, transparency and reproducibility continues to expose friction points between privacy law and the evidentiary needs of clinical AI auditing.

Table 4. Documentation essentials for auditability

Item	Purpose
Data sheet per dataset (provenance, demographics, labelling)	Assess bias/representativeness; support reproducibility
Model card (intended use, performance, limits)	Align expectations; support clinical governance
Change log and versioning	Link updates to evidence and risk assessments

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[28] I. Susnea, E. Pecheanu, A. Cocu, S. M. Susnea, *Superintelligence Revisited in Times of ChatGPT*, in *BRAIN – Broad Research in Artificial Intelligence and Neuroscience*, 15, 2, 2024, 344-362.

[29] World Health Organization, *Ethics and governance of AI for health: Guidance on large multimodal models*, Geneva, 2025.

[30] European Parliament and Council, *Regulation (EU) 2024/1689 (Artificial Intelligence Act)*, in *Official Journal of the European Union*, 2024; Id, *Regulation (EU) 2017/745 on medical devices (MDR)*, cit., 2017, 1-175; Id, *Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR)*, cit., 2017, 176-332; European Medicines Agency (EMA), *Reflection paper on the use of Artificial Intelligence (AI) in the medicinal product lifecycle*, Amsterdam, 30 September 2024; World Health Organization, *Ethics and governance of artificial intelligence for health*, Geneva, 2021; High Level Expert Group on Artificial Intelligence, *Ethics guidelines for trustworthy AI*, Brussels, European Commission, 2019; Organisation for Economic Co-operation and Development (OECD), *AI in Health: Huge potential, huge risks*, Paris, 2024.

Item	Purpose
Post-market monitoring plan with KPIs	Detect drift; trigger CAPA and updates
Incident reporting workflow	Ensure learning and accountability

3.8. Italy Operationalisation under Law 24/2017

Facilities can adopt a three-layer governance model to integrate AI within the Italian liability framework: (i) Clinical governance approves use cases, integrates AI into care pathways and ensures training; (ii) Risk management monitors incidents, oversees audits, liaises with manufacturers/insurers and channels documentation into quality systems; (iii) Ethics/data oversight reviews fairness metrics, consent language and patient communications. Physicians should document the role of AI and justify deviations from AI suggestions. Manufacturers should provide Italian-language Instructions for Use (IFU), performance summaries and known limitations; distributors should assist with updates/vigilance.[31]

The Italian implementation illustrates how national frameworks can translate EU principles into practice, yet its success depends on maintaining flexibility to adapt living guidelines and audit cycles to the rapid evolution of AI technologies.

Table 5. Mapping L. 24/2017 duties to AI governance actions

Legal duty (illustrative)	AI-aligned operational action
Guideline-concordant practice	Adopt living guidelines with AI-specific update triggers
Organisational responsibility	Establish a multidisciplinary audit committee; integrate logs into quality systems
Professional diligence	Train on model scope/limits; document rationale for divergence
Learning from adverse events	Link incident system to AI logs; conduct extraordinary audits and CAPA

4. Discussion

This structure was designed not merely to juxtapose legal and clinical requirements but to show how they co-evolve within a single co-regulatory ecosystem. By tracing the continuity from statutory norms to clinical governance tools, the discussion highlights how abstract principles of fairness, safety and accountability can be operationalised through measurable compliance and audit mechanisms. The analysis also underscores the bidirectional dialogue between academic theorisation and regulatory evolution: scholarly debates on fairness, autonomy and accountability actively inform the design of EU instruments, while emerging legal norms reshape the ethical vocabulary and operational standards of AI governance in medicine.

The AI Act and MDR/IVDR are complementary layers that, if implemented coherently, reduce ambiguity and strengthen safety. MDR/IVDR deliver the clinical safety/performance backbone (classification, clinical evaluation, PMS/PMCF, vigilance), while the AI Act supplies data-governance, logging, human-

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[31] W. NICHOLSON PRICE II, S. GERKE, I. G. COHEN., *op.cit.,* 123-140; ITALIAN PARLIAMENT, *Legge 8 marzo 2017, n. 24 (Gelli-Bianco): Disposizioni in materia di sicurezza delle cure e responsabilità professionale*. Gazzetta Ufficiale della Repubblica Italiana, 64, 17 March 2017.

oversight and fairness controls across the lifecycle. Interplay guidance encourages a single, integrated technical file encompassing both.[32]

Three implications follow:

Living guidelines. Static protocols cannot keep pace with adaptive software. Living guidelines should integrate audit outputs and real-world evidence, with explicit triggers for update when performance drifts or the patient mix shifts. EMA's reflection paper points to analogous lifecycle controls in medicines (validation, documentation, monitoring) that can be aligned with device-side governance.[33]

Auditability and contestability. Logs, versioning and declared intended uses are clinical-safety tools. Published summaries of fairness/performance metrics enable scrutiny and patient understanding without compromising trade secrets. Embedded in incident-learning systems, audits drive risk-proportionate CAPA and equitable outcomes.[34]

Liability and insurance. The revised PLD aligns strict liability with software and improves disclosure presumptions. Insurers can accelerate safe adoption by linking cover to demonstrable conformance (external audits; drift monitoring; data governance). This aligns with Italy's risk-management emphasis under Law 24/2017 and supports provider confidence.[35]

Fairness and equity. The moral case for AI in socialised medicine rests on measurable improvements for the least advantage. Unexamined proxies and non-representative data can degrade subgroup performance. Routine subgroup reporting (sensitivity/specificity, calibration error, false-negative gaps) and stakeholder participation must be hard-wired into evaluation and surveillance, as WHO/HLEG/OECD emphasise.[36]

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[32] European Parliament and Council, *Regulation (EU) 2024/1689 (Artificial Intelligence Act)*, in *Official Journal of the European Union*, 2024, 1-120; Id, *Regulation (EU) 2017/745 on medical devices (MDR)*, cit., 2017, 1-175; Id, *Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR)*, cit., 2017, 176-332; Medical Device Coordination Group (MDCG), *MDCG 2019-11 rev.1: Guidance on Qualification and Classification of Software under MDR/IVDR*, Brussels, European Commission, June 2025; Medical Device Coordination Group (MDCG), AI Board, *MDCG 2025-6 / AIB 2025-1: Interplay between MDR/IVDR and the AI Act*, 19 June 2025; European Medicines Agency (EMA), *Reflection paper on the use of Artificial Intelligence (AI) in the medicinal product lifecycle*, Amsterdam, 30 September 2024; M. Veale, F. Zuiderveen Borgesius. *op.cit.,* 97-112.

[33] European Medicines Agency (EMA), *Reflection paper on the use of Artificial Intelligence (AI) in the medicinal product lifecycle*, Amsterdam, 30 September 2024.

[34] Organization for Economic Co-operation and Development (OECD), *AI in Health: Huge potential, huge risks*, Paris, 2024; European Medicines Agency (EMA), *Reflection paper on the use of Artificial Intelligence (AI) in the medicinal product lifecycle*, Amsterdam, 30 September 2024; X. Liu, B. Glocker, M.M. Mccradden, M. Ghassemi, A.K. Denniston, L. Oakden-Rayner, *op.cit.*, e384–e397; A.J.L. Cross, M.A. Choma, And J.A. Onofrey, *op.cit*., 1-19; S. C. Nouis, V. Uren, S. Jariwala, *op.cit*.

[35] Italian Parliament, *Legge 8 marzo 2017, n. 24 (Gelli-Bianco): Disposizioni in materia di sicurezza delle cure e responsabilità professionale*, in *Gazzetta Ufficiale della Repubblica Italiana*, 64, 17 March 2017; European Parliament and Council, *Directive (EU) 2024/2853 on liability for defective products (revised Product Liability Directive)*, in *Official Journal of the European Union*, 2024, 1-41.

[36] World Health Organization, *Ethics and governance of artificial intelligence for health*, Geneva, 2021; High Level Expert Group on Artificial Intelligence, *Ethics guidelines for trustworthy AI*, Brussels, European Commission, 2019; Organization for Economic Co-operation and Development (OECD), *AI in Health: Huge potential, huge risks*, Paris, 2024; J. Zhang, Z. Zhang, *op.cit*; X. Liu, B. Glocker, M.M. Mccradden, M. Ghassemi, A.K. Denniston, L. Oakden-Rayner, *op.cit.*, e384–e397; Z. Obermeyer, E. J. Topol, *op.cit.*, 2038.

Limitations. This is a doctrinal/policy mapping rather than an empirical trial. Proposed KPIs for audits and HTA/insurance reflect current guidance/literature and will require empirical calibration across domains (radiology, cardiology, oncology, mental health). Dates/duties were anchored in official sources.[37]
Practice points. (i) Build a single integrated technical file satisfying MDR/IVDR and AI Act obligations; (ii) appoint a multidisciplinary audit committee; (iii) publish audit abstracts and fairness dashboards; (iv) link insurance cover to lifecycle compliance; (v) implement living guidelines with update triggers; (vi) train clinicians to document AI use and reasons for divergence.[38]

5. Conclusion

European socialised medicine can integrate AI safely and fairly by treating MDR/IVDR and the AI Act as a single, continuous lifecycle. The law already provides the building blocks: device safety/performance requirements; horizontal AI governance; revised strict product liability; and national regimes such as Italy's Law 24/2017. The operational challenge is to weave these into a co-regulatory cycle living guidelines, algorithmic audits, transparent logging, adaptive HTA and risk-based insurance that preserves professional autonomy and ensures distributive justice. The blueprint offered here integrated documentation; pre/post-market audits with KPIs/fairness metrics; documented oversight and justified deviation; coverage/reimbursement aligned to lifecycle compliance and real-world performance translates ethical imperatives of dignity, transparency and equity into day-to-day governance, turning AI's technical reliability into social reliability.[39]

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[37] European Parliament and Council, *Regulation (EU) 2024/1689 (Artificial Intelligence Act)*, in *Official Journal of the European Union*, 2024, 1-120; Id, *Regulation (EU) 2017/745 on medical devices (MDR)*, cit., 2017, 1-175; Id, *Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR)*, cit., 2017, 176-332; Id*, Directive (EU) 2024/2853 on liability for defective products (revised Product Liability Directive)*, 2024, 1-41.

[38] W. Nicholson Price Ii, S. Gerke, I. G. Cohen, *op.cit.,* in B. Solaiman, I.G. Cohen (eds.), *op.cit.*, 123-140; European Parliament and Council, *Regulation (EU) 2024/1689 (Artificial Intelligence Act)*, cit., 2024, 1-120; Id, *Regulation (EU) 2017/745 on medical devices (MDR)*, cit., 2017, 1-175; Id, *Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR)*, cit., 2017, 176-332; Medical Device Coordination Group (MDCG), *MDCG 2019-11 rev.1: Guidance on Qualification and Classification of Software under MDR/IVDR*, Brussels, European Commission, June 2025; Medical Device Coordination Group (MDCG), AI Board, *MDCG 2025-6 / AIB 2025-1: Interplay between MDR/IVDR and the AI Act*, 19 June 2025; European Medicines Agency (EMA), *Reflection paper on the use of Artificial Intelligence (AI) in the medicinal product lifecycle*, Amsterdam, 30 September 2024; World Health Organization, *Ethics and governance of artificial intelligence for health*, Geneva, 2021; High Level Expert Group on Artificial Intelligence, *Ethics guidelines for trustworthy AI*, Brussels, European Commission, 2019; Organisation for Economic Co-operation and Development (OECD), *AI in Health: Huge potential, huge risks*, Paris, 2024; European Parliament and Council, *Directive (EU) 2024/2853 on liability for defective products (revised Product Liability Directive)*, cit., 2024, 1-41; X. Liu, B. Glocker, M.M. Mccradden, M. Ghassemi, A.K. Denniston, L. Oakden-Rayner, *op.cit.*, e384–e397; A.J.L. Cross, M.A. Choma, J.A. Onofrey, *op.cit.*, 1-19; S.C. Nouis, V. Uren, S. Jariwala, *op.cit*.

[39] L. Floridi, J. Cowls, M. Beltrametti, *et al*., *op.cit.,* 689–707; B. Mittelstadt, *op.cit.,* 501-507; W. Nicholson Price Ii, S. Gerke, I.G. Cohen, *op.cit.*, in B. Solaiman, I.G. Cohen (eds.), *op.cit.*, 123-140; European Medicines Agency (EMA), *Reflection paper on the use of Artificial Intelligence (AI) in the medicinal product lifecycle*, Amsterdam, 30 September 2024; World Health Organization, *Ethics and governance of artificial intelligence for health*, Geneva, 2021; High Level Expert Group on Artificial Intelligence, *Ethics guidelines for trustworthy AI*, Brussels, European Commission, 2019; Organisation for Economic Co-operation and Development (OECD), *AI in Health: Huge potential, huge risks*, Paris, 2024; European Parliament and Council, *Directive (EU) 2024/2853 on liability for defective products (revised Product Liability Directive)*, cit., 2024, 1-41.

As an original contribution, the proposed co-regulatory cycle can be read as a synthetic conceptual framework that operationalizes the continuum between ethical principles, legal duties and clinical governance, offering a replicable model for the safe and equitable deployment of AI in socialized healthcare systems.

Structural Determinants of Intention to Leave in Healthcare and Social Medicine-Based Strategies to Counteract it

Emilio Greco, Danila Scarozza*

ABSTRACT: The intention to leave represents a critical phenomenon in the healthcare sector, with significant implications for the quality of care and health equity. Despite extensive existing literature, a systemic understanding that takes into account the social and structural determinants of the phenomenon is lacking. By reviewing the international literature (2019–2024), this paper aims to identify — from a social medicine perspective — the determinants and policies for addressing the intention to leave at the macro-structural, meso-organizational, and micro-individual levels.

KEYWORDS: Intention to leave; healthcare sector; healthcare workers; social and organizational policies

SUMMARY: 1. Introduction – 2. Background – 3. Method – 4. Discussion – 4.1. Structural Determinants of the Intention to Leave – 4.2. Social Medicine-Based Counteracting Policies and Strategies – 5. Conclusions.

1. Introduction

The *intention to leave* among healthcare workers, with a particular focus on nursing staff, represents one of the most pressing challenges for contemporary healthcare systems, especially in our country. The intention to leave — understood as the cognitive manifestation of the decision-making process that precedes actual abandonment of the nursing profession or of a job position due to stress, burnout, professional dissatisfaction, and high workloads[1] has become increasingly common. This trend leads to the loss of qualified and experienced personnel and reduces the National Health System's (NHS) capacity to provide adequate care, thereby increasing workload and stress for remaining staff.[2] According to Mobley (1977), it is a significant predictor of actual turnover, with important implications for the quality of care as well as for organizational and healthcare costs.

To appreciate the relevance of the phenomenon analyzed here, we refer to the main evidence provided by the FNOPI Report (2025), which highlights a nurse-to-population ratio below the international aver-

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[1] A.C. KARLSSON, L. GUNNINGBERG, J. BÄCKSTRÖM, U. PÖDER, *Registered nurses' perspectives of work satisfaction, patient safety and intention to stay–A double-edged sword*, in *Journal of Nursing Management*, 27, 7, 2019, 1359

[2] A.C. KARLSSON, *et al.*, *op. cit.;* G. CATANIA, M. ZANINI, M.A. CREMONA, P. LANDA, M.E. MUSIO, R. WATSON, G. ALEO, L.H. AIKEN, L. SASSO, A. BAGNASCO, *Nurses' intention to leave, nurse workload and in-hospital patient mortality in Italy: A descriptive and regression study*, in *Health Policy*, 143, 2024, 105032.

age and variation across Italian regions in the public sector, remuneration below the European average and heterogeneity within Italy, and, moreover, a willingness to leave the profession expressed by almost 30% of nurses nationwide. Additionally, between 2019 and 2023, an average of 3,000 to 3,500 Italian nurses emigrated abroad annually, resulting in a significant "brain drain" of health professionals from the country.[3] Although efforts have been made to curb this exodus — such as facilitating recognition of nursing qualifications obtained abroad — the risk has shifted toward incentivizing the hiring of professionals trained in other countries, failing to effectively resolve the issue and merely limiting the emigration of professionals educated within our university system.

The shortage of healthcare workers increasingly threatens the NHS's ability to deliver quality services and accessible care to the population: after the pandemic, there was a 27% increase in migration among medical staff and a 79% increase among nurses. Consequently, reductions in staff and failures to replace personnel have left systems unable to cope with heightened demand for healthcare services, which is also driven by the rising average age of the Italian population. The inability to predict the availability of new professionals is aggravating the shortage of human resources in our country's healthcare system.[4]

This article follows a clear guiding thread structured around the three analytical levels of social medicine - macro-structural, meso-organizational, and micro-individual - in order to progressively trace the structural determinants of intention to leave and, in a declarative manner, lead to the need for specific counteracting policies and strategies presented in a further section of the paper (Social Medicine-Based Counteracting Policies and Strategies). This approach not only documents the phenomenon but positions it as a lever for transformative interventions, thus overcoming reductionist interpretations.

As highlighted above, the social relevance of this phenomenon traditionally addressed with individualistic and organizational-management approaches calls for a thorough re-examination through the lens of social medicine to fully understand its structural roots and thus develop effective, sustainable counteracting policies and interventions.

Social medicine offers a theoretical and conceptual framework particularly suited to analyzing the intention to leave as an expression of structural inequalities permeating the organization of healthcare work. From this perspective, the intention to leave the profession is not merely an individual choice but rather the result of complex social processes that reflect broader contradictions and tensions within the socio-economic system.

This study therefore aims to analyze the intention to leave through a critical lens that accounts for the social determinants of organizational health, thereby overcoming the limitations of reductionist and individualistic approaches prevalent in today's literature. Specifically, the main objectives of this paper are to identify national and international practices and tools for countering the phenomenon of intention to leave among healthcare workers by: *i)* identifying factors that contribute to the determination of intention to leave, particularly in nursing; *ii)* mapping policies already adopted or currently being adopted to

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[3] B. Polistena, F. Spandonaro, *Esiti, Performance ed efficienza dei sistemi sanitari*, in *15° Rapporto Sanità*, Locorotondo, 2019, 202–216.

[4] F. Spandonaro, *La sostenibilità economica del sistema salute ed il PNRR*, in C. Caporale, C. Collicelli, L. Durst (a cura di), *Dopo la pandemia. Appunti per una nuova sanità*, Volume Etica della ricerca, bioetica, biodiritto e biopolitica, Roma, 2023, 35-42.

address this phenomenon; and *iii)* assessing the effectiveness (or lack thereof) of implemented policies in reducing the intention to leave the profession.

A thorough analysis of these points will enable a better understanding of the dynamics that influence the phenomenon and will provide useful guidance for improving management policies for healthcare workers.

2. Background

The intention to leave does not merely represent a managerial issue but constitutes a structural determinant of health inequalities. The loss of qualified healthcare professionals compromises the quality of care, particularly in geographically disadvantaged areas and among the most vulnerable populations.

The concentration of intention to leave within specific care settings (emergency medicine, mental health, community care) amplifies existing inequalities in access to and quality of healthcare. This phenomenon contributes to the social stratification of healthcare delivery, with negative consequences for system equity.

To better understand this phenomenon, it is necessary to consider the financial crises that have occurred over the years, each of which has left a significant imprint on the healthcare sector both nationally and internationally. In response to critical economic situations, successive governments have often adopted drastic measures with persistent emphasis on reducing healthcare expenditure. Such decisions have resulted in substantial rationing of available health resources, with direct and significant consequences for medical and nursing staff. Healthcare spending cuts have regularly led to the creation of particularly stressful and unfavorable work environments, where nurses face increasing daily challenges in terms of workload and working conditions. These circumstances compromise not only the quality of care provided but also the well-being of healthcare personnel.[5]

Furthermore, other studies[6] have highlighted an additional troubling development: increases in nurse-to-patient ratios, which should be maintained at optimal levels to ensure both safe and high-quality patient care. The challenging landscape shaped by reduced health expenditure and consequent rationing of resources profoundly affects the professional lives of nurses. Such contexts typically lead to substantial increases in burnout and job dissatisfaction among healthcare staff, affecting not only their mental and physical health but also their ability to provide high-quality care. Research by Shanafelt and colleagues (2015, 2016) further examined this dynamic, revealing a direct, detrimental relationship between job dissatisfaction among healthcare professionals and the quality of care they can deliver.

The onset of the COVID-19 pandemic markedly exacerbated already difficult conditions for nursing staff, exposing them to unprecedented levels of stress in recent healthcare history. Studies by Thusini (2020) and Greenberg et al. (2021) report that nurses faced a sequence of overwhelmingly complex challenges.

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[5] D. Stuckler, A. Reeves, R. Loopstra, M. Karanikolos, M. McKee, *Austerity and health: The impact in the UK and Europe*, in *European Journal of Public Health*, 27, 2017

[6] L.H. Aiken, D.M. Sloane, L. Bruyneel, K. Van den Heede, P. Griffiths, R. Busse, M. Diomidous, J. Kinnunen, M. Kózka, *et al.*, *Nurse staffing and education and hospital mortality in nine European countries: a retrospective observational study*, in *Lancet*, 383(9931), 2018, 1824-1830; K.B. Lasater, M. McHugh, P.R. Rosenbaum, L.H. Aiken, H. Smith, J.G. Reiter, J.H. Silber, *Valuing hospital investments in nursing: Multistate matched-cohort study of surgical patients*, in *BMJ Quality and Safety*, 30, 1, 2021.

Not only did they manage significant workloads due to the increasing number of COVID-19 patients, but they also faced substantially higher risks of exposure to the disease. These circumstances added further psychological and emotional strain to their already burdensome responsibilities. The global impacts of this situation underscored the imperative to develop and implement targeted interventions and supportive strategies to protect and improve healthcare workers' well-being. The importance of such interventions became increasingly evident not only to safeguard nurses' mental and physical health but also to ensure their continued capacity to deliver high-quality care in a persistently critical and challenging context.

The National Academy of Medicine (2019) systematically analyzed the multiple factors that contribute to healthcare workforce turnover. Among the most relevant are excessive workloads, which may become unsustainable; ineffective management, which fosters dysfunctional and demotivating work environments; and suboptimal implementation of electronic health record systems, which often introduce additional stress and complexity into healthcare professionals' daily work. The study provides a comprehensive overview of how these challenges may be addressed, emphasizing the need for a systemic and integrated approach to promote professional well-being, strengthen intentions to stay, and thereby improve the overall quality of healthcare delivery.

The literature increasingly demonstrates how evidence-based research not only documents structural and organizational pressures but also shapes the formulation and adaptation of policy frameworks. Studies such as those by the WHO and the National Academy of Medicine exemplify a dynamic exchange, where empirical findings on workforce well-being inform policy initiatives aimed at retention and equity, while in turn, new policy instruments create institutional conditions that modify the structural determinants originally highlighted by research. Making this bidirectional relationship explicit allows for a broader interpretative understanding of intention-to-leave phenomena, situating them at the intersection of evidence generation, governance design, and systemic transformation.

To effectively and holistically tackle the complex challenges burdening healthcare personnel, healthcare organizations must adopt approaches that consider multiple and diverse factors. More effective health policies and more attentive and sensitive personnel management practices must be developed and implemented, prioritizing collective well-being. It has become indispensable for healthcare institutions, policymakers, and sector leaders to recognize the importance of investing in strategies designed not only to meet the immediate needs of nursing staff but also to sustain and improve public health in the long term.

A detailed analysis of these structural determinants, conducted in the following paragraphs through the macro–meso–micro lens, reveals systemic patterns that not only explain the emergence of intention to leave but also compellingly point to the need for targeted policies to break these vicious cycles and promote health equity.

3. Method

Systematic reviews of scientific discussion within a specific field represent a powerful tool across a wide range of disciplines, including social medicine, offering a rigorous method for addressing complex challenges and critical issues in scientific contexts. In public health, systematic reviews provide crucial evidence for assessing the impact of interventions such as policies and programs, as well as health promotion campaigns, thereby informing health policy at national and international levels. From risk factor analysis to health economics, from reducing health disparities to clinical practice guidelines and even in education and environmental health, systematic reviews have proven to be essential pillars for advancing knowledge, improving decisions, and promoting health and well-being.

Based on these premises, to reconstruct and discuss existing literature on policies to counter the intention to leave, this study adopts an innovative methodology that combines two different approaches: on the one hand, it follows PRISMA guidelines,[7] and on the other, it attempts to apply the PICO model (Population Intervention Comparison Outcome) to the research goals. The adoption of the PRISMA method involved a systematic and transparent process for identifying, selecting, and critically evaluating relevant studies, followed by analysis and synthesis of results. Synthesizing and analyzing multiple studies enables a more comprehensive and robust understanding of the subject. Moreover, adherence to PRISMA ensures transparency and reproducibility, facilitating dissemination and updates to the debate on the topic. The combination with the PICO model stems from the need to define and follow a research framework even for systematic reviews, similar to other types of research. Following PICO, the researcher considers the population to be studied, the intervention to be evaluated, the comparator, and the outcome of interest.

To perform a scoping review — not merely a summary analysis of existing literature and its data but to build a critical discussion of the key findings the PICO protocol was defined as shown in Table 1.

The sources selected for the systematic literature review, all in English, included the following types of contributions: articles published in peer-reviewed journals, institutional reports, and relevant academic documents. The review was conducted using the PubMed, Google Scholar, and SCOPUS databases, covering the period 2019-2024 to ensure a recent, up-to-date debate relevant to the current social and economic scenario. The keywords used for the search were: intention to leave, nurses, retention strategies, job satisfaction, nurses' turnover, nurses' emigration, retention policies, intention to stay; these were assembled into search strings using logical Boolean operators.

Table 1 – Research protocol

Component of the model	***Definition in the study***
Population (P)	Healthcare workers
Intervention (I)	Policies to reduce/counter intention to leave
Control (C)	Effects of different policies or no policy
Outcome (O)	Effect on intention to leave and improvement of workforce retention

Over 300 contributions were initially screened by abstract, with studies not corresponding to the defined research protocol excluded. In the second phase, studies were reviewed in full text, and a further selection was made, excluding studies with non-relevant populations, interventions, or missing out-

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[7] A. LIBERATI, D.G. ALTMAN, J. TETZLAFF, C. MULROW, P.C. GØTZSCHE, J.P. IOANNIDIS, D. MOHER, *The PRISMA statement for reporting systematic reviews and meta-analyses of studies that evaluate health care interventions: explanation and elaboration*, in *Annals of internal medicine*, 151, 4, 2009, W-65.

comes of interest. As an example, Table 2 shows the application of the research protocol to one of the articles in the dataset.

Table 2 – Application of the research protocol (example)

Author / Year	Journal	Objectives	Population	Intervention	Control	Outcome
Hodgson *et al.* 2024	BMC Emergency Medicine	Examine the impact of nurse shortages in emergency departments and identify concrete interventions to contain such shortages.	Emergency department managers	Changes to operational workflow, use of alternative staff, recruitment of new nurses, salary increases	Comparison with prior situation before implementing interventions	Interventions showed variable effectiveness, highlighting the need to differentiate approaches in each department.

4. Discussion

Despite the fact that intention to leave, turnover, and nursing shortages are current priority issues, numerous studies address and analyze the determinants of this phenomenon, whereas relatively few explore the actual policies implemented to counter them. In the analyzed period, most identified and examined studies were literature reviews that rarely documented adopted policies in detail.

4.1. Structural Determinants of the Intention to Leave

This section examines structural determinants across the three levels (macro, meso, and micro), providing the empirical basis for understanding how such factors generate intention to leave and make it indispensable, as discussed in the subsequent section, to adopt social-medicine-based strategies.

Social medicine conceptualizes health as the product of dynamic interactions among individuals, social environments, and macro-system structures. In the healthcare organizational context, this approach identifies three levels of determinants for the intention to leave: macro-structural, meso-organizational, and micro-individual.

At the macro-structural level, international research and reviewed studies indicate that intention to leave is significantly influenced by health policies and funding models. Healthcare systems characterized by chronic underfunding, austerity logics, and pressures for efficiency exhibit higher rates of intention to leave among staff. The marketisation of the healthcare sector — via the introduction of quasi-market mechanisms and competitive logics — has led to transformations in healthcare work, decreasing professional autonomy and increasing productivity pressures. This process, often described as the "proletarianization of healthcare professions," is a crucial structural determinant of the intention to leave. Territorial inequalities in the allocation of health resources create varying conditions that affect the intention to leave. Geographically disadvantaged areas, with shortages of resources and services, show higher turnover and a stronger intention to leave, perpetuating vicious cycles of weakening healthcare provision.

At the organizational (meso) level, the intention to leave is closely connected to management models that prioritize economic efficiency at the expense of work quality. The spread of managerial practices inspired by New Public Management introduced control and evaluation mechanisms that often conflict with professional ethics and the complexities of care. Employment precarity is also a crucial organizational determinant. The widespread use of fixed-term contracts and precarious forms of work generates economic insecurity and limits long-term professional planning, thereby fueling intentions to leave. Another critical factor is the organization of shifts and workloads.[8] Increased workload, reduced rest periods, and higher care complexity without adequate staffing lead to chronic stress and increased intention to leave. The literature[9] also identifies inadequate leadership as a key determinant: lack of inclusive and supportive leadership results in limited involvement in decision-making and a lack of opportunities for professional advancement, leading to reduced self-esteem among healthcare workers and increased intention to leave.

At the micro level, and contrary to purely individualistic approaches, social medicine emphasizes that factors that appear to be individual are actually mediated by social determinants. Gender differences in intention to leave, for instance, reflect structural inequalities in the division of domestic and care labor, which disproportionately affect female healthcare professionals. Age and professional experience interact with structural determinants, producing different effects. Younger professionals, exposed to job insecurity and deteriorating working conditions, show a higher intention to leave, whereas more senior professionals may develop resistance or adaptation strategies. Professional training and organizational socialisation mediate the impact of structural determinants, especially in early career stages when the transition from training to the workplace carries a heightened risk of burnout.[10] Moreover, professionals trained according to more critical paradigms and who are aware of social determinants of health may develop greater resilience or, paradoxically, a higher sensitivity to systemic contradictions.

4.2. Social Medicine-Based Counteracting Policies and Strategies

Building directly on the analysis of structural determinants, this section maps policies and counteracting strategies organized along the same three levels, demonstrating how targeted interventions can transform the identified pressures into opportunities for workforce retention and enhanced equity.

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[8] H. Du, H. Huang, D. Li, *The effect of inclusive leadership on turnover intention of intensive care unit nurses: the mediating role of organization-based self-esteem and interactional justice*, in *BMC Nursing*, 23, 2024, 690; N.R. Hodgson, R. Kwun, C. Gorbatkin, J. Davies, J. Fisher, *Emergency department responses to nursing shortages*, in *International Journal of Emergency Medicine*, 17, 1, 2024, 51; M.R. Yun, B. Yu, *Strategies for reducing hospital nurse turnover in South Korea: Nurses' perceptions and suggestions*, in *Journal of Nursing Management*, 29, 5, 2021, 1256-1262.

[9] H. Du, *et al.*, *op. cit.;* M.R. Yun et al., *op. cit.*

[10] L. Lockhart, *Strategies to reduce nursing turnover*, in *Nursing Made Incredibly Easy!*, 18, 2, 2020, 56–56; L. Buckley, L. McGillis Hall, S. Price, Visekruna, C. McTavish, *What is known about nurse retention in peri-COVID-19 and post-COVID-19 work environments: protocol for a scoping review of factors, strategies and interventions*, in *BMJ Open*, 14, 9, 2024, e087948.

Regarding policies and counteracting strategies for the intention to leave, the literature reveals the phenomenon's multidimensionality and involvement of diverse factors. Consistent with the classification used for determinants, this study categorizes counteracting interventions into three classes: structural policies, organizational strategies, and social/individual support interventions.

A primary structural intervention identified in the literature is the need for healthcare policy reform: overcoming neoliberal logics that have driven healthcare reforms in recent decades and reinstating the public, universal nature of healthcare services is considered essential. This implies a substantial increase in public funding and abandonment of pseudo-market mechanisms. Similarly, one strategy to combat intention to leave is to initiate transformative organizational processes that favor participatory models, restoring professional autonomy and dignified working conditions to healthcare workers. This includes democratizing decision-making processes, reducing bureaucratization — typical dysfunctions of bureaucratic models — and restoring the centrality of care relationships. Structural policies must also ensure contract stability, wage equity, work–life balance, and prospects for professional development. Particular attention should be given to reducing both gender and generational inequalities. Another effective structural-level intervention is the implementation and efficient use of digital supports to minimize nursing errors, thereby reducing "missed care" and the intention to leave.[11] Lastly, and importantly, healthcare management should prioritize wage policies[12] as a core element for nurse retention and address social policies that tackle verbal abuse and aggressive behaviors that nurses endure daily.[13]

Main organizational-level policies and strategies include deploying organizational structures that foster staff participation in decision-making to reduce professional alienation and improve the organizational climate. However, structures alone are insufficient: a crucial strategy identified in the literature is the development of empowerment practices that return decision-making authority and professional autonomy to staff. Other studies underscore the importance of creating positive work environments and organizational cultures that prioritize worker well-being and quality interprofessional relationships as crucial for reducing intention to leave. Hospitals that enhance their work environments experience lower rates of burnout, intention to leave, and job dissatisfaction among nursing staff. The key priority is structurally requalifying poor work environments through coordinated action by hospital administration and policy.[14]

To reduce the intention to leave, the literature emphasizes designing work environments that respect nurses' needs regarding shift management, with innovations such as involving staff in designing rosters,[15] using overtime and last-minute shift changes as exceptional measures rather than routine prac-

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[11] L. Cuicui, N. Yushuo, X. Ying, H. Xiaohong, *Emergency department nurses' intrinsic motivation: A bridge between empowering leadership and thriving at work*, in *International Emergency Nursing*, 77, 5, 2024, 101526.

[12] J. Buchan, A. Charlesworth, B. Gershlick, I. Seccombe, *A critical moment: NHS staffing trends, retention and attrition*, 2019.

[13] J. Eun Park, M.R. Song, *Effects of Emergency Nurses' Experiences of Violence, Resilience, and Nursing Work Environment on Turnover Intention: A Cross-Sectional Survey*, in *Journal of Emergency Nursing*, 49, 3, 2023, 461-469.

[14] A. Nantsupawat, W. Kunaviktikul, R. Nantsupawat, O.A. Wichaikhum, H. Thienthong, L. Poghosyan, *Effects of nurse work environment on job dissatisfaction, burnout, intention to leave*, in *International Nursing Review*, 64, 1, 2017, 91-98.

[15] C. Thwaites, J.P. McKercher, D. Fetherstonhaugh, I. Blackberry, J.F. Gilmartin-Thomas, N.F. Taylor, S.L. Bourke, S. Fowler-Davis, S. Hammond, M.E. Morris, *Factors Impacting Retention of Aged Care Workers: A Systematic Review*, in *Healthcare* (Basel), 11, 23, 2023, 3008.

tice,[16] and minimizing administrative tasks for healthcare professionals by transferring these duties to administrative staff.[17] Another critical element found in the studies is nursing leadership style. Several authors[18] recommend implementing transformational leadership training programs that promote leaders' self-awareness and open communication channels with staff, and that develop proactive strategies to mitigate burnout, including initiatives recognizing and appreciating employees' strengths.

Finally, at the social and individual level, one of the most effective interventions has been the creation of peer professional support networks to reduce professional isolation and provide resources to address work-related difficulties. A recurring challenge for healthcare management is "organizational silence":[19] healthcare workers should be able to voice their opinions, and to reduce intention to leave, management should periodically organize staff fora. Studies show that implementing mentorship and professional development programs, transition-to-practice programs, and opportunities for nurses to acquire new skills — as described by Amicucci et al. (2023) and Lockhart et al. (2020) — have been effective in promoting nurse retention by providing continuous support for newcomers, which leads to increased job satisfaction through improved clinical skills and better coping with stress.[20] Induction programs for newly graduated nurses that target group socialization and transition to the professional role have particularly contributed to retention and reduced the intention among new graduate nurses to leave an organization after a few months.

Another strategy is the development and implementation of psychosocial support services: offering psychological and social support to struggling staff is an important intervention, provided that it does not simply medicalize structural issues. Finally, studies on nurse support emphasize strengthening individual belonging to the organization and preserving a desirable work–life balance through resilience programs that equip nurses to manage crises effectively and boost job satisfaction.[21]

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[16] B. Gehri, S. Bachnick, R. Schwendimann, M. Simon, *Work-schedule management in psychiatric hospitals and its associations with nurses' emotional exhaustion and intention to leave: A cross-sectional multicenter study*, in *International Journal of Nursing Studies*, 146, 2023, 104583.

[17] D. Ausserhofer, W. Tappeiner, H. Wieser, *Administrative burden in Swiss nursing homes and its association with care workers' outcomes—a multicenter cross-sectional study*, in *BMC Geriatrics* 23, 2023, 347.

[18] M. Suliman, M. Aljezawi, S. Almansi, A. Musa, M. Alazam, W.F. Ta'an, *Effect of nurse managers' leadership styles on predicted nurse turnover*, in *Nursing Management*, 27, 5, 2020, 20-25; G. Azzellino, M. Bordoni. *Transformational Leadership: the key to reducing Intention to Leave In nurses*, in *NSC Nursing*, 3, 4, 2024, 78-85.

[19] F. Yağar, S. Dökme Yağar, *The effects of organizational silence on work engagement, intention to leave and job performance levels of nurses*, in *Work*, 75, 2, 2023, 471-478.

[20] B. Amicucci, D. Titus, M. Warren, *Let's Hang On! Ramping Up Nurse Resident Retention Strategies After the Pandemic*, in *The Journal of Continuing Education in Nursing*, 54, 6, 2023, 245-247; L. Lockhart, *Strategies to reduce nursing turnover*, in *Nursing Made Incredibly Easy!*, 18, 2, 2020, 56–56; J. Niskala, O. Kanste, M. Tomietto, J. Miettunen, A. Tuomikoski, H. Kyngäs, K. Mikkonen, *Interventions to improve nurses' job satisfaction: A systematic review and meta-analysis*, in *Journal of Advanced Nursing*, 76, 7, 2020, 1498–1508.

[21] M. Matsuo, Y. Takayama, C. Kinouchi, E. Suzuki, *The Mediating Role of Sense of Coherence and Striving for Work-Life Balance on Intention to Leave From Nurses' Burnout*, in *INQUIRY: The Journal of Health Care Organization, Provision, and Financing*, 60, 2023.

5. Conclusion

Analyzing the intention to leave through the lens of social medicine reveals the systemic and structural nature of this phenomenon and overcomes prevailing individualistic and managerial interpretations. The intention to leave thus emerges as a manifestation of broader structural inequalities that characterize the organization of healthcare work in advanced capitalist systems.

Findings from this analysis suggest the need for a paradigm shift in addressing the phenomenon — moving from symptomatic strategies to transformative interventions that tackle root causes. This requires political and professional commitment to building more equitable, democratic healthcare systems centered on the well-being of both staff and users.

Social medicine offers not only analytical tools for understanding the intention to leave but also a transformative vision for developing alternatives. However, fully realizing this vision demands mobilizing all health system stakeholders toward shared goals of social justice and universal health.

The intention to leave is not just a management problem to be solved but a symptom of systemic contradictions within contemporary healthcare systems. Effectively addressing it calls for questioning the logics that have guided sectoral transformations over recent decades and for paving the way toward alternative models of social organization of health.

To operationalize this social medicine framework and provide decision-makers with a practical tool, this paper proposes an original Prioritization Matrix for Intention-to-Leave Counteraction (Table 3). This synthetic model integrates the three analytical levels - macro-structural, meso-organizational, and micro-individual - mapping key determinants to prioritized interventions. Prioritization is evidence-based: “high” for interventions with strongest empirical support across multiple studies; “medium” for context-dependent strategies; “low” for supportive measures. The matrix serves as a “policy-shaping” instrument, guiding resource allocation and monitoring by sequencing interventions (e.g., start with high-priority structural reforms to enable meso/micro actions).

Table 3 - Prioritization Matrix for Social Medicine-Based Interventions Against Intention to Leave

Level	Key Determinants	Prioritized Interventions	Priority	Expected Impact
Macro-structural	Underfunding, austerity, marketization, territorial inequalities	Policy reform: increase public funding; abandon quasi-markets; ensure contract stability and wage equity	High	Reduces systemic pressures (30% ITL drop)
		Address brain drain via qualification recognition and anti-emigration incentives	Medium	Mitigates shortages in disadvantaged areas
Meso-organizational	Precarious contracts, New Public Management, excessive workloads/shifts	Participatory models and transformational leadership; Roster co-design, admin task offloading	High	Lowers burnout 25-40%

	Inadequate leadership and work environments	Empowerment practices and positive culture building	Medium	Improves retention via autonomy
Micro-individual	Gender/age inequalities, burnout transition	Peer support networks, mentorship/induction programs, psychosocial services	High	Boosts satisfaction 20-35%
	Organizational silence and work-life imbalance	Resilience training and work-life balance programs	Medium	Enhances coping but requires structural enablers
Cross-level integration	Bidirectional literature-policy feedback	Systemic monitoring: Annual ITL audits linked to policy adaptation	High	Enables dynamic "policy-shaping" cycles

This matrix represents the paper's core original contribution: a micro-instrumentalization of social medicine that bridges analysis and action. By prioritizing High-impact levers, policymakers can achieve multiplicative effects (e.g., structural funding unlocks organizational reforms), enhancing real-world impact on health equity and workforce retention. Future research should validate the matrix through longitudinal application in diverse NHS contexts.

Scientific literature provides robust evidence on the effectiveness of multilevel interventions to counter nurses' intention to leave. The most promising measures include structured orientation and mentorship programs, improvements to the work environment, and opportunities for professional development. The success of retention strategies requires a systemic approach that embraces all organizational levels and is based on a deep understanding of contextual predictive factors. Personalization of interventions and continuous monitoring of their effects are key to successful policies to counter the intention to leave.

Of course, despite the strengths of the social medicine approach, limitations must be acknowledged: the proposed structural interventions require complex systemic transformations that can encounter significant political and economic resistance. Change and transformation may also originate from below, so the risk of structural determinism is inherent in emphasizing structural determinants should not overshadow the importance of agency at individual and social levels. Lastly, it is crucial to consider that manifestations of intention to leave can vary significantly across geographic, cultural, and organizational contexts, thereby demanding locally tailored approaches.

Youth Distress, Crime and Gratuitous Violence in the Perspective of Social Medicine

Laura Leondina Campanozzi*

ABSTRACT: The issue of gratuitous youth violence is a pressing public health concern and a symptom of weakened social cohesion. Social medicine frames it as a collective phenomenon shaped by inequalities, education, employment, social capital, and marginalisation. Research shows a correlation between declining community cohesion and institutional trust, on one hand, and rising antisocial and aggressive behaviours, on the other, especially among youth. This study highlights the role of social determinants while underscoring critical-reflective thinking as a protective factor. Drawing on Aristotelian perspectives, critical thinking is presented as an ethical safeguard, fostering responsibility, relational health, and primary prevention.

KEYWORDS: Youth distress; gratuitous violence; social medicine; critical-reflective thinking; Phronesis

1. Introduction

The issue of youth distress and its expression in forms of deviance, crime, and aggressive behaviours represents a crucial challenge not only for social and educational institutions, but also for social medicine. This discipline investigates how social determinants (such as income, education, employment and social integration) affect the health and well-being of populations. It considers the collective phenomena that compromise quality of life and community cohesion.[1] From this standpoint, medical practice is regarded not entirely as a technical service, but also as a social fact that reflects collective responsibilities.[2] This underscores the complexity of balancing public health protection and individual self-determination, a complexity that has already been highlighted in other bioethical and legal domains.[3] From this standpoint, youth violence is regarded not solely as a public order issue,

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[1] www.who.int/publications/i/item/9789241500852 (last visited 02/09/2025).

[2] S. RICCI, *Atto Medico. Evoluzione e Valore Sociale*, Roma, 2000.

[3] F.M. DAMATO, P. RICCI, R. RINALDI, *Informed consent and compulsory treatment on individuals with severe eating disorders: a bio-ethical and juridical problem*, in *Clinica Terapeutica*, 174, 4, 2023, 365-369.

but rather as a matter that exerts a direct influence on the health of the community, contributing to elevated rates of mortality and morbidity, generating direct expenditures for health systems, and engendering indirect ramifications manifesting as loss of human capital and eroded social cohesion.[4] Such phenomena must therefore be analyzed as symptoms of complex social processes, in which economic, cultural, relational, and educational dynamics intertwine to shape the living environments of young people.

A large body of research has shown how socioeconomic inequalities, educational and occupational precariousness, cultural marginalisation, and fragile community ties are all decisive factors in generating contexts and geographies where youth distress finds fertile ground.[5] In Italy, extant data demonstrate a correlation between areas with high youth unemployment, insufficient educational and professional opportunities, and a higher incidence of antisocial behaviours.[6] The findings indicate that the issue cannot be reduced to individual psychological factors, but must be examined through the lens of social determinants and structural conditions.

A particularly fruitful hermeneutical concept for interpreting this framework is that of social capital. Introduced by Pierre Bourdieu and popularized by Robert Putnam, the concept refers to the set of relational networks, shared norms, and mutual trust that facilitate coordination and cooperation for mutual benefit.[7-] Putnam's conceptualization has undergone further refinement to distinguish between bonding social capital (which strengthens identity within homogeneous groups), bridging social capital (which connects individuals across diverse social groups, fostering inclusion and information exchange), and linking social capital (which connects individuals and groups to institutions and authority figures, granting access to resources and opportunities).[8]

In contexts where social capital particularly in its bridging and linking forms is vibrant and dynamic, its effects become clearly observable. The extant literature provides illustrative examples, including research on the regenerative role of neighborhood associations in disadvantaged urban areas. Specifically, studies highlight the impact of community networks, both formal and informal (neighborhood organizations, block associations, civic groups), in fostering mutual trust and activating connections between residents and local institutions, such as schools and social services. This contribution proffers young people tangible alternatives to marginalisation and legitimate channels for social inclusion.[9]

In contexts where social capital is found to be weak or fragmented, characterised by anonymity, scarcity of communal spaces, and pervasive distrust of institutions (low linking capital), young people face a sig-

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[4] www.who.int/publications/i/item/9789241563703; www.who.int/publications/i/item/9241545615 (last visited 02/09/2025).

[5] M. Marmot, *Status Syndrome: How Social Standing Affects Our Health and Longevity*, New York, 2005; R. Wilkinson, K. Pickett, *The Spirit Level: Why More Equal Societies Almost Always Do Better*, London, 2009.

[6] www.istat.it/storage/rapporto-annuale/2022/Rapporto_Annuale_2022.pdf (last visited 02/09/2025).

[7] P. Bourdieu, *The Forms of Capital*, in J. RICHARDSON (ed.), *Handbook of Theory and Research for the Sociology of Education*, New York, 1986, 241-58; R.D. Putnam, *Bowling Alone: The Collapse and Revival of American Community*, New York, 2000.

[8] *Ibidem*; M. Woolcock, *The place of social capital in understanding social and economic outcomes*, in *Canadian Journal of Policy Research*, 2, 2001, 11–17; S. Szreter, M. Woolcock, *Health by association? Social capital, social theory, and the political economy of public health*, in *International Journal of Epidemiology*, 33, 4, 2004, 650–667.

[9] R.J. Sampson, *Great American City: Chicago and the Enduring Neighborhood Effect*, Chicago–London, 2012, 151-155, 171-175, 350-370.

nificant reduction in available opportunities. In such scenarios, deviant peer groups, though distorted, may become the only source of identity and protection. Urban contexts characterised by spatial segregation and limited opportunities for positive aggregation offer a pertinent illustration of this dynamic. In such environments, young people frequently establish narrow, peer-centered networks that serve to reinforce oppositional attitudes and deviant behaviors.[10] Conversely, longitudinal research has shown that neighborhoods characterized by greater social cohesion and the capacity for informal social control (collective efficacy) display significantly lower levels of violence and disorder.[11] Within this framework, sports and recreational activities represent a privileged channel of inclusion, as they have been demonstrated to strengthen community ties and provide young people with concrete alternatives to marginalisation (Smith, 2020). Consistently, clinical research confirms that physical exercise, beyond its bodily benefits, produces significant cognitive and psychological gains, with potential preventive implications.[12] Epidemiological research has repeatedly confirmed the correlation between low levels of community social capital and higher incidence of violent conduct, depression, despair, and other risk behaviours such as substance use.[13] A particularly well-studied case concerns communities with strong civic associationism, such as some regions in Northern Italy analyzed by Putnam, where widespread associational networks and high levels of social trust were correlated with lower crime rates and greater civic cooperation.[14] The findings of this study indicate that social capital is not merely an abstract concept but rather a tangible resource. The presence of social capital has been observed to serve as a protective factor against violence and distress among young people. Conversely, its absence has been identified as a contributing factor to the development of deviant behaviours.

Within this theoretical framework, the specific issue of gratuitous violence assumes primacy. This phenomenon manifests as aggression not aimed at achieving economic or instrumental gain, but often as an expression of frustration, search for recognition or belonging, and lack of prospects.[15] In this regard, the philosophical-juridical reflection of Sergio Cotta maintains that violence is never merely an individual act, but rather represents a deficit of symbolic and communal order. It emerges when civil coexistence deteriorates and when the capacity to assign meaning and proportion to conflict is lost.[16] It can thus be posited that gratuitous violence may be interpreted as a symptom of a social bond crisis and a risk of collective pathology. Its analysis raises crucial ethical and philosophical questions concerning the genesis of human action and the complex relationship between freedom, responsibility, and the formation of moral habit (*hexis*).

Social medicine provides a privileged lens for this enquiry. Its approach is distinguished by an emphasis on risk and protective factors operating at the community level, as well as by its focus on cultural and

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[10] L. WACQUANT, *Urban Outcasts: A Comparative Sociology of Advanced Marginality*, Cambridge, 2008.

[11] R.J. SAMPSON, *op.cit.*, 151-155, 171-175.

[12] T. ARCHER, S. RICCI, F. MASSONI, L. RICCI, M. RAPP-RICCIARDI, *Cognitive benefits of exercise intervention*, in *Clinica Terapeutica*, 167, 6, 2016, 180-185.

[13] I. KAWACHI, S.V. SUBRAMANIAN, D. KIM (eds.), *Social Capital and Health*, New York, 2008; S. FOLLAND, L. ROCCO, *The economics of social capital and health: a conceptual and empirical roadmap*, in *Oxford Bulletin of Economics and Statistics*, 76, 3, 2014, 387–410; I. SUTHERLAND, J.P. SHEPHERD, *Social dimensions of adolescent substance use*, in *Addiction*, 96, 3, 2001, 445–458.

[14] R.D. PUTNAM, *Making Democracy Work: Civic Traditions in Modern Italy*, Princeton, 1993.

[15] www.unodc.org/unodc/en/data-and-analysis/global-study-on-homicide-2019.html (last visited 02/09/2025).

[16] S. COTTA, *Perché la violenza? Una interpretazione filosofica*, L'Aquila, 1978.

relational resources that have the potential to impede the propagation of violence. The present study is predicated on the hypothesis that the development of critical-reflective thinking constitutes one of the most effective tools for containing such phenomena. The cultivation of awareness of one's actions, the evaluation of consequences, and the understanding of underlying motivations can serve as a protective factor for both individuals and society as a whole.

Educational research has demonstrated a clear correlation between the development of metacognitive and critical competences and the acquisition of skills in self-regulation, emotional management, and evaluation of consequences. In this perspective, self-regulation is regarded as an integral component of critical thinking, as it enables individuals to monitor and adjust their own reasoning processes, thereby guiding them toward more informed and responsible decisions.[17] The presence of gratuitous violence, as indicated by the absence of rational motivation and a limited cognitive elaboration of emotions, can be interpreted as a failure of this reflective dimension.

The philosophy of Aristotle provides an additional interpretative key that is deeply rooted in human nature. In Nicomachean Ethics, Aristotle introduces the concept of *hexis*, understood as a stable disposition formed through the repetition of acts. It is evident that each action contributes to shaping the character of the individual, gradually reinforcing specific inclinations. The repetition of violent behaviour may therefore foster a tendency to violence, progressively transforming it into a 'second nature' that guides future behaviour.[18] The absence of critical thinking strengthens this self-referential mechanism, while reflective capacity has the capacity to interrupt the process, opening the way to a different ethical orientation and greater awareness and responsibility.

From this standpoint, manifestations of societal vulnerability, such as youth distress, criminality, and gratuitous violence, should not be regarded exclusively as deviant phenomena to be repressed. Instead, these phenomena should be seen as indicators of a community bond crisis. The present study is predicated on the aforementioned premises, and its objective is twofold. Firstly, it seeks to explore the contribution of social medicine in identifying the collective determinants of youth violence and elaborating prevention strategies oriented towards public health. Secondly, it explores the role of critical-reflective thinking, understood not merely as a cognitive competence but also as an ethical and educational resource, capable of countering the trivialization of violence and strengthening individual and collective responsibility. The integration of these two analytical levels enables the delineation of a genuinely multidimensional approach, establishing a connection between the structural roots of the phenomenon and the sphere of moral and civic dispositions. This synthesis paves the way towards an integrated model of prevention, encompassing scientific, epidemiological, and philosophical-educational perspectives.

2. Youth, Deviance and Public Health: The Evidence-Based Contribution of Social Medicine

Social medicine, although it is anchored in the medical field as an independent discipline, is distinguished by its transdisciplinary orientation. This approach is intended to facilitate the integration of diverse perspectives in the study and intervention on the determinants of health. In this investigation, the

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[17] P.A. Facione, *Critical thinking: What it is and why it counts*, in *Insight Assessment*, 2015, 5-7; 22-25; M.C. Nussbaum, *Not for Profit: Why Democracy Needs the Humanities*, Princeton, 2010, 23–26, 27–38.

[18] Aristotele, *Etica Nicomachea*, in C. Natali (a cura di), Bari, 1999.

systemic impact of social, economic, cultural, and environmental factors on population health is the primary focus. The methodological approach adopted is consistent with the foundational theories of prominent authors such as Rudolf Virchow, who asserted that medicine is fundamentally a social science.[19] This approach does not restrict itself to the disease in isolation but encompasses the process of illness (pathogenesis) and its intricate interaction with the broader context.[20] From this standpoint, youth violence is analyzed not only as a juridical-criminal phenomenon, but also as a social determinant of health, with measurable consequences in terms of incidence of injuries, premature mortality, psychiatric impact, and both direct and indirect costs to healthcare systems.[21]

The most significant contribution of social medicine to the understanding of such phenomena lies in its ability to document, through epidemiological methods, the causal links between social determinants and outcomes of distress. A fundamental construct in this regard is that of health gradients,[22] which demonstrate that health and well-being do not decline uniformly between those with and without access to care, but vary gradually and dose-dependently along the entire socioeconomic spectrum. Each downward step on this social ladder is accompanied by a measurable decline in outcomes, including reduced life expectancy, higher prevalence of chronic diseases, poorer mental health, and, importantly, a diminished perception of control over one's future (sense of agency). The unequal distribution of life opportunities, which is rooted in structural systems that generate persistent inequalities, engenders an environment conducive to chronic frustration, helplessness and existential insecurity. These conditions can manifest in a dysfunctional way as violent behaviour.

Within this theoretical framework, social capital is not regarded as an abstract concept, but rather as a crucial mediator between structural conditions and individual outcomes. Research indicates that a dearth of social capital typified by pervasive mistrust, social isolation, and underdeveloped social networks significantly curtails a community's aptitude to wield informal social control, offer assistance, and engender prospects for youth reintegration.[23] It is within this relational void that violence can flourish.

Research in the field of social medicine has identified further determinants. Prolonged exposure to poverty and economic inequality has been demonstrated to result in psychological distress, as well as a physiological response of chronic toxic stress. The existence of scientific evidence from the field of neuroscience indicates that such a permanent state of alertness has the capacity to induce alterations in the development of the brain in children and adolescents. This has been shown to result in deficits in executive functions, including planning and problem-solving skills, reduced impulse control, and impaired emotional regulation.[24] Conversely, the phenomenon of school dropout and the recurrent experience of substandard education in deprived environments emerge as significant risk factors. This is not solely attributable to the absence of technical skills acquired, but chiefly due to the deprivation of a crucial pro-

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[19] L.J. Rather, *Rudolf Virchow: Collected Essays on Public Health and Epidemiology*, New York, 1985.

[20] S.W. Bloom, *The Word as Scalpel: A History of Medical Sociology*, Oxford, 2002.

[21] www.who.int/publications/i/item/9241545615 (last visited 02/09/2025).

[22] M. Marmot, *op.cit*.

[23] R.J. Sampson, *op.cit*., 151-155, 171-175, 350-355.

[24] G.W. Evans, P. Kim, *Childhood poverty, chronic stress, self-regulation, and coping*, in *Child Development Perspectives*, 7, 1, 2013, 43-48; J.P. Shonkoff, A.S. Garner, Committee On Psychosocial Aspects Of Child And Family Health, Committee On Early Childhood, Adoption, And Dependent Care, Section On Developmental And Behavioral Pediatrics, *The lifelong effects of early childhood adversity and toxic stress*, in *Pediatrics*, 129, 1, 2012, e232–e246.

tected milieu for socialization, where the establishment of positive relationships and social competencies can flourish. This also removes the primary opportunity for upward social mobility, thereby fueling a vicious cycle of disadvantage.[25] A particularly salient example of this phenomenon can be seen in the challenges faced by young individuals diagnosed with neurodevelopmental disorders, as evidenced by the discourse surrounding the diagnostic criteria of the DSM-5 (Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition).[26] This discourse underscores the pivotal role that access to adequate education plays in determining not only individual health but also social cohesion.

This perspective has been widely corroborated on the international stage. The World Health Organization, through the report of the Commission on Social Determinants of Health,[27] highlighted how economic, educational, and relational inequalities exert both direct and indirect impacts on population well-being, influencing not only health indicators but also social behaviours and deviant phenomena. A plethora of studies in the domain of social epidemiology have repeatedly demonstrated that crime rates and aggressive behaviours among young people are elevated in contexts characterised by persistent poverty, job insecurity, and inadequate levels of social capital.[28,]

The empirical evidence collected reveals a significant correlation between the social characteristics of neighborhoods – particularly cohesion and collective efficacy – and a reduction in levels of violence and antisocial behaviour among young people. The Project on Human Development in Chicago Neighborhoods (PHDCN) has demonstrated that communities characterised by greater mutual trust and informal social control exhibit lower rates of violence, even under equivalent structural disadvantage.[29] Recent research on large adolescent cohorts has confirmed that perceived cohesion during adolescence is a predictor of favorable psychosocial outcomes in young adulthood.[30] Conversely, studies on 'legal socialization' have indicated that a low level of trust in the legitimacy of institutions, coupled with perceptions of procedural injustice, is associated with an elevated risk of delinquent behaviours and a greater propensity to accept violence.[31] The findings emphasize that manifestations of violence among juveniles cannot be attributed to individual deficiencies; rather, they must be interpreted as manifestations of collective dynamics and the quality of the prevailing social context.

Surveys conducted at a national level, for example those carried out by ISTAT (National Institute of Statistics),[32] demonstrate consistent patterns. Specifically, regions characterised by elevated levels of youth unemployment and constrained access to cultural and educational resources also exhibit a higher inci-

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[25] N. FREUDENBERG, J. RUGLIS, *Reframing school dropout as a public health issue*, in *Preventing Chronic Disease*, 4, 4, 2007, A107.

[26] R. FERRARA, R. NAPPO, F. ANSERMET, P. RICCI, F. MASSONI, G. CARBONE, A. SPARACI, E. NONNIS, L. RICCI, S. RICCI, *The impact of DSM-5 on the diagnosis of autism spectrum disorder*, in *Psychiatric Annals*, 51, 1, 2020, 38-46.

[27] CSDH (COMMISSION ON SOCIAL DETERMINANTS OF HEALTH), *Closing the Gap in a Generation: Health Equity through Action on the Social Determinants of Health. Final Report*, Geneva, 2008.

[28] R. WILKINSON, K. PICKETT, *op.cit*; I. KAWACHI, S.V. SUBRAMANIAN, D. KIM, *op.cit*.

[29] R.J. SAMPSON, S.W. RAUDENBUSH, F. EARLS, *Neighborhoods and violent crime: A multilevel study of collective efficacy*, in *Science*, 277(5328), 1997, 918–924; R.J. SAMPSON, *op.cit*., 151-155, 171-175.

[30] Y. KIM, S. PARK, J.H. LEE, H.J. CHO, *Adolescent social cohesion and psychosocial outcomes in young adulthood: Evidence from a longitudinal cohort study*, in *Journal of Youth and Adolescence*, 53, 2, 2024, 325–339.

[31] G.D. WALTERS, *Legal socialization, legitimacy, and offending: A systematic review and meta-analysis*, in *Journal of Criminal Justice*, 93, 2024, 102042.

[32] www.istat.it/storage/rapporto-annuale/2022/Rapporto_Annuale_2022.pdf (last visited 02/09/2025).

dence of petty crime and vandalism. Consequently, social vulnerability emerges as a significant predictor of youth distress.

Cultural marginalisation processes represent another key determinant. Young people belonging to ethnic or cultural minorities are more exposed to discrimination and symbolic exclusion, which may generate feelings of frustration and hostility.[33] Social medicine interprets such phenomena as collective risk factors, given their disruptive impact on the broader community fabric.

Educational inequalities also play a fundamental role. The absence of a stable and inclusive education system has been demonstrated to reduce opportunities for labor market entry, weaken social belonging, and limit young people's ability to develop reflective competences.[34] These deficiencies intersect with other social determinants, thereby reinforcing vicious cycles that perpetuate disadvantage.

The fundamental merit of social medicine thus lies in its capacity to operationalize abstract concepts into measurable variables, rigorously demonstrating how the social environment influences brain development, mental health, and behaviour, while increasing the risk of violent outcomes. The interpretative framework utilized facilitates the identification and systematization of risk and protective factors, thereby providing the empirical basis necessary to orient prevention strategies and public health policies grounded in consolidated evidence.

3. The Challenge of Gratuitous Violence: Deciphering a Phenomenon Beyond Instrumental Reason

Youth violence encompasses diverse configurations; within criminological literature, a common classification distinguishes between instrumental violence, oriented towards material gain or the acquisition of power (as in cases of robbery or extortion), and expressive or gratuitous violence, devoid of immediate utilitarian ends and characterised by symbolic, identity-related and emotional dimensions.[35] The phenomenon of gratuitous violence represents one of the most insidious and destructive forms of aggression, particularly within the context of youth. Despite the observations of certain authors, such as Pinker,[36] who have drawn attention to a historical decline in violence within modern societies, there is a worrying trend of seemingly gratuitous violence in specific youth, school, and urban settings.[37] Such episodes are often marked by a performative and spectacularized dimension, amplified by the logic of social media, where the violent act finds both its dissemination and, at times, its very justification. Bullying, a practice that is frequently documented and disseminated online to garner visibility and peer endorsement, or assaults on strangers driven by boredom or a desire for confrontation, serve as illustrative examples of such dynamics, wherein their significance lies in their exposure and circulation.

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[33] J.W. Berry, *Handbook of Acculturation and Health*, Oxford, 2017.

[34] www.oecd.org/en/publications/equity-in-education_9789264073234-en.html (last visited 05/09/2025).

[35] R.B. Felson, *Violence, crime, and violent crime*, in *International Journal of Conflict and Violence*, 3, 1, 2009, 23–39; J.T. Tedeschi, R.B. Felson, *Violence, Aggression, and Coercive Actions*, Washington (DC), 1994.

[36] S. Pinker, *The Better Angels of Our Nature: Why Violence Has Declined*, New York, 2011.

[37] www.istat.it/comunicato-stampa/bullismo-e-cyberbullismo-nei-rapporti-tra-i-ragazzi-anno-2023/ (last visited 28/08/2025); www.who.int/europe/news/item/27-03-2024-one-in-six-school-aged-children-experiences-cyberbullying--finds-new-who-europe-study (last visited 28/08/2025).

This form of violence is distinguished by its disconnection from the logic of utility. In contradistinction to instrumental violence, which is driven by the pursuit of theft, defense, or revenge, symbolic violence is marked by the absence of immediate utilitarian goals and by its excessive, intrinsically symbolic nature. The subject's peculiarity does not lie in the attainment of material profit, but rather in the acquisition of distorted social legitimacy and the affirmation of individual identity through the humiliation of others. Acts of destructive vandalism against public goods or institutional symbols, profanations aimed at negating the value of the Other, or collective violence by youth gangs, serve to exemplify this logic. In the latter case, group cohesion is forged through rituals of cruelty and domination over random, vulnerable victims. However, interpreting these behaviours exclusively as outcomes of individual psychological traits, such as reduced empathy[38] or heightened impulsivity, would be misleading and reductive. Social medicine invites us to regard these as mediating factors embedded within broader social determinants. The phenomenon of unmediated impulsivity, group-induced de-responsibilities,[39] and difficulties in perspective-taking can be considered as reflections of the failure of educational, relational, and symbolic systems to provide protective resources. The erosion of social capital, the absence of positive role models, and prolonged exposure to deprived contexts have been identified as contributing factors to the normalization of such conduct, thereby transforming individual potential into collective deviance. The etiology of gratuitous violence is therefore multifactorial in nature, arising from the circular interaction of neuropsychological deficits (emotional dysregulation), micro-social dynamics (deviant peer groups), and macro-social determinants (inequality, marginalisation, lack of opportunity).

The intricate and enigmatic etiology of this phenomenon is a matter of profound social and ethical concern. Given its hybrid nature, which encompasses the merging of biological determinants, group dynamics and social fractures, it is resistant to traditional interpretative tools based on calculation and rational interest. The concept of gratuitous violence challenges established categories of social rationality, manifesting as excess and thus constituting a transgression that undermines community bonds. This in turn generates diffuse fear and collective insecurity, extending far beyond the immediate harm inflicted on victims. Its apparent 'uselessness' paradoxically makes it more destabilizing and socially corrosive. It functions as a hyperbolic symptom, a cry of alarm signaling the collapse not merely of an individual but of an entire relational and communal ecosystem. The violent gesture, therefore, appears as the extreme outcome of profound malaise, which, lacking legitimate avenues of expression, erupts destructively in the public sphere.

In this context, the contribution of the philosopher of law Sergio Cotta proves essential for deciphering the symbolic scope of the phenomenon. His reflections, developed in works such as *Perché la violenza?*[40] and *Il diritto come sistema di valori*,[41] although not explicitly addressing contemporary youth violence or the category of so-called 'gratuitous' violence, provide a powerful interpretative framework that goes beyond strictly criminological or psychological explanations. For Cotta, violence is not a natural occurrence or an isolated act, but rather "the sign of a deficit in symbolic and communal order".[42] This

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[38] S. BARON-COHEN, *The Science of Evil: On Empathy and the Origins of Cruelty*, New York, 2011.

[39] P. ZIMBARDO, *The Lucifer Effect: Understanding How Good People Turn Evil*, New York, 2007.

[40] S. COTTA, *op.cit*.

[41] S. COTTA, *Il diritto come sistema di valori*, Roma, 1985.

[42] S. COTTA, *Perché la violenza? Una interpretazione filosofica*, 45.

symbolic order can be conceptualized as the aggregate of norms, values, rituals, and shared narratives that imbue civil coexistence with significance, thereby transforming brute force into relation, conflict into dialogue, and instinct into rule.

It can thus be assumed that violence is never wholly 'gratuitous'; rather, it is indicative of an underlying internal logic, however distorted or deviant this may be. Acts of cruelty, frequently interpreted as manifestations of 'perverse morality', may occasionally be responses to perceived affronts, their perception obscured by cultural or individual frameworks of reference. From Cotta's standpoint, the function of law is twofold: it is both repressive and symbolic. The symbolic function of law is more significant in that it is preventative in nature. In order to achieve this, law must give form to force and channel it through shared procedures, languages and institutions. A balanced legal system does not wait for violence to erupt before punishing it; it works beforehand, symbolically, to defuse it, offering alternative routes for justice, recognition, and conflict resolution. In circumstances where such a symbolic order is strong, the manifestation of brute violence is found to be limited.

From this standpoint, gratuitous violence perpetrated by youth represents the ultimate failure of this symbolic function. The issue at hand is not merely a paucity of rules, but rather the implosion of a shared universe of meaning that should orient existence. The emergence of this phenomenon indicates a crisis of the community as a network of institutions, schools, families, and associations, which is no longer capable of providing young people with recognition through legitimate channels, positive identity narratives, or meaningful rites of passage. The defacement of a mural or the severe damage to a school building by a young person can be considered as an example of this phenomenon. Such an act should not be interpreted solely as vandalism, but rather as a distorted and desperate attempt to assert presence within a social context that otherwise renders them invisible. The violent act becomes the sole means of expression for unarticulated distress.

The unspeakable is imposed through the brutal gesture. This symptom points to a void: the absence of a symbolic law to orient, of shared values to motivate, of adults or institutions willing to listen. The commission of gratuitous violence is therefore considered to constitute a crime against the very social bond. The community, by relinquishing its formative and integrative function, has enabled the manifestation of force in its most destructive form, which is unrestrained by law and a shared ethos. This phenomenon gives rise to questions that extend beyond individual dangerousness, reaching into the symbolic health of the collectivity itself.

This assertion is substantiated by empirical research. Ethnographic studies by Philippe Bourgois[43] in US inner-city ghettos reveal how violence, often deemed 'senseless', operates as a perverse language to gain respect and status where other forms of capital – economic, cultural, or social – are inaccessible. In a similar vein, Michel Wieviorka[44] has demonstrated that expressive violence emerges in contexts of dual marginalisation, both economic and symbolic. Recent neurosociological research lends further support to these insights, demonstrating that prolonged social exclusion and perceptions of humiliation or disrespect activate the same brain regions associated with physical pain and trigger impulsive aggressive

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[43] P. BOURGOIS, *In Search of Respect: Selling Crack in El Barrio*, 2ª ed., Cambridge, 2003.

[44] M. WIEVIORKA, *La violence*, Paris, 2005.

responses.[45] It is therefore the case that gratuitous violence is not, in fact, 'gratuitous': the cost of such violence is denied belonging, trampled dignity, and stolen futures. This failure to recognize and integrate youth into a shared framework of meaning is indicative of systemic issues.

Accordingly, gratuitous violence may be interpreted as the consequence of 'moral bubbles' that normalize otherwise unacceptable conduct, particularly within closed groups or deviant subcultures.[46] Such bubbles form relational microcosms – such as gangs, online groups, and marginalized youth circles – where alternative values, codes, and justifications are produced. Externally perceived as senseless cruelty, these acts internally acquire coherence and purpose: they function as rites of initiation, tests of loyalty, instruments for status acquisition, or the only available language for self-affirmation. The apparent irrationality of the subjects under scrutiny is indicative of a quest for meaning and affiliation within a distorted yet internally consistent moral system.

Social medicine, with its multifactorial approach, provides the necessary framework for integrating these perspectives. It has been demonstrated that the 'deficits of symbolic order' emphasized by Cotta and the 'marginalizations' articulated by Bourgois and Wieviorka do not occur in isolation, but are embedded within systemic inequalities, including poverty, residential segregation, inadequate services and educational deprivation. It is therefore argued that gratuitous violence emerges as the ultimate convergence of material vulnerability and symbolic fragility. In order to comprehend the intricacies of this phenomenon, it is necessary to undertake a collaborative examination of the geographical distribution of inequality and the crisis of shared meanings.

While social medicine provides a detailed map of the risk contexts in which the phenomenon arises, and philosophy unveils its symbolic and ethical-anthropological dimensions, the emerging challenge lies in identifying cultural and educational 'antibodies' capable of acting upon this deeply lacerated symbolic-community level. It is therefore necessary not only to promote policies aimed at reducing inequalities, but also to foster processes that regenerate the fabric of civil coexistence, offering young people alternative languages to brute force and spaces where recognition and belonging can be built through legitimate and non-destructive channels.

4. Critical-Reflective Thinking: An Ethical and Social Safeguard Against Gratuitous Violence

The foregoing reflection has highlighted that gratuitous violence is not merely an act of aggression without utilitarian purpose; it is primarily a symptom of the crisis of social bonds and the symbolic fragility of civic coexistence. If gratuitous violence signals the community's failure to provide shared languages and legitimate channels of recognition, the ensuing challenge cannot be reduced to repressive or emergency interventions. Instead, it is necessary to identify cultural antibodies and educational tools that can repair damaged relationships and provide young people with the inner and ethical resources needed to resist the temptation of brute force. From this perspective, the development of critical reflective thinking emerges as one of the most effective and promising instruments.

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[45] N.I. Eisenberger, *The pain of social disconnection: Examining the shared neural underpinnings of physical and social pain*, in *Nature Reviews Neuroscience*, 13, 6, 2012, 421–434.

[46] L. Magnani, *Filosofia della violenza*, Milano, 2022, 25, 33.

Critical thinking cannot be reduced to a logical-argumentative skill or a mere abstract intellectual exercise. Rather, it is a complex set of dispositions and cognitive abilities that enable individuals to analyse, evaluate, and correct their thought processes, with ethical and practical consequences. In a now classic work, Facione defines critical thinking as an intentional, self-regulated, reflective process leading to sound judgement.[47] He emphasizes that critical thinking is not an occasional competence, but rather a systematic practice of evaluating and revising one's cognitive acts. His model identifies fundamental skills such as interpretation, analysis, evaluation, inference and explanation, accompanied by dispositions such as open-mindedness, truth-seeking, prudence in judgement and the capacity for self-regulation. In this light, critical-reflective thinking becomes an exercise in continuous awareness, guiding the individual to make responsible choices.

From a philosophical and humanistic standpoint, Nussbaum[48] has demonstrated that critical thinking is inextricably linked to an ethical dimension. Simply analyzing arguments logically is not enough; one must also cultivate the ability to 'see the world through the eyes of another', developing empathetic imagination and a sense of justice. According to Nussbaum, this attitude enables the 'cultivation of humanity', or the recognition of the intrinsic dignity of every individual beyond group affiliations. Therefore, critical thinking is not a neutral exercise, but a process oriented towards civic coexistence and mutual respect.

The convergence of the perspectives of Facione and Nussbaum enables us to understand the preventive value of critical reflective thinking in relation to gratuitous violence. According to Facione, this evaluation and self-regulation practice enables individuals to consider the consequences of their actions before acting. For Nussbaum, its strength lies in the capacity to decenter oneself and recognize others as interlocutors rather than objects of domination. These two dimensions — cognitive and ethical — combine to form a genuine antidote to gratuitous violence: rational self-regulation curbs blind impulsivity, while empathetic imagination reduces the likelihood of dehumanizing others.

This integration highlights that critical-reflective thinking is not an academic luxury, but a crucial element of public health. It interrupts the vicious circle that leads from a lack of reflection to the adoption and repetition of violent behaviours, thereby strengthening young people's capacity to develop identities and a sense of belonging based on responsibility rather than brute force.

From an educational standpoint, empirical research has consistently demonstrated that developing critical and metacognitive competencies constitutes a protective factor against aggressive and antisocial behaviours. One of the most authoritative syntheses is the meta-analysis by Durlak et al.,[49] which evaluated over two hundred social and emotional learning programs. The results show that students significantly reduce the incidence of problematic behaviours when training paths include practices of critical reflection and activities of metacognitive awareness, improving their emotional management and capacity for self-regulation. These outcomes suggest that, when applied to real educational contexts, critical thinking is not confined to a cognitive dimension, but produces tangible transformations in the way young people interpret and manage their relationships.

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[47] P.A. FACIONE, *op.cit.*, 4–9; 22–23.

[48] M.C. NUSSBAUM, *op.cit*.

[49] J.A. DURLAK, R.P. WEISSBERG, A.B. DYMNICKI, *et al.*, *The impact of enhancing students' social and emotional learning: A meta-analysis of school-based universal interventions*, in *Child Development*, 82, 1, 2011, 405–432.

Another significant contribution comes from evaluations of the widely tested Life Skills Training program in the United States.[50] This educational program integrates the development of socio-emotional skills with critical reflection and conflict management activities. Longitudinal studies and controlled trials involving thousands of secondary school students have demonstrated a substantial decrease in violent and antisocial behaviours, alongside improvements in emotional regulation and peaceful conflict resolution. These results suggest that promoting cognitive and ethical skills oriented towards critical reflection benefits not only academic learning, but also directly affects how young people interpret and manage their relationships, reducing the likelihood of violence becoming a means of belonging or identity affirmation.

From this standpoint, critical-reflective thinking is regarded as a pivotal competence, not only in academic learning but also in the prevention of deviance and violence. The educational value of this approach is inextricably linked to its social value: the cultivation of individuals who possess the capacity for introspection and the ability to empathize with the perspectives of others serves to fortify the foundations of civic coexistence and to mitigate the risk of gratuitous violence becoming an alternative means of belonging or recognition.

The educational and empirical dimension is firmly rooted in Aristotelian reflection, providing a solid philosophical foundation. In the Nicomachean Ethics, Aristotle introduces the concept of *hexis*, understood as a stable disposition formed through the repetition of acts.[51] It is important to note that actions are not merely isolated events; rather, they are constitutive elements of a broader process that contributes to the formation of character. It is evident that each gesture, when reiterated over an extended period, exerts a profound influence on inclinations and habits, thereby augmenting the likelihood of its subsequent repetition. In the absence of intervention or critical re-evaluation, such behaviours can lead to the development of a disposition to violence, which gradually becomes entrenched. This suggests that gratuitous violence, despite its apparently occasional and unmotivated nature, often becomes embedded within repetitive behavioural patterns, where the absence of reflection contributes to the consolidation of a destructive habitus.

Furthermore, Aristotle expounds the concept of phronesis, or practical wisdom,[52] which functions as a corrective and orientation force. Phronesis cannot be reduced to mere technical calculation or the ability to achieve an end; rather, it represents ethical discernment. That is to say, it is the disposition to evaluate which action is good and just in a given circumstance, taking into account the consequences and the dignity of the other. In other words, while *hexis* describes the inertial force of habits, phronesis represents the possibility of interrupting such force through critical deliberation. In the absence of considered reflection, violent action becomes progressively automatic and self-referential; however, with phronesis, the individual regains the possibility of reopening the space of choice, transforming an impulsive gesture into a conscious and responsible action.

It is therefore possible to interpret critical-reflective thinking as a contemporary declination of Aristotelian phronesis. The concept functions as a conduit between cognition and ethics, facilitating the sub-

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[50] G.J. Botvin, K.W. Griffin, T.D. Nichols, *Preventing youth violence and delinquency through a universal school-based prevention approach*, in *Prevention Science*, 7, 4, 2006, 403–408.

[51] Aristotele, *op.cit.*, II, 1103a-1104b.

[52] Aristotele, *op.cit.*, VI, 1138b-1145.

ject's transition from habitual behaviour to a more deliberative and ethical conduct. As with the Aristotelian model, critical thinking does not seek to annul the passions or eliminate conflict, but rather provides the tools to integrate them into a process of personal and civic growth.

The reference to Aristotle's philosophy is pivotal in clarifying the notion that the prevention of gratuitous violence should not be confined to repressive or emergency interventions. Instead, it should be integrated into educational and community practices, with the objective of cultivating phronesis among young individuals. Social medicine, acknowledging the pivotal role of cultural and relational determinants, aligns with this perspective: the promotion of critical thinking is instrumental in fortifying the capacity for individual choice and responsibility, whilst concurrently revitalizing the community fabric. This process offers symbolic and moral alternatives to the logic of brute force.

The relevance of critical-reflective thinking is not confined to its individual function of self-regulation and moral discernment, but extends to the collective sphere, acquiring the significance of a public health resource. In accordance with the tenets of social medicine, the analysis and modification of human behaviour must be considered within the relational and symbolic context in which they occur.[53] The promotion of critical thinking, understood as the capacity for analysis, empathy and reasoned confrontation, fosters not only personal awareness but also the creation of social capital, understood as a network of trust, cooperation and mutual recognition. Several studies have shown that a high level of social capital is correlated with a reduction in violent and antisocial behaviours. Communities that exhibit greater cohesion and reflection possess a plethora of symbolic and practical resources, which they utilize to moderate aggressive tendencies.[54] In this regard, education in critical thinking is not merely a pedagogical goal, but rather constitutes a comprehensive strategy of primary prevention. This contribution is fundamental to the regeneration of eroded community bonds, the return to young people of cognitive and ethical tools to interpret reality in a less impulsive and destructive manner, and the positioning of young people within a web of relationships founded on mutual recognition and shared responsibility.

As previously mentioned, contemporary philosophical reflection has emphasized that violence does not solely stem from individual impulses or material conditions of disadvantage, but rather, it is predominantly derived from voids of meaning that emerge during the symbolic collapses of communities. In this context, Magnani[55] describes the so-called 'moral bubbles' that form within deviant youth subcultures: closed microcosms within which alternative codes develop, and violence becomes both an identity language and a tool of belonging. In a complementary manner, Byung-Chul Han[56] proposes an interpretation of violence that is more subtle and pervasive, which he defines as 'microphysical' or 'subcutaneous': it does not always manifest as overt aggression but permeates social and economic structures through invisible mechanisms of pressure, exclusion and performative competition. In other words, violence insinuates itself into everyday relationships, spaces of interaction and symbolic codes, acting silently but with profound effects. Despite their methodological and conceptual differences, both perspectives concur in indicating that the prevention of violence necessitates the regeneration of a symbol-

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[53] www.who.int/publications/i/item/9789241500852 (last visited 04/09/2025).

[54] R.D. PUTNAM, *op.cit*; I. KAWACHI, S.V. SUBRAMANIAN, D. KIM, *op.cit.*

[55] L. MAGNANI, *op.cit*.

[56] B.C. HAN, *Topologia della violenza*, Milano, 2020.

ic and critical horizon. In order to achieve this, there is a requirement for tools that can interrogate dominant models, deconstruct deviant languages and offer young people possibilities of recognition that do not translate into destruction or domination. In this perspective, critical-reflective thinking assumes a significant ethical and social value, insofar as it facilitates the identification of symbolic distortions, the recognition of violence as a failure of shared meaning, and the reconfiguration of legitimate and inclusive paths of belonging.

It can therefore be affirmed that the promotion of critical thinking belongs fully to the domain of interventions in social medicine. The issue at hand extends beyond the mere reduction of violent behaviours; it pertains to the enhancement of the symbolic and relational well-being of communities. This is conceptualized as the capacity to generate shared meanings and to ensure modes of coexistence that are not solely reliant on external control. Critical thinking functions as a protective factor on multiple levels: at the individual level, it fosters self-awareness and personal responsibility; at the collective level, it contributes to the generation of cultural antibodies capable of countering the drift of gratuitous violence, thereby fostering contexts in which reciprocal recognition and trust replace the logic of domination.

A parallel approach is discernible in Aristotelian reflection. As previously stated, Aristotle emphasizes the role of action in shaping *hexis*, which is defined as the stable disposition of character. Over time, this disposition may consolidate into what is referred to as a ‘second nature’.[57] The concept of ethos, understood as a way of life and a set of daily practices, has been demonstrated to generate habits that structure moral personality. It is important to note that, from this premise, a crucial point is derived. In the absence of a reflective exercise capable of guiding decisions, it is possible for habits to consolidate into destructive inclinations, thereby transforming violence into an instinctive and almost automatic tendency. Conversely, when action is supported by phronesis, the practical wisdom that enables orientation in concrete situations,[58] the formation of *hexis* takes on a virtuous direction. It is therefore argued that critical-reflective thinking is not merely a cognitive instrument; rather, it constitutes a true ethical safeguard. This in turn contributes to the shaping of an ethos that enables the realization of a good life for both the individual and the community.

The relevance of this perspective extends beyond the philosophical level, revealing how the promotion of critical thinking constitutes a factor of public health, capable of influencing the social determinants of violence. In accordance with the principles of social medicine, which emphasize that behaviours must be considered within their social context, Aristotelian ethics similarly instructs that habits are never purely individual but originate and consolidate within the polis.[59] Education in critical thinking is thus configured as a process that simultaneously engages individual prevention and collective regeneration. This approach facilitates the interruption of cycles of violent behaviour, whilst concomitantly fostering community bonds predicated on trust, dialogue and mutual recognition. It is within this dual dimension—both individual and social—that critical-reflective thinking can emerge as a genuine instrument for transforming reality and preventing gratuitous violence.

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[57] ARISTOTELE, *op.cit.*, II, 1103a-1104b.

[58] ARISTOTELE, *op.cit.*, VI, 1140a-1140b.

[59] ARISTOTELE, *Politica*, in C.A. VIANO (a cura di), Milano, 2002, I, 1253a2–18.

5. Concluding Reflection and Preventative Approaches

The analysis previously undertaken suggests that the phenomenon of gratuitous youth violence cannot be understood through unidimensional explanations that seek causes solely in individual psychology or exclusively in material conditions. Instead, a multifaceted picture emerges, in which structural factors (inequalities, deficiencies in linking and bridging social capital, marginalisation) and individual and symbolic factors (crisis of community bonds, search for identity, lack of meaning) interact in a vicious cycle. As demonstrated by research in the field of neuroscience, the absence of social contexts conducive to development can indeed have a detrimental effect on the development of emotional regulation and impulse control capacities.[60] However, as previously noted, violence can also manifest in privileged contexts, taking the form of an 'existential malaise', that is, as a distorted response to a lack of meaning and performance pressures.[61] In both cases, gratuitous violence manifests as a symptom of a deeper deficit in symbolic and community order,[62] a failure to provide young people with shared languages and legitimate channels for recognition and belonging.

In view of this multifactorial diagnosis, any strategy that is purely security-oriented or emergency-driven has been shown to be ineffective and short-sighted. This is because it intervenes on the effect (i.e. violent behaviour) without addressing the underlying causes that are embedded in the social and symbolic fabric. Consequently, prevention must be integrated and multidimensional, operating concurrently across two complementary axes:

The Structural-Community Axis postulates the necessity of the implementation of public policies that are oriented towards the reduction of socioeconomic inequalities and the regeneration of social capital. This is particularly relevant in the context of its bridging (connecting different groups) and linking (connecting citizens to institutions) forms. This calls for the strategic allocation of resources to promote dignified employment, improve educational standards, ensure adequate youth services, and create accessible community spaces. Interventions of this nature have been shown to rebuild institutional trust and foster social cohesion, thereby addressing the material and relational conditions that allow violence to take root.

The Educational-Symbolic Axis posits that the cultivation of critical-reflective thinking must begin in early childhood, developing in parallel and in synergy with cognitive, emotional, and social growth. This concept should not be construed as merely a logical-argumentative skill, but rather as an integrated ethical and civic competence that combines emotional self-regulation with empathy, judgment, and responsibility towards others. The implementation of structured educational programs, encompassing social-emotional learning, practical philosophy, and restorative justice, has been identified as a pivotal strategy to empower young individuals with the internal tools necessary to deconstruct deviant narratives, resist peer pressure, and seek recognition through constructive channels.

In this context, the concept of habit (*hexis*) assumes a central role. It is erroneous to consider habits as mere routines or automatic behaviours; rather, they constitute stable dispositions that shape character and reveal the individual's deep-seated ethics. These values serve to delineate our identities and

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[60] J.P. Shonkoff, A.S. Garner, Committee On Psychosocial Aspects Of Child And Family Health, Committee On Early Childhood, Adoption, And Dependent Care, Section On Developmental And Behavioral Pediatrics, *op.cit*.

[61] B.C. Han, *op.cit*.

[62] S. Cotta, *Perché la violenza? Una interpretazione filosofica*, *op.cit*.

demonstrate, through action, what we truly value. It is evident that each reiterated action serves to reinforce a cognitive structure, which can, in turn, manifest as either virtuous or vicious. The depiction of gratuitous violence frequently symbolizes the culmination of a destructive *hexis* that has been perpetuated through the reiteration of unexamined actions. The potential for 'reversing' habitual practices, therefore, offers benefits that extend beyond the scope of self-help. The daily practice of critical reflection and empathy fosters the development of a virtuous habitus that functions as a preventative measure. This proactive approach engenders an environment wherein young individuals can not only deliberately disrupt cycles of violent behaviour, but can also, in advance of their actualization, cultivate a resilient identity anchored in responsibility and the acknowledgement of others. Primary prevention, therefore, aims to inoculate, through the repeated practice of critical-reflective thinking and emotional regulation, the ethical and cognitive antibodies necessary to neutralize impulses toward violence before they crystallize into stable character dispositions. The educated community, through the adoption of such measures, does not merely repair the damage caused, but establishes the foundations for peaceful and responsible coexistence.

Social medicine provides a diagnosis of collective pathology, mapping risk determinants. Philosophy, as a discipline, is capable of revealing the profound nature of the issue at hand, and it is here that the crisis of the symbolic becomes the core of the problem. Pedagogy, in synergy with other humanistic and social disciplines, provides the necessary operational tools. Critical-reflective thinking has been identified as a fundamental element in constructing a complex therapeutic approach aimed at rebuilding, both individually and communally, the capacity to attribute meaning to coexistence without resorting to brute force. This integrated approach, which mobilizes diversified knowledge from a range of disciplines including sociology, community psychology, law and neuroscience, is the only one capable of addressing the multifactorial nature of the phenomenon.

Acting along these two dimensions — structural and educational-symbolic — is an ethical imperative and a crucial lever for public health, grounded in scientific evidence. At the micro-relational level of care, the physician–patient relationship embodies this logic: self-determination, informed consent and freedom of choice are not just formalities, but practices of phronesis that reduce asymmetries, rebuild trust and ensure that the interaction is non-coercive. This reinforces a horizon of social cohesion and personal reflexivity that is consistent with the trajectory outlined in this work. Promoting cohesive communities and reflective individuals reduces the human, social and economic costs of violence while fostering the construction of a more resilient, just and future-oriented society in which mutual recognition replaces domination as the primary language of belonging. The effective prevention of youth violence cannot be attributed to a single discipline, but is instead the outcome of a collective, transdisciplinary project aligned with the shift in paradigm from safeguarding physical integrity to the right to health. This shift expresses the intrinsic interweaving of medicine and society[63] and identifies the regeneration of social bonds and critical interiority as its most powerful resources.

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[63] S. RICCI, A. MIGLINO, *Medicina e Società: dalla tutela dell'integrità fisica al diritto alla salute*, Roma, 2005, 1-99.

Il fenomeno delle nuove dipendenze: revisione critica su alcune dipendenze di particolare allarme sociale

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THE PHENOMENON OF EMERGING ADDICTIONS: A CRITICAL REVIEW OF SELECTED BEHAVIORAL DISORDERS OF SIGNIFICANT SOCIAL CONCERN

ABSTRACT: This critical review examines emerging behavioural addictions, focusing on gambling disorder, Internet addiction (including gaming disorder), cybersex and love addiction. Although not substance-related, they share psychopathological and neurobiological mechanisms with traditional addictions, requiring a multidimensional diagnostic and rehabilitative approach. It highlights the importance of functional diagnosis, holistic assessment and evidence-based psychosocial treatments (CBT, DBT). Comorbidity with personality disorders, particularly dependent personality disorder, is discussed, as well as the relevance of a recovery-oriented approach and neuroplasticity. It concludes by emphasising the need for further research and greater integration into diagnostic systems to improve clinical management.

KEYWORDS: Behavioural addictions; gambling disorder; cybersex addiction; love addiction; dual diagnosis

ABSTRACT: Questa revisione critica esamina le nuove dipendenze comportamentali emergenti, concentrandosi sul disturbo da gioco d'azzardo, sulla dipendenza da Internet (incluso il disturbo da gaming), sulla dipendenza da cybersex e sulla dipendenza affettiva. Sebbene non siano correlate a sostanze, tali condizioni condividono meccanismi psicopatologici e neurobiologici con le dipendenze tradizionali, richiedendo quindi un approccio diagnostico e riabilitativo multidimensionale. Il lavoro sottolinea l'importanza di una diagnosi funzionale, di una valutazione olistica e di trattamenti psicosociali basati sull'evidenza (come la CBT e la DBT). Viene inoltre discussa la comorbidità con i disturbi di personalità, in particolare con il disturbo

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dipendente di personalità, nonché la rilevanza di un approccio orientato al recupero e dei processi di neuroplasticità. In conclusione, si evidenzia la necessità di ulteriori ricerche e di una maggiore integrazione nei sistemi diagnostici al fine di migliorare la gestione clinica.

PAROLE CHIAVE: Dipendenze comportamentali; disturbo da gioco d'azzardo; dipendenza da cybersex; dipendenza affettiva; doppia diagnosi

SOMMARIO: 1. Introduzione – 2. Classificazione delle dipendenze comportamentali: criteri diagnostici e panorama nosografico – 3. La complessità della personalità dipendente dalla doppia diagnosi – 4. *Assessment* riabilitativo e multidimensionale – 5. Trattamenti psicosociali basati sulle evidenze (EBP) – 6. Orientamento agli atti di valutazione multidimensionale – 7. Discussione – 8. Conclusioni.

1. Introduzione

Negli ultimi decenni, il panorama delle dipendenze ha subito una significativa evoluzione essendosi inoltrato ben oltre il tradizionale focus dell'abuso di sostanze. Infatti, un numero crescente di comportamenti, pur non coinvolgendo l'ingestione di sostanze, ha mostrato di poter assumere pari caratteristiche di compulsività e autodistruttività, andando ad impattare negativamente sulla vita degli individui e sulla società. Questo fenomeno è comunemente indicato come nuove dipendenze comportamentali il cui riconoscimento clinico e la comprensione dei meccanismi sottostanti sono diventati un campo di studio di intervento di crescente rilevanza[1].

Questi nuovi disturbi comportamentali sono caratterizzati da un modello di comportamento ripetuto che conduce a una compromissione clinicamente significativa o di stress, che si manifestano con sintomi caratterizzati da una forte componente compulsiva e con forti difficoltà a controllarli, con persistenza nel comportamento nonostante le conseguenze negative e del comportamento rispetto alle altre attività e obblighi quotidiani[2]. Nonostante la loro natura le distingue dalla dipendenza da sostanze chimiche, le somiglianze in termini neurobiologici e fenomenologici sono molte, troviamo ad esempio lo stesso coinvolgimento dei circuiti della ricompensa, nonché gli stessi meccanismi di *craving*, tolleranza ed astinenza. Inoltre, le morbilità psichiatriche suggeriscono meccanismi patogenici condivisi e giustificano un approccio integrato[3].

Parlando delle dipendenze comportamentali maggiormente studiate figurano: il disturbo da gioco d'azzardo o ludopatia, la dipendenza da Internet, la *addiction cybersex* e la *love addiction*. Ciascuna di queste presenta caratteristiche specifiche che richiedono un'analisi attenta al fine di poter produrre una diagnosi

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[1] Y.H.C. YAU *et al.*, *Are Internet use and video-game-playing addictive behaviors? Biological, clinical and public health implications for youths and adults*, in *Minerva psichiatrica*, 53(3), 2012, 153-170. D.C. HODGINS, J.N. STEA, J.E. GRANT, *Gambling disorders*, in *The Lancet*, 378(9806), 2011, 1874-1884.

[2] AMERICAN PSYCHIATRIC ASSOCIATION, *Diagnostic and Statistical Manual of Mental Disorders, DSM-5, 5th ed.*, Arlington, VA, 2013. WORLD HEALTH ORGANIZATION, *International Classification of Diseases*, 11th Revision, Ginevra, 2018.

[3] J.E. GRANT *et al.*, *Introduction to behavioral addictions*, in *The American journal of drug and alcohol abuse*, 36(5), 2010, 233-241. M.R. MITCHELL, M.N. POTENZA, *Importance of sex differences in impulse control and addictions*, in *Frontiers in psychiatry*, 6, 2015, 24.

accurata e studiare interventi mirati. La crescente diffusione è facilitata dalla sempre maggiore accessibilità alle tecnologie digitali e dai cambiamenti socioculturali; ciò solleva preoccupazioni significative per la salute pubblica individuale rendendo fondamentale l'approfondimento e la conoscenza di tali disturbi. L'esordio di queste problematiche si colloca spesso in un contesto di vulnerabilità psicologica persistente oppure derivante dalla difficoltà di adattamento alle rapide e irrefrenabili trasformazioni sociali e tecnologiche.

La Ludopatia o disturbo da gioco d'azzardo è l'unica dipendenza comportamentale inclusa nel *Diagnostic and Statistical Manual of Mental Disorders 5th Edition [DSM-5]* dell'American Psychiatric Association e nella *International Classification of Diseases 11th Revision* [ICD-11] dell'organizzazione mondiale della sanità a testimonianza del suo impatto riconosciuto.

Altre forme di dipendenze relazionali e tecnologiche stanno emergendo con forza nel dibattito clinico e scientifico. Un esempio ne è la dipendenza da Internet; termine ombrello che può includere problematiche correlate all'eccessivo utilizzo di social media e altre attività digitali come anche i videogame, anche se l'abuso di questi si configura nel gaming disorder o disturbo da gioco già inserito nel ICD-11[4].La dipendenza dai *cybersex* è una sottocategoria della dipendenza sessuale mediata dal mezzo tecnologico e la *love addiction* è una dipendenza relazionale non sessuale, queste rappresentano sfide diagnostiche e terapeutiche, da una natura spesso nascosta con comportamenti culturalmente accettati che rendono confusiva la diagnosi, oltre alla tendenza ad essere sottostimate tanto da chi ne soffre che dal contesto sociale che li circonda[5].

Lo scopo di questo articolo è fornire un'analisi critica di quelle che sono le numerose dipendenze comportamentali con un focus sulla dipendenza da gioco d'azzardo, da Internet, da *cybersex* e la *love addiction*. Esplorando i criteri diagnostici, i modelli teorici sottostanti principali, l'eco morbilità più comuni nello specifico con i disturbi di personalità e le strategie di *assessment* e trattamento psicosociale più adeguate, con un'attenzione particolare sull'approccio bio-psicosociale all'orientamento agli agiti della riabilitazione.

L'ipotesi principale è che nonostante le differenze fenomenologiche queste dipendenze condividono meccanismi psicopatologici e neurobiologici comuni alle dipendenze da sostanze richiedendo pertanto approcci diagnostici funzionali, interventi riabilitativi multidimensionali[6]. Inoltre, l'ipotesi è che la comprensione della persona dipendente e la gestione della doppia diagnosi siano cruciali al fine di migliorare la prognosi e favorire percorsi di ricoveri che siano sostenibili per gli individui affetti, promuovendo un senso di autoefficacia, andando anche a contrastare lo stigma interno. L'analisi della letteratura in materia ha permesso di delineare un quadro approfondito delle nuove dipendenze comportamentali, riuscendo ad evidenziare le specificità diagnostiche, i meccanismi psicopatologici condivisi e le strategie di intervento.

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[4] K.S. YOUNG, *Internet Addiction: The Emergence of a New Clinical Disorder*, in *CyberPsychology & Behavior*, 1998.

[5] I.G.N. AGASTYA, K. SISTE, M.W.S. NASRUN *et al.*, *Cybersex addiction: an overview of the development and treatment of a newly emerging disorder*, in *Medical Journal of Indonesia*, 29(2), 2020, 233-241. S. SUSSMAN, *Love addiction: Definition, etiology, treatment*, in *Sexual Addiction & Compulsivity*, 17(1), 2010, 31-45.

[6] C. ILIE, I.V. ŞERBAN, A.N. DAN, *Probation counseling for substance uses disorders in Romania: An analysis of challenges and opportunities*, in *European Journal of Probation*, 16(3), 2024, 248-265. A. BUCIUȚA, H.G. COMAN, B. NEMEȘ, R. OROIAN, M.E. VUȘCAN. *HLA Allele's Role in Cannabis Addiction*, in *BRAIN. Broad Research in Artificial Intelligence and Neuroscience*, 15(4), 2024, 6.

2. Classificazione delle dipendenze comportamentali: criteri diagnostici e panorama nosografico

Un passo cruciale per la legittimazione critica delle nuove dipendenze comportamentali è stato il riconoscimento da parte del DSM-5 dell'APA e ICD-11 nell'organizzazione mondiale della sanità. Attualmente l'unica dipendenza comportamentale inclusa ufficialmente nel DSM-5 è la Ludopatia o disturbo da gioco d'azzardo, classificata nella sezione "disturbi correlati a sostanze e disturbi additivi". I criteri diagnostici includono la necessità di aumentare la quantità di denaro al fine di ottenere l'eccitazione desiderata (c.d. tolleranza), irritabilità o irrequietezza quando si tenta di ridurre o smettere di giocare cadendo in astinenza, fallimenti ripetuti né tentativi di controllare o interrompere l'azione di gioco, preoccupazione costante per il gioco d'azzardo, giocare d'azzardo quando ci si sente in difficoltà, tentativo di recuperare le perdite economiche con ulteriore gioco d'azzardo e scommesse, menzogne per nascondere il coinvolgimento e compromissione delle relazioni significative oppure considerare l'altro solo in funzione del recupero del denaro[7]. Per poter diagnosticare un disturbo da gioco d'azzardo i criteri sovrascritti devono essere presenti (almeno quattro) per un periodo di almeno 12 mesi, questo riconoscimento ha certamente facilitato lo sviluppo di linee guida per il trattamento e la copertura assicurativa di molti contesti sanitari. L'ICD-11 ha introdotto il disturbo da gioco come condizione riconosciuta rientrante nella categoria dei disturbi da comportamenti di dipendenza, i criteri principali del gaming disorder riguardano un modello di comportamento di gioco persistente e ricorrente, caratterizzato da una compromissione del controllo sul gioco nello specifico sul suo contesto, la durata, la frequenza e l'intensità ma anche un aumento della priorità data dal gioco nella misura in cui il gioco assume la precedenza sugli altri interessi della vita e le attività quotidiane, ma anche un'intensificazione del gioco, nonostante il verificarsi di conseguenze negative. Questo si chiama comportamentale deve essere sufficientemente grave, per poter essere diagnosticato, da causare una significativa compromissione del funzionamento personale, sociale, familiare, educativo e occupazionale o in altre aree importanti. Questo disturbo è stato oggetto di un intenso dibattito ma la sua inclusione nell'ICD 11 riflette un crescente consenso sulla sua natura patologica e sull'impatto significativo che può avere sulla vita degli individui, soprattutto negli adolescenti[8].

La Dipendenza da Internet o Internet Addiction Disorder IAD è un termine ombrello non ancora formalmente riconosciuto dai principali manuali diagnostici come diagnosi separata, ma oggetto di forte dibattito e di un'intensa ricerca. Anche questa come anticipato si manifesta attraverso comportamenti specifici come l'uso compulsivo dei videogiochi, che ad ora ha il suo riconoscimento specifico come gaming disorder nell'ICD-11, ma anche eccessivo dei social media[9], la navigazione in rete compulsiva lo shopping online. I criteri diagnostici proposti per l'ID da Young[10] includono preoccupazione per Internet, il bisogno di aumentare il tempo online e raggiungere la propria soddisfazione, nonché tentativi falliti di controllarne

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[7] AMERICAN PSYCHIATRIC ASSOCIATION, *op. cit.*

[8] M.J. KNIGHT, B.T. BAUNE, *Executive subdomains are differentially associated with psychosocial outcomes in major depressive disorder*, in *Frontiers in psychiatry*, 9, 2018, 309. D.J. KUSS, H.M. PONTES, M.D. GRIFFITHS, *Neurobiological correlates in internet gaming disorder: A systematic literature review,* in *Frontiers in psychiatry*, 9, 2018, 166.

[9] M. DUMITRESCU, N. DUMITRESCU, Ş. TURLIUC. *The Social Media Addiction: What Have We Learned So Far? - A Review*, in *BRAIN. Broad Research in Artificial Intelligence and Neuroscience*, 14(1), 2023, 117-137.

[10] K.S. YOUNG, *op. cit.*

l'uso[11] non senza irrequietezza o irritabilità quando si cerca di ridurre l'uso del mezzo digitale[12]. L'uso di Internet serve anche per allontanarsi da problemi esistenziali impegnativi, mentire sulla quantità di tempo speso online e si corre anche spesso il rischio di perdere relazioni al lavoro[13] a causa di Internet con un conseguente mascheramento delle conseguenze negative della propria dipendenza da Internet. Questa è spesso associata a comorbilità come depressione, ansia isolamento sociale[14].

La dipendenza da sesso online è una forma specifica di dipendenza sessuale che si manifesta attraverso l'uso compulsivo di Internet per attività sessuali come, ad esempio, pornografia chat sessuali o incontri virtuali. Nonostante non sia una diagnosi ufficiale presente nei manuali, è ampiamente riconosciuta nella letteratura clinica e si sovrappone spesso al concetto di disturbo di sessualità o alla dipendenza sessuale più ampia[15]. Tra i sintomi sono inclusi l'uso eccessivo di controllo delle relazioni sessuali on-line che interferisce con le relazioni offline, con il lavoro con altre aree della vita dell'individuo attanagliato da un senso di colpa e vergogna, con tentativi ripetuti e falliti di ridurre o smettere tale comportamento[16]. Spesso l'individuo sperimenta una vergogna profonda che l'ostacola nella ricerca di aiuto, portandolo a un isolamento crescente.

La dipendenza affettiva "love addiction" nota anche come dipendenza da relazioni affettive è una condizione caratterizzata da una impulsività e disfunzionale ricerca e mantenimento di relazioni, spesso a scapito della propria autonomia e benessere[17]. Anche questa non è una diagnosi formalmente presente nei manuali, ma viene studiata in contesti psicodinamici e cognitivo comportamentali[18]. Tra i sintomi figurano una preoccupazione eccessiva per la relazione, un bisogno compulsivo di essere in una relazione nonché la paura dell'abbandono, la rinuncia ai propri bisogni per accontentare il partner, la tendenza a stabilire relazioni disfunzionali o abusive in senso di vuoto o d'ansia quando non si è in una relazione. Le caratteristiche del DDP si sovrappongono spesso con la *love addiction*, suggerendo una base comune nella dinamica della dipendenza relazionale e nella difficoltà a mantenere un sé autonomo e differenziato[19]. In

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[11] C. CRUCIANU, V. POROCH, Ş. BURLEA, O.M. ŞTEFĂNESCU, A. CIUBARA. *Video Game Addiction Among Adolescents*, in *BRAIN. Broad Research in Artificial Intelligence and Neuroscience*, 15(1), 2024, 34-40.

[12] C. HURSEN, H. KARAOKÇU, T.T. HATIPOĞLU, Ş. KARASALIH, D. SUHANBERDYYEVA, D. BEYOĞLU, *Determination of Internet and Digital Game Addiction Level of Students According to the Opinions of Parents, Teachers and Students*, in *BRAIN. Broad Research in Artificial Intelligence and Neuroscience*, 14(1), 2023, 194-212.

[13] M.A.A. DĂSCĂLESCU, *Virtual Addictions, Teleworking and Artificial Intelligence in the Pandemic*, in *BRAIN. Broad Research in Artificial Intelligence and Neuroscience*, 2022.

[14] R.C. HO, M. WB ZHANG, T. Y TSANG *et al.*, *The association between internet addiction and psychiatric co-morbidity: a meta-analysis*, in *BMC psychiatry*, 14(1), 2014, 183.

[15] R.J. KAFKA, *Hypersexual Disorder: A Proposal for DSM-V*, in *Archives of Sexual Behavior*, 2010.

[16] AGASTYA, *op. cit.* J.P. SCHNEIDER, *Understanding and diagnosing sex addiction,* in *Handbook of addictive disorders: A practical guide to diagnosis and treatment*, 2004, 197-232.

[17] M. CALDERARO, V. MASTRONARDI, I.V. SERBAN. *Addictions not related to the use and abuse of substances and some assessment tools in the clinical-forensic field*, in *BRAIN. Broad Research in Artificial Intelligence and Neuroscience*, 16(2), 2025, 224-250.

[18] A.W. KWEE, *Constructing addiction from experience and context: Peele and Brodsky's Love and Addiction revisited*, in *Sexual Addiction & Compulsivity*, 14(3), 2007, 221-237. R. WESTERMEYER, *The Codependency Idea: When Caring Becomes a Disease*, 2005. S. SUSSMAN, *op. cit*.

[19] L.A. CLARK *et al.*, *Longitudinal prediction of psychosocial functioning outcomes: Diagnostic and Statistical Manual of Mental Disorders, Section-II personality disorders versus alternative model personality dysfunction and traits. Personality Disorders: Theory, Research, and Treatment*, 2024.

questi casi la relazione diventa il regolatore emotivo principale e il tentativo di evitarne l'abbandono da parte del partner domina il comportamento, anche a fronte di abusi e un forte distress.

Dipendenza Comportamentale	Riferimento Diagnostico Principale	Criteri Essenziali (Sintesi)	Note Aggiuntive
Ludopatia	DSM-5	Compulsione, tolleranza, astinenza, menzogne, compromissione.	Unica dipendenza comportamentale nel DSM-5.
Gaming Disorder	ICD-11	Controllo compromesso, priorità al gioco, persistenza nonostante conseguenze negative.	Riconosciuto dall'OMS, sottocategoria di Dipendenza da Internet.
Dipendenza da Internet	Dibattito Clinico	Preoccupazione, uso crescente, tentativi falliti di controllo, compromissione funzionale.	Termine ombrello, non diagnosi formale in DSM-5/ICD-11.
Addiction da Cybersex	Letteratura Clinica	Uso compulsivo di cybersex, interferenza con la vita, senso di colpa/vergogna.	Spesso legata a dipendenza sessuale o iper-sessualità.
Love Addiction	Letteratura Clinica	Bisogno compulsivo di relazioni, paura abbandono, relazioni disfunzionali, perdita autonomia.	Spesso sovrapposta al Disturbo Dipendente di Personalità.

3. La complessità della personalità dipendente dalla doppia diagnosi

Cruciale nella comprensione delle dipendenze comportamentali è la loro frequente co morbilità con i disturbi di personalità nello specifico nel disturbo dipendente di personalità e i disturbi del cluster B, come ad esempio borderline, narcisistico, antisociale[20]. La personalità dipendente è caratterizzata dalla necessità profonda di essere accuditi, da un'insicurezza, dalla sottomissione dall'incapacità decisionale autonoma che porta alla costante ricerca di un «Magic helper»[21]. Ciò può predisporre lo sviluppo di dipendenze comportamentali e non solo, gli individui con un disturbo dipendente di personalità tendono ad evitare il conflitto e a subire relazioni disfunzionali, rendendoli vulnerabili a dipendenze relazionali come la game *addiction* o alla ricerca di conforto e gratificazione in comportamenti compulsivi nella sfera sessuale o digitale, poiché questi atteggiamenti offrono un senso di controllo e gratificazione immediata in assenza di una sana auto efficacia.

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[20] D. La Barbera, V. Caretti, G.Craparo, *Ipotesi di nuovi criteri diagnostici per l'addiction*, in *S&P Salute e Prevenzione*, 43, 2006.

[21] S. Freud, *Tre saggi sulla teoria sessuale*, Leipzig, 1905.

La coesistenza di un disturbo di dipendenza e di un altro disturbo psichiatrico, ovvero una doppia diagnosi, complicano notevolmente il quadro clinico, nonché l'esito terapeutico, molti studi indicano che la presenza di un disturbo di personalità in soggetti con dipendenze comportamentali sia associata a una maggiore compromissione generale nonché una maggiore impulsività, con difficoltà nel costruire l'alleanza terapeutica e con un elevato rischio di *drop-out*[22].

Tuttavia, i ricercatori non hanno visione univoca e alcuni studi suggeriscono che un trattamento integrato e mirato può mitigare questi effetti negativi[23]. Nei casi in cui è presente una doppia diagnosi, richiesta un'attenta valutazione diagnostica e un piano di trattamento che affronti simultaneamente entrambi i disturbi poiché la gestione di uno senza considerare l'altro può portare a ricadute o ad un trasferimento della sintomatologia dipendente su un altro comportamento compulsivo. La complessità diagnostica richiede l'uso di strumenti avanzati come la SWAP-200 Shendler-Westen Assesment Procedure-200**,** permettendo così una diagnosi funzionale, con compromissione delle dinamiche profonde della personalità, andando oltre l'etichettamento puramente sintomatico[24].

4. *Assessment* riabilitativo e multidimensionale

Quando si ha a che fare con dipendenze comportamentali, l'*assessment* riabilitativo deve andare oltre la semplice diagnosi sintomatologica e deve essere condotto con il paziente all'interno del suo intero contesto di vita. Questo approccio olistico valuta aspetti cruciali come il senso di sé, il contesto familiare e i fattori prognostici, in generale ivi inclusi i fattori iatrogeni e le modalità specifiche di comunicazione della diagnosi al paziente e alla famiglia.

Parlando dell'identità e del senso di sé, ci sono livelli di dipendenza che portano a sentimenti di colpa e vergogna, questa internalizzazione dello stigma può favorire il fenomeno della progressiva identificazione della persona con la propria malattia, con effetti nefasti sul percorso di recupero. Questo processo può inibire la capacità del paziente di percepire un futuro al di là della propria dipendenza.

Il grado di dipendenza del paziente dalla famiglia e viceversa è complesso, è frequente che i pazienti con disturbi di dipendenza provino colpa e vergogna per la delusione provocata alla propria famiglia e tendono ad assumere un ruolo protettivo nei confronti dei genitori con limitazione dei propri spazi e rinuncia ai progetti personali o a non sentirsi meritevoli di un successo migliorativo della propria esistenza.

Quando parliamo di fattori iatrogeni dei trattamenti è importante sottolineare le abituali congeniali attitudini negative dei personali approcci interpersonali, che possano minare l'efficacia del percorso terapeutico rafforzando la dipendenza dai servizi con la persistenza dello status quo; ciò è da decidere anche in base alla tipologia di esordio, se precoce o tardivo e al periodo della malattia non trattata. Il deterioramento funzionale avviene spesso nei primi 12 mesi dall'esordio della malattia, ma anche alla presenza, oltre che di comorbilità come la "sindrome da deficit", di disfunzioni sociali e cognitive precedenti presenti

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[22] T.R. KOSTEN, *Personality and Substance Use Disorders*, Washington, D.C., 1991. E. ATZORI, S. PACIOTTI, *La questione della doppia diagnosi: una ricerca sui fattori psichici alla base delle dipendenze patologiche*, in *Sogno della farfalla: rivista di psichiatria e psicoterapia*: XX, 4, 2011, 53-74.

[23] P. HOFFMAN JUDD, N. THOMAS, T. SCHWARTZ *et al., A dual diagnosis demonstration project: Treatment outcomes and cost analysis*, in *Journal of Psychoactive Drugs*, 35, 2003, 181-192. D. LA BARBERA, V. CARETTI, G. CRAPARO, *op. cit.*

[24] D. WESTEN, J. SHEDLER, *A Prototype Matching Approach to Diagnosing Personality Disorders: toward DSM-V*, in *Journal of Clinical Psychology*, 14(2), 2000, 109-26.

al primo episodio. Importante è anche il modo in cui viene presentata la diagnosi psichiatrica che può avere effetti nefasti sul paziente favorendo il già menzionato fenomeno dell'*engulfment* o imbottigliamento statico nella impossibilità di perseguire obiettivi di vita significativi.

L'*assessment* nei casi di nuove dipendenze comportamentali deve essere volto a identificare non solo i deficit ma anche quelli che sono i punti di forza dell'individuo, sfruttando le sue risorse interne ed esterne, l'abilità preservata e le potenzialità di crescita del paziente in un'ottica di recupero e autodeterminazione, nonché valutazione degli elementi eterogenei. Risultando pertanto cruciale al fine di correggere pratiche che potrebbero ostacolare l'autonomia del paziente.

5. Trattamenti psicosociali basati sulle evidenze (EBP)

La ricerca ha dimostrato che i trattamenti psicosociali riabilitativi basati sull'EBP hanno un impatto significativo sugli esiti esistenziali e quindi anche lavorativi per gli individui con dipendenze comportamentali. Questi trattamenti sono basati sui principi del social Learning, riconoscendo che per i pazienti con dipendenze comportamentali è fondamentale lavorare su disfunzioni e deficit che sono misurabili e definibili. La malattia mentale e il comportamento compulsivo, pur avendo una componente biologica è sperimentata da un essere sociale e l'ambiente in cui esso vive risulta fondamentale per dare forma al suo comportamento a cambiarlo[25].

Tra i trattamenti psicosociali e B.P. applicabili alle dipendenze comportamentali figurano:

- La psico educazione individuale e familiare è in grado di fornire informazioni dettagliate sul disturbo, sui suoi fattori scatenanti, sui sintomi, sulle strategie di gestione, coinvolgendo attivamente anche la famiglia all'interno del processo terapeutico al fine di demistificare la patologia e ridurre il senso di isolamento.
- Social skill training, in grado di insegnare abilità sociali interpersonali necessarie al paziente per funzionare efficacemente nella vita quotidiana, nelle relazioni e nel reinserimento sociale lavorativo. Per chi soffre la dipendenza da Internet, questo può significare sviluppare delle abilità per interagire off line in modo più significativo.
- Terapia cognitivo comportamentale e terapia dialettico comportamentale sono approcci estremamente efficaci per identificare e modificare schemi di pensiero e comportamenti disfunzionali associati alle dipendenze[26]. La terapia cognitivo comportamentale è particolarmente rilevante per la ludopatia e la dipendenza da Internet. Poiché mira a ristrutturare le distorsioni cognitive, a sviluppare strategie di *copying* alternative e a gestire il *craving*. Anche la DBP ha la sua utilità in quanto all'enfasi sulla regolazione emotiva e le abilità interpersonali, è particolarmente utile per le dipendenze comportamentali che presentano comorbilità con gli disturbi di personalità come la *love addiction*.
- Programmi di ambienti supportati, favoriscono contesti strutturati o protetti per il recupero, come comunità terapeutiche, alloggi assistiti, possono essere incrociate nelle fasi iniziali di astinenza o per il consolidamento dell'abilità di vita.

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[25] A. BANDURA, *Social Learning Theory*, New Jersey, 1977.

[26] A.T. BECK, *Cognitive Therapy of Depression*, New York, 1993. M.M. LINEHAN, *Cognitive-Behavioral Treatment of Borderline Personality Disorder,* New York, 1993.

- L’Illness Management and Recovery OMR è un approccio che aiuta i pazienti a sviluppare abilità per gestire i propri sintomi, prevenendo le ricadute e proseguendo obiettivi di recovery autodeterminati, promuovendo l’autonomia.
- Case management, un servizio di coordinamento che aiuta i pazienti ad accedere a risorse e servizi fondamentali per la riabilitazione, come lavoro istruzioni o cure mediche, agendo come ponte tra il paziente e il sistema di supporto.
- Il trattamento integrato per la doppia diagnosi è essenziale per i casi complessi in cui la dipendenza comportamentale coesiste con altri disturbi psichiatrici. Questo approccio riconosce che entrambi i disturbi influenzano l’un l’altro e devono essere trattati simultaneamente al fine di massimizzare la possibilità di successo dell’intervento.

Una base neurobiologica per l’efficacia di questi trattamenti è la neuro plasticità, l’apprendimento esperienziale e la pratica di trattamenti psicosociali intensivi possono infatti modificare i meccanismi dell’attività neuronale e contribuire allo sviluppo di nuove connessioni sinaptiche, correggendo potenzialmente disfunzioni bio-neurologiche sottostanti alle dipendenze e migliorando non solo la regolazione emotiva ma anche la cognizione e la motivazione[27]. Questo processo di cambiamento a livello celebrale va a rafforzare l’idea che il recupero sia un percorso dinamico e che gli interventi psicosociali non siano semplicemente supportati ma attivamente modificativi.

6. Orientamento agli atti di valutazione multidimensionale

Trattamento Psicosociale (EBP)	Obiettivi Principali (Sintesi)	Applicabilità (Esempi)
Psicoeducazione	Aumentare la comprensione del disturbo, ridurre lo stigma, migliorare l'adesione al trattamento.	Tutte le dipendenze comportamentali (paziente e famiglia).
Terapia Cognitivo-Comportamentale (CBT)	Identificare e modificare pensieri/comportamenti disfunzionali, gestire il craving.	Ludopatia, Dipendenza da Internet, Cybersex Addiction.
Terapia Dialettico-Comportamentale (DBT)	Migliorare la regolazione emotiva, la tolleranza della distress, le abilità interpersonali.	Love Addiction, Dipendenza da Internet (con comorbilità).
Social Skill Training	Sviluppare abilità sociali e comunicative, ridurre l'isolamento.	Tutte le dipendenze comportamentali (per migliorare il funzionamento sociale).

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[27] N. Doidge, *The Brain That Changes Itself: Stories of Personal Triumph from the Frontiers of Brain Science*, New York, 2007.

Trattamento Psicosociale (EBP)	Obiettivi Principali (Sintesi)	Applicabilità (Esempi)
Rimedio Cognitivo	Migliorare funzioni cognitive (attenzione, memoria, problem solving).	Tutte le dipendenze (specie se con deficit cognitivi).
Trattamento Integrato (Doppia Diagnosi)	Affrontare simultaneamente dipendenza e disturbi psichiatrici in comorbilità.	Tutte le dipendenze in presenza di disturbi di personalità, umore, ansia.

Nel trattamento riabilitativo delle dipendenze, un principio centrale è rappresentato dall'orientamento all'esito, che distingue la relazione terapeutica meramente accogliente da una relazione finalizzata al cambiamento e all'emancipazione del paziente. In quest'ultima prospettiva, la relazione terapeutica non si limita alla funzione di contenimento, ma assume un ruolo attivo nel promuovere processi di autonomia, responsabilizzazione e trasformazione personale. Di conseguenza, l'interazione terapeutica dovrebbe essere valutata in funzione del suo contributo al raggiungimento degli obiettivi personali del paziente, favorendo lo sviluppo dell'autoresponsabilità e dell'autonomia funzionale. Tale approccio consente di superare una concezione assistenzialistica dell'intervento, orientandolo verso esiti misurabili e clinicamente rilevanti.

La valutazione dei percorsi di riabilitazione per le dipendenze comportamentali dovrebbe pertanto adottare un modello dimensionale, focalizzato su molteplici domini del funzionamento individuale. In linea con i principi dell'International Classification of Functioning, Disability and Health (ICF), l'attenzione valutativa si estende oltre la riduzione del sintomo, includendo il funzionamento psicologico, sociale e adattivo della persona nel suo contesto di vita.

La dimensione intrapersonale è fondamentale, in quanto permette di avere una connessione con i propri stati affettivi e con un'espressione socializzata dei propri sentimenti, opinioni e valori; fornisce anche consapevolezza delle difficoltà quotidiane e delle relative risposte disfunzionali come nel caso delle dipendenze. Permette di avere consapevolezza dei comportamenti utilizzati come distanziatori sociali, i livelli di dipendenza dagli altri la convinzione dell'idea di incapacità identificazione con la malattia nonché la gestione della colpa e della vergogna.

Dimensione del funzionamento globale, il paziente può avere delle difficoltà in particolari ruoli e domini specifici, motivo per cui risulta fondamentale misurare esiti più generali specifici set di comportamenti.

La dimensione abitativa di adattamento all'ambiente, il paziente deve essere analizzato sotto ogni punto di vista anche quindi nelle sue abilità domestiche, interpersonali, le sue abilità cognitive, di pianificazione del tempo, *problem solving*, esecuzione dei compiti, autogestione del denaro. Nella dimensione lavorativa, il paziente deve essere valutato per la qualità e per la sua performance, capendo come riesce a cooperare con gli altri colleghi, accettare le critiche, mostrarsi distante, nonché in tutte le abilità di gestione delle emozioni nell'ambiente stressogeno. La dimensione educativa si può analizzare con le abilità correlate all'ambiente di studio, le abilità accademiche e cognitive con le abilità emotive e le abilità sociali conoscendo nuovi studenti e partecipando a iniziative sociali promosse dalle istituzioni educative.

La valutazione delle dimensioni dell'utilizzazione dei servizi riguarda sia i bisogni di servizio dell'utente se sono stati soddisfatti o no e include le risorse messe a disposizione e i bisogni dell'utente. La valutazione dei risultati riguarda anche la dimensione del supporto sociale e come è stato utilizzato nel processo riabilitativo di sostegno e strumentale, la qualificazione nell'ambiente dove il tempo esercita un ruolo sociale, i sostegni naturali finalizzati ad aumentare le qualità e le quantità delle relazioni.

Gli operatori devono avere abilità specifiche al fine di monitorare questi esiti alimentando la fiducia del paziente, dimostrando comprensione per le sue reazioni emotive sia in caso di successo che di fallimento, motivandolo e aiutandolo a essere consapevole dei risultati raggiunti. Inoltre, sapere evidenziare i punti di forza del paziente prima di lavorare su quelli meno positivi, aiutandolo ad essere più consapevole degli alti e dei bassi fisiologici della vita, informandolo sulla natura del suo disturbo, preparandolo a riconoscere i primi sintomi e ad ampliare le strategie di *copying*. Tutto ciò è causale anche per la realizzazione dei fattori di rischio e protezione, questi ultimi fondamentali in quanto funzionano in modo tale che si attivano in circostanze critiche[28].

7. Discussione

Alla luce di quanto esposto è fondamentale evidenziare la crescente rilevanza e complessità delle "nuove dipendenze comportamentali", come la ludopatia, ma anche la dipendenza da Internet incluso il gaming disorder, la dipendenza dai *cybersex* e la dipendenza affettiva. La loro inclusione, seppur parziale, nei principali manuali diagnostici internazionali riflette un significativo cambiamento paradigmatico nella comprensione delle dipendenze. Tale evoluzione concettuale estende il focus oltre l'uso di sostanze chimiche, includendo fenomeni che, pur in assenza di una sostanza, condividono meccanismi psicopatologici e neurobiologici fondamentali[29]. Questo spostamento di focus richiede un aggiornamento costante nelle conoscenze cliniche e un adeguamento delle strategie terapeutiche. L'analisi clinica dei metodi impiegati per la scrittura di questo articolo di tipo narrativo, ha permesso di sintetizzare e organizzare una vasta mole di informazioni da diverse fonti, fornendo un quadro concettuale e approfondito. Questo è stato essenziale dalla natura emergente e multidisciplinare di queste nuove dipendenze, dove una rigorosa metanalisi potrebbe non essere ancora fattibile per tutte quante le tipologie esistenti, soprattutto per quelle meno studiate per le quali la standardizzazione diagnostica è ancora in fase di dibattimento.

Le implicazioni principali di questo articolo sono significative per la pratica clinica e la ricerca, in primo luogo la distinzione e la coesistenza di queste dipendenze comportamentali sottolinea la necessità di una attenta diagnostica differenziale e di una comprensione approfondita dei pattern specifici di ogni condizione. Esempio i disturbi da gaming disorder, hanno un riconoscimento nosografico che facilita l'accesso ai trattamenti, mentre altre condizioni come la dipendenza da sesso e la dipendenza affettiva, pur essendo clinicamente rilevanti e con un impatto devastante sulla vita dell'individuo che ne soffre, mancano ancora di una piena legittimazione diagnostica che può ostacolarne non solo l'identificazione ma anche l'accesso alle cure. Il confronto con i dati esistenti e sulle doppie diagnosi con i disturbi della personalità è cruciale; la presenza di tratti di personalità dipendente con disturbi del cluster B, aggrava il quadro clinico con rischi di risultati negativi e di *drop-out* terapeutico[30].

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[28] S. SUSSMAN, *op. cit*.

[29] M.R. MITCHELL, M.N. POTENZA, *Importance of sex differences in impulse control and addictions,* in *Frontiers in psychiatry*, 6, 2015, 24.

[30] T.R. KOSTEN, *op. cit.* ATZORI, *op. cit.*

Questo suggerisce un intervento mirato sulla personalità sottostante, usando strumenti di valutazione dinamica come la SWAP-200[31], sì, essenziale per costruire un'alleanza terapeutica solida. Questo è particolarmente vero per la *love addiction* dove la patologia è legata a dinamiche di attaccamenti in seguito a relazioni disfunzionali[32]. L'importante è considerare la modalità di comunicazione della diagnosi al fine di prevenire l'identificazione della persona. La malattia è un'implicazione quindi diretta di questi risultati, sottolineando la necessità di un approccio centrato sulla persona e sulle sue risorse.

L'enfasi sulla stessa multidimensionalità sui trattamenti psicosociali basati sull'evidenze EBP, rappresenta una reazione necessaria nonché promettente; l'approccio incentrato sul contesto di vita del paziente, sulla sua identità nonché sui fattori iatrogeni è fondamentale per superare una visione riduzionista della patologia[33]. L'efficacia della terapia cognitivo comportamentale del social skill training nel modificare gli schemi cognitivi del paziente e i comportamenti disfunzionali è ben documentata anche per queste dipendenze. La neuro plasticità offre una base scientifica convincente per le capacità del cervello di adattarsi a cambiare in funzione di nuove esperienze, rafforzando la razionalità di interventi che mirano all'apprendimento di nuove abilità e strategie di *copying*. Questa prospettiva bio-psicosociale integrata è l'unica che può cogliere appieno la complessità delle nuove dipendenze e proporre soluzioni durature[34].

Le implicazioni di questi risultati per la pratica clinica sono chiare. I professionisti della salute mentale devono essere formati non solo sulle diagnosi categoriali, ma anche sulla valutazione funzionale e sui principi della riabilitazione orientata alla *recovery*. L'approccio multidisciplinare, che coinvolge diverse figure professionali e incorpora i sostegni naturali e l'inclusione sociale, è cruciale per una presa in carico efficace. Gli operatori devono essere in grado di motivare, insegnare e supportare il paziente, promuovendo la sua *self-efficacy* e la capacità di stabilire obiettivi autodeterminati. È vitale considerare i fattori di rischio e protezione, e fornire strumenti per riconoscere i primi sintomi di ricaduta, ampliando le strategie operative per affrontarli. La qualità della relazione terapeutica orientata agli esiti è un fattore predittivo fondamentale per il successo del trattamento.

Nonostante i progressi nel riconoscimento e nel trattamento, la ricerca sulle nuove dipendenze è ancora in evoluzione. Sono necessari studi longitudinali e randomizzati controllati per comprendere meglio la traiettoria naturale di queste condizioni e l'efficacia a lungo termine dei vari interventi, specialmente per le dipendenze meno studiate. Inoltre, una maggiore integrazione tra i *framework* diagnostici [DSM-5, ICD-11] per includere esplicitamente tutte le dipendenze comportamentali emergenti sarà fondamentale per la standardizzazione della diagnosi e del trattamento a livello globale, facilitando la ricerca comparativa e lo sviluppo di linee guida *evidence-based*. L'attenzione deve essere spostata anche sulle strategie preventive, agendo sui fattori di rischio e potenziando quelli protettivi fin dalle prime fasi di vita, specialmente nell'era digitale.

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[31] D. WESTEN, J. SHEDLER, *op. cit.*

[32] S. SUSSMAN, *op. cit.*

[33] *Ibid.*

[34] M. CRUSCO, F. MASSONI, E. LUZI, P. RICCI, M. PELOSI, P. CORBOSIERO, M. RAPP RICCIARDI, S. RICCI, *Gambling and the need for new responses in public health with an addiction sine substantia,* in *Clinica Terapeutica*, 167(6), 2016, 162-67.

8. Conclusioni

Il significato principale dello studio risiede nell’evidenziazione delle condizioni che pur non implicando l’abuso di sostanze condividono con esse caratteristiche psicopatologiche neuro biologiche e richiedono pertanto un approccio diagnostico e riabilitativo, altrettanto rigoroso e multidimensionale. La loro crescente prevalenza e la pervasività sulla vita degli individui che ne soffrono sottolineano urgenza di un riconoscimento clinico e sociale più ampio. È emerso che una diagnosi funzionale e un *assessment* riabilitativo in grado di considerare il paziente nella sua globalità risultano elementi imprescindibili per la pianificazione di interventi efficaci. In particolare, la valutazione dovrebbe includere il contesto di vita dell’individuo, la sua identità, i fattori contestuali (sia ambientali sia personali) nonché i livelli e le dinamiche della dipendenza, comprese le componenti familiari. La valutazione deve andare oltre il sintomo per poter cogliere la complessa profondità delle menomazioni del funzionamento e delle partecipazioni identificando sia le barriere che i facilitatori al recupero. La co-morbilità con i disturbi della personalità soprattutto sulla personalità dipendente rappresenta una sfida significativa che richiede strategie terapeutiche integrate con una profonda comprensione delle dinamiche relazionali di attaccamento sottostanti al comportamento compulsivo.

Per il futuro sembrerebbe innanzitutto cruciale continuare ricerca per consolidare la base di evidenze sulle dipendenze comportamentali non ancora pienamente riconosciute al fine di favorirne la diagnosi e il trattamento sempre più standardizzato, nonché l’accesso ai servizi. Secondo poi: è imperativo sviluppare e implementare i programmi di formazione continua per i professionisti della salute mentale e del sociale che li preparino a gestire la complessità dello spettro delle dipendenze inclusa la doppia diagnosi, spingendoli a utilizzare approcci basati sull’evidenze scientifiche con un’attenzione alla neuroplasticità come fondamento dei processi di cambiamento.

Infine, l'approccio multidisciplinare e orientato agli esiti deve diventare la norma nei servizi di salute mentale e per le dipendenze. Questo implica non solo la riduzione dei sintomi, ma anche il miglioramento del funzionamento globale, della partecipazione sociale, dell'autonomia lavorativa e abitativa, e la promozione di un solido supporto sociale, inclusi i sostegni naturali. La relazione terapeutica deve essere proattiva e focalizzata sugli obiettivi autodeterminati dal paziente, promuovendo il suo *self-efficacy* e contrastando il senso di colpa, vergogna e l'identificazione con la malattia. La *recovery* da queste nuove dipendenze non è solo possibile, ma deve essere l'obiettivo centrale di un sistema di cura che valorizzi la persona nella sua interezza e promuova la sua piena integrazione nella comunità, prevenendo l'esclusione sociale e favorendo una vita significativa e autonoma.

Disability and Artificial Intelligence: Possible Connections

Rosaria Ferrara, Leonardo Iovino, Angiola Avallone*

ABSTRACT: Artificial intelligence (AI) is one of the most innovative and promising technologies, with applications ranging from healthcare to education and social services. In the field of disability, new AI-based technologies offer numerous benefits, such as greater autonomy, motor rehabilitation and new opportunities for accessibility and inclusion. Although there are ethical and social challenges, the application of AI in disability is one of the most promising areas for an inclusive society. Finally, the importance of an interdisciplinary and inclusive approach is emphasised as necessary to ensure equity and sustainability in the development of these technologies.

KEYWORDS: Disability; artificial intelligence; accessibility; inclusion; assistive technology

SUMMARY: 1. The Term 'Disability': Etymology and Interpretative Frameworks – 1.1. Linguistic Roots and Early Definitions – 1.2. Early Medical-Biological Conceptualisations and Their Limitations – 1.3. Language as a Constructor of Reality: The Word 'Disability' as a Device of Power and Inclusion/Exclusion – 1.4. From Individual Deficit to the Relationship with Barriers: The Social Model of Disability – 2. The New Frontiers of AI in Disability – 2.1. AI-Enhanced Assistive Technologies – 2.2. Communication and Language – 2.3. Digital Accessibility and Inclusion.

1. The Term 'Disability': Etymology and Interpretative Frameworks

The concept of 'disability' has never been neutral or static: it is a category that reflects historical, cultural and political changes, as well as transformations in language and social practices. Talking about disability means questioning not only the bodies and minds that are classified as 'different' from a normative model, but also the linguistic devices, interpretative frameworks and systems of power that have constructed this category over time. Analysis of the the term, its etymological roots and its earliest defnitions allows us to understand how society has framed the issue, oscillating between logics of exclusion and attempts at inclusion.

At the same time, it is fair to say that the theories that have interpreted disability – from the medical-biological to the social model – have provided different interpretations to explain the difficulties encountered by people and to identify possible remedies. In this context, there are two models of reference:

- The traditional medical model, which focuses on individual deficits;

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- The social model and more recent perspectives, which focus on environmental and cultural barriers that limit participation.

This paper aims to explore the linguistic origins of the term 'disability', comparing them with other terms such as 'invalidity' and 'handicap', and to discuss early medical-biological conceptualisations, highlighting their limitations and social implications. These passages form the basis for understanding the need to rethink disability as a social construct, but also as a field in which language, power and rights are intertwined.

1.1. Linguistic Roots and Early Definitions

The etymology of words related to disability offers a first glimpse into how societies have historically interpreted physical or mental difference. The English word 'disability' comes from the combination of the prefix 'dis-' with 'ability', literally meaning 'absence of ability' or 'lack of capacity', with attestations dating back to the 16th century.[1] The privative element highlights a logic of deficit: defining someone by what they do not have, rather than by their actual abilities. This approach has long influenced the collective imagination, reinforcing the tendency to think of disability as a loss, a limitation or a defect. The term 'handicap', on the other hand, has completely different origins. It derives from the English expression *'hand in* cap', referring to a gambling game popular in the 17th century, in which advantages and disadvantages were balanced between players. It was later adopted in horse racing to indicate an artificially imposed disadvantage on a stronger horse in order to rebalance the race. Only later did it come to refer to a condition of personal or social disadvantage.[2] The use of this sporting and competitive metaphor is not neutral: talking about 'handicap' means placing the person in a logic of competition and comparison, as if they were inevitably 'less' than an established norm. In Italian, the term *invalidità* (disability) has played an important role, especially in the legal and healthcare fields. It derives from the Latin *invalidus,* meaning 'weak, not strong', and has been used in legal and social security systems to indicate the inability to perform certain work or social activities.[3] Here too, the logic is strongly focused on lack and inadequacy in relation to a socially recognised function. It is no coincidence *that* 'civil invalid' is still an administrative category today, used to define rights, pensions and benefits, but at the same time contributing to a stigmatising categorisation. These terms ('disability', 'handicap', 'impairment') show, therefore, how language has constructed bodily and cognitive difference in terms of deficiency, disadvantage and weakness. Although in recent decades the use of 'disability' has become widespread as a preferable and less stigmatising term, its etymological and historical roots continue to influence the way people are perceived and treated. As Hogan has observed, the words we use are not simply labels, but convey worldviews that guide policies, practices and social relations.[4]

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[1] Etymonline, *Disability,* in *Online Etymology Dictionary*. https://www.etymonline.com/word/disability

[2] Etymonline, *Handicap*, in *Online Etymology Dictionary* https://www.etymonline.com/word/handicapped

[3] Treccani, *Disabled; invalid*, in *Vocabulary of the Italian language* (accessed 19 September 2025). https://www.treccani.it/vocabolario/disabile

[4] A.J. HOGAN, *Social and medical models of disability and mental health: evolution and renewal*, in *Canadian Medical Association Journal*, 191, 1, 2019, E16–E18.

1.2. Early Medical-Biological Conceptualisations and Their Limitations

Alongside linguistic developments, early modern theories of disability focused primarily on a medical-biological approach. From this perspective, disability is interpreted as a direct consequence of physical, sensory or cognitive impairment. The focus is on the individual body: the 'cause' of the problem lies within the person, and the solution consists of medical treatment, rehabilitation or, where possible, correction of the impairment.

For most of the 20th century, the 'medical model' prevailed, in which the person was seen almost exclusively as a clinical condition. Consequently, having a disability meant that the person was 'sick' or 'defective' and society's task was to 'fix' them and restore them to a normal condition.[5] In this view, disability is therefore not a problem of social relations or external barriers, but a biological defect that reduces a person's abilities.

While this approach has fostered the development of disciplines such as rehabilitative medicine, physiotherapy and prosthetics, it has also had problematic consequences. This approach has undoubted merits, but anyone who has experienced a disability knows that reducing everything to a biological deficit means ignoring much of the daily experience, which consists not only of therapies and treatments, but also of relationships, environmental obstacles and cultural barriers. Firstly, it has contributed to reducing the person to their clinical condition, obscuring the complexity of their life experience. Secondly, it has legitimised welfare policies that have often reinforced isolation rather than promoting participation. As Hogan pointed out, the medical model has undoubtedly contributed to advances in rehabilitation, but at the same time it has conveyed a reductive view of the person.[6]

Furthermore, this perspective has fuelled the social perception of disability as a 'personal tragedy'. The difficulties encountered are not attributed to architectural, cultural or communication barriers, but to the individual's condition. The risk, Adam observes, is that this reinforces stigma: if the problem lies entirely with the person, then they become the bearer of a defect that justifies exclusion.[7]

It is therefore not surprising that, since the 1970s and 1980s, increasingly strong criticism of this paradigm has emerged. The disability movement, especially in the United Kingdom, has challenged the idea that disability is merely a biological consequence, calling instead for attention to social barriers and rights. However, the weight of the medical-biological model continues to influence policies and representations today, making constant critical deconstruction necessary.

1.3. Language as a Constructor of Reality: The Word 'Disability' as a Device of Power and Inclusion/Exclusion

Language does not merely describe reality, but also functions as a lens that magnifies some differences and obscures others. Talking about 'disability' therefore activates a set of meanings that are not neutral, but reflect power relations, ideologies and cultural models. In this sense, the word itself can function as a device capable of including or excluding.

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[5] Z. ZAKS, *Changing the medical model of disability to the normalisation model of disability: clarifying the past to create a new future direction*, in *Disability & Society*, 39, 12, 2023, 3233–3260.

[6] A.J HOGAN*, op. cit.*, E18.

[7] S. ADAM, A. KOUTSOJLENIS, *Who needs the social model of disability*?, in *Frontiers in Sociology*, 8, 2023, 1305301.

Michel Foucault's reflections on the role of discourse are particularly illuminating: language is not only a tool for communication, but also a field in which practices of classification, control and normalisation are exercised.[8] Applied to disability, this means that the labels attributed to individuals, such as 'handicapped', 'invalid' or 'disabled', are not simply adjectives, but performative acts that contribute to defining who has the right to participate fully in social life and who is instead placed on the margins.

Adam observes that the power of language is also manifested in its ability to generate stigma. Being named using terms that evoke deficit or weakness means being constantly reminded of a lack, regardless of one's skills or aspirations.[9] This applies not only to the words used in legislative texts or medical diagnoses, but also to everyday language, the media and education. Every time a person is reduced to their condition, a hierarchy between 'normality' and 'abnormality' is reinforced.

At the same time, however, language can be a tool for emancipation. Choosing different terms, redefining categories, introducing concepts that value diversity rather than deficit, is a way to dismantle power relations and imagine new forms of inclusion. It is no coincidence that many movements of people with disabilities have called for the use of 'person-first language' (e.g., 'person with a disability' instead of 'disabled person'), emphasising the centrality of the person rather than the condition.[10]

However, the debate remains open and complex. Some activists prefer 'identity-first language' ('disabled person') because they interpret disability not as a negative characteristic to be mitigated, but as an aspect of identity that can become a source of pride and belonging to a community. In this sense, linguistic choice is itself a political act, reflecting tensions between assimilation and the assertion of difference.

The use of the word 'disability' as a device of power is also evident in institutional practices. As Zaks' studies (2024) show, defining a person as 'disabled' in a medical-legal context can mean giving them access to services, support and rights, but it can also pigeonhole them into a rigid classification system that risks limiting their autonomy. It is an ambivalent language: on the one hand, it opens up possibilities, but on the other, it produces exclusion.

This ambivalence shows that simply replacing one word with another is not enough to radically transform social reality. Rather, we need to work on the meaning attributed to terms and the practices that accompany them. Ultimately, the language of disability is not just a semantic issue, but a field of political and cultural struggle, in which processes of recognition and exclusion are at play.

1.4. From Individual Deficit to the Relationship with Barriers: The Social Model of Disability

Criticism of the medical-biological model has paved the way for new interpretations, including the so-called 'social model of disability'. Originating in the 1970s in the United Kingdom, mainly thanks to the work of Michael Oliver, this approach represented an essential turning point: disability is no longer seen as a simple consequence of an individual impairment, but as a product of physical, cultural and institutional barriers that hinder people's full participation in social life.[11] According to the social model, physical or cognitive differences are not in themselves an insurmountable problem: it is society that creates exclusion through environments designed for able-bodied people. A prime example is architectural barriers:

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[8] M. Foucault, *Discipline and Punish: The Birth of the Prison (Italian translation)*, Turin, 1996.

[9] S. Adam, A. Koutsojlenis, *op. cit*., 1305301.

[10] A.J Hogan, *op. cit*., E18.

[11] M. Oliver, *Social Work with Disabled People*. Basingstoke, 1983.

anyone who has pushed a wheelchair, even if only as a tourist in a historic city, knows how a simple staircase can become an insurmountable wall.

Hogan points out that the social model has had the merit of shifting the discourse from 'personal tragedy' to collective responsibility. It is no longer a question of 'fixing' the person, but of transforming society so that it becomes truly inclusive.[12] This perspective has had a huge impact on policy s for the rights of persons with disabilities, inspiring fundamental documents such as the UN Convention on the Rights of Persons with Disabilities (2006).

However, the social model is not without its critics. Adam notes that, while it has raised awareness of social barriers, it sometimes risks underestimating the physical and medical dimensions. Some persons with disabilities point out that pain, fatigue or physical limitations cannot be explained solely as the effect of social barriers. In this sense, the most recent interpretations refer to 'hybrid' models, which bring together biological and social dimensions, avoiding reductionism.[13]

Zaks (2024) proposes considering disability as a complex and situated phenomenon that requires the integration of different perspectives. On the one hand, it is necessary to recognise clinical conditions and provide appropriate medical and rehabilitative interventions; on the other hand, it is essential to eliminate barriers and discrimination. The challenge lies in overcoming the clear opposition between the medical model and the social model, building a truly inclusive and multidimensional approach.

The shift from individual deficit to the relationship with barriers has therefore marked a paradigm shift: disability becomes a matter of social justice and rights, not just health. This change paves the way for contemporary reflections on the use of language, inclusion practices and, as we will see in the next chapter, new technologies – in particular artificial intelligence – as tools capable of redefining the boundaries of autonomy and participation.

2. The New Frontiers of AI in Disability

In recent years, artificial intelligence (AI) has become an integral part of everyday life, gaining increasing relevance in many sectors. AI is a technology designed to find, store, process and provide information to users to help them. By imitating human intelligence, it is capable of simulating certain functions, such as problem solving.[14] Today, thanks to its rapid and continuous evolution, it is one of the most promising solutions for improving the quality of life of people with disabilities. AI-based solutions can improve and facilitate the performance of daily activities, open up new possibilities for learning, communication and social participation, and help overcome barriers that until recently seemed insurmountable.[15]

AI is not just an additional technological support, but has applications in many areas of disability, offering innovative tools that promote individual autonomy and reduce inequalities. In particular, in the field of healthcare and rehabilitation, it is emerging as a valuable resource in assessment, diagnosis and treatment

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[12] A.J. HOGAN, *op. cit.*, E18.

[13] S. ADAM, A. KOUTSOJLENIS, *op. cit.*, 1305301.

[14] I. SENADHEERA, P. HETTIARACHCHI, B. HASLAM, R. NAWARATNE, J. SHEEHAN, KJ. LOCKWOOD, D. ALAHAKOON, LM. CAREY, *AI Applications in Adult Stroke Recovery and Rehabilitation: A Scoping Review Using AI*, in *Sensors (Basel)*, 24, 20, 2024, 6585.

[15] V. KUMAR, S. BARIK, S. AGGARWAL, D. KUMAR, V. RAJ, *The use of artificial intelligence for persons with disability: a bright and promising future ahead, in Disability and Rehabilitation*, in *Assistive Technology*, 19(6), 2023, 2415–2417.

processes, making interventions personalised and effective.[16] Paying attention and intervening early in the course of atypical development has a significant positive impact in limiting the difficulties of the individual, the negative impact on families and containing costs for the individual.[17]

Today, there are numerous artificial intelligence applications available in this field that can support functional recovery and adapt to the specific needs of each individual.

Islam and colleagues (2018) explored the use of artificial intelligence in rehabilitation processes. In their study, they developed a system based on machine learning techniques, aimed at predicting self-care difficulties in children with physical and motor disabilities.[18] This approach allowed therapists to identify problems early, make more accurate clinical decisions, and optimise healthcare time and costs.

Song and colleagues applied AI to support the diagnosis of children with autism spectrum disorder and intellectual disabilities, and Yperman and colleagues (2020) developed a machine learning model aimed at increasing the accuracy of the Autism Diagnostic Observation Schedule (ADOS-2) in the assessment of ASD.[19][20] These data are particularly useful considering that the diagnosis of ASD continues to present challenges and the complexity of the cognitive profile in people with ASD .[21][22]

Nicolas Blanc and colleagues (2019) used computer vision and machine learning to design a tool that helps people with disabilities get around town, suggesting the most suitable routes based on their disability.[23]

Current applications of AI

Disability	AI-based technologies	Main benefits	Critical issues and limitations
Motor disabilities	Exoskeletons, smart prostheses, autonomous mobility systems	Improved mobility and autonomy	Inequalities in access: digital divide and technology costs

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[16] D. Lee, S.N. Yoon, *Application of artificial intelligence-based technologies in the healthcare industry: Opportunities and challenges,* in *Int. J. Environ. Res. Public Health*, 18, 2021, 271.

[17] R. Ferrara, L. Iovino, M. Di Renzo, P. Ricci, *Babies under 1 year with atypical development: Perspectives for preventive individuation and treatment,* in *Frontiers in Psychology*, 13, 2022, 1016886. See also R. Ferrara, F. Damato, L. Iovino, F. Marti, R. Latina, C. Colombi, P. Ricci, *ESDM intervention in severe preschool autism: An Italian Case report, psychological and social medicine reflections*, in *Ital. J. Paediatr.,* 5, 2024, 1-7.

[18] B. Islam, Nim. Ashafuddula, F. Mahmud, *A machine learning approach to detect self-care problems of children with physical and motor disability,* in *21st International Conference of Computer and Information Technology (ICCIT). Piscataway: IEEE*, 2018, 1-4.

[19] C. Song, Zq. Jiang, Hu. Lf *et al.*, *A machine learning-based diagnostic model for children with autism spectrum disorders complicated with intellectual disability*, in *Front Psychiatry*, 13, 2022, 993077.

[20] J. Yperman, T. Becker, D. Valkenborg *et al., Machine learning analysis of motor evoked potential time series to predict disability progression in multiple sclerosis,* in *BMC Neurol*, 20, 1, 2020.

[21] R. Ferrara, R. Nappo, F. Ansermet, P. Ricci, F. Massoni, G. Carbone, A. Sparaci, E. Nonnis, L. Ricci, S. Ricci, *The impact of DSM-5 on the diagnosis of autism spectrum disorder,* in *Psychiatric Annals*, 51, 1, 2021, 38-46.

[22] R. Ferrara, F. Ansermet, F. Massoni, L. Petrone, E. Onofri, P. Ricci, T. Archer, S. Ricci, *Autism Spectrum Disorder and intact executive functioning,* in *Clinica Terapeutica*, 167, 2016, 96-101.

[23] N. Blanc, Z. Liu, O. Ertz *et al.*, *Building a crowdsourcing-based disabled pedestrian level of service routing application using computer vision and machine learning*, in *2019 16th IEEE Annual Consumer Communications & Networking Conference (CCNC). Piscataway: IEEE*, 2019, 1-5.

Sensory disabilities	Voice recognition for the hearing impaired, computer vision for the blind/visually impaired	Reducing communication and social barriers	Algorithmic bias, technological dependence
Neurodevelopmental disorders	Augmentative communication platforms, personalised learning tools	Support for inclusion in education, work and society	Technological dependence and technology costs
Cognitive disabilities	Virtual assistants and predictive systems for memory support and daily life management	Improving independence and quality of life	Ethical issues: privacy, informed consent, reliability

These applications reflect the predominance of the medical model in the literature, favouring technological solutions aimed at managing health conditions and neglecting the social and environmental factors of disability. The reduced integration of the social model in research on artificial intelligence highlights the need for a broader and more inclusive approach that takes into account the obstacles that people with disabilities experience in their daily lives.

The World Health Organisation has identified digital technologies, including artificial intelligence, as key tools for promoting the inclusion of people with disabilities. These solutions transform access to and management of health services, thereby improving the efficiency of care. The WHO, in particular, emphasises two priorities: adopting a systemic approach to ensure health equity and adherence to international accessibility standards.[24]

Scientific literature shows that people with disabilities value their direct involvement in the development of technological interventions, especially when this recognises their dignity, autonomy and lived experiences. Therefore, in order to broaden our understanding of disability, it is essential to promote truly interdisciplinary research between artificial intelligence specialists and disability scholars, and a central aspect of this process is the direct involvement of people with disabilities.[25] Their active participation allows for the development of artificial intelligence systems that respond concretely to their needs. Integrating their perspectives not only helps to reduce the biases inherent in technological systems, but also ensures that AI is used as a tool to promote equity, justice and social inclusion. In this way, it is possible to fully exploit the transformative potential of artificial intelligence and reduce the risk that these solutions end up excluding rather than promoting inclusion.[26]

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[24] World Health Organization, *Global report on health equity for persons with disabilities,* 2022.

[25] E. Umucu, *Artificial Intelligence and Health Equity for People with Disabilities: An Integrated Framework for Disability-Inclusive AI Design,* in *Inquiry: a journal of medical care organisation, provision and financing*, 62, 2025. See also A. Roman-Urrestarazu, R. Van Kessel, *Inaccurate prevalence estimates impacts autism policy: A letter to the editor in relation to "Global prevalence of autism: A systematic review update"* by Zeidan *et al.*, in *Autism Res*, 15, 7, 2022, 1184-1186.

[26] C. El Morr, B. Kundi, F. Mobeen, S. Taleghani, Y. El-Lahin, R. Gorman, *AI and disability: A systematic scoping review,* in *Health Informatics J*, 30, 3, 2024.

In conclusion, the integration of an inclusive, ethical and sustainable approach is necessary for artificial intelligence to truly meet the needs of people with disabilities.

In this regard, scientific literature has highlighted that autistic people encounter multiple barriers in accessing health services and, very often, professionals do not know how to manage problematic behaviours during routine medical examinations.[27]

It is essential to develop and review guidelines, protocols and regulations to ensure compliance with accessibility and inclusion standards. Despite the potential of artificial intelligence to improve the quality of life of people with disabilities, several challenges remain. The main ones include high costs, technological limitations and the ethical and social implications of its use. In order to fully exploit the benefits of AI, collaboration between the research community, professionals, institutions and communities is crucial, so that AI can be transformed into a truly enabling resource, capable of promoting autonomy, inclusion and a better quality of life for people with disabilities.

2.1. AI-Enhanced Assistive Technologies

In recent years, artificial intelligence (AI) has established itself as one of the main drivers of transformation in assistive technologies. Whereas prostheses, wheelchairs and support systems were once relatively static tools, AI now allows for a degree of adaptation and customisation that was previously unthinkable. Assistive technologies enhanced by machine learning algorithms make it possible to better respond to individual needs, anticipate requirements and optimise the use of resources.

A recent study conducted in Saudi Arabia highlighted the impact of AI-based assistive technologies on the daily lives of children with Down syndrome. The results show significant improvements in mobility and the ability to perform daily activities independently.[28] It is not just a question of increasing the efficiency of devices, but of promoting a greater sense of independence and social participation. This aspect is crucial: intelligent assistive technologies do not merely compensate for a deficit, but help to redesign the relationship between the individual and their environment.

A particularly promising field is that of robotic prostheses and intelligent movement systems. As Giansanti observes, the integration of AI into prostheses not only allows motor functions to be replicated, but also enables desired movements to be predicted and anticipated, making interaction more natural. [29] Through sensors and machine learning algorithms, prostheses can adapt to the user's habits, recognise patterns and modify their operation in real time. Looking ahead, this means reducing the cognitive effort required and improving the quality of daily life. Imagine, for example, a child who, thanks to a smart prosthesis, can finally grasp an object without having to think about every single movement: that simple gesture

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[27] R. Ferrara, L. Ricci, P. Ricci, L. Iovino, S. Ricci, F.M. Damato, G. Cicinelli, R. Keller, *How autistic women are aware of their body and take care of their health? Focus on menstruation cycles and gynaecological care,* in *Clinica Terapeutica,* 175, 3, 2024, 168-175. See also R. Ferrara, P. Ricci, F.M Damato, L. Iovino, L. Ricci, G. Cicinelli, R. Simeoli, R. Kelle, *Pregnancy in autistic women and social medical considerations: Scoping review and meta-synthesis,* in *Frontiers in Psychiatry*, 14, 2023, 1222127.

[28] R. Alanazi, A.S Alanazi, S. Alqazlan *et al.*, *Assessing the impact of AI tools on mobility and daily assistance for children with Down syndrome in Saudi Arabia,* in *Scientific Reports*, 15, 2025, 30826.

[29] D. Giansanti, A. Pirrera, *Integrating AI and Assistive Technologies in Healthcare: Insights from a Narrative Review of Reviews*, in *Healthcare*, 13, 5, 2025, 556.

encapsulates the difference between technology that compensates and technology that truly frees up everyday life.

A further development concerns autonomous navigation systems for people with visual or motor disabilities. Ahmmad and colleagues have shown how AI can be used to create multimodal interfaces, based on voice, touch and visual feedback, which guide the person through urban spaces, reducing risks and increasing independence. In this case, technology not only breaks down a practical barrier, but also redesigns the relationship with the city, making it more accessible and liveable.[30]

The potential is enormous, but some critical issues also emerge. Alanazi and colleagues point out that the costs of these devices and their unequal distribution can accentuate social inequalities: those who can afford intelligent assistive technologies gain a significant advantage, while others risk being excluded. These innovations, therefore, while emancipatory, raise urgent questions of distributive justice.[31]

2.2. Communication and Language

A second area in which AI is breaking new ground is communication. For many people with disabilities, the ability to express themselves and interact is hampered by linguistic, sensory, or cognitive barriers. In this context, AI-based technologies offer a number of innovative solutions, such as:

- Augmentative and alternative communication (AAC);
- Automatic sign language translation.

In education, Kooli shows how speech recognition and synthesis tools can support students with motor or hearing difficulties. Through machine learning algorithms, these tools transform speech into written text, or text into natural speech, facilitating classroom participation and access to teaching materials. These are concrete examples of how AI can promote educational inclusion, transforming contexts that have traditionally excluded or marginalised.[32]

It is easy to get excited about these advances, but it is legitimate to wonder what might happen if the technology were unable to truly reflect the richness of real sign languages. Another point for reflection concerns the automatic translation of sign language, which is a rapidly expanding field of research. Baumgärtner and colleagues highlighted the potential of computer vision and gesture recognition techniques to translate sign language into text or speech in real time.[33] However, they also pointed out some critical issues, namely:

- Sign language is not universal, but varies nationally and culturally;
- The available datasets are often limited and unrepresentative.

This carries the risk of developing inaccurate systems that do not reflect the linguistic and cultural complexity of deaf communities.

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[30] J. AHMMAD, O.A. AL-DAYEL, M.A. KHAN *et al.*, *AI-assisted technology optimisation in disability support systems using fuzzy rough MABAC decision-making,* in *Scientific Reports*, 2025, 18335.

[31] R. ALANAZI, A.S ALANAZI, S. ALQAZLAN *et al.*, *op. cit.*, 30826.

[32] C. KOOLI, R. CHAKRAOUI, *AI-driven assistive technologies in inclusive education: benefits, challenges, and policy recommendations,* in *Sustainable Futures*, 10, 2025, 101042. See also R. ALANAZI, A.S ALANAZI, S. ALQAZLAN *et al.*, *op. cit.* 30826.

[33] L. BAUMGARTNER, S. JAUSS, J. MAUCHER, G. ZIMMERMANN, *Automated sign language translation: The role of artificial intelligence now and in the future*, in *Proceedings of the 6th International Conference on Computer-Human Interaction Research and Applications*, 2020, 237-244.

New approaches based on deep learning architectures, such as spatio-temporal transformers, are improving performance. Ruiz and Martinez show how these models can take into account both movement over time and spatial relationships between body parts, increasing the accuracy of machine translation . Despite progress, the problem of poor participation by deaf people in the development of such technologies remains: without their direct contribution, there is a risk that the systems will reproduce prejudices and reductive views.[34]

Looking ahead, the combination of AAC and machine translation could open up completely new avenues of communication. Wearable devices, mobile apps and multimodal interfaces promise to make interaction more fluid and natural, breaking down barriers that have limited access to information and socialising for centuries. Once again, however, the effectiveness of these tools will depend on their ability to include the real diversity of users and respect cultural specificities.

2.3. Digital Accessibility and Inclusion

There is no doubt that digital technology has become the main environment for socialisation, work and political participation. Ensuring accessibility means ensuring citizenship, and AI, in this context, is a powerful tool for creating more inclusive digital environments.

The most obvious applications are voice recognition and speech synthesis systems. As Giansanti points out, advances in natural language processing have made voice interfaces increasingly fluid, allowing people with motor difficulties to control electronic devices without having to use their hands.[35] At the same time, speech synthesis has reached levels of naturalness that facilitate understanding, reducing the feeling of artificiality. Digital inclusion also depends on these more natural interaction experiences, which reduce the perceived distance between people and technology. Anyone who has tried a voice assistant knows how liberating it can be to simply say ‘turn on the light’ or ‘open the file’ and see the action take place without having to lift a finger. For a person with motor difficulties, this simplicity is not a detail: it is autonomy that is gained every day. [36]

Another area of great interest is the automatic generation of subtitles, image descriptions and accessible texts. Ahmmad et al. describe AI-based systems that not only transcribe audio in real time, but also generate image descriptions for blind users. This feature is essential not only for enjoying multimedia content, but also for accessing information on social media, educational platforms and institutional websites.[37] The ability to make the invisible visible – through textual descriptions of visual content – represents a significant advance for inclusion.[38]

However, digital accessibility is not just a technical issue. As Scully points out, it is also a political and ethical field: deciding which bodies and minds to include in training datasets means determining who will truly benefit from these technologies. When AI is trained primarily on ‘neurotypical’ speakers or voices without particular inflections, it risks failing to recognise input from people with speech impairments or

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[34] C. Ruiz, F. Martinez, *Spatio-temporal transformer to support automatic sign language translation*, 2025.

[35] D. Giansanti, A. Pirrera, *op. cit.*, 556.

[36] J.L. Scully, *Disability and AI: Much more than assistive technologies*, in *Science, 389*, 2025. See also D. Giansanti, A. Pirrera, *op. cit.*, 556.

[37] J. Ahmmad, O.A. Al-Dayel, M.A. Khan *et al., op. cit.*, 18335.

[38] J.L. Scully, *op. cit.*, 389. See also J. Ahmmad, O.A. Al-Dayel, M.A. Khan *et al., op. cit.*, 18335.

strong accents. This is what Scully calls ‘algorithmic ableism’: the systematic exclusion of non-conforming experiences, which ends up reinforcing existing discrimination.

Finally, digital accessibility also requires consideration of infrastructure: fast internet connections, up-to-date devices and accessible software are not evenly distributed. Without careful public policy, there is a risk that AI-based assistive technologies will remain the privilege of the few, turning the promise of inclusion into a new factor of social exclusion.[39]

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[39] J.L. SCULLY, *op.cit.*, 389.

Omics Sciences and Artificial Intelligence: Future Directions for Tailored Social Medicine

Marianna Talia, Eugenio Cesario, Rosamaria Lappano, Marcello Maggiolini *

ABSTRACT: Biomedical research is rapidly advancing through the convergence of omics sciences with artificial intelligence (AI) applications. Genomics, transcriptomics, proteomics, and metabolomics, among others, generate multidimensional data that embrace molecular complexity of diseases, whereas AI enables the integration, interpretation, and prediction from these datasets. Together, they contribute to enhance patient-tailored medicine by supporting biomarker discovery, disease classification, patient stratification, and personalized therapies. However, challenges such as data quality, cost, reproducibility, and model interpretability remain. Emerging strategies including federated learning and large language models provide promising solutions, bridging precision and social medicine to promote health equity, improve clinical decision-making, and maximize the societal impact of digital health innovations.

KEYWORDS: Omics data, artificial intelligence, machine learning, social medicine, personalized medicine

1. Introduction

Biomedical research is experiencing unprecedented progress through the integration of digital technologies. A wide array of digital health innovations, including interventions, applications and devices are being continuously developed and optimized in order to refine personalized medicine from the perspectives of patient, healthcare professional, healthcare infrastructures and industry stakeholders.[1] In this context, recent advancements in omics technologies, including genomics, transcriptomics and proteomics, is empowering our knowledge on various diseases, offering insights in-

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[1] N. BIT-AVRAGIM, J. BOUSQUET, S. CANTÙ, S. OMBONI, E. RAVOT, P. TUNNAH, *The evolving reality of digital health*, in *Digit Health*, 10, 2024.

to the underlying molecular mechanisms.[2] Additionally, artificial intelligence (AI) has become an essential resource to interrogate the huge amount of omics data generated by high-throughput technologies, enabling to capture the full degree of disease-related complexity. In this scenario, the convergence of omics and AI holds great promise in precision and social medicine. Indeed, integrating patient-derived data can disclose hidden patterns that predict disease, inform diagnosis, guide care and support both patients and clinicians in decision making, potentially outperforming existing conventional protocols. While AI provides the analytical and statistical powers to interrogate datasets, omics sciences constitute the backbone of this information. By capturing multiple layers of biological organization in both health and disease, integrating DNA sequence data, RNA expression as well as protein and metabolite abundance, omics approaches create a bridge that links molecular profiling to phenotype manifestation.[3] A pivotal milestone in the rise of omics studies is represented by the human genome sequencing project, which was achieved in the early 2000s through two independent initiatives, the publicly funded Human Genome Project and a private effort led by J. Craig Venter. Genomics investigations catalogue the entire DNA of an organism, aiming to identify gene structures, functions and interactions, as well as their correlation to biological processes.[4] Beyond the initial view of describing the human genome through a single reference sequence, recent studies revealed a growing collection of human genomes that reflect population-specific variations, encompassing single nucleotide polymorphisms (SNPs), insertions and deletions, copy number variations (CNVs) and structural variants.[5] Beginning with genomics, subsequent omics disciplines, depicting additional layers of gene expression, have emerged and led to the generation of multi-dimensional datasets.[6] The genome dynamic expression, represented by the entire RNA set, reveals how genes are differentially regulated within specific tissues or conditions. Advances in RNA-sequencing (RNA-seq) approaches have greatly expanded our ability to study the transcriptome respect to previous microarray-based approaches. RNA-seq has provided critical insights into the complexity of gene expression regulation, including alternative splicing and the roles of non-coding and enhancer RNAs in modulating transcriptional activity.[7] Following these advancements, single-cell RNA-seq (scRNA-seq), was developed to explore the transcriptional dynamics at single cell resolution.[8] More recently, spatial transcriptomics has further implemented RNA-seq technology by preserving the spatial context of gene expression within tissues, allowing to map the cellular organization and interactions at unprecedented resolution. In oncology, these approaches represent precious resources able to reveal how tumor cells interact and arrange toward immune evasion, drug resistance and metastatic features, provid-

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[2] A. Sharma, A. Lysenko, S. Jia, K.A. Boroevich, T. Tsunoda, *Advances in AI and machine learning for predictive medicine*, in *J Hum Genet*, 69, 2024, 487–497.

[3] K.Y.X. Wang, G.M. Pupo, V. Tembe, E. Patrick, D. Strbenac, S-J. Schramm, *et al.*, *Cross-Platform Omics Prediction procedure: a statistical machine learning framework for wider implementation of precision medicine*, in *NPJ Digital Med.*, 5, 2022, 85.

[4] C. Manzoni, D.A. Kia, J. Vandrovcova, J. Hardy, N. W. Wood, P. A. Lewis, *et al.*, *Genome, transcriptome and proteome: the rise of omics data and their integration in biomedical sciences*, in *Brief Bioinform*, 19, 2018, 286–302.

[5] R.M. Sherman, S.L. Salzberg, *Pan-genomics in the human genome era*, in *Nat Rev Genet*, 21, 2020, 243–254.

[6] M. Mann, C. Kumar, W.F. Zeng, M.T. Strauss, *Artificial intelligence for proteomics and biomarker discovery*, in *Cell Syst*, 12, 2021, 759–770.

[7] X. Li, C.-Y. Wang., *From bulk, single-cell to spatial RNA sequencing*, in *Int J Oral Sci*, 13, 2021, 36.

[8] D. Jovic, X. Liang, H. Zeng, L. Lin, F. Xu, Y. Luo, *Single-cell RNA sequencing technologies and applications: A brief overview*, in *Clin Transl Med.*, 12, 2022, e694.

ing critical insights for precision medicine.[9] Mass spectrometry (MS)-based proteomics and metabolomics finally represents the functional output of the genome and transcriptome, assessing the dynamic molecular layers linked to cellular phenotypes in health and disease conditions.[10] Although the comprehensive understanding of biological systems derived from omics studies, the high dimensionality of data, as well as the intricate relationships existing between data layers represent analytical challenges. In this vein, machine learning (ML) and deep learning (DL) approaches enable the extraction of biological and clinically meaningful insights from complex datasets, thereby paving the way for precision and social medicine. AI facilitates biomarker discovery, disease classification, patient stratification, disease risk prediction, and target identification toward personalized therapies. ML, a branch of AI, learns from data to improve prediction tasks, whereas DL, a sub-field of ML, uses multi-layered models for automated feature extraction and pattern recognition in complex datasets. Nevertheless, most DL applications hold limited transparency and explainability that restrain their applicability in omics studies.[11] Beyond model interpretability, additional challenges are represented by data quality and standardization since large differences exist across different protocols and platforms regarding specificity, sensitivity, chemistry of library construction and bioinformatics.[12] Additionally, in many cases, datasets contain a limited number of patients, for example due to phenotype rarities, making the reproducibility a critical concern.[13] Another limitation is related to the high costs for generating omics data that often limits cohort size, reducing the statistical power and the reproducibility of ML models. Aiming to maximize the value of clinical and related omics data, politicians, funders, and publishers should support and implement data sharing policies that further restrict biomedical advancements. Simultaneously, researchers should be trained to effectively reuse existing datasets to strengthen their studies and the robustness of their conclusions.[14] In this context, federated learning (FL), a distributed ML approach, where data is decentralized and models are trained locally, is emerging as a promising strategy for omics data analysis further supporting personalized and social medicine. FD overcomes the problem of collecting and integrating data from medical institutions, enabling collaborative model training without the need to centralize sensitive patient data.[15] At the same time, large language models (LLMs) could enhance trust and facilitate clinical adoption thanks to their capability in language understanding and the ability to tackle new tasks through in-context learning.[16]

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[9] X. LI, C.Y. WANG, *op. cit*.

[10] T. KOWALCZYK, M. CIBOROWSKI, J. KISLUK, A. KRETOWSKI, C. BARBAS, *Mass spectrometry based proteomics and metabolomics in personalized oncology*, in *Biochim Biophys Acta Mol Basis Dis*, 1866, 2020, 165690.

[11] S. SHAFI, A.V. PARWANI, *Artificial intelligence in diagnostic pathology*, in *Diagn Pathol*, 18, 2023, 109.

[12] M. WYSOCKA, O. WYSOCKI, M. ZUFFEREY, D. LANDERS, A. FREITAS, *A systematic review of biologically-informed deep learning models for cancer: fundamental trends for encoding and interpreting oncology data*, in *BMC Bioinformatics*, 24, 2023, 198.

[13] X. CHEN, Z. YANG, W. CHEN, Y. ZHAO, A. FARMER, B. TRAN, *et al.*, *A multi-center cross-platform single-cell RNA sequencing reference dataset*, in *Sci Data*, 8, 2021, 39.

[14] Y. LIANG, A. KELEMEN, A. KELEMEN, *Reproducibility of biomarker identifications from mass spectrometry proteomic data in cancer studies*, in *Stat Appl Genet Mol Biol*, 18, 2019.

[15] C. LOCHER, G. LE GOFF, A. LE LOUARN, U. MANSMANN, F. NAUDET, *Making data sharing the norm in medical research*. In *BMJ*, 382, 2023, 1434.

[16] Q. WANG, M. HE, L. GUO, H. CHAI, *AFEI: adaptive optimized vertical federated learning for heterogeneous multi-omics data integration*, in *Brief Bioinform*, 24, 2023.

Social medicine, which focuses on social, economic and cultural conditions that impact health, disease and the practice of medicine[17], may take useful advantages from these technological innovations. It frames biomedical progress within the context of health equity, public health priorities and the reduction of disparities, ensuring that data-driven advances comprehensively allow individual and society benefit.

2. Methods

High-throughput technologies advent has represented a turning point in medical science, enabling the generation of multi-omics datasets.[18] Next generation sequencing (NGS) approaches produce vast amounts of DNA sequence data, offering detailed insights into genetic variation, mutations, as well as DNA methylation profiles.[19] RNA-seq measures average transcript abundance within a sample, encompassing both coding and non-coding RNAs.[20] MS-based methods allow the detection and quantification of proteins and metabolites, thereby completing the multi-omics framework toward a comprehensive phenotype characterization.[21] Advances in genomics, transcriptomics and proteomics have been achieved through the development of single-cell technologies, which capture the complexity of clinical conditions that are characterized by molecular heterogeneity at the single cell level, such as in tumors.[22]

Genomics. Genome sequencing has accelerated the discovery of disease-associated genes, novel gene variants and their related phenotypes.[23] After DNA extraction from biological samples, typical NGS pipelines involve DNA fragmentation and ligation to platform-specific adapters, followed by amplification and sequencing. Next steps comprise quality control (QC) of the reads and alignment to the reference genome.[24] A base-pair resolution across the entire genome is provided by whole genome sequencing (WGS), whereas whole exome sequencing (WES) only targets protein-coding regions.[25] The resulting data allow comprehensive characterization of genomic variation and integrative analyses with further omics layers.

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[17] *Z.* WANG, H. WANG, B. DANEK*,* Y. LI*,* C. MACK*,* L. ARBUCKLE*,* et al., *A perspective for adapting generalist AI to specialized medical AI applications and their challenges*, in *NPJ Digital Med.*, 8, 2025, 429.

[18] N. NOUR*,* D. ONCHONGA*,* S. NEVILLE*,* P. O'DONNELL*,* M. E. ABDALLA*, Integrating the social determinants of health into graduate medical education training: a scoping review*, in *BMC Med Educ.*, 24, 2024, 565.

[19] B. HWANG*,* J.H. LEE*,* D. BANG, *Single-cell RNA sequencing technologies and bioinformatics pipelines*, in *Exp Mol Med.*, 50, 2018, 1–14.

[20] X. LI, C.Y. WANG, *op. cit*.

[21] Y.J. HEO*,* C. HWA*,* G.H. LEE*,* J.M. PARK*,* J.Y. AN*, et al.*, *Integrative multi-omics approaches in cancer research: From biological networks to clinical subtypes*, in *Mol Cells*, 44, 2021, 433–443.

[22] B. ASLAM, M. BASIT, M.A. NISAR, M. KHURSHID, M.H. RASOOL, *Proteomics: Technologies and their applications*, in *J Chromatogr Sci.*, 55, 2017, 182–196.

[23] D.T. MELNEKOFF, A. LAGANÀ, *Single-cell sequencing technologies in precision oncology,* in *Adv Exp Med Biol.*, 1361, 2022, 269–282.

[24] M.L. METZKER, *Sequencing technologies - the next generation*, in *Nat Rev Genet.*, 11, 2010, 31–46.

[25] R. RAMAKRISHNAN, A. WASHINGTON, S. SUVEENA, J.R. RANI, O.V. OOMMEN, *From DNA to big data: NGS technologies and their applications*, in *Methods Mol Biol.*, 2952, 2025, 459–482.

2.1. Transcriptomics

RNA-seq workflow starts from raw sequencing data and culminates with the identification of differentially expressed genes (DEGs) across experimental groups. It involves mRNA-only library and whole transcriptome library that includes all RNA species except for rRNA.[26] Total RNA is extracted from biological samples, RNA quality is evaluated, and RNA is then fragmented and reverse-transcribed to produce double stranded complementary DNA (cDNA). Sequencing libraries are constructed through adaptor ligation and amplification, followed by sequencing to produce millions of reads.[27] The generated raw sequences undergo QC and filtering to remove low-quality reads and adaptors. Processed reads are then aligned to the reference genome and quantified. The resulting data is then normalized and DEGs are identified by comparing normalized expression profiles across conditions.

2.2. Proteomics and Metabolomics

To comprehensively assess the molecular alterations in biological samples, including protein abundance, peptide composition, and post-translational modifications, high-resolution MS offers the most robust approach.[28] Proteins are extracted using appropriate lysis buffers and enzymatically digested to generate peptides. These peptides are separated by liquid chromatography, ionized through electrospray ionization (ESI) or matrix-assisted laser desorption/ionization (MALDI), and analyzed by MS, which measures their mass-to-charge ratios and provide sequence information. The most commonly used mass analyzers are quadrupole, time of flight (ToF), and Orbitrap. Identification and quantification are carried out by comparison with protein databases and spectral matching. Similar approaches are employed to identify metabolic intermediates. Metabolites are extracted using solvent-based protocols and profiled by liquid or gas chromatography coupled to high-resolution MS.[29] Specialized software that detects peaks in the spectra enables alignment, annotation and quantification. In both proteomic and metabolomic analyses, data are subjected to QC, normalization, and statistical evaluation.[30]

2.3. Single-Cell Technologies

Omics studies are increasingly moving to single cell resolution with scRNA-seq being the most employed technique, particularly in oncology.[31] Compared to bulk approaches, individual cells are first isolated through microfluidic or droplet-based systems, lysed to release RNA that is captured through primers or barcoded beads.[32] RNA is then reverse-transcribed into cDNA, amplified, and subjected to high-throughput sequencing. Downstream processing, including QC, read alignment, normalization, and di-

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[26] X. Li, C.Y. Wang, *op. cit*.

[27] C. Manzoni, D.A. Kia, J. Vandrovcova, J. Hardy, N.W. Wood, P. A. Lewis, *et al., op. cit.*

[28] S. Rozanova, K. Barkovits, M. Nikolov, C. Schmidt, H. Urlab, K. Marcus, *Quantitative mass spectrometry-based proteomics: An overview*, in *Methods Mol Biol*, 2228, 2021, 85-116.

[29] S. Alseekh, A. Aharoni, Y. Brotman, K. Contrepois, J. D'auria, J. Ewald, *et al.*, *Mass spectrometry-based metabolomics: a guide for annotation, quantification and best reporting practices*, in *Nat Methods*, 18, 2021, 747–756.

[30] J. Sun, Y. Xia, *Pretreating and normalizing metabolomics data for statistical analysis*, in *Genes Dis*, 11, 2024, 100979.

[31] Y. Zhang, D. Wang, M. Peng, L. Tang, J. Ouyang, F. Xiong, *et al.*, Single-cell RNA sequencing in cancer research, in J Exp Clin Cancer Res, 40, 2021, 81.

[32] B. Hwang, J. H. Lee, D. Bang, *op. cit.*

mensionality reduction, enable the identification of cell clusters with peculiar transcriptional profiles, allowing the reconstruction of developmental trajectories and functional annotation. A further RNA-seq implementation is spatial transcriptomics, that dissects spatially patterned gene expression across tissue sections.[33] In this context, tissue sections are fixed, stained and imaged; RNA is released, captured by spatially barcoded probes and converted to cDNA for library preparation. Downstream analyses follow approaches developed in single-cell studies. Further single cell techniques include single-cell DNA-sequencing, single-cell proteomics and single-cell metabolomics, although these are less routinely applied due to technical limitations such as low input material, and limited sensitivity.[34]

The advent of high-throughput omics technologies has generated richly layered, high-dimensional datasets that reveal the intricate dynamics of biological systems. AI, and in particular ML and DL techniques, provides advanced approaches and methodologies to extract meaningful patterns and knowledge from high-dimensional, heterogeneous, and complex data.

One of the most widely used AI methodologies in omics is supervised ML, where algorithms learn to predict outcomes based on labeled datasets. For example, classifiers such as support vector machines (SVMs), random forests, and gradient boosting are frequently adopted for biomarker identification, disease classification, and patient stratification, leveraging annotated datasets to guide model inference.[35] These models are particularly valuable for precision medicine, where the objective is to predict patient responses to treatments or to stratify patients according to molecular signatures.

In addition to supervised learning, unsupervised learning plays a crucial role in omics data exploration. In particular, dimensionality reduction methods, clustering algorithms, and self-organizing maps support exploratory analysis by identifying latent structure and molecular subtypes without reliance on labeled data.[36] More precisely, dimensionality reduction methods, such as principal component analysis (PCA) and t-distributed stochastic neighbor embedding (t-SNE) are frequently applied to visualize complex datasets and to reduce redundancy before further modeling. Moreover, both hierarchical and partitional clustering approaches allow researchers to group samples or genes with similar expression patterns, revealing hidden structures and biological subtypes.

A particularly promising area of AI is the application of DL. Neural networks, including convolutional and recurrent architectures, can model non-linear and hierarchical relationships in omics data. DL has shown success in tasks such as predicting gene–disease associations, inferring regulatory networks, and integrating multi-omics layers. Moreover, autoencoders are often used to perform robust nonlinear transformations for dimensionality reduction and feature extraction. For example, techniques such as denoising autoencoders and variational autoencoders (VAEs) have been deployed to denoise data, stratify

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[33] A. Rao, D. Barkley, G.S. França, I. Yanai, *Exploring tissue architecture using spatial transcriptomics*, in *Nature*, 596, 2021, 211–220.

[34] H.M. Bennett, W. Stephenson, C.M. Rose, S. Darmanis, *Single-cell proteomics enabled by next-generation sequencing or mass spectrometry*, in *Nat Methods*, 20, 2023, 363–374.

[35] A. Yetgin, *Revolutionizing multi-omics analysis with artificial intelligence and data processing*, in *Quant Biol.*, 13, 2025.

[36] N. Vahabi, G. Michailidis, *Unsupervised multi-Omics data integration methods: A comprehensive review*, in *Front Genet*, 13, 2022, 854752.

patients, and discover latent omic embeddings.[37] Complementarily, the Multi-view Factorization Auto-Encoder (MAE) integrates biological network constraints into autoencoders to improve the integration of multi-omic data and to boost prediction accuracy.[38]

Another important methodological aspect is multi-omics integration, where AI approaches are used to combine information from different omics layers in order to provide a more comprehensive understanding of biological systems. Methods such as multi-view learning, Bayesian networks, and graph-based models enable the integration of genomics, epigenomics, transcriptomics, and proteomics data, supporting the identification of cross-level interactions and pathways. For example, Graph Neural Networks (GNNs) map multiple omics layers onto graph structures and capture inter-entity relationships via message passing, enabling prediction and inference within network contexts.[39] Also, concatenation-based, transformation-based, and network-based strategies have been recently proposed to harness complementary layers of biological information.[40] Finally, Bayesian relational learning frameworks further facilitate integrative analysis by discovering latent interactions across omics layers via graph-encoded relationships.[41]

3. Results

AI, encompassing ML and DL techniques, has found multiple applications in omics sciences and is profoundly transforming biomedical research. These approaches are enabling the generation of novel results and the extraction of actionable biological insights with direct relevance to medicine. Below, we provide a concise overview of the most significant applications and advancements in this domain.

Biomarker Discovery and Disease Diagnosis. Biomarker discovery is the process of identifying measurable indicators, such as molecules or physiological changes, that signal the presence of a disease, predict its risk, or monitor treatment response. This multi-stage process involves high-throughput screening of biological samples like blood or tissue using techniques such as genomics and proteomics, followed by data analysis and rigorous validation to confirm the candidate markers. The identification of biomarkers across multiple omics layers has become a challenging and innovative task in omics science, with the aim of improving diagnostic and prognostic precision in diseases like cancer and liver disorders. This task is faced by the application of supervised ML algorithms such as SVMs, random forests, and neural networks, which are extensively applied to detect molecular signatures associated with disease.[42]

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[37] Y. Wen, L. Zheng, D. Leng, C. Dai, J. Lu, Z. Zhang, *et al., Deep learning-based multiomics data integration methods for biomedical application,* in *Adv Intell Syst*, 5, 2023.

[38] T. Ma, A. Zhang, *Integrate multi-omics data with biological interaction networks using Multi-view Factorization AutoEncoder (MAE)*, in *BMC Genomics*, 20, 2019, 944.

[39] W. Jiang, W. Ye, X. Tan, Y.J. Bao, *Network-based multi-omics integrative analysis methods in drug discovery: a systematic review*, in *BioData Min.*, 18, 2025, 27.

[40] Y. Nam, J. Kim, S.H. Jung, J. Woerner, E.H. Suh, D.G. Lee, *et al.*, *Harnessing artificial intelligence in multimodal omics data integration: Paving the path for the next frontier in precision medicine*, in *Annu Rev Biomed Data Sci*, 7, 2024, 225–250.

[41] E. Hajiramezanali, A. Hasanzadeh, N. Duffield, K.R. Narayanan, X. Qian, *BayReL: Bayesian Relational Learning for multi-omics data integration,* 2020.

[42] A. Yetgin., *op. cit.*; T. Wu, S.A. Cooper, V.H. Shah, *Omics and AI advance biomarker discovery for liver disease*, in *Nat Med*, 28, 2022, 1131–1132.

3.1. Patient Stratification and Precision Medicine

Patient stratification refers to the process of categorizing individuals into subgroups based on shared characteristics, such as genetic variants, molecular biomarkers, or clinical features. This stratification forms the foundation of precision medicine, which seeks to tailor therapeutic interventions to the unique biological and clinical profiles of individual patients. By aligning treatments with patient-specific characteristics, precision medicine offers the potential for enhanced therapeutic efficacy, minimized adverse effects, and more efficient drug development compared to traditional "one-size-fits-all" approaches. In oncology, AI and multi-omics integration have become particularly powerful in advancing patient stratification. AI-driven frameworks are capable of uncovering molecular subtypes of cancer associated with distinct prognoses and therapeutic responses. Such insights enable more accurate risk assessment and the identification of patients most likely to benefit from specific interventions. Moreover, DL architectures, including convolutional neural networks (CNNs) and recurrent neural networks (RNNs), are increasingly employed for classification tasks in high-dimensional omics datasets. These models facilitate the discovery of subtle, non-linear patterns across diverse data types and thereby support the development of highly personalized therapeutic strategies.[43]

3.2. Multi-Omics Integration and Systems-Level Insights

Multi-omics profiling is an emerging approach in which molecular phenomics data from multiple omics layers (including genomes, epigenomes, transcriptomes, proteomes, and metabolomes) are comprehensively measured, analyzed, and integrated from the same set of samples on a genome-wide scale. By capturing and quantifying diverse biological signals across complementary molecular layers, multi-omics profiling enables the exploration of intricate interconnections between biological molecules and supports the identification of system-level biomarkers that cannot be discerned from single-omics analyses alone. AI methodologies play a pivotal role in the integration of these heterogeneous datasets, providing advanced methods to model complex biological interactions. Integration strategies range from concatenation and transformation-based approaches to more sophisticated frameworks such as GNNs and multimodal DL.[44] These methodologies uncover cross-layer relationships that inform systems biology, improve mechanistic understanding, and advance precision medicine applications.

4. Discussion

Human health is shaped by a complex interplay of biological factors, social influences, healthcare access, education, economic conditions, and environmental surroundings. This intricate network of influences helps explain why the World Health Organization identifies the rising burden of non-communicable disease (NCD), or chronic conditions, as a critical public health concern especially in low- and middle-

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[43] A. Yetgin., *op. cit*; X. He, X. Liu, F. Zuo, H. Shi, J. Jing, *Artificial intelligence-based multi-omics analysis fuels cancer precision medicine*, in *Semin Cancer Biol*., 88, 2023, 187–200.

[44] Y. Nam, J. Kim, S.H. Jung, J. Woerner, E. H. Suh, D.G. Lee, *et al., op. cit.*

income countries.[45] The majority of NCD deaths are due to cardiovascular diseases, accounting for 17.9 million annually, followed by cancers (9.3 million), chronic respiratory diseases (4.1 million) and diabetes (2 million). A growing body of evidence indicate that advances in omics technologies and omics-driven AI have untangled specific molecular mechanisms predictive of, or underlying, these diseases.[46] As an example, in cardiovascular research, genomics approaches enabled the identification of both rare pathogenic variants and common causative genetic variations. Additionally, transcriptomic profiling revealed novel molecular drivers and regulatory networks in nonfailing and failing human hearts and identified druggable targets and variability in patient therapeutic responses. Furthermore, advances in metabolic syndrome research were empowered by the integration of omics data with gut microbiome profiles, constant glucose monitoring, and dietary intake, analyzed by AI-based methodologies that for instance predict post-prandial glycemic responses. This integrative method provided a powerful framework for predicting diabetes risk.[47]

Similar approaches have empowered our knowledge on chronic respiratory disease biology. Omics technologies and AI enable the integration of complex molecular, genetic and clinical data, leading to novel insights in disease mechanisms, biomarkers, and risk factors. Such strategies exemplify how advanced tools uncover shared pathways and predictive features across asthma, chronic obstructive pulmonary disease, and related conditions.[48] Multi-omics approaches have also emerged as powerful tools for accelerating cancer research, allowing to unravel the complex molecular interactions and dysregulations associated with specific tumor cohorts of patients. These strategies have already led to advances regarding molecular subtyping, disease-gene association prediction and drug discovery.[49] Despite the advancements in generating and integrating omics data with AI, several limitations remain. As already mentioned, these include the small sample sizes within individual datasets, difficulties in combining data from diverse cohorts due to technical biases, and the limited availability of information that may be crucial for assuming robust conclusions. Additionally, it is worth mentioning that beyond genetic and physiologic factors, disease occurrence is driven by a combination of global demographic and social tendencies, such as population aging, environmental factors, economic transitions, as well as dietary and lifestyle modifications.[50] In this framework, omics data on NCD alone are insufficient to capture the diversi-

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[45] P. Geldsetzer, S. Flores, G. Wang, B. Flores, A.B. Rogers, A. Bunker, *et al.*, *A systematic review of healthcare provider-targeted mobile applications for non-communicable diseases in low- and middle-income countries*, in *NPJ Digit Med*, 5, 2022, 99.

[46] X. He, X. Liu, F. Zuo, H. Shi, J. Jing, *op. cit.*; R.S. Wang, B.A. Maron, J. Loscalzo, *Multiomics network medicine approaches to precision medicine and therapeutics in cardiovascular diseases*, in *Arterioscler Thromb Vasc Biol.*, 43, 2023, 493–503.

[47] M. Subramanian, A. Wojtusciszyn, L. Favre, S. Boughorbel, J. Shan, K. B. Letaief, *et al.*, *Precision medicine in the era of artificial intelligence: implications in chronic disease management*, in *J Transl Med*, 18, 2020; 472.

[48] E. Maiorino, S.H. Baek, F. Guo, X. Zhou, P.H. Kothari, E.K. Silverman, *et al.*, *Discovering the genes mediating the interactions between chronic respiratory diseases in the human interactome*, in *Nat Commun*, 11, 2020, 811; Y. Guo, Q. Liu, Z. Zheng, M. Qing, T. Yao, B. Wang, *et al.*, *Genetic association of inflammatory marker GlycA with lung function and respiratory diseases*, in *Nat Commun*, 15, 2024, 3751; S. Aishwarya, P. C. Siddalingaswamy, K. Chadaga, *Explainable artificial intelligence driven insights into smoking prediction using machine learning and clinical parameters,* in *Sci Rep*, 15, 2025, 24069.

[49] X. He, X. Liu, F. Zuo, H. Shi, J. Jing, *op. cit.*

[50] P. Geldsetzer, S. Flores, G. Wang, B. Flores, A.B. Rogers, A. Bunker, *et al.*, *op. cit.;* R. Ferrara, R. Nappo, F. Ansermet, P. Ricci, F. Massoni, G. Carbone, *et al.*, *The impact of dsm-5on the diagnosis of autism spectrum disorder*, in *Psychi-*

ty across different populations and the gathering of additional data beyond omics, is an imperative need toward both precision and social medicine purposes.[51] Hence, the inclusion of data from heterogeneous resources, including clinical records, socioeconomic indicators, geospatial exposures, and environmental monitoring systems may aid omics-driven AI models to unravel hidden causative relationships. Cumulative measures of environmental exposure can be therefore combined with omics data to uncover how factors such as pollution, diet, accessibility to healthcare, among others, shape NCD trajectories. AI offers a transformative framework for this integration with ML algorithms that are increasingly applied to harmonize multi-layered datasets. Furthermore, LLMs may be employed to facilitate the communication of these insights to diverse stakeholders, ranging from researchers with diverse backgrounds, clinicians, bioinformaticians, data scientists, epidemiologists, ethicists, and policymakers as well as patients.[52] These approaches may promote a more inclusive understanding of health within a broader social and ecological ecosystem that comprise multidisciplinary collaborations and targets. Likewise, important ethical and governance challenges arise regarding privacy protection and fair access to data. To this aim, AI models must ensure transparency and explainability.[53] All these factors combined together will contribute to design frameworks that advance both precision medicine and precision public health, helping to tackle the combined challenge of molecular complexity and health inequities, especially in NCD.

5. Conclusions

The integration of omics technologies and AI offers unique chances toward the advancement of both personalized and social medicine, particularly in addressing the complexity of NCD. Future progress will depend on the ability to integrate molecular data with social, environmental, and lifestyle determinants, while ensuring methodological robustness and reducing technical and cohort-related biases.

At the same time, ethical determinants remain central. Transparency, fairness, and explainability of AI systems must be prioritized to ensure equitable benefits across populations.[54] Importantly, patients should be regarded as active partners in this process: their autonomy, informed consent, and freedom of choice must guide the clinical implementation of AI-driven approaches.

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atric Annals, 51, 1, 2020, 38-46; T. Archer, S. Ricci, F. Massoni, L. Ricci, M. Rapp-Ricciardi, *Cognitive benefits of exercise intervention*, in *Clinica Terapeutica*, 167, 6, 2016, 180-85; M.V. Rosati, A. Sancini, F. Tomei, C. Sacco, V. Traversini, A. De Vita, D.P. De Cesare, G. Giammichele, F. De Marco, F. Pagliara, F. Massoni, L. Ricci, G. Tomei, S. Ricci, *Correlation between benzene and testosterone in workers exposed to urban pollution*, in *Clinica terapeutica*, 168, 6, 2017, e380-87; P. Ricci, F. Massoni, L. Ricci, E. Onofri, G. Donato, S. Ricci, *Quality of life in dementia sufferers: The role of diet and exercise*, in *Current Alzheimer Research*, 15, 5, 2018, 400-07; R. Businaro, M. Corsi, G. Azzara, T. Di Raimo, G. Laviola, E. Romano, L. Ricci, M. Maccarrone, E. Aronica, A. Fuso, S. Ricci, *Interleukin-18 modulation in autism spectrum disorders*, in *Journal of Neuroinflammation*, 13, 1, 2016, 1-13.

[51] M. Pentecost, V. Adams, R. Baru, C. Caduff, J.A. Greene, H. Hansen, *et al.*, *Revitalising global social medicine*, in *Lancet*, 398, 2021, 573–574.

[52] C. Lin, C.F. Kuo, *Roles and potential of large Language Models in healthcare: A comprehensive review*, in *Biomed J*, 2025, 100868.

[53] L. Ricci, B. Di Nicolò, P. Ricci, F. Massoni, S. Ricci, *The exercise of rights beyond therapy: on Human Enhancement*, in *BioLaw Journal*, 1, 2019, 497-512; S. Ricci, A. Miglino, *Medicina e Società: dalla tutela dell'integrità fisica al diritto alla salute*, Roma, 2005, 1-99.

[54] F.M. Damato, P. Ricci, R. Rinaldi, *Informed consent and compulsory treatment on individuals with severe eating disorders: a bio-ethical and juridical problem*, in *Clinica Terapeutica*, 174, 4, 2023, 365-69.

In this perspective, the transformative potential of omics-informed AI lies both in predictive accuracy and therapeutic innovation, as well as in fostering a more participatory and socially-centered model of medicine.

Applications of Artificial Intelligence and Robotics in Surgical Practice

Gianluca Costa, Vincenzo Schiavone, Pierpaolo Castagliuolo, Marco Caricato*

ABSTRACT: Robotic surgery and artificial intelligence are transforming modern surgery by enhancing precision, minimizing invasiveness, and supporting clinical decision-making. This narrative review, based on 40 studies published between 2020 and 2025, explores their applications, benefits, and challenges. Robotic surgery improves ergonomics and reduces complications and hospital stays, though it often involves longer procedures and higher costs. Artificial intelligence supports all surgical stages through predictive modeling, image guidance, and performance evaluation. Despite ongoing issues with algorithm transparency, data quality, and ethics, both technologies show great potential to advance surgical care toward safer, more efficient, and personalized medicine.

KEYWORDS: Robot; artificial intelligence; surgery; future; technology

1. Introduction

Robotic surgery is a major medical innovation that improves precision, reduces invasiveness, and enhances recovery, leading to its growing use across specialties. Although the idea dates back to 1967, its practical development accelerated later, with the U.S. Department of Defense pioneering early systems to reduce battlefield casualties.[1] In 1985, it was performed the first robotic-assisted surgery using the Puma 560 for a brain biopsy, [2] but its industrial design limited medical use. Late 1980s innovations included the Robodoc for hip replacements and early robotic urology advances, while NASA and SRI developed telemanipulation and virtual reality systems that laid the founda-

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[1] S. CHATTERJEE, S. DAS, K. GANGULY, *et al.*, *Advancements in robotic surgery: innovations, challenges and future prospects*, in *Journal of Robotic Surgery* 18, 2024, 28.

[2] K. MYLA, N. BOU-AYASH, W.C. KIM, *et al.*, *Is implementation of robotic-assisted procedures in acute care general surgery cost-effective?* in *Journal of Robotic Surgery*, 18, 2024, 223.

tion for modern remote surgery. From 2012 to 2019,[3] robotic-assisted surgery (RAS) represented more than 15% of all general surgical operations. Between 2003 and 2015, the use of RAS increased by 25.5%, driven by the rising preference for minimally invasive techniques. The evolution of robotic platforms, has transformed surgery by improving 3D vision, precision, and dexterity, promoting minimally invasive techniques. Benefits include reduced trauma and faster recovery, but these come with high costs, complex training, and a steep learning curve, requiring integration into surgical education. Also for anesthesia teams, new challenges arise, such as prolonged Trendelenburg positioning, CO_2 insufflation, and limited patient access after robot docking.[4]

Despite high initial costs, robotic surgery may reduce overall expenses by lowering complications, shortening hospital stays, and enabling faster recovery — benefits highlighted during COVID-19. Same-day discharge is feasible with proper patient selection, considering factors like age, lung health, intraoperative events, and surgery timing.

In recent years another big innovation has exploded: the artificial intelligence (AI).

AI has assumed an increasingly central role in the medical field, establishing itself as a strategic resource for the evolution of clinical practice. The COVID-19 pandemic accelerated interest in applying artificial intelligence to manage large volumes of clinical data and care for critically ill patients. Technologies based on machine learning and computer vision have shown significant potential in improving diagnosis, continuous monitoring, and decision support in surgical settings. In particular, the surgical domain is undergoing a deep transformation, wherein the integration of intelligent systems enables a more effective approach to the complexity of clinical decision-making, data management, and the execution of operative procedures.[5]

AI provides advanced tools for the collection, analysis, and interpretation of large volumes of clinical data and diagnostic images, facilitating treatment personalization and more precise surgical planning. During surgery, intelligent technologies assist the surgeon through automatic recognition of anatomical structures, guidance in movements, and real-time monitoring, thereby contributing to error reduction and improved clinical outcomes. AI also proves valuable in the postoperative phase for predictive monitoring, complication management, and optimization of the post-surgical recovery process.[6]

Despite significant progress, the application of AI in surgery remains in its early stages. Substantial challenges persist, including the standardization of methodologies, scientific validation of models, and the need for harmonious integration between technology and clinical practice.

The introduction of AI into the surgical context elicits diverse reactions among professionals: enthusiasts, skeptics, and cautious operators coexist, reflecting the complexity and uncertainties still present in the field.[7] Although the majority acknowledge the benefits, particularly in diagnostics, few foresee a central role for AI in the operating room, and its practical integration remains limited. This gap between

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[3] *Ibidem.*

[4] Y. Tameze, Y.H. Low, *Outpatient Robotic surgery: Considerations for the Anesthesiologist*, in *Advances in Anesthesia*, 40, 2022, 15.

[5] H. Li, Z. Han, H. Wu, *et al.*, *Artificial intelligence in surgery: evolution, trends, and future directions,* in *International Journal of Surgery*, 111, 2025, 2101.

[6] *Ibidem.*

[7] O. Chevalier, G. Dubey, A. Benkabbou, *et al.*, *Comprehensive overview of artificial intelligence in surgery: a systematic review and perspectives,* in *Pflugers Archiv-European Journal of Physiology*, 477, 2025, 617.

expectations and application underscores the urgency to critically examine the real opportunities and challenges posed by AI adoption.

Only a balanced and multidisciplinary approach can foster a safe, responsible, and sustainable integration of AI in surgical practice, paving the way for a new frontier in medicine.

Aim of this work is analysing all aspects of Robotic surgery and of AI in surgery, its progress, prospects, and their challenges.

2. Material and Methods

A narrative review of the literature was conducted. This review followed a narrative approach and has not been intended as a systematic review. The aim was to synthesize the most recent and relevant literature on artificial intelligence and robotic surgery. Two independent reviewers (V.S and P.C.) evaluated studies through titles and abstract data.

The search was narrowed to articles between 2020 and 2025. The time frame was restricted to 2020–2025 to ensure that the review captured the most recent developments in two rapidly evolving fields (artificial intelligence and robotic surgery). Both domains have undergone major technological, regulatory, and clinical advancements in the past few years, making older literature rapidly outdated. In particular, the period beginning in 2020 corresponds to: the widespread clinical implementation of next-generation robotic platforms; the accelerated integration of AI-driven decision-support systems, fuelled by advances in machine learning and deep learning architectures; and a significant increase in high-quality publications assessing clinical, ethical, and economic implications of these technologies. Limiting the search to the last five years therefore allowed us to focus on state-of-the-art evidence, avoiding dilution from early or obsolete work, and providing a synthesis that is maximally relevant to current clinical practice and policy discussions. We searched on PUBMED; Studies were included if they were full-text articles or review or case reports published in English involved human adult participants (>18 years), and addressed aspects of the diagnosis, management, treatment, economics and ethics. Studies were excluded if they were in other languages, without a visible abstract, not relevant. The research was conducted using the following terms: “robotic surgery for the first topic and “artificial intelligence” and “surgery” for the second one. We selected 40 papers (20 for each macro-area) (Table 1-2).

Title	Authors	Year	Type
Advancements in robotic surgery: innovations, challenges and future prospects.[8]	Chatterjee *et al.*	2024	Review
Is implementation of robotic-assisted procedures in acute care gen-	Myla *et al.*	2024	Review

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[8] S. Chatterjee, S. Das, K. Ganguly, *et al.*, *op cit.*

eral surgery cost-effective?[9]			
Robotic Surgery Techniques to Improve Traditional Laparoscopy.[10]	Williamson *et al.*	2022	Review
Robotic surgery for rectal cancer as a platform to build on: review of current evidence.[11]	Achilli *et al.*	2021	Review
Robotic surgery for colorectal liver metastases resection: A systematic review.[12]	Rocca *et al.*	2021	Review
Robotic surgery for gynecologic cancers: indications,techniques and controversies.[13]	Clair *et al.*	2020	Review
Robotic versus laparoscopic general surgery in the emergency setting: a systematic review.[14]	Anyomih *et al.*	2024	Review
Does robotic surgery have a role in abdominal wall reconstruction? A systematic review and meta-analysis.[15]	Awad *et al.*	2025	Review

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[9] K. Myla, N. Bou-Ayash, W.C. Kim, *et al.*, *op cit.*

[10] T. Williamson, S.E. Song, *Robotic Surgery Techniques to Improve Traditional Laparoscopy*, in *Journal of the Society of Laparoendoscopic,* 26, 2, 2022.

[11] P. Achilli, F. Grass, D.W. Larson, *Robotic surgery for rectal cancer as a platform to build on: review of current evidence,* in *Surgery Today*, 51, 2021, 44.

[12] A. Rocca, A. Scacchi, M. Cappuccio, *et al.*, *Robotic surgery for colorectal liver metastases resection: A systematic review*, in *International Journal of Medical Robot*, 17, 2021, e2330.

[13] K.H. Clair, K.S. Tewari, *Robotic surgery for gynecologic cancers: indications, techniques and controversies*, in *Journal of Obstetrics Gynaecology Research*, 46, 2020, 828.

[14] T.T.K. Anyomih, A. Mehta, D. Sackey, *et al.*, *Robotic versus laparoscopic general surgery in the emergency setting: a systematic review*, in *Journal of Robotic Surgery,* 18, 2024, 281.

[15] L. Awad, B. Reed, E. Bollen, *et al.*, *Does robotic surgery have a role in abdominal wall reconstruction? A systematic review and meta-analysis*, in *Journal of Plastic Reconstructive and Aesthetic Surgeons,* 106, 2025, 353.

Current Status of Robotic Hepatobiliary and Pancreatic Surgery.[16]	Minamimura *et al.*	2024	Review
Advanced Robotic Surgery: Liver, Pancreas, and Esophagus – The State of the Art?[17]	Scognamiglio *et al.*	2021	Review
The safety of urologic robotic surgery depends on the skills of the surgeon.[18]	Palagonia *et al.*	2020	Review
Robotic bariatric surgery for the obesity: a systematic review and meta-analysis.[19]	Zhang *et al.*	2021	Systematic review and meta-analysis
Robotic surgery versus open surgery for thyroid neoplasms: a systematic review and meta-analysis.[20]	Liu *et al.*	2020	Systematic review and meta-analysis
Advancements in Bariatric Surgery: A Comparative Review of Laparoscopic and Robotic Techniques.[21]	Velardi *et al.*	2024	Review
Robotic surgery costs: Revealing the real villains.[22]	Rodrigues Martins *et al.*	2021	Original article
Costs of Robotic-Assisted	Schmidt *et al.*	2021	Original article

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[16] K. Minamimura, Y. Aoki, Y. Kaneya, *et al.*, *Current Status of Robotic Hepatobiliary and Pancreatic Surgery*, in *Journal of Nippon Medical School,* 91, 2024, 10.

[17] P. Scognamiglio, B.O. Stüben, A. Heumann, *et al. Advanced Robotic Surgery: Liver, Pancreas, and Esophagus - The State of the Art?,* in *Visceral Medicine,*37, 2021, 505.

[18] E. Palagonia, E. Mazzone, G. De Naeyer, *et al., The safety of urologic robotic surgery depends on the skills of the surgeon,* in *World Journal of Urology,* 38, 2020, 1373.

[19] Z. Zhang, L. Miao, Z. Ren, *et al.*, *Robotic bariatric surgery for the obesity: a systematic review and meta-analysis* in *Surgical Endoscopy*, 35, 2021, 2440.

[20] H. Liu, Y. Wang, C. Wu, *et al.*, *Robotic surgery versus open surgery for thyroid neoplasms: a systematic review and meta-analysis*, in *Journal of Cancer Research and Clinical Oncology*, 146, 2020, 3297.

[21] A.M. Velardi, P. Anoldo, S. Nigro, *et al.*, *Advancements in Bariatric Surgery: A Comparative Review of Laparoscopic and Robotic Techniques* in *Journal of Personalized Medicine*, 14, 2024.

[22] Y.M. Rodrigues Martins, P. Romanelli de Castro, A.P. Drummond Lage, *et al.*, *Robotic surgery costs: Revealing the real villains*, in *The International Journal of Medical Robotics and Computer Assisted Surgery*, 17, 2021, e2311.

Radical Prostatectomy 1 Year After Surgery Pay Now and Save Later?[23]			
A systematic review of robotic breast surgery versus open surgery.[24]	Maes-Caballo *et al.*	2024	Review
Perioperative considerations for robotic-assisted thoracic surgery.[25]	Bandopadhyay *et al.*	2024	Original article
Robotic versus laparoscopic gastrectomy for gastric cancer: The largest meta-analysis.[26]	Guerrini *et al.*	2020	Meta-analysis
Robotic colorectal surgery and ergonomics. [27]	Wong *et al.*	2022	Review

Table 1

Title	Authors	Year	Type
Artificial intelligence in surgery: evolution, trends, and future directions.[28]	Li *et al.*	2025	Review
Comprehensive overview of artificial intelligence in surgery: a systematic review and perspectives.[29]	Chevalier *et al.*	2025	Review

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[23] B. SCHMIDT, J.T. LEPPERT, *Costs of Robotic-Assisted Radical Prostatectomy 1 Year After Surgery: Pay Now and Save Later?*, in *JAMA Network Open*, 4, 2021, e212548.

[24] M. MAES-CARBALLO, M. GARCÍA-GARCÍA, I. RODRÍGUEZ-JANEIRO, *et al.*, *A systematic review of robotic breast surgery versus open surgery*, in *Journal of Robotic Surgery*, 17, 2023, 2583.

[25] R. BANDOPADHYAY, *Perioperative considerations for robotic-assisted thoracic surgery*, in *British Journal of Hospital Medicine*, 85, 2024, 1.

[26] G.P. GUERRINI, G. ESPOSITO, P. MAGISTRI, *et al.*, *Robotic versus laparoscopic gastrectomy for gastric cancer: The largest meta-analysis*, in *International Journal of Surgery*, 82, 2020, 210.

[27] S.W. WONG, Z.H. ANG, P.F. YANG, *et al.*, *Robotic colorectal surgery and ergonomics*, in *Journal of Robotic Surgery*, 16, 2022, 241.

[28] H. LI, Z. Han, H. Wu, *et al., op cit.*

[29] O. CHEVALIER, G. DUBEY, A. BENKABBOU, *et al.*, *Comprehensive overview of artificial intelligence in surgery: a systematic review and perspectives,* in *Pflugers Archiv-European Journal of Physiology*, 477, 2025, 617.

Introduction to Artificial Intelligence for General Surgeons: A Narrative Review.[30]	Lee *et al.*	2025	Review
Machine learning perioperative applications in visceral surgery: a narrative review.[31]	Hossain *et al.*	2024	Review
The Future of Artificial Intelligence in Surgery.[32]	Hamilton *et al.*	2024	Review
Current and future applications of artificial intelligence in surgery: implications for clinical practice and research.[33]	Morris *et al.*	2024	Review
Artificial intelligence in surgery.[34]	Varghese *et al.*	2024	Review
Artificial intelligence in surgery: A research team perspective.[35]	Mohamadipanah *et al.*	2022	Retrospective observational study
Investigating the Ethical and Data Governance Issues of Artificial Intelligence in Surgery: Protocol for a Delphi Study.[36]	Lam K *et al.*	2021	Qualitative / Consensus-based
Artificial intelligence and pediatric surgery: where are we?[37]	Miyake *et al.*	2024	Review

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[30] B. Lee, N. Narsey, *Introduction to Artificial Intelligence for General Surgeons: A Narrative Review*, in *Cureus*, 17, 2025, e79871.

[31] I. Hossain, A. Madani, S. Laplante, *Machine learning perioperative applications in visceral surgery: a narrative review*, in *Frontiers in Surgery*, 11, 2024, 1493779.

[32] A. Hamilton, *The Future of Artificial Intelligence, in Surgery* in *Cureus*, 16, 2024, e63699.

[33] M.X. Morris, D. Fiocco, T. Caneva, *et al.*, *Current and future applications of artificial intelligence in surgery: implications for clinical practice and research*, in *Frontiers in Surgery,* 11, 2024, 1393898.

[34] C. Varghese, E.M. Harrison, G. O'Grady, *et al.*, *Artificial intelligence in surgery*, in *Nature Medicine*, 30, 2024, 1257.

[35] H. Mohamadipanah, C. Perumalla, S. Yang, *et al.*, *Artificial intelligence in surgery: A research team perspective,* in *Current Problems in Surgery*, 59, 2022, 101125.

[36] K. Lam, F.M. Iqbal, S. Purkayastha, *et al.*, *Investigating the Ethical and Data Governance Issues of Artificial Intelligence in Surgery: Protocol for a Delphi Study*, in *JMIR Research Protocols*, 10, 2021, e26552.

[37] Y. Miyake, G. Retrosi, R. Keijzer, *Artificial intelligence and pediatric surgery: where are we?*, in *Pediatric Surgery International*, 41, 2024, 19.

Applications of artificial intelligence in surgery: clinical, technical, and governance considerations.[38]	Mascagni *et al.*	2024	Narrative Review
Critical view of safety assessment in sentinel node dissection for endometrial and cervical cancer: artificial intelligence to enhance surgical safety and lymph node detection (LYSE study).[39]	Pavone *et al.*	2025	Observational Study
AI chatbots in surgery: What does the future hold?[40]	Goldenberg *et al.*	2024	Letter to the Editor / perspective piece
Future of Artificial Intelligence in Surgery: A Narrative Review.[41]	Amin *et al.*	2024	Narrative Review
Artificial Intelligence in Surgery: The Future is Now.[42]	Guni *et al.*	2024	Review
Bringing Artificial Intelligence to the operating room: edge computing for real-time surgical phase recognition.[43]	Choksi *et al.*	2023	Experimental / applied technical study
AI's potential in LC for detecting anatomical landmarks, distinguishing safe	Fernicola *et al.*	2024	Review

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[38] P. MASCAGNI, D. ALAPATT, L. SESTINI, *et al., Applications of artificial intelligence in surgery: clinical, technical, and governance considerations*, in *Cirugía Española (English Edition)*, 102, 2024, S66.

[39] M. PAVONE, B. BABY, E. CARLES, *et al., Critical view of safety assessment in sentinel node dissection for endometrial and cervical cancer: artificial intelligence to enhance surgical safety and lymph node detection (LYSE study)*, in *International Journal of Gynecological Cancer*, 35, 2025, 101789.

[40] C.B. GOLDENBERG, B.J. KIRBY, P.A. ALBRECHT, *et al., AI chatbots in surgery: What does the future hold?,* in *Journal of Plastic, Reconstructive & Aesthetic Surgery*, 88, 2024, 310.

[41] A. AMIN, S.A. CARDOSO, J. SUYAMBU, *et al., Future of Artificial Intelligence in Surgery: A Narrative Review*, in *Cureus*, 16, 2024, e51631.

[42] A. GUNI, P. VARMA, J. ZHANG, *et al., Artificial Intelligence in Surgery: The Future is Now* in *European Surgical Research,* 2024.

[43] S. CHOKSI, S. SZOT, C. ZANG, *et al., Bringing Artificial Intelligence to the operating room: edge computing for real-time surgical phase recognition*, in *Surgical Endoscopy, 37,* 2023, 8778.

from unsafe zones, and recognizing surgical phases.[44]			
Artificial intelligence in surgery: the emergency surgeon's perspective (the ARIES project).[45]	De Simone *et al.*	2022	Review
Situating Artificial Intelligence in Surgery: A Focus on Disease Severity.[46]	Korndorffer *et al.*	2020	Retrospective observational and experimental study
Potential and Promise: Artificial Intelligence in Pediatric Surgery.[47]	Sinha *et al.*	2024	Review

Table 2

3. Results

Starting from the analysis of the results about the robotic surgery, Williamson *et al.* conducted a review aimed at showing how these surgical techniques can enhance traditional laparoscopy.[48] The study outlines current trends and encourages discussion on using robotic systems to enhance laparoscopy. In some surgeries, robotics offered better management of complex cases, improved ergonomics (notably in obese patients), and superior 3D vision, but involved longer operating times and higher costs than laparoscopy. For example, in liver surgery, while laparoscopy remains the most common minimally invasive technique, robotic liver resections (RLR) have emerged as a promising alternative. Studies indicate that RLR may offer a safer and more ergonomic approach, especially for complex cases involving major resections or lesions in postero-superior liver segments. Rocca *et al.* evaluated the role of robotic surgery in managing colorectal liver metastases (CRCLM).[49] Their findings show that robotic surgery is safe and effective, with blood loss and complication rates comparable to or better than open and laparoscopic procedures. Scognamiglio *et al.* suggest that robotic surgery could soon become a viable alternative to laparoscopy, especially for complex liver, esophageal, and pancreatic surgeries.[50] Minimally invasive hepatobiliary and pancreatic surgery provides better short-term outcomes than open surgery but is technically challenging. Awad et Al analyzed the use of robotic approach in abdominal wall repair. When

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[44] A. Fernicola, G. Palomba, M. Capuano, *et al.*, *Artificial intelligence applied to laparoscopic cholecystectomy: what is the next step? A narrative review*, in *Updates in Surgery*, 76, 2024, 1655.

[45] B. De Simone, E. Chouillard, A.A. Gumbs, *et al.*, *Artificial intelligence in surgery: the emergency surgeon's perspective (the ARIES project)*, in *Discover Health Systems*, 1, 2022, 9.

[46] J.R. Korndorffer, M.T. Hawn, D.A. Spain, *et al.*, *Situating Artificial Intelligence in Surgery: A Focus on Disease Severity*, in *Annals of Surgery*, 272, 2020, 523.

[47] A. Sinha, S. Bhatt, *Potential and Promise: Artificial Intelligence in Pediatric Surgery*, in *Journal of Indian Association of Pediatric Surgeons*, 2024, 400.

[48] T. Williamson, S.E. Song, *op. cit.*

[49] A. Rocca, A. Scacchi, M. Cappuccio, *et al., op. cit.*

[50] P. Scognamiglio, B.O. Stüben, A. Heumann, *et al., op. cit.*

compared to laparoscopic surgery, robotic operations tended to result in fewer complications as well, although the difference was not statistically significant with longer operating times and shorter length of hospital stay.[51] Always considering abdominal surgery, minimally invasive surgery (MIS) is increasingly used to treat gastric cancer (GC). While laparoscopic gastrectomy (LG) offers advantages over open surgery, it remains technically challenging. Robotic gastrectomy (RG) is gaining popularity worldwide and may overcome some limitations of LG. The metanalysis from Guerrini *et al.* compared surgical and oncological outcomes between RG and LG. Results showed that RG had longer operating times but less blood loss and fewer severe surgical complications. Oncologically, RG retrieved more lymph nodes, though resection margins and recurrence rates were similar between RG and LG. Overall, RG and LG were comparable in safety, feasibility, and oncological effectiveness, with RG showing some improved short-term surgical outcomes.[52] In colorectal surgery laparoscopy improves outcomes but is challenging for rectal cancer, leading to more open surgeries. Robotics may overcome pelvic technical difficulties while maintaining oncologic safety and minimally invasive benefits with longer operative times and higher costs.[53] Zhang *et al.* analyzed robotic bariatric surgery (RBS) and found it associated with lower 90-day mortality and longer operative times compared to laparoscopic bariatric surgery (LBS). Other safety and effectiveness outcomes were comparable. RBS may offer future advantages pending long-term, comprehensive evaluations.[54] In revisional bariatric procedures, RBS in connected with fewer complications, shorter hospital stays, and less need for conversion to open surgery.[55] Anyomih *et al.* examined the use of the robotic approach in emergency surgical settings, for procedures such as cholecystectomy and colectomy and hospital stays were significantly shorter in the robotic surgery group.[56] Liu *et al.* compared robotic surgery versus laparoscopic surgery in thyroid neoplasms' treatment.[57] Robotic surgery appears to be a safe and viable option that minimizes intraoperative trauma and enhances quality of life, though its longer duration and reduced lymph node removal require careful consideration. In other surgeries such as breast surgery, robotic appears to be better in aesthetic results and patient satisfaction with bigger costs and operative time. At the same time robotic-assisted thoracoscopic surgery is gaining popularity for lung and mediastinal procedures due to better outcomes, less pain, and faster recovery compared to thoracotomy. Its minimally invasive approach offers greater precision but also presents physiological and logistical challenges, especially in patients with complex conditions, requiring careful perioperative management. Robotic-assisted surgery has transformed also gynaecologic oncology over the past 15 years, expanding patient access to minimally invasive benefits such as less blood loss, shorter hospital stays, fewer wound complications, and faster recovery. While cost-effectiveness and long-term out-

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[51] L. Awad, B. Reed, E. Bollen, *et al.*, *Does robotic surgery have a role in abdominal wall reconstruction? A systematic review and meta-analysis*, in *Journal of Plastic, Reconstructive & Aesthetic Surgery*, 106, 2025, 353.

[52] G.P. Guerrini, G. Esposito, P. Magistri, *et al.*, *op. cit.*

[53] F.Rondelli, A. Lucarini, G.M. Garbarino, *et al.*, *Comparison of Laparoscopic and Robotic Lateral Lymph Node Dissection for Rectal Cancer: A Systematic Review and Meta-analysis of Short- and Long-term Outcomes*, in *Annali Italiani di Chirurgia,* 96*,* 2025, 847.

[54] Z. Zhang, L. Miao, Z. Ren, *et al.*, *op. cit.*

[55] A.M. Velardi, P. Anoldo, S. Nigro, *et al.*, *op. cit.*

[56] T.T.K. Anyomih, A. Mehta, D. Sackey, *et al.*, *op. cit.*

[57] H. Liu, Y. Wang, C. Wu, *et al.*, *op. cit.*

comes remain debated due to limited trials, robotic technology's advanced features like 3D vision and improved ergonomics are widely valued.[58]

And what about costs?

Assessing the cost-effectiveness of robotic-assisted surgery (RAS) is complex, particularly in emergency settings due to case variability. Myla *et al.* highlight a lack of studies on the economic impact of RAS in acute care.[59] This review examines its cost-effectiveness in elective surgery, with potential applications to urgent contexts. Some studies suggest lower costs compared to laparoscopy, attributed to reduced use of materials and disposable instruments, shorter operative times due to increased proficiency, and decreased hospitalization, readmissions, and recovery times. Rodrigues Martins *et al.* and Schmidt *et al.* the robotic approach for one of the first uses that has been made of it, the urological. [60], [61] In the first one study, costs rose with higher ASA scores, longer surgeries, greater use of clip packs, and extended hospitalization, but dropped by 11.5% when using four instead of five robotic instruments. The second one study compared costs of open vs robotic-assisted radical prostatectomy (RARP) using one-year claims data. While RARP had higher initial hospitalization costs, the gap narrowed by six months and shifted to a $383 saving at one year, suggesting long-term cost advantages.[62] Finally in colorectal surgery evidence shows similar surgical quality and outcomes between robotic and laparoscopic methods, with robotics offering fewer conversions and less surgeon fatigue but longer operative times and higher costs. Finally, robotic surgery offers ergonomic benefits for surgeons, including improved visualization with 3D vision and surgeon-controlled cameras, better posture from a seated position, and enhanced instrument manoeuvrability with greater freedom of movement and tremor reduction. However, drawbacks include lack of tactile feedback, visual and mental fatigue from longer surgeries, and workflow interruptions. Most ergonomic disadvantages may be reduced with experience and technological advances. While many studies are lab-based, more clinical research is needed to explore these ergonomic benefits, focusing on visualization, posture, instrument control, and issues like port placement and robotic arm collisions.

Regarding the second focus of our paper, Li et al highlight that over the past twenty-five years, research on artificial intelligence applied to surgery has shown steady growth, confirming its transition from an emerging technology to a well-established component of surgical innovation.[63] At the same time the analysis conducted by Hossain *et al.* highlighted a steady growth in the literature on AI in surgery, with a significant acceleration starting from 2018.[64] In general AI is progressively acquiring a strategic role in all phases of the surgical pathway — preoperative, intraoperative, and postoperative — contributing to improved diagnostic accuracy, operational efficiency, and patient safety. An example is its application in the management of thoracoabdominal trauma, providing tangible benefits in the preoperative phase [diagnosis and triage], intraoperative phase [safety and decision support], and postoperative phase [risk

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[58] K.H. Clair, K.S. Tewari, *op. cit.*

[59] K. Myla, N. Bou-Ayash, W.C. Kim, *et al.*, op. cit.

[60] Y.M. Rodrigues Martins, P. Romanelli de Castro, A.P. Drummond Lage, *et al.*, *op. cit.*

[61] B. Schmidt, J.T. Leppert, *op. cit.*

[62] K.H. Clair, K.S. Tewari, *op. cit.*

[63] H. Li, Z. Han, H. Wu, *et al.*, *op. cit.*

[64] I. Hossain, A. Madani, S. Laplante, *op. cit.*

assessment and complication management].[65] However, the adoption of AI in emergency surgery is progressing more slowly compared to other fields, due to the complex decision-making involving multiple clinical and human factors. The findings of an article by Morris *et al.* highlight that AI holds significant potential to enhance both surgical training and clinical decision-making but with some difficulties in understanding and interpreting AI algorithm mechanisms and the risk of inaccurate predictions.[66] The crucial role of artificial intelligence as a tool to improve accuracy, efficiency, and standardization in the evaluation of surgical performance, with future prospects for integrating video data to further refine the predictive capabilities of models, emerged from the study conducted by Mohamadipanah *et al.*[67] Machine learning and deep learning algorithms have proven effective in predicting postoperative complications, estimating mortality, preventing readmissions, and optimizing hospital length of stay. Five main application areas have emerged: predictive modelling of surgical risks; preoperative simulations through augmented reality and digital twins; real-time intraoperative decision support; safety monitoring using systems like the OR Black Box; partial automation of procedures via intelligent robotics. These tools show potential to transform the current surgical paradigm into a data-driven clinical ecosystem. Additionally, multidimensional AI models for home monitoring of activities of daily living (ADLs) suggest new possibilities for personalized postoperative care. Promising results have also emerged in the pediatric field. Artificial intelligence is transforming pediatric surgery by enhancing diagnosis, planning, perioperative care, training, and doctor-patient communication.[68] A relevant example of artificial intelligence's application is in the treatment of colorectal cancer. As highlighted by the study of Mascagni et al., AI is demonstrating a transformative impact throughout the entire care pathway. In diagnostics, AI would significantly improve the detection and classification of polyps during colonoscopy, with expected benefits in reducing mortality and healthcare costs. In the preoperative phase, predictive algorithms assist in assessing tumor invasion and lymph node risk, facilitating more targeted surgical decisions. AI also enhances the safety of endoscopic dissection and personalized surgical planning, improving intraoperative precision and reducing the risk of complications. However full integration of AI in surgery requires a multidisciplinary approach focused on safety, transparency, and appropriate use. Postoperatively, predictive models assist in preventing complications and optimizing follow-up, thereby improving clinical efficiency and patient management. A clear example of how artificial intelligence can be applied in surgery is provided by Pavone *et al.* in the field of gynecology. Their study explored the feasibility of using video-based assessments to evaluate the Critical Views of Safety (CVS) criteria for sentinel lymph node dissection in patients with endometrial or cervical cancer. The CVS approach is designed to standardize the evaluation of surgical quality, enhance the accuracy of sentinel lymph node identification, and ultimately improve patient outcomes.[69] The researchers collected surgical videos from patients undergoing minimally invasive sentinel lymph node dissection for cervical and endometrial carcinoma. They proposed three CVS criteria—lateral pararectal space, lateral paravesical space, and internal iliac artery—based on anatomical landmarks deemed essential to identify before proceeding with sentinel node dis-

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[65] B. Lee, N. Narsey, *op. cit.*
[66] M.X. Morris, D. Fiocco, T. Caneva, *et al.*, *op. cit.*
[67] H. Mohamadipanah, C. Perumalla, S. Yang, *et al.*, *op. cit.*
[68] Y. Miyake, G. Retrosi, R. Keijzer, *op. cit.*
[69] M. Pavone, B. Baby, E. Carles, *et al.*, *op. cit.*

section, as established by previous expert consensus. Introducing video-based assessment of these criteria provides a foundation for testing the feasibility of artificial intelligence algorithms capable of automatically identifying and documenting the CVS in surgical recordings. This represents an important first step toward developing AI systems that can autonomously assess and record these safety views in both laparoscopic and robotic surgeries. Beyond identifying anatomical structures during laparoscopic cholecystectomy (LC), artificial intelligence has also been trained to recognize surgical phases. Fernicola *et al.* in their review highlighted AI's potential in LC for detecting anatomical landmarks, distinguishing safe from unsafe zones, recognizing surgical phases using surgical videos. [70] Best performance was seen for Calot's triangle dissection, clipping/cutting, and gallbladder dissection, while preparation was often misclassified as Calot's dissection. Accuracy decreased with increasing procedural complexity (92% for low vs. 81% for high complexity) and was influenced by adverse events such as major bile leak (77%). Cross-hospital testing revealed variations in accuracy (79–90.6%) due to differing devices and techniques. Such semantic and temporal segmentation could help prevent bile duct injury, enhance surgical training, and eventually enable real-time decision support in the operating room. In education, AI supports the analysis of surgical performance and personalized training. Furthermore, the automated annotation of laparoscopic cholecystectomy videos has significantly increased the efficiency of video review, allowing the analysis of approximately 50 videos per hour. Correct identification of the Critical View of Safety was observed in less than 10% of cases, with a higher frequency of clear visualization of the hepatocystic triangle in less severe procedures. The agreement between AI annotations and clinical evaluations exceeded 75%, reaching 99% for intraoperative events, which were significantly associated with the severity of the pathology and the failure to achieve proper exposure of the CVS. Notably, the frequency of intraoperative events was more than double in the more severe cases. [71]

4. Discussion

Robotic surgery and artificial intelligence represent two of the most significant modern innovations in the surgical field, each contributing in unique ways to the evolution of clinical practice.

The robotic system enables 3D surgery without assistant-held instruments, unlike traditional laparoscopy, which relies heavily on assistants. A clear gap exists in technical capabilities and applications, with some procedures positioned between the two methods. Robotic surgery has been proposed for emergency procedures; its role compared to traditional laparoscopy remains debated. Current evidence shows that robotic assistance is technically feasible in urgent general surgery and achieves outcomes comparable to laparoscopy, especially in clinically stable patients. Considering the economic problems, the "easier" is the surgery the more this problem is felt. One of these surgeries is abdominal wall reconstruction. While robotic procedures tend to be more expensive than laparoscopic surgery, the total cost may be offset by quicker patient recovery and a lower rate of complications compared to open surgery. Also, in bariatric surgery the use of robotic surgery appears to be more expansive such as in the paper of Velardi *et al.* [72] In urological surgery hospitalization costs were mainly driven by robotic surgical supplies,

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[70] A. Fernicola, G. Palomba, M. Capuano, *et al.*, *op. cit.*

[71] J.R. Korndorffer, M.T. Hawn, D.A. Spain, *et al.*, *op. cit.*

[72] A.M. Velardi, P. Anoldo, S. Nigro, *et al.*, *op. cit.*

operating room time, patient health status, and length of stay. Reducing instrument use was the most impactful modifiable factor for lowering costs. Similar patterns are seen in other urologic procedures, though robotic approaches often have higher short-term costs. The findings support that, despite early scepticism and high purchase costs, robotic prostatectomy has not imposed undue long-term financial burdens, underscoring the importance of balancing innovation with cost-effectiveness in surgical care. High-quality comparative studies between robotic-assisted surgery and laparoscopy are needed to justify costs and assess patient benefits.

Considering operative time compared to open surgery, Robotic surgery involves longer operative time as in the paper of Liu at al.[73] Always in this paper we have the problem of results; fewer lymph nodes retrieved, higher postoperative thyroglobulin levels before radioactive iodine ablation, similar complication rates. Longer operative time are described in papers about gastric and bariatric robotic surgery. In line with bigger costs and longer operative times Maes-Carballo *et al.* explained the possibility of breast robotic approach.[74] Despite higher costs and longer operation times, robotic surgery is expected to grow, especially in specialized canters. It offers similar outcomes to open surgery, with potential for improved precision as technology advances. Robotic platforms have redefined minimally invasive surgery by enhancing precision, reducing surgeon fatigue, and improving patient recovery times. At the same time, AI is transforming contemporary surgery towards data-driven and personalized models, although challenges related to standardization, clinical validation, and interdisciplinary collaboration persist. Ethical and legal aspects, such as medical liability, algorithmic bias, privacy, and inequality of access, require stringent regulation These critical issues also emerge in the Australian context, where clinical use of AI remains limited, albeit with promising prospects, particularly in surgical training. AI holds great potential to enhance both surgical training and clinical decision-making processes, yet concerns persist regarding users' understanding and interpretation of algorithms and the risk of predictive errors. The introduction of AI in surgery represents a paradigmatic evolution compared to previous innovations, extending the surgeon's sensory enhancement to the cognitive domain. This includes preoperative support for risk assessment, resource management, and complication prediction, as well as intraoperative guidance through augmented reality and robotics. The role of AI in standardizing and objectively evaluating surgical performance is crucial, with prospects for integrating video data to further refine predictive capabilities. Furthermore, AI has enabled an objective assessment of surgical skills with high precision and significant correlation with traditional evaluation methods.[75] AI represents a significant breakthrough in modern surgery, offering tangible clinical benefits alongside vast potential yet to be fully explored and consolidated. Achieving full integration of AI into the surgical pathway requires rigorously addressing technical, ethical, educational, and regulatory challenges, while promoting a multidisciplinary approach focused on safety, transparency, and appropriate use.[76] Next-generation robots will integrate surgeon-guided movements with personalized surgical plans from preoperative 3D segmentation. Advances in cloud computing, big data, and AI are driving the development of smart robotic systems, with surgical

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[73] H. Liu, Y. Wang, C. Wu, *et al.*, *op. cit.*

[74] M. Maes-carballo, M. García-García, I. Rodríguez-Janeiro, *et al.*, *op. cit.*

[75] T. Kinoshita, M. Komatsu, *Artificial Intelligence in Surgery and Its Potential for Gastric Cancer* in *Journal of Gastric Cancer,* 23, 2023, 400.

[76] N. Kenig, J. Monton Echeverria, A. Muntaner Vives, *Artificial Intelligence in Surgery: A Systematic Review of Use and Validation*, in *Journal of Clinical Medicine,* 13, 2024.

technology companies partnering with major tech firms to create advanced intelligent robots.[77] While its integration offers significant benefits, it also raises complex ethical concerns.[78] Precisely with regard to the ethical problem, the works of Ricci *et al.*[79] and Damato *et al.*[80] address, from different perspectives, the delicate balance between individual autonomy, medical intervention and ethical-legal responsibility. On the one hand, the topic of human enhancement as an exercise of freedom beyond therapy is discussed, raising the need for clear rules for a conscious and non-discriminatory use of enhancement technologies. On the other, the problem of compulsory medical treatment in serious eating disorders is analysed, where the patients would be compromised and informed consent is difficult to evaluate. The centrality of human dignity emerges as a guiding criterion for balancing the right to treatment, personal freedom and the limits of medical intervention. In both cases, it is noted that the tools for measuring awareness, will, and decision-making capacity are often imperfect, and that greater interdisciplinary understanding (medical, psychological, ethical, legal) is needed; the constraint of respect for dignity emerges, which must be the guiding criterion for regulating what is permitted, what is obligatory and what is prohibited. On the other hand, the educational and formative value of innovations must also be considered; robotic surgery mixed to the new technologies, plays a crucial role in training future surgeons by offering varied exercises to develop basic motor skills like joystick handling, pedal use, camera control, and energy application, before advancing to complex tasks such as suturing and dissection. Its key benefit is supporting self-assessment, allowing learners to quickly gain autonomy by identifying and correcting mistakes early. Although simulation training requires significant investment in equipment and staff, it is essential due to the increasing use of robotic techniques alongside traditional surgery. Well-structured education is necessary to ensure a safe and effective transition to clinical practice.[81] Robotic-assisted surgical training is rapidly evolving, with approaches like online platforms, hands-on sessions, and advanced simulators developed over the past decade to address the growing demand for skilled robotic surgeons. Early validation studies show promising results, but there remains a need for specialized simulation modules for specific surgical fields. Future research should compare training methods to help establish a standardized curriculum for education and certification.[82] Robotic surgery demands both technical and non-technical expertise, making the learning curve for certain procedures longer than expected. Structured training programs play a key role in supporting surgeons during this phase and can lead to outcomes comparable to those of experienced professionals. However, only a few validated curricula currently exist. To ensure patient safety and optimize results, the development of standardized and comprehensive training programs is essential. While training opportunities are expanding, an addi-

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[77] M. Bhandari, T. Zeffiro, M. Reddiboina, *Artificial intelligence and robotic surgery: current perspective and future directions*, in *Current Opinion in Urology,* 30, 2020, 48.

[78] J.E. Knudsen, U. Ghaffar, R. Ma, *et al.*, *Clinical applications of artificial intelligence in robotic surgery*, in *Journal of Robotic Surgery,* 18, 2024, 102.

[79] L. Ricci, B. Di Nicolò, P. Ricci, *et al., The exercise of rights beyond therapy: on Human Enhancement,* in *BioLaw Journal*, 1, 2019, 497.

[80] F.M. Damato, P. Ricci, R. Rinaldi, *Informed consent and compulsory treatment on individuals with severe eating disorders: a bio-ethical and juridical problem*, in *La Clinica Terapeutica,* 174, 2023, 365.

[81] L. Bresler, M. Perez, J. Hubert, *et al.*, *Residency training in robotic surgery: The role of simulation*, in *Journal of Visceral Surgery,* 157, 2020, S123.

[82] R. Chen, P. Rodrigues Armijo, C. Krause, *et al.*, *A comprehensive review of robotic surgery curriculum and training for residents, fellows, and postgraduate surgical education*, in *Surgical* Endoscopy, 34*,* 2020, 361.

tional challenge is the potential over-reliance on automated or semi-automated systems. There is a risk that younger surgeons may develop reduced proficiency in fundamental open or laparoscopic techniques, which remain essential in complex or emergent situations where robotic platforms may not be available. Despite the promising advantages described, it is important to acknowledge that much of the available evidence remains heterogeneous and often derived from single-center or retrospective studies. This raises the risk of overestimating the clinical benefits of robotic platforms and AI-based tools, especially when long-term outcomes are not consistently reported. A more cautious interpretation is therefore required when translating current findings into broad clinical recommendations. We also note that on September 17, 2025, Italy approved the first national law on artificial intelligence in the EU, integrating the European AI Act with internal rules to regulate the development and use of AI. One of the main focuses is healthcare, where the law aims to ensure the centrality of the physician, data security, and algorithm transparency, even in the most advanced clinical applications such as AI-assisted surgery. The legislation provides for: traceability of automated decisions, to protect patients; enhancement of clinical data for research, while respecting privacy; development of AI tools to support diagnoses and surgical procedures, always under human supervision.

With this regulatory framework, Italy intends to encourage the adoption of AI in healthcare by ensuring ethics, safety, and responsibility, and promoting innovation in surgical practices through reliable and regulated technologies. In conclusion, sometimes we could question us “where are we going?”; we still can’t answer but travel appears to be so beautiful.

5. Conclusions

Robotic surgery and artificial intelligence are transforming surgical practice by integrating cognitive technology and predictive tools. The da Vinci system has improved precision, ergonomics, and training, with the greatest benefits seen in complex procedures. Its use is increasing in general and emergency surgery, although high costs and longer operating times still limit its applicability in simpler interventions. Ethical, legal, and economic issues also remain open, requiring procedure-specific evaluations and more standardized cost–benefit analyses.

Future developments point to greater integration between advanced robotics and AI, with systems becoming increasingly autonomous. However, the surgeon’s central role remains essential, as do the principles of patient autonomy, informed consent, and freedom of therapeutic choice. The adoption of technologies that enhance or replace human capabilities calls for clear regulation that distinguishes between support and substitution. In this regard, the recent Italian law on artificial intelligence (which mandates traceability, safety, and human oversight in healthcare) is a significant step forward.

Robotics and AI should be regarded as tools that serve the individual and play a key role in training future surgeons, provided they are embedded in validated, multidisciplinary educational programs. The ongoing transformation therefore requires a constant balance between technological innovation, patient dignity, and ethical responsibility.

Increased Incidence of Alzheimer's Disease: Lifestyle and Supplementation with Nutraceuticals and Probiotics as New Prevention and Treatment Strategies

Rita Businaro, Serafino Ricci*

ABSTRACT: Alzheimer's disease is a neurodegenerative disorder that mainly affects individuals over the age of 60, progressively rendering them unable to care for themselves. The incidence of the disease has increased dramatically in recent decades, posing a significant challenge to healthcare systems worldwide. Currently, there is no definitive and effective treatment, partly because the etiopathogenesis of the disease has not been fully elucidated. The disease, characterized histologically by amyloid plaques and neurofibrillary tangles, has very likely a multifactorial etiology. Neuroinflammation is thought to be the primary cause of the neurotoxicity observed in brain areas, including hippocampus and prefrontal cortex. Innovative methodologies and new tools derived from artificial intelligence have allowed us to define several risk factors and identify nutraceuticals and probiotics capable of counteracting neuroinflammation and disease progression.

KEYWORDS: Alzheimer's disease; neuroinflammation; oxidative stress; microglia; nutraceuticals; probiotics

1. Introduction

The rising incidence and mortality associated with neurodegenerative diseases, particularly Alzheimer's disease (AD), is a growing public health concern. The growing prevalence of the disease poses significant financial challenges, as patients with severe AD require intensive long-term care.[1] In 2015, the global economic burden of dementia was estimated at $818 billion.[2] These are highly debilitating diseases that undermine patients' ability to live independently and pose increasingly

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[1] S. NIZAMI, H. HALL-ROBERTS, S. WARRIER *et al.*, *Microglial inflammation and phagocytosis in Alzheimer's disease: Potential therapeutic targets.*, in *Br J Pharmacol,* 176, 2019, 3515–32.

difficult and emotional challenges for family members and caregivers in managing the patient. Unfortunately, despite the enormous advances in contemporary medicine and the accumulation of relevant knowledge over the past decades, there remains a continuing shortage of effective drugs and therapies. The need to intensify prevention efforts, improve the quality of care, and adopt targeted policies that address the complexities of disease management is therefore highlighted.

2. Pathophysiological Process

Changes Alzheimer's disease is the most common form of dementia, characterized by the extracellular senile plaques, formed by the accumulation of amyloid peptide and the presence of intracellular tangles of hyperphosphorylated tau protein. This histopathological picture is initially accompanied by synaptic rarefactions and then neuronal death in certain brain regions, such as the hippocampus and prefrontal cortex. At the macroscopic level, there is a progressive reduction of the cerebral cortex, corresponding to an enlargement of the cerebral ventricles. The morphological characterization of AD is characterized by cerebral atrophy and enlargement of the cerebral ventricles.[3] The morphological that characterize the development of this chronic neurodegenerative disease result in specific cognitive impairments. These initially affect memory processes with short-term memory loss, and then affect normal daily activities, resulting in a loss of independence, language difficulties, and spatial and temporal disorientation. The first and most common symptom of AD is short-term memory loss. As the disease progresses, symptoms such as aggression, irritability, agitation, confusion or difficulty recognizing objects (agnosia), language problems (aphasia), impaired motor skills (apraxia), inattention, behavioral disturbances, executive dysfunction, and long-term memory loss frequently occur. This is due to alterations in specific brain regions such as the hippocampus, entorhinal cortex, and amygdala, which are responsible for learning, memory, emotion, and behavior.[4]

To date, more than a century after neurologists Alzheimer and Perusini described the disease, its etiopathogenesis has not been identified. What is extremely clear, however, is the sharp increase in incidence, also in relation to increased life expectancy, given that the sporadic, non-familial form of Alzheimer's disease mostly manifests after age 50. Current estimates indicate that the number of people

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[2] A. WIMO, M. GUERCHET, G.C. ALI *et al.*, *The worldwide costs of dementia 2015 and comparisons with 2010, in Alzheimers Dement,* 13, 2017, 1–7.

[3] B.P. IMBIMBO, J. LOMBARD, N. POMARA, *Pathophysiology of Alzheimer's disease, in Neuroimaging Clin N Am*, 15(4), 2005, 727-53.

[4] E. ONOFRI, S. RICCI, M. MERCURI *et al.*, *Cognitive fluctuations in connection to dysgraphia a comparison of Alzheimer's disease with dementia Lewy bodies,* in *Clinical Interventions in Aging*, 10, 2015, 623-33. M. NASB, W. TAO, N. CHEN, *Alzheimer's Disease Puzzle: Delving into Pathogenesis Hypotheses,* in *Aging Dis*, 15, 2024, 43–73. B. HIGHET, J.A. WISEMAN, H. MEIN *et al., PSA-NCAM Regulatory Gene Expression Changes in the Alzheimer's Disease Entorhinal Cortex Revealed with Multiplexed in situ Hybridization,* in *J Alzheimers Dis,* 92(1), 2023, 371-390. K. KUMAR, A. KUMAR, R.M. KEEGAN *et al.*, *Recent advances in the neurobiology and neuropharmacology of Alzheimer's disease, in Biomed Pharmacother,* 98, 2018, 297-307.

affected by Alzheimer's disease worldwide currently reaches 50 million, and if the upward trend continues, the number is expected to reach 82 million in 2030 and 152 million in 2050.[5]

3. Familial AD (Early Onset Alzheimer's Disease, EOAD) and Sporadic AD (Late Onset Alzheimer's Disease, LOAD)

Over the age of 65, one in ten people is affected by AD, and approximately 35% of people aged 85 and older have Alzheimer's disease. Depending on the age of onset, two types of AD are distinguished: familial AD or EOAD and sporadic AD or LOAD.[6] People between the ages of 30 and 60 are usually affected by EOAD. Sixty percent of early-onset forms are called familial as multiple members of the same family are affected, and approximately 13% of these cases are due to a mutation affecting the presenilin-1 (PSEN1), presenilin-2 (PSEN2), and beta-amyloid precursor protein (APP) genes. This is transmitted in an autosomal dominant fashion, meaning that 50% of offspring may be carriers of the mutation. LOAD, or sporadic form, affects individuals over the age of 60.[7] There are genetic variants associated with an increased risk of Alzheimer's disease. The best known is a variant of the gene encoding apolipoprotein E (APOE), the APOE4 variant.[8] In fact, carriers of the ApoE4 variant of the gene encoding apolipoprotein E have an 8- to 18-fold higher risk of developing the sporadic form of AD compared to carriers of other haplotypes. It is well known that genetic association studies using SNPs have proven highly complicated due to the difficulty of examining the large number of subjects required to obtain reliable results. By applying artificial intelligence through machine learning (ML), it was possible to examine the genomic data of 41,686 individuals from the largest European AD consortium to investigate the effectiveness of various ML algorithms in replicating known results, discovering new loci, and identifying individuals at risk.[9] The ML study identified all previously identified genomically significant genetic variants and 22% of the associations resulting from larger meta-analyses. It also highlighted 6 new loci including variants mapping to ARHGAP25, LY6H, COG7,SOD1 and ZNF597, implicating alterations: in phagocytosis (ARHGAP25), in binding to the nicotinic acetylcholine receptor,[10] at the level of Oligomeric Golgi Complex Component 7 (COG7) whose mutations are associated with Congenital Disorders of Glycosylation (CDG)32,[11] at the level of SOD1 which plays an essential role in anti-oxidant defenses.[12]

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[5] https://www.alzint.org/resource/world-alzheimer-report-2021/ C.S. Aguzzoli, K.J. Anstey, A. Atri, *et al.*, *World Alzheimer Report 2024 Global Changes in Attitudes to Dementia*, *Alzheimer's Disease International*, London, UK, 2024.

[6] C.A. Valdez-Gaxiola, F. Rosales-Leycegui, A. Gaxiola-Rubio *et al.*, *Early- and Late-Onset Alzheimer's Disease: Two Sides of the Same Coin?,* in *Diseases*, 12(6), 2024, 110.

[7] R.C. Barber. *The genetics of Alzheimer's disease,* Cairo, 2012.

[8] A. Christensen, C.J. Pike, *APOE genotype affects metabolic and Alzheimer-related outcomes induced by Western diet in female EFAD mice,* in *FASEB J*, 33, 2019, 4054–4066.

[9] M. Bracher-Smith, F. Melograna, B. Ulm *et al.*, *Machine learning in Alzheimer's disease genetics,* in *Nat Commun*, 16, 2025, 6726.

[10] M. Wu, C.Z. Liu, E.A. Barrall *et al.*, *Unbalanced Regulation of α7 nAChRs by Ly6h and NACHO Contributes to Neurotoxicity in Alzheimer's Disease,* in *J Neurosci*, 41, 2021, 8461-8474.

[11] H. Haukedal, K.K. Freude, *Implications of Glycosylation in Alzheimer's Disease,* in *Front Neurosci,* 14, 2021, 625348.

[12] L. Cao, Y.T. Dong, J. Xiang *et al.*, *Reduced expression of SIRT1 and SOD-1 and the correlation between these levels in various regions of the brains of patients with Alzheimer's disease,* in *J Clin Pathol*, 71, 2018, 1090-1099.

4. Etiopathogenesis

The etiopathogenesis of AD is still not fully understood. Numerous studies undertaken since Selkoe[13] formulated the hypothesis that the disease resulted from the accumulation of amyloid peptides in senile plaques, have made it clear that AD is a complex, multifactorial disease, determined by complex interactions between glia and neurons and favored by a genetic predisposition and exposure to specific exogenous and endogenous stimuli.

The Aβ peptide, which accumulates in senile plaques, is formed following the proteolytic processing of a precursor protein, known as APP (amyloid precursor protein), by gamma-secretase, a multiprotein complex that releases Aβ peptides of varying lengths, implicated in the pathogenesis of AD. APP, a 100-140 kD protein encoded by a gene on chromosome 21q21.3, is a transmembrane protein with about ten known isoforms. It is expressed in various cell types; at the neuronal level, the 695-amino acid isoform is expressed, which is cleaved by the enzymes β-secretase and γ-secretase to generate Aβ peptides and oligomers that aggregate to form neurotoxic fibrils and plaques in the brain.[14]

Aβ aggregation promotes synaptic dysfunction, tau phosphorylation, mitochondrial dysfunction, and the expression of autophagy-related genes and apoptotic proteins, contributing to neuronal death.[15]

Among the multiple factors involved in this disease, a significant role is played by the accumulation of amyloid-beta (Aβ), a 42-residue peptide whose production and clearance are finely regulated in the brain. Research has shown that impaired Aβ clearance is a significant factor in the progression of AD.[16]

5. Genetics and Epigenetics Factors Underlying AD Development

Much evidence points out that AD is a multifactorial disease, depending on the interplay between exposome, genetic and epigenetic factors. The Genome Wide association Study (GWAS) enabled the discovery of novel genetic associations with AD, beyond the well-established APOE ε4 allele, that, already known reduces the efficiency of microglial clearance of Aβ, further exacerbating amyloid accumulation. Five new loci have been identified, including IQCK, ACE, ADAM10, ADAMTS1, and WWOX, that are involved in lipid metabolism, amyloid precursor protein (APP) processing, tau biology, and neuroinflammation.[17]

It is known that, although present, not all genes are expressed at the same time and in all cells. Gene expression characterizes the physiological properties and any pathological processes that occur in cells and directs the fundamental characteristics of organs and systems. Therefore, there is a temporal and tissue modulation of the expression of various genes, the correct balance of which is the basis of homeostatic mechanisms. The science that studies the machinery underlying this modulation is called epige-

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[13] D.J. Selkoe, *The molecular pathology of Alzheimer's disease,* in *Neuron*, 6, 1991, 487–498.

[14] M. Pasteris, S. Cakir, A. Bellizzi *et al.*, *Alternative splicing in Alzheimer's disease: Mechanisms, therapeutic implications, and 3D modeling approaches,* in *J Alzheimers*, 2025.

[15] M.S. Hussain, N. Agrawal, B. Ilma *et al.*, *Autophagy and Cellular Senescence in Alzheimer's Disease: Key Drivers of Neurodegeneration*, in *CNS Neurosci Ther*, 31(7), 2025.

[16] J. Zukowska, S.J. Moss, V. Subramanian *et al.*, *Molecular Basis of Selective Amyloid-β Degrading Enzymes in Alzheimer's Disease*, in *FEBS J*, 291, 2024, 2999–3029.

[17] P. Tiwari, R. Dwivedi, M. Kaushik, M. Tripathi, R. Dada, *Genetics and Epigenetics of Alzheimer's Disease: Understanding Pathogenesis and Exploring Therapeutic Potential,* in *J Mol Neurosci*, 75, 2025, 72.

netics[18] and refers to changes in gene expression not coded in the DNA sequence, taking place without modifying the genotype. These changes are dependent on DNA methylation or hydroxymethylation, histone post-translational modifications, microRNAs (miRNAs), and long non-coding RNAs (lncRNAs).[19] Epigenetic changes are plastic and include DNA methylation, which generally suppresses gene expression and at the level of brain is involved in memory formation and storage,[20] is obtained by adding a methyl group to cytosine. DNA methyltransferases (DNMTs) catalyze DNA methylation by shifting a methyl group from S-adenosyl methionine (SAM) to the fifth carbon of a cytosine residue, resulting in 5methyl Cytosine, mainly at the level ofCpG islands in the promoter region.[21] DNA methylation and demethylation may be dysregulated in the decreased cognition that is linked with neurodegeneration.[22]

Histone methylation is responsible for both transcriptional activation and repression and occurs mainly on arginine and lysine residues; generally, monomethylation is linked with transcription activation, whereas trimethylation has been connected to transcription repression. Histone acetylation has been linked to the formation of memory; it relaxes histone–DNA connections, resulting in a more open configuration that allows transcriptional machinery to reach gene promoters and upregulate transcription.

5.1. MicroRNAs

miRNA are small, non-coding RNA molecules that regulate gene expression at the posttranscriptional level by binding to the 3′ untranslated regions (UTRs) of target mRNAs, leading to either their degradation or inhibition of translation. The dysregulation of several miRNAs has been connected to synaptic dysfunction, neuroinflammation and apoptosis. For example, miR-29a/b and miR-34a have been linked to AD, as they play roles in amyloid-beta (Aβ) accumulation and tau hyperphosphorylation. miR-29a/b specifically targets the BACE1 gene, which encodes the enzyme responsible for Aβ production. When these miRNAs are downregulated, BACE1 expression increases, leading to elevated Aβ levels and subsequent plaque formation.[23] In this connection a recent paper by Raia et al.[24] demonstrated that the expression of miR-29a and of its target, BACE1, are inversely correlated and that environmental conditions, such as modulation of one carbon metabolism by diet, modulate miR-29a through DNA methylation, that is MiR-29a is repressed in hypomethylating and expressed in hypermethylating conditions. In

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[18] C.H. Waddington, *The epigenotype*, in *Int J Epidemiol*, 41, 2012, 10–13.

[19] Z. Firdaus, X. Li, *Epigenetic Explorations of Neurological Disorders, the Identification Methods, and Therapeutic Avenues*, in *Int J Mol Sci*, 25, 2024, 11658.

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[21] S. Maity, K. Farrell, S. Navabpour, S.N. Narayanan, T.J. Jarome, *Epigenetic mechanisms in memory and cognitive decline associated with aging and Alzheimer's disease*, in *Int J Mol Sci*, 22, 2021, 12280.

[22] J.M. Levenson, T.L. Roth, F.D. Lubin, C.A. Miller, I.C. Huang, P. Desai, L.M. Malone, J.D. Sweatt, *Evidence that DNA(cytosine-5) methyltransferase regulates synaptic plasticity in the hippocampus.* Much evidence points out that AD is a multifactorial disease, depending on the interplay between exposome, genetic and epigenetic factors. in *Biol Chem*, 281, 2006, 15763–15773.

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[24] T. Raia, R.A. Cavallaro, L.D.F. Borges, S. Cinti, M. Bizzarri, I. Ferrer, M. Lucarelli, A. Fuso, *One-carbon metabolism modulates miR-29a-DNA methylation crosstalk in Alzheimer's disease,* in *Alzheimers Dement*, 21, 2025.

this way, ·miR-29 targets BACE1 mRNA reducing β-secretase expression and amyloidogenesis in Alzheimer's disease. As a consequence, miR-29a and other miRNAs hold potential as biomarkers for AD. Moreover, it may be possible to modulate these miRNAs to treat or even prevent the pathology.

Long Non-Coding RNAs (lncRNAs) are longer transcripts (>200 nucleotides) that regulate gene expression at multiple levels, including chromatin remodeling, transcriptional control, and posttranscriptional processing. A very important point that comes from epigenetics is that it will be possible to use new tools to set up new therapeutic treatments for Alzheimer's patients. The most promising treatments are HDAC inhibitors and DNA-demethylating agents. To control DNA methylation, two treatment approaches can be used: the first involves the use of DNMT inhibitors, and the second involves the administration of methyl donor substances such as folates and other B-group vitamins needed for SAM formation. Nutraceuticals such as polyphenols and isoflavones were showed to have the potential to modulate the epigenetic machinery.[25] Curcumin for example is an effective HDAC inhibitor and resveratrol acts as an activator of SIRT, a nicotinamide adenine dinucleotide (NAD^+)-dependent histone deacetylase.

6. Glia and Neuroinflammation

Another potential factor contributing to the development of AD is neuroinflammation, which plays a critical role in both the initiation and progression of the disease. Long-term neuroinflammation can cause cellular damage by increasing inflammatory cells, producing reactive oxygen species (ROS), and causing significant changes in DNA.[26] The fact that many of the comorbidities associated with AD are linked to dysregulated metabolic pathways suggests that lifestyle variables play a role in the etiology of the disease. In this sense, lifestyle changes such as exercise and diet can interact with inherited susceptibility genes to improve cognitive abilities in AD patients.[27] The development of innovative treatments and the promotion of interventions aimed at promoting a healthy lifestyle are essential to improve the lives of people affected by this debilitating condition.[28]

Numerous studies have identified immunosenescence and neuroinflammation as the primary factors involved in the development of the disease.[29] The microenvironment that leads to the loss of specific neuronal populations, primarily in the hippocampus and prefrontal cortex, is thought to be dependent on the release of proinflammatory and neurotoxic factors, secondary to close interactions between neu-

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[26] S. Samanta, S. Chakraborty, D. Bagchi, *Pathogenesis of Neurodegenerative Diseases and the Protective Role of Natural Bioactive Components,* in *Journal of the American Nutrition Association*, 43, 2024, 20-32.

[27] T. Archer, S. Ricci, F. Massoni *et al.*, *Cognitive benefits of exercise intervention,* in *Clinica Terapeutica* 167, 2016, 180-85. P. Ricci, F. Massoni, L. Ricci *et al.*, *Quality of life in dementia sufferers: The role of diet and exercise. Current Alzheimer Research*, 15, 2018, 400-407. F. Galkin, O. Kovalchuk, D. Koldasbayeva *et al.*, *Stress, Diet, Exercise: Common Environmental Factors and Their Impact on Epigenetic Age,* in *Ageing Research Reviews*, 88, 2023, 101956. L. Yang, Z. Yuan, C. Peng, *Effects of Aerobic Exercise on Cognitive Function and Quality of Life in Patients with Alzheimer's Disease: A Systematic Review and Meta-Analysis,* in *BMJ Open,* 15, 2025.

[28] Y.L. Zhao, Y.N. Hao, Y.J. Ge *et al.*, *Variables Associated with Cognitive Function: An Exposome-Wide and Mendelian Randomization Analysis,* in *Alzheimer's Research and Therapy,* 17, 2025, 13.

[29] C. Franceschi, M. Capri, D. Monti *et al.*, *Inflammaging and Anti-Inflammaging: A Systemic Perspective on Aging and Longevity Emerged from Studies in Humans,* in *Mechanisms of Ageing and Development,* 128, 2007, 92–105.

rons and glia. While early research focused on beta-amyloid plaques and tau protein aggregates as the primary pathological factors, recent advances highlight the critical involvement of non-neuronal components, particularly astrocytes, microglia, oligodendrocytes, and NG2 glial cells, in disease progression. The recent development of new technologies, such as in situ glial imaging, in vitro cultures of human glial cells derived from induced pluripotent stem cells (iPSCs), and molecular analyses, has allowed to study the role of glia in specific brain functions and the development of diseases. Indeed, it has been established that microglia, astrocytes, oligodendrocytes, and NG2 glia influence disease progression. Microglia, initially involved in the clearance of amyloid-beta (Aβ) plaques, can also contribute to neuronal damage by inducing synapse loss, potentially through complement-dependent pathways. Similarly, astrocytes, which typically support neuronal health, can exacerbate excitotoxicity and oxidative stress when their homeostatic function is disrupted. The emergence of activated astrocytes occurs early in the pathophysiology of AD, exhibiting imbalances in neurotransmitter homeostasis, astroglial atrophy, disruptions in synaptic associations, neuroinflammation, and ultimately neurodegeneration.[30]

6.1. Microglia

Microglia, of mesodermal origin, are part of the innate immune system and are responsible for immune surveillance to eliminate agents recognized as foreign. They have phagocytic capacity and trigger inflammatory and repair processes to restore tissue integrity after various types of injury.[31] Microglial cells are characterized by different states of polarization: at one extreme, the M1 phenotype, induced, for example, by the inflammatory agent LPS (lipopolysaccharide obtained from the cell wall of Gram-negative bacteria), which promotes the production of pro-inflammatory cytokines such as IL-1β and TNF-α, and chemokines capable of recruiting other microglial cells, amplifying inflammatory processes. At the other extreme there is the alternative M2 phenotype, associated with the production of anti-inflammatory cytokines such as IL-4, IL-10, and TGF-β, which are involved in repair processes and the fight against neuroinflammation.[32] Between these two extremes, there are intermediate degrees of polarization that characterize the various stages of the pathology. The different phenotypes are associated with morphological changes: resting microglia have a small soma with long ramifications that perceive changes in the surrounding microenvironment; microglia activated by an inflammatory stimulus increase in size, assuming an amoeboid morphology.[33] The accumulation of amyloid aggregates activates microglia, polarizing them toward an M1 phenotype, triggering chronic inflammation that causes cytotoxicity, apoptosis, autophagy dysfunction, increased oxidative stress, neuroinflammation, and brain atrophy.[34]

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[30] H. HIRBEC, N. DÉGLON, L.C. FOO *et al.*, *Emerging technologies to study glial cells,* in *Glia,* 68, 2020, 1692-1728.

[31] X. KANG, J. TIAN, Q. SHU *et al.*, *Microglia-neuron crosstalk in Alzheimer's disease: an exploration of molecular mechanisms and pathological implications,* in *Neuroscience,* 583, 2025, 1-9.

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[33] H. KETTENMANN, F. KIRCHHOFF, A. VERKHRATSKY, *Microglia: new roles for the synaptic stripper,* in *Neuron,* 77, 2013.

[34] V. LACHANCE, Q. WANG, E. SWEET, I. CHOI, C.Z. CAI, X.X. ZHUANG, Y. ZHANG, J.L. JIANG, R.D. BLITZER, O. BOZDAGI-GUNAL, B. ZHANG, J.H. LU *et al.*, *Autophagy protein NRBF2 has reduced expression in Alzheimer's brains and modulates memory and amyloid-beta homeostasis in mice,* in *Molecular Neurodegeneration,* 14, 2019, 43. T. ICHIMIYA, T. YAMAKAWA, T. HIRANO *et al.*, *Autophagy and Autophagy-Related Diseases: A Review,* in *International Journal of Molecular Science,* 21, 2020, 8974. Z. VALIUKAS, K. TANGALAKIS, V. APOSTOLOPOULOS *et al.*, *Microglial activation states and their implications for Alzheimer's Disease,* in *The Journal of Prevention of Alzheimer's Disease,* 12, 2025, 100013.

Pro-inflammatory mediators such as IL-1β and TNF-α may contribute to hypothalamic dysfunction, impaired neurogenesis, and cognitive decline.[35] Another process that manifests in AD progression is mitochondrial dysfunction, a key process underlying AD pathology, in which mitophagy (or selective degradation of mitochondria by autophagy) and autophagic pathways are altered.[36]

6.2. Macroglia

Macroglia, characterized by larger cells of ectodermal origin, are composed of astrocytes and oligodendrocytes, the former implicated in the formation of the blood-brain barrier, the latter in the formation of the myelin sheath. Recent studies have identified subpopulations of these cell types, differing in morphology and function. Aβ aggregates interact with Toll-like receptors (TLRs) and the NRLP3 inflammasome, increasing astrogliosis and the release of pro-inflammatory cytokines such as TNF-α and IL-1β.[37] Furthermore, Aβ deposition also contributes to BBB damage, making it more permeable to harmful substances, and can also induce the release of inflammatory cytokines and chemokines, thus contributing to chronic neuroinflammation.[38]

6.3. Astrocytes

Reactive astrocytes alter clearance processes, resulting in increased Aβ peptide and the release of pro-inflammatory cytokines and oxidants, exacerbating neuroinflammation and oxidative stress. Astrocytes are essential for Aβ clearance across the BBB, mediated by the LRP1 receptor,[39] while RAGE promotes amyloid influx from the bloodstream into the CNS.[40]

6.4. Oligodendrocytes

Oligodendrocyte progenitor cells (OPCs) are identified by their cell-surface neuronal marker NG2, also known as NG2 glia.[41] These glial cells express APP and the enzyme BACE1, critical components of the amyloidogenic pathway. Aβ leads to the generation of ceramide, which induces mitochondrial dysfunction, oxidative stress, and apoptosis; the damage to oligodendrocytes leads to morphological changes such as cell body shrinkage, increased lactate dehydrogenase release, and reduced metabolic activity. In

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[35] B. PENKE, M. SZŰCS, F. BOGÁR. *New Pathways Identify Novel Drug Targets for the Prevention and Treatment of Alzheimer's Disease. International Journal of Molecular Sciences.* 24, 2023, 5383.

[36] S.N. RAI, C. SINGH, A. SINGH *et al., Mitochondrial Dysfunction: A Potential Therapeutic Target to Treat Alzheimer's Disease,* in *Molecular Neurobiology,* 57, 2020, 3075–3088.

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[39] W. LI, C. CHEN, B. XU *et al.*, *The LDL Receptor-Related Protein 1: Mechanisms and roles in promoting Aβ efflux transporter in Alzheimer's disease,* in *Biochemical Pharmacology,* 231, 2025, 116643.

[40] R. BUSINARO, S. LEONE, C. FABRIZI *et al.*, *S100B protects LAN-5 neuroblastoma cells against Abeta amyloid-induced neurotoxicity via RAGE engagement at low doses but increases Abeta amyloid neurotoxicity at high doses,* in *Journal of Neuroscience Research,* 83, 2006, 897-906. Z. CAI, N. LIU, C. WANG *et al.*, *Role of RAGE in Alzheimer's Disease,* in *Cellular and Molecular Neurobiology,* 36, 2016, 483-95.

[41] J. YANG, X. CHENG, J. QI *et al.*, *EGF Enhances Oligodendrogenesis from Glial Progenitor Cells*, in *Frontiers in Molecular Neurosciences,* 10, 2017, 106.

AD, OPC dysfunction leads to active myelin degeneration and reduced repair capacity, resulting in progressive axonal dysfunction and neurodegeneration.

6.5. Glial Cell Crosstalk

The sustained release of pro-inflammatory cytokines accelerates Aβ production and impairs the ability of glial cells to clear and phagocytose Aβ. The interaction between microglia, astrocytes, and oligodendrocytes induces AD progression by amplifying neuroinflammation and neurodegeneration. Pro-inflammatory cytokines such as tumor necrosis factor alpha (TNF-α), interleukin-6 (IL-6), and interleukin-1 beta (IL-1β) are largely involved in this crosstalk. The inability of glial cells to clear amyloid plaques due to impaired phagocytosis significantly contributes to neural loss in AD.[42] Activated astrocytes, stimulated by Aβ plaques and tau aggregates, secrete TNF-α and IL-6, and chemokines such as CCL2 (MCP-1) and CXCL10, which interact with various receptors on the surface of microglia. Microglia are hyperstimulated and trigger neuroinflammatory pathways, promoting neurodegeneration.[43] Microglia and astrocytes generate ROS, including superoxide anion and nitric oxide (NO), thus intensifying oxidative stress.[44]

Activated microglia also release high levels of C1q, causing chronic inflammation and neuronal damage.

In addition to these pro-inflammatory signals, astrocytes and microglia also release anti-inflammatory mediators, including transforming growth factor-beta (TGF-β) and interleukin-10 (IL-10), to mitigate and regulate the inflammatory response. However, in AD, this repair process is often insufficient, shifting the balance toward chronic inflammation. Astrocytes and microglia also produce neurotrophic factors such as BDNF and glial cell-derived neurotrophic factor (GDNF). A reduction in these factors in AD further compromises neuronal survival.[45]

7. Risk Factors

7.1. Exposome

The fundamental role of environmental factors, including diet, lifestyle, head trauma, toxins, and others[46] in modulating the risk and progression of AD has been established. The exposome, which encom-

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[42] C. Pomilio, R.M. Gorojod, M. Riudavets *et al.*, *Microglial autophagy is impaired by prolonged exposure to β-amyloid peptides: evidence from experimental models and Alzheimer's disease patient,* in *Geroscience*, 42, 2020, 613-63. K. Clayton, J.C. Delpech, S. Herron *et al.*, *Plaque associated microglia hyper-secrete extracellular vesicles and accelerate tau propagation in a humanized APP mouse model,* in *Molecular Neurodegeneration,* 16, 2021, 18.

[43] M. Sil, N. Mukherjee, I. Chatterjee *et al.*, *Glial Cells in Alzheimer's Disease: Pathogenic Mechanisms and Therapeutic Frontiers*, in *Journal of Molecular Neurosciences,* 75, 2025, 87. M. Azmal, J.K. Paul, F.S. Prima *et al.*, *Microglial dysfunction in Alzheimer's disease: Mechanisms, emerging therapies, and future directions,* in *Experimental Neurology,* 392, 2025, 115374.

[44] A. Vilalta, Y. Zhou, J. Sevalle *et al.*, *Wild-type sTREM2 blocks Aβ aggregation and neurotoxicity, but the Alzheimer's R47H mutant increases Aβ aggregation*, in *Journal of Biological Chemistry*, 296, 2021, 100631. C.F. Tsai, G.W. Chen, Y.C. Chen *et al.*, *Regulatory Effects of Quercetin on M1/M2 Macrophage Polarization and Oxidative/Antioxidative Balance,* in *Nutrients*, 14, 2021, 67.

[45] H. Park, M. Ni, Y. Le, *Neuroinflammation and nutrition in Alzheimer's disease,* in *Frontiers in Neurology,* 1, 2025, 1622571.

[46] F. Ippoliti, P. Corbosiero, N. Canitano *et al.*, *Work-related Stress, over nutrition and cognitive disability,* in *Clinica Terapeutica,* 168, 2017, 42-47. P. Ricci, F. Massoni, L. Ricci *et al.*, *Quality of life in dementia sufferers: The role of diet*

passes all environmental exposures throughout an individual's lifetime, provides fundamental insights into the complex etiology of AD.[47] The fact that many of the comorbidities associated with AD are linked to dysregulated metabolic pathways suggests that lifestyle variables, particularly diet, play a role in the etiology of AD. In this sense, lifestyle changes such as physical exercise and diet can interact with inherited susceptibility genes to improve cognitive abilities in AD patients,[48] underlining their relevance for CNS homeostasis, so much so that we now speak of a 'neural exposome'[49] which includes a whole series of environmental factors, of different kinds, ranging from air pollution and dietary habits to occupational exposures and psychosocial stresses – which impact the physiological balance of the CNS.[50]

A relationship between education level and amyloid accumulation has also been identified: a higher level of education is associated with greater amyloid deposition in individuals with MCI, but with a reduced amyloid burden in those with AD. This pattern supports the cognitive reserve hypothesis, according to which education can strengthen compensatory neural mechanisms, delaying the clinical onset of dementia symptoms.[51] Loneliness has been shown to significantly contribute to cognitive impairment and dementia in older adults. Social isolation and loneliness (perceived social isolation) are considered risk factors for the development of dementia in the elderly population.[52] In this regard, the development of innovative treatments and the promotion of interventions aimed at promoting a healthy lifestyle are essential to improve the lives of people affected by AD.[53]

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and exercise, in *Current Alzheimer Research,* 15, 2018, 400-407. C.E. Finch, A.M. Kulminski, *The Alzheimer's Disease Exposome,* in *Alzheimer's Dementia,* 15, 2019, 1123–1132. N. Soldevila-Domenech, A. Ayala-Garcia, M. Barbera *et al.*, *Adherence and intensity in multimodal lifestyle-based interventions for cognitive decline prevention: state-of-the-art and future directions,* in *Alzheimer's Research and Therapeutics,* 17, 2025, 61. M.A. Kareem, A. Ashwini, T. Sunil, *The Role of the Exposome in Aging and Age-Related Diseases: A Comprehensive Review*, in *Journal of Pharmacy and Bioallied Sciences*, 17(1), 2025, S2-S5.

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[48] C.E. Finch, A.M. Kulminski, *The Alzheimer's Disease Exposome,* in *Alzheimer's Dementia,* 15, 2019, 1123–1132. F. Galkin, O. Kovalchuk, D. Koldasbayeva *et al.*, *Stress, Diet, Exercise: Common Environmental Factors and Their Impact on Epigenetic Age,* in *Ageing Research Reviews*, 88, 2023, 101956. L. Yang, Z. Yuan, C. Peng, *Effects of Aerobic Exercise on Cognitive Function and Quality of Life in Patients with Alzheimer's Disease: A Systematic a systematic review and meta-analysis,* in *BMJ Open,* 15, 2025.

[49] R. Granov, S. Vedad, S.H. Wang *et al.*, *The Role of the Neural Exposome as a Novel Strategy To Identify and Mitigate Health Inequities in Alzheimer's Disease and Related Dementias,* in *Molecular Neurobiology,* 62, 2025, 1205–1224.

[50] R. Vermeulen, E.L. Schymanski, A.L. Barabsi *et al.*, *The Exposome and Health: Where Chemistry Meets Biology*, in *Science,* 367, 2020, 392–396.

F. Sedghi, E. Foroughi, F. Sheikhzadeh *et al.*, *Association between educational attainment and amyloid deposition across the spectrum from normal cognition to dementia: A meta-analysis,* in *IBRO Neuroscience Reports,* 19, 2025, 133-142.

[51] R.H. Aunsmo, B.H.Strand, S. Bergh *et al.*, *Loneliness trajectories and dementia risk: Insights from the HUNT cohort study,* in *Alzheimer's Dementia (Amst),* 17, 2025, e70154.

[52] W. Araki, *Social Isolation as a Risk Factor for Dementia: Insights from Animal Model Studies,* in *Current Alzheimer Research,* 22, 2025, 165-173.

[53] Y.L. Zhao, Y.N. Hao, Y.J. Ge *et al.*, *Variables Associated with Cognitive Function: An Exposome-Wide and Mendelian Randomization Analysis,* in *Alzheimer's Research and Therapeutics,* 17, 2025, 13.

7.2. Immunosenescence

An emerging key factor contributing to the decline in brain organization and function is cellular senescence, characterized at the genomic level by stable cell cycle arrest, primarily driven by the p16INK4a/Rb and p21CIP1/p53 pathways, accompanied by macromolecular and metabolic alterations associated with a pro-inflammatory hypersecretory phenotype known as senescence-associated secretory phenotype (SASP).[54] SASP is characterized by the synthesis of various biologically active molecules, such as inflammatory mediators, growth factors, and extracellular matrix proteins, which can influence the microenvironment, affecting neighboring cells. The process is also characterized by oxidative stress, chromatin remodeling, telomere shortening, accumulation of DNA damage and reactive oxygen species (ROS), lysosomal enlargement, macromolecular breakdown, and metabolic imbalance. The number of senescent cells increases with age, and their involvement has been suggested in the pathogenesis of AD[55] since at the CNS level, glial cells are also affected by a senescence process: microglia become neurotoxic and harmful by producing inflammatory cytokines, superoxide anions and nitric oxide, promoting the phenomenon of 'oxi-inflamm-aging'. Senescent astrocytes promote inflammation through SASP factors.[56] Indeed, several SASP factors, including MMP-3, IL-1α, IL-6 and IL-8, are increased in the brains of PD and AD patients, indicating that senescent cells could contribute to neurodegeneration.[57] Therefore, eliminating senescent cells within the CNS, or at least delaying their senescence, and mitigating the adverse effects of widespread SASP have been identified as targets for the prophylaxis and adjunctive treatment of neurodegenerative diseases.

7.3. Obesity

Overnutrition, resulting from excess caloric intake, directly contributes to overweight and obesity. Eating habits and nutrient intake can have a profound impact on the body's resilience to various stressors. Stress is one of the main factors inducing the development of visceral fat associated with obesity. Overweight and obesity are responsible for the development of chronic low-grade inflammation and represent one, if not the main, modifiable risk factor, as dietary changes can modulate the risk of developing AD and subsequently disease progression.[58] Numerous studies have established a correlation between obesity and dementia, and AD has been described as a metabolic disease or type 3 diabetes, influenced

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[54] Q. Zhang, G. Yang, Y. Luo *et al.*, *Neuroinflammation in Alzheimer's Disease: Insights from Peripheral Immune Cells,* in *Immunity and Ageing,* 21, 2024, 38.

[55] S. Ristori, G. Bertoni, E. Bientinesi *et al., The Role of Nutraceuticals and Functional Foods in Mitigating Cellular Senescence and Its Related Aspects: A Key Strategy for Delaying or Preventing Aging and Neurodegenerative Disorders,* in *Nutrients,* 17, 2025, 1837.

[56] K. Simmnacher, F, Krach, Y. Schneider *et al.*, *Unique Signatures of Stress-Induced Senescent Human Astrocytes,* in *Experimental Neurology*, 334, 2020, 113466.

[57] W.Y. Wang, M.S. Tan, J.T. Yu *et al.*, *Role of Pro-Inflammatory Cytokines Released from Microglia in Alzheimer's Disease*, in *Annals of Translational Medicine,* 3, 2015, 36.

Z. Si, L. Sun, X. Wang, *Evidence and Perspectives of Cell Senescence in Neurodegenerative Diseases*, in *Biomedicine and Pharmacotherapy*, 137, 2021, 111327.

[58] D. Khanna, S. Khanna, P. Khanna *et al., Obesity: A Chronic Low-Grade Inflammation and Its Markers*, in *Cureus,* 14, 2022, 22711.

Y. Dhurandhar, S. Tomar, A. Das *et al.*, *Chronic inflammation in obesity and neurodegenerative diseases: exploring the link in disease onset and progression*, in *Molecular Biology Reports,* 52, 2025,424.

by the development of hypertrophic adipose tissue with the release of proinflammatory adipokines and various mechanisms of leptin and insulin resistance.[59] Adipose tissue is currently considered an active endocrine organ, producing important mediators involved in the regulation of metabolism and inflammatory mechanisms. Insulin and leptin resistance have been linked to dysregulation of energy balance and the induction of a chronic inflammatory state, important cofactors in cognitive impairment and the onset and progression of AD.[60] Obesity is associated with dysregulated leptin secretion due to adipose tissue dysfunction, contributing to metabolic abnormalities and hippocampal synaptic disorders, factors that increase the risk of comorbidities, cognitive decline, and neurodegenerative diseases. Furthermore, obesity increases inflammatory molecules such as RAGE, cytokines (IL-6 and TNF-α), leptin, insulin, and free fatty acids, which disrupt the degradation of β-amyloid peptide and promote its accumulation in the brain.[61] The elevated leptin levels observed in obese individuals lead to leptin resistance in the brain. Signal transduction and communication between adipokines secreted by adipose tissue and the central nervous system have an increasingly recognized role in metabolic and neurological regulation. This action contributes to the vulnerability of obese individuals to the development of cognitive impairment.[62]

8. Nutraceuticals

Growing interest is focusing on nutraceuticals and functional foods as potential modulators of cellular senescence, potentially influencing the development of neurodegenerative diseases.[63] Various natural compounds, known as 'bioactive compounds', present in foods can interact with biological processes to provide benefits and because of this they have been included in a new class of compounds called 'nutraceuticals' (a crasis between the words 'nutrients' and 'pharmaceuticals').[64] A growing body of evidence suggests that nutraceuticals and whole-food dietary approaches can influence brain health and cognitive function, offering a promising avenue for intervention.[65] Several bioactive compounds function as epigenetic modulators, influencing gene expression, chromatin organization, DNA methylation patterns, and noncoding RNA expression, and both diet quality and quantity epigenetically modulate DNA

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[59] S.M. De La Monte, *Type 3 diabetes is sporadic Alzheimer's disease: mini-review,* in *European Neuropsychopharmacology*, 24, 2014, 1954-60. M. Kciuk, W. Kruczkowska, J. Gałęziewska *et al.*, *Alzheimer's Disease as Type 3 Diabetes: Understanding the Link and Implications*, in *International Journal of Molecular Sciences,* 25, 2024, 11955.

[60] R. Businaro, F. Ippoliti, S. Ricci *et al.*, *Alzheimer's disease promotion by obesity: induced mechanisms-molecular links and perspectives,* in *Current Gerontology and Geriatric Research,* 2012, 986823.

[61] E.A. Al-Suhaim, A.A. Alrubaish, H.A. Aldossary *et al.*, *Obesity and Cognitive Function: Leptin Role Through Blood-Brain Barrier and Hippocampus,* in *Molecular Neurobiology*, 62, 2025, 16280-16301.

[62] E.A. Al-Suhaim, A.A. Alrubaish, H.A. Aldossary *et al.*, *Obesity and Cognitive Function: Leptin Role Through Blood-Brain Barrier and Hippocampus,* in *Molecular Neurobiology*, 62, 2025, 16280-16301.

[63] S. Ristori, G. Bertoni, E. Bientinesi *et al.*, *The Role of Nutraceuticals and Functional Foods in Mitigating Cellular Senescence and Its Related Aspects: A Key Strategy for Delaying or Preventing Aging and Neurodegenerative Disorders,* in *Nutrients,* 17, 2025, 1837.

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methylation and mental health.[66] For example, the presence of antioxidants in fruits and vegetables has been shown to mitigate oxidative stress induced by environmental contaminants[67] and dietary polyphenols showed several benefits in AD, mitigating pathological manifestations in part due to their ability to cross the blood-brain barrier.[68] Neuroprotective effects vary depending on the nutrient used and may include a reduction in neuroinflammation, activation of the endogenous antioxidant defense system, and modulation of the structure and function of the gut microbiota.[69] Supplementation of essential nutrients, such as long-chain polyunsaturated fatty acids, vitamin E, and minerals, can minimize inflammation, enhance antioxidant defenses, and reduce the risk and incidence of age-related diseases, such as cardiovascular disease and neurodegenerative diseases. Dietary supplementation strategies have been shown to be effective in subjects with mild cognitive impairment, while weaker results have been obtained in patients with advanced neurodegenerative diseases. Additional supplementation has also been shown to improve depression, which is of considerable benefit considering the comorbidity between cognitive impairment/dementia and depression.[70] Natural antioxidant and anti-inflammatory compounds found in plant-based foods, such as fruits, particularly berries (such as strawberries, blueberries, blackcurrants, blackberries, cranberries, and mulberries), exert neuroprotective activity.[71] Specifically, in the presence of hydroalcoholic extracts obtained from blueberries, the mRNA expression of the pro-inflammatory cytokines IL-1β, IL-6, and TNF-α decreased, as did the expression of iNOS, while that of Arg-1 increased, markers of pro- and anti-inflammatory phenotypes, respectively. It has been shown that during the inflammatory response, blueberry extract shifts M1 polarization toward the M2 phenotype.[72] A pilot study in obese/overweight patients with metabolic syndrome demonstrated that significant changes in cytokine gene expression levels were observed after the intake of high-fat/high glycemic load meals enriched with blueberries. In particular, the mRNA expression of IL-6 and TGF-β, pro- and anti-inflammatory cytokines, respectively, was significantly decreased and increased after blueberry supplementation, indicating a positive impact of blueberry ingestion in reducing the risk of inflammation.[73] Curcumin, a polyphenolic compound derived from Curcuma longa, has attracted considerable attention

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for its potential therapeutic benefits, particularly in combating inflammation, oxidative stress, and metabolic disorders. Its chemical structure, characterized by conjugated double bonds between two aromatic rings, allows it to act as an electron donor, thus mitigating the formation of free radicals. Curcumin's anti-inflammatory properties are related to the inhibition of the NF-κB pathway, resulting in the reduction of inflammatory markers in adipocytes and macrophages. Furthermore, curcumin modulates oxidative stress by activating the NRF2 pathway, enhancing the cell's antioxidant defenses.[74]

Furthermore, the ancient durum wheat variety Senatore Cappelli was analyzed at four stages of the food chain (seeds, flour, pasta, and chaff) by NMR spectroscopy, revealing the presence of bioactive molecules such as phenolic acids and carotenoids. The hydroalcoholic extracts obtained from the components of the chain showed the ability to polarize microglial cells towards an anti-inflammatory phenotype, even after the addition of LPS. An antioxidant response was detected in both microglia and the nematode Caenorhabditis elegans, where the extracts also implemented an anti-stress resilience response, stimulated innate immunity, and were able to extend lifespan, indicating potential anti-aging and pro-longevity properties. These results position the ancient wheat Senatore Cappelli as a valuable resource for the enhancement of bioactive compounds, supporting its reintroduction into modern diets and its use in the development of functional foods.[75]

The 36-month LipiDiDiet study demonstrated that a multinutrient intervention slowed cognitive decline and brain atrophy and improved memory performance in individuals with prodromal AD, thus highlighting the role of diet in modifying AD risk.[76]

Both the ketogenic diet (KD) and the Mediterranean diet have been shown to exert anti-inflammatory effects by reducing the expression of pro-inflammatory cytokines, decreasing microglial activation, and restoring the integrity of the blood-brain barrier.[77] The primary activity of the ketogenic diet has been linked to improved mitochondrial function and reduced oxidative stress. β-Hydroxybutyrate, the most studied ketone body, has been shown to reduce the production of reactive oxygen species (ROS) by improving mitochondrial respiration: stimulating the cellular endogenous antioxidant system with the activation of nuclear factor erythroid-derived factor 2-related (Nrf2), modulating the ratio between the oxidized and reduced forms of nicotinamide adenine dinucleotide (NAD^+/NADH), and increasing the efficiency of the electron transport chain through the expression of uncoupling proteins. Furthermore, the ketogenic diet exerts anti-inflammatory activity by inhibiting the activation of nuclear factor kappa-light-chain-enhancer of activated B cells (NF-κB) and the inflammasome, as well as by inhibiting histone

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deacetylases (HDACs), enhancing memory encoding.[78] Similarly, the Mediterranean diet, rich in antioxidants, reduces postprandial levels of hydrogen peroxide and lipid peroxides.[79] In particular, polyphenols, abundant in this diet, combat neuroinflammation by reducing pro-inflammatory cytokines (IL-1β, IL-6, TNF-α) and inhibiting the NF-κB pathway.[80] Their antioxidant properties neutralize ROS, enhance antioxidant enzymes, strengthen the blood-brain barrier, and modulate the gut microbiota, all contributing to neuroprotection. A recent study confirms the link between an anti-inflammatory diet and the decreased risk to develop neurodegenerative diseases.[81]

9. Gut-Brain Axis: New Therapeutic Strategies with Probiotic Administration

Recent studies have highlighted the central role of the gut microbiota in maintaining homeostasis and preventing CNS imbalances.[82] Some inflammatory diseases, including AD, share alterations in the gut microbiome and immune pathways that have been associated with disease progression.[83]

The intestine, especially the colon, hosts numerous microorganisms, including approximately 1,000 bacterial species and 7,000 strains, with a predominance of Firmicutes and Bacteroidetes, as well as yeasts and viruses,[84] collectively referred to as the microbiota. Under physiological conditions, this set of microorganisms promote health by regulating metabolism, breaking down complex dietary polysaccharides, modulating intestinal motility, strengthening the intestinal barrier, and influencing fat distribution and immune function. Through the gut-brain axis, the gut microbiota can indirectly modulate CNS function by producing immune activators, neurotransmitters, neuromodulators, and endocrine factors that can cross the blood-brain barrier or communicate through neural pathways.[85] Some microbial metabolites, such as lipopolysaccharides and short-chain fatty acids, can compromise the integrity of the blood-brain barrier, facilitating neuroinflammation and neuronal damage, as has been demonstrated in cases of dysbiosis (alteration in the number and types of microorganisms that make up the host's microbiota). It is important to note that the composition of the gut microbiota can be influenced by diet, lifestyle, and even environmental factors, with alterations in microbiota diversity often resulting in various neuro-

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[83] M. Luca, M. Di Mauro, M. Di Mauro *et al.*, *Gut microbiota in Alzheimer's disease, depression, and type 2 diabetes mellitus: the role of oxidative stress*, in *Oxidative Medicine and Cellular Longevity*, 2019, 4730539.

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logical and psychiatric disorders. Dysbiosis can lead to increased intestinal permeability, a condition often referred to as 'leaky gut'. This allows harmful substances to enter the bloodstream, triggering systemic inflammation, which can then affect brain function. There is growing evidence that the gut microbiota plays a significant role in modulating brain function, primarily through the production of specific metabolites. Some bacteria, such as Bacillus subtilis and Escherichia coli, produce amyloid-like proteins, which can penetrate the intestinal barrier, enter the bloodstream, and potentially contribute to neurodegenerative processes.[86]

Long-term use of broad-spectrum antibiotics has been associated with alterations in the composition of the gut microbiota, resulting in cognitive impairment and an increased risk of developing Alzheimer's disease.[87]

Patients with AD have lower gut microbial diversity, characterized by an increase in pro-inflammatory bacteria and a decrease in beneficial species.[88] Furthermore, differences in microbiota composition are observed between patients with mild cognitive impairment (MCI) and those with advanced AD, indicating a gradual shift in the microbiota as the disease progresses.[89] Dysbiosis is believed to contribute to early AD pathology by promoting immune aging, cytokine imbalances, and neuroinflammation.[90] The promotion of neurodegenerative disorders, also induced by systemic inflammation, has been linked to a decrease in bacterial strains capable of producing short-chain fatty acids such as butyrate. Butyrate, along with other ketone bodies, is able to cross the BBB and replace the energy functions of glucose in situations of glucose deficiency. Reduced production of SCFAs leads to the accumulation of amyloid plaques, metabolic dysfunction, and microglial deterioration, all of which accelerate cognitive decline.[91] Furthermore, the decline in butyrate-producing bacteria is often accompanied by an increase in pro-inflammatory bacteria, triggering both local and systemic inflammation, further exacerbating neuroinflammation.[92] The results of these studies have led to the hypothesis that modulating the gut microbiome could offer potential therapeutic strategies to improve the treatment of neurodegenerative diseases.[93] Furthermore, reduced gut microbiota diversity can alter tryptophan and serotonin levels, influencing the production of critical molecules such as dopamine and brain-derived neurotrophic factor

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[93] W. Liu, J. Guo, Y. Dong *et al.*, *Efficacy of probiotic supplementation in influencing cognitive function in Alzheimer's disease: A systematic review and meta-analysis*, in *Journal of Food Science,* 90, 2025.

(BDNF).[94] Various strategies have been developed to shift the microbiota composition toward neuroprotective species, such as the administration of probiotics, prebiotics, synbiotics, postbiotics, and fecal microbiota transplantation (FMT). Probiotics are live microorganisms that can significantly contribute to mitigating inflammatory processes by acting on the gut-brain axis, reducing the release of inflammatory mediators, and counteracting oxidative stress.[95] Lactobacilli species have demonstrated benefits in aging by improving immunity and maintaining the balance of the gut microbiota. With some preclinical studies, we have demonstrated that the yeast Milmed, obtained from S. cerevisiae after exposure to millimeter-wavelength electromagnetic radiation, reverses pro-inflammatory M1-polarized microglia to an anti-inflammatory phenotype, as demonstrated morphologically by the recovery of the quiescent phenotype by microglia, by the decrease in IL-1β, IL-6, TNF-α mRNAs, and by the decreased expression of iNOS. Furthermore, Milmed induced the secretion of IL-10 and the expression of Arginase-1, cellular markers of anti-inflammatory-polarized M2 microglia. These data suggest that Milmed can be considered a probiotic with diversified anti-inflammatory activity, capable of directing the polarization of microglial cells.[96] Treatment with Milmed cultured yeast or its dried powder promoted autophagic flux, as demonstrated by increased expression of Beclin-1, ATG7, LC3, and p62 mRNAs and by inhibition of mTOR. It also enhanced the antioxidant response by increasing the expression of NRF2, SOD1, and GPX. Dietary supplementation with Milmed prolonged the survival of C. elegans and reduced age-related ROS accumulation. The pro-longevity effect was dependent on SKN-1/Nrf2 activation, as demonstrated by the lack of benefit in skn-1 mutants. Thus, Milmed yeast demonstrated significant pro-autophagy and antioxidant activity with significant pro-longevity effects in C. elegans, thus extending its lifespan and improving its resistance to stress. This, combined with the Milmed previously demonstrated anti-inflammatory activity, highlights its role as a highly effective probiotic for its beneficial health effects. Activation of the SKN-1/NRF2 pathway and modulation of autophagy support the therapeutic potential of Milmed in neuroprotection and healthy aging.

Confirming these results, several clinical trials included in a meta-analysis have indicated that probiotic supplementation may improve cognitive function in individuals with mild cognitive impairment (MCI), a prodromal phase of AD.[97]

New therapeutic horizons are emerging thanks to complementary medicines that complement traditional pharmacological treatments. Probiotics, supported by prebiotics, have demonstrated an im-

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[94] G. Morris, M. Berk, A. Carvalho *et al.*, *The Role of the Microbial Metabolites Including Tryptophan Catabolites and Short Chain Fatty Acids in the Pathophysiology of Immune-Inflammatory and Neuroimmune Disease*, in *Molecular Neurobiology,* 54, 2017, 4432-4451. R. Hashemi, M.M.H.M. Raouf, T.S. Salih *et al.*, *Impact of probiotic supplementation on serum levels of brain-derived neurotrophic factor: GRADE-based dose-response meta-analysis,* in *BMC Nutrition,* 11, 2025, 61.

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[96] F. Armeli, B. Mengoni, E. Maggi *et al.*, *Milmed Yeast Alters the LPS-Induced M1 Microglia Cells to Form M2 Anti-Inflammatory Phenotype*, in *Biomedicines*, 10, 2022, 3116.

[97] G. Zhu, J. Zhao, H. Zhang *et al.*, *Probiotics for Mild Cognitive Impairment and Alzheimer’s Disease: A Systematic Review and Meta-Analysis,* in *Foods,* 10, 2021, 1672

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portant role in reducing systemic inflammation and oxidative stress, two essential pathogenetic factors in the promotion of chronic neurodegenerative diseases.

Climate Change, Cutaneous Ageing, and Skin Cancer: Mechanistic Pathways, Epidemiological Evidence, and Public Health Implications

Carmen Cantisani, Ardeshir Bayat[*]

ABSTRACT: Climate change is transforming the environmental exposures that shape human skin health. Rising ultraviolet (UV) radiation, heat extremes, humidity fluctuations, and escalating air pollution form a shifting cutaneous exposome. Together, these stressors accelerate extrinsic skin ageing and increase the burden of skin cancer. At the mechanistic level, pathways include oxidative stress, extracellular matrix degradation, mitochondrial dysfunction, immunosuppression, and pollutant– UV synergy. Epidemiological evidence supports growing risks across populations, though data gaps remain. Particularly vulnerable groups include outdoor workers, climate migrants, children, the elderly, and immunocompromised patients. This article synthesizes current knowledge, identifies mechanistic and epidemiological links, and emphasizes prevention, from personal photoprotection to systemic climate adaptation. Situating dermatology within planetary health underscores the urgency of integrating skin health into climate policy and research priorities.

KEYWORDS: Climate change; cutaneous ageing; public health; skin cancer; ultraviolet radiation

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tective Strategies – 7. Prevention and Protective Strategies – 7.1. Behavioral Measures – 7.2. Clinical and Technological Measures – 7.3. Policy and Structural Measures – 8. Research Gaps and Future Directions – 9. Conclusion.

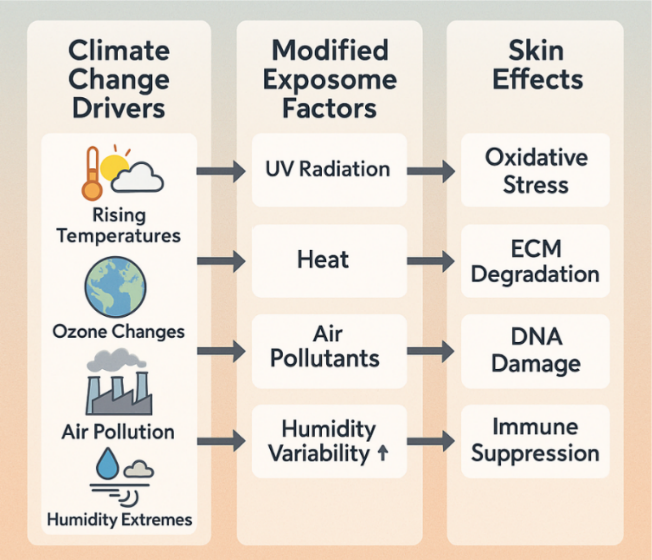
1. Introduction

Human skin is the body's largest organ and its primary environmental interface. It protects against ultraviolet radiation, toxins, pathogens, and fluctuating temperatures, while also serving as a visible marker of biological and environmental ageing. With accelerating climate change, this protective interface is under unprecedented strain.

The skin's health is governed by the cutaneous exposome, the cumulative external and internal factors influencing ageing, carcinogenesis, and disease.[1] Climate change acts as a multiplier across exposome domains, altering the intensity, duration, and interaction of exposures such as UV radiation, particulate matter, ozone, heat stress, and humidity extremes.[2] These exposures converge mechanistically via oxidative stress, chronic inflammation, impaired DNA repair, and immune dysregulation, producing two major clinical outcomes of concern: premature skin ageing and increased risk of skin cancer.[3]

Globally, skin cancer is the most common malignancy, and its incidence continues to rise (Parker, 2020). Meanwhile, extrinsic skin ageing contributes not only to aesthetic change but also to functional decline in barrier integrity, wound healing, and immune competence.[4] The intersection of climate change with these processes raises urgent questions for clinicians, researchers, and policymakers (Figure 1).

Figure 1. Climate change drivers and the cutaneous exposome.



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This article addresses five aims:

1. To outline how climate change is reshaping the cutaneous exposome.
2. To detail mechanistic pathways linking these exposures to ageing and carcinogenesis.
3. To review epidemiological evidence for climate-related skin outcomes.
4. To identify vulnerable populations.
5. To propose preventive and adaptive strategies spanning individuals, clinical practice, and public health.

2. Climate Change and the Cutaneous Exposome

The cutaneous exposome encompasses ultraviolet radiation, air pollutants, meteorological conditions (temperature, humidity), lifestyle, and endogenous factors. A relevant addition to this list is high-energy visible light (HEVL), or blue light, from both solar and digital sources, which contributes to oxidative stress and pigmentary changes. Climate change alters these domains in complex, interactive ways.

2.1. Ultraviolet Radiation Shifts

Although the Montreal Protocol has facilitated partial ozone recovery, climate feedback loops continue to influence surface UV patterns.[5] Stratospheric cooling linked to greenhouse gases may slow ozone repair, while loss of reflective surfaces such as ice and snow amplifies ground-level UV.[6] Changes in cloud dynamics further alter UV intensity. Modeling suggests that by 2100, mid-latitude regions may experience a net increase in erythemally effective UV radiation, despite global emission reductions.

For dermatology, this means heightened exposure to DNA-damaging wavelengths, UVB driving mutagenesis and UVA driving oxidative stress and photoageing. Importantly, UV interacts with other exposome factors. For example, pollutants such as polycyclic aromatic hydrocarbons (PAHs) absorb UV and become more reactive, compounding oxidative stress.

2.2. Heatwaves and Extreme Temperatures

Heat is one of the most direct climate hazards. Global warming has increased both the frequency and severity of heatwaves, with profound consequences for skin physiology. Elevated temperatures disrupt barrier function by increasing trans-epidermal water loss (TEWL) and altering lipid organization[4]. Heat shock proteins are upregulated, modulating immune and inflammatory responses.

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[5] S. Madronich, G.H. Bernhard, P.J. Neale, *et al*, *Continuing benefits of the Montreal Protocol and protection of the stratospheric ozone layer,* in *Photochem Photobiol Sci,* 23, 6, 2024, 1087–1115.

[6] N. Singh, C. Wigmann, P. Vihay, *et al., Combined Effect of Ambient Temperature and Relative Humidity on Skin Aging Phenotypes in the Era of Climate Change: Results From an Indian Cohort Study,* in *Dermatitis*, 36, 1, 2025, 72-79.

Chronic or repeated heat stress may accelerate intrinsic ageing processes through mitochondrial dysfunction and epigenetic alterations.[7] Behavioral effects compound these risks: during heat events, individuals often increase outdoor exposure and reduce protective clothing, inadvertently raising UV dose.[8]

2.3. Air Pollution Intensification

Climate change exacerbates air pollution through stagnant weather patterns, wildfire smoke, and altered photochemistry. Key pollutants affecting the skin include:

- *Particulate matter* (PM2.5 and PM10): Penetrates follicular openings, inducing oxidative stress and inflammation.
- *Ground-level ozone* (O3): Damages lipids and antioxidants in the stratum corneum, compromising barrier integrity.[9]
- *Nitrogen oxides* (NOx) and *sulfur oxides* (SOx): Potentiate inflammatory cascades.
- *Polycyclic aromatic hydrocarbons* (PAHs): UV-activated mutagens forming DNA Adducts.[10]

Epidemiological studies link chronic pollution exposure to pigmentary disorders, lentigines, and wrinkle formation.[11] Pollutants also exacerbate UV-induced DNA damage, acting as co-carcinogens.

2.4. Humidity Extremes

Changing precipitation patterns produce alternating extremes of low and high humidity. Low humidity compromises stratum corneum hydration, leading to barrier fragility, xerosis, and accentuated wrinkling. High humidity promotes microbial dysbiosis, fungal infections, and irritant dermatitis.[12] These shifts modulate both skin ageing and susceptibility to neoplasia via immune perturbation.

2.5. Multiplicative Impacts

The *synergistic effects* of combined climate stressors are particularly concerning. UVA and ozone exposures synergistically increase oxidative burden, while UV–PAH interactions yield enhanced DNA adduct formation[1]. Urban heat islands exemplify convergence:

elevated local temperatures intensify ozone formation, while socioeconomic disparities limit access to protective resources.[13]

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[7] W. Ni, N. Nikolaou, C.K. Ward-Caviness, *et al.*, *Associations between medium- and long-term exposure to air temperature and epigenetic age acceleration,* in *Environ Int*, 2023, 178.

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[10] G. Bocheva, R.M. Slominski, A.T. Slominski, *Environmental Air Pollutants Affecting Skin Functions with Systemic Implications,* in *Int J Mol Sci*, 24, 13, 2023, 10502.

[11] J.C. Fussell, F.J. Kelly, *Oxidative contribution of air pollution to extrinsic skin ageing,* in *Free Radic Biol Med,* 1, 151, 2020, 111-122.

[12] N. Singh, C. Wigmann, P. Vijay, *et al.*, *Combined effect of ambient temperature and humidity on skin ageing phenotypes,* in *Dermatitis*, 36, 1, 2025, 72–79.

[13] N. Balato, F. Ayala, M. Megna, *et al.*, *Climate change and skin,* in *G Ital Dermatol Venereol*, 148, 1, 2013, 135–146.

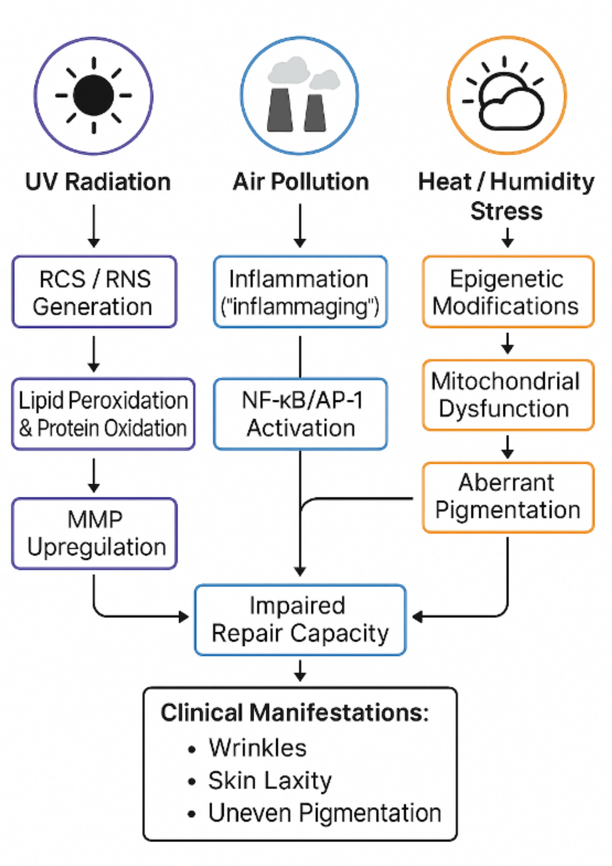
Thus, the exposome under climate change is not a linear addition of risks but a network of interactions, amplifying dermatological damage beyond single exposures.

3. Mechanistic Pathways Linking Climate Stressors to Skin Ageing

3.1. Extracellular Matrix (ECM) Degradation

One of the hallmarks of extrinsic skin ageing is the breakdown of collagen and elastin, the structural proteins that maintain dermal integrity. Both UV radiation and pollutants upregulate matrix metalloproteinases (MMP-1, MMP-3, MMP-9), which degrade ECM proteins.[14] UVA penetrates into the dermis, activating AP-1 and NF-κB signaling that stimulate MMP transcription, while ozone oxidizes skin lipids to bioactive mediators that further enhance MMP expression.[15] Clinically, these processes manifest as coarse wrinkles, loss of elasticity, and sagging (Figure 2).

Figure 2. Mechanistic pathways from climate stressors to skin ageing.



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[14] J. Krutmann, W. Liu, L. Li, X. Pan, M. Crawford, *et al., Pollution and skin: from epidemiological and mechanistic studies to clinical implications*, in *J Dermatol Sci*, 76, 3, 2014, 163-8.

[15] G. Bocheva, R.M. Slominski, A.T. Slominski, *Environmental Air Pollutants Affecting Skin Functions with Systemic Implications,* in *Int J Mol Sci*, 24, 13, 2023, 10502.

3.2. Oxidative Stress

Reactive oxygen species (ROS) are central mediators of environmentally induced ageing. UVA generates ROS such as singlet oxygen and superoxide, while ozone and PAHs contribute additional oxidative load.[16] Excess ROS overwhelms endogenous antioxidant defenses (e.g., catalase, superoxide dismutase, glutathione), leading to lipid peroxidation, protein oxidation, and DNA base modifications such as 8-oxo-deoxyguanosine.

Persistent oxidative damage depletes stem cell pools, accelerates telomere shortening, and drives cellular senescence in fibroblasts and keratinocytes.[17] The accumulation of senescent cells further amplifies tissue ageing via thesenescence-associated secretory phenotype (SASP), characterized by chronic inflammatory cytokine release.

3.3. Inflammaging

Environmental stressors provoke low-grade, persistent inflammation that contributes to inflammaging. UV irradiation activates pattern recognition receptors and inflammasomes, triggering secretion of IL-1β, TNF-α, and IL-6. Heat stress enhances NF-κB activation and cytokine expression.[18] Pollutants such as PM2.5 activate aryl hydrocarbon receptors, leading to pro-inflammatory gene transcription.

Over time, this chronic inflammation remodels dermal ECM, impairs barrier function, and establishes a pro-tumorigenic microenvironment.

3.4. Epigenetic Alterations

Epigenetic drift, accumulated changes in DNA methylation, histone modifications, and noncoding RNA profiles, represents another key link between climate stressors and skin ageing. Long-term exposure to elevated ambient temperature is associated with accelerated epigenetic ageing.[19] UV exposure alters methylation of tumor suppressor genes, impairing genomic stability. Heat and oxidative stress modify histone acetylation, altering transcription of genes regulating repair and antioxidant responses.[20]

These changes are not purely theoretical: miRNA signatures such as circulating miR-19a-3p and miR-19b-3p have been correlated with human ageing trajectories.[21] Epigenetic marks therefore represent both biomarkers of environmental ageing and potential therapeutic targets.

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[16] J.C. Fussell, F.J. Kelly, *Oxidative contribution of air pollution to extrinsic skin ageing,* in *Free Radic Biol Med,* 1, 151, 2020, 111-122.

[17] I. Khmaladze, M. Leonardi, S. Fabre, *The Skin Interactome: A Holistic "Genome-Microbiome-Exposome" Approach to Understand and Modulate Skin Health and Aging,* in *Clin Cosmet Investig Dermatol*, 13, 2020, 1021-1040.

[18] N. Singh, C. Wigmann, P. Vihay, *et al., Combined Effect of Ambient Temperature and Relative Humidity on Skin Aging Phenotypes in the Era of Climate Change: Results From an Indian Cohort Study,* in *Dermatitis*, 36, 1, 2025, 72-79.

[19] W. Ni, N. Nikolaou, C.K. Ward-Caviness, *et al., Associations between medium- and long-term exposure to air temperature and epigenetic age acceleration,* in *Environ Int*, 2023, 178.

[20] A. Cardenas, R. Fadadu, S. Bunyavanich, *Climate change and epigenetic biomarkers in allergic and airway diseases,* in *J Allergy Clin Immunol*, 152, 5, 2023, 1060–1072.

[21] C. Morsiani, L. Terlecki-Zaniewicz, S. Skalicky, *et al, Circulating miR-19a-3p and miR- 19b-3p characterize the human aging process,* in *Aging Cell*, 20, 7, 2021, e13409.

3.5. Mitochondrial Dysfunction

Mitochondria are particularly susceptible to oxidative insults due to limited DNA repair capacity. UVA and pollutants induce mitochondrial DNA (mtDNA) deletions, impairing oxidative phosphorylation and ATP production. Dysfunctional mitochondria release further ROS, creating a feed-forward loop of damage.[22]

This decline in bioenergetic capacity compromises fibroblast collagen synthesis and keratinocyte renewal, accelerating visible ageing. Moreover, mtDNA mutations are increasingly recognized in actinic keratoses and early carcinogenesis.[23]

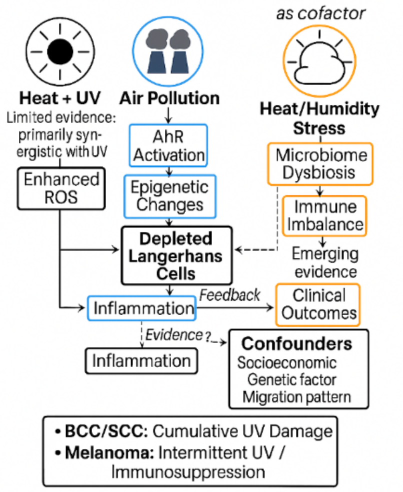
4. Mechanistic Pathways Linking Climate Stressors to Skin Carcinogenesis

While ageing and cancer share overlapping mechanisms, several distinct carcinogenic pathways emerge under climate change exposures.

4.1. Direct DNA Damage

UVB is the principal inducer of direct mutagenesis, forming cyclobutane pyrimidine dimers (CPDs) and 6-4 photoproducts. These lesions, if unrepaired, cause hallmark C→T transitions in p53 and other tumor suppressor genes.[24] UVA contributes indirectly via ROS, producing oxidative lesions such as 8-oxoguanine that mispair during replication (Figure 3).

Figure 3. Potential mechanistic pathways from climate stressors to the development of skin carcinogenesis.



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[22] I. Khmaladze, M. Leonardi, S. Fabre, *The Skin Interactome: A Holistic "Genome-Microbiome-Exposome" Approach to Understand and Modulate Skin Health and Aging,* in *Clin Cosmet Investig Dermatol*, 13, 2020, 1021-1040.

[23] T.P.G. Watson, M. Tong, J. Baillie, *et al., Relationship between climate change and skin cancer: a scoping review,* in *Public Health,* 227, 2024, 243–249.

[24] R.M. Lucas, S. Yazar, A.R. Young, *et al.*, *Human health in relation to exposure to solar ultraviolet radiation under changing stratospheric ozone and climate,* in *Photochem Photobiol Sci,* 18, 3, 2019, 641–680.

4.2. Pollutant-Driven Mutagenesis

Airborne PAHs (e.g., benzo[a]pyrene) penetrate skin, undergo metabolic activation by cytochrome P450 enzymes, and form bulky DNA adducts.[25] When combined with UV, DNA repair capacity becomes overwhelmed, escalating mutation rates. Heavy metals in PM2.5 also interfere with repair pathways, compounding mutagenesis.

4.3. Immunosuppression

UV radiation reduces cutaneous antigen-presenting cell function, particularly by depleting Langerhans cells and skewing T-cell responses toward tolerance. IL-10 and regulatory T-cell expansion create an immunosuppressive milieu.[26] Pollution exacerbates this by promoting oxidative stress and regulatory cytokine expression.[27] This immune dampening undermines tumor surveillance and facilitates malignant progression.

4.4. Microbiome Disruption

The skin microbiome is increasingly recognized as a modulator of carcinogenesis. Heat, humidity, and pollutants shift microbial communities, sometimes increasing pro-inflammatory taxa or reducing protective commensals.[28] Dysbiosis may promote carcinogenesis indirectly by altering immune tone and epithelial barrier integrity.

4.5. Synergistic Hazards

In practice, climate-linked stressors rarely occur in isolation; instead, the skin is exposed to clustered insults that interact non-linearly, producing damage greater than the sum of their parts Synergistic interactions magnify cancer risk:

- UV + PAHs: Mutagenic synergy through DNA adducts and ROS.
- UV + Ozone: Additive oxidative stress and lipid peroxidation.
- Heat + UV: Behavioral (less protective clothing) and biological (enhanced ROS) Amplification.[29]

Thus, climate change creates carcinogenic exposome clusters, rather than isolated risks.

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[25] E.R. Parker, *The influence of climate change on skin cancer incidence*, in *Int J Womens Dermatol*, 7, 1, 2020, 17–27.

[26] R.M. Lucas, S. Yazar, A.R. Young, *et al.*, *Human health in relation to exposure to solar ultraviolet radiation under changing stratospheric ozone and climate,* in *Photochem Photobiol Sci,* 18, 3, 2019, 641–680

[27] F.M. Isler, S.J. Coates, M.D. Boos, *Climate change, the cutaneous microbiome and skin disease,* in *Int J Dermatol,* 62, 3, 2023, 337–345.

[28] *Ibidem.*

[29] A. Anderson, F. Bruce, H.P. Soyer, C. Williams, R.B. Sauderson, *The impact of climate change on skin health*, in *Med J Aust*, 218, 9, 2023, 388–390.

5. Epidemiological Evidence

5.1. UV Radiation and Skin Cancer

Epidemiological links between UV exposure and skin cancer are long-established. Lifetime cumulative UV dose strongly predicts non-melanoma skin cancer (NMSC) incidence, with latitude-dependent gradients.[30] Recent modeling studies suggest climate-driven increases in UV could further elevate global skin cancer incidence by mid-century, particularly in regions with ozone thinning.[31]

Outdoor workers remain disproportionately affected. The WHO/ILO Joint Estimates project over 180,000 new NMSC cases annually worldwide attributable to occupational solar UV exposure.[32] However, the claim that 'nearly 30% of global NMSC between 2000– 2019 were attributable to occupational UV' is inaccurate; the WHO/ILO data indicates ~30% of NMSC deaths, not cases, though case estimates are similarly high.

5.2. Heat and Temperature Extremes

Heat itself is not traditionally classified as a carcinogen, but epidemiological signals are emerging. Analyses in Texas found higher melanoma incidence in regions with prolonged high temperatures, independent of UV dose, Global studies suggest female cancer mortality rises disproportionately with increasing mean annual temperature[17]. Moreover, heat influences behavioral risk factors, greater sun exposure during heatwaves, and may act biologically to enhance UV carcinogenicity.[33]

5.3. Air Pollution and Ageing

Cohort studies in Europe and Asia have linked chronic exposure to PM2.5 and NO2 with extrinsic ageing markers, including pigment spots, lentigines, and coarse wrinkles.[34] One German cohort showed significant associations between traffic-related pollution and facial lentigines in women >50 years.[35]

5.4. Air Pollution and Skin Cancer

Evidence linking pollution to cancer is less consistent. Mendelian randomization studies in European populations found no causal association between pollution and melanoma[36]. However, experimental da-

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[30] F. Pega, N.C. Momen, K.N. Streicher, *et al.*, *Global burden of NMSC attributable to occupational UV exposure,* in *Environ Int,* 181, 2023, 108226.

[31] S. Madronich, G.H. Bernhard, P.J. Neale, *et al.*, *Continuing benefits of the Montreal Protocol and protection of the stratospheric ozone layer*, in *Photochem Photobiol Sci*, 23, 6, 2024, 1087–1115.

[32] F. Pega, N.C. Momen, K.N. Streicher, *et al.*, *Global burden of NMSC attributable to occupational UV exposure,* in *Environ Int.,* 181, 2023, 108226.

[33] W.L. Kenney, D.H. Craughead, L.M. Alexander, *Heat waves, aging, and human cardiovascular health,* in *Med Sci Sports Exerc.,* 46, 10, 2014,1891-9.

[34] J.C. Fussell, F.J. Kelly, *Oxidative contribution of air pollution to extrinsic skin ageing,* in *Free Radic Biol Med,* 1, 151, 2020, 111-122.

[35] J. Krutmann, W. Liu, L. Li, X. Pan, M. Crawford, G. Sore, S. Seite, *Pollution and skin: from epidemiological and mechanistic studies to clinical implications*, in *J Dermatol Sci*, 2014, 76, 3, 163-8.

[36] M. Zhang, J. Wang, R. Huo, *et al.*, *Association between air pollution and skin cutaneous melanoma: A Mendelian randomization study,* in *Medicine* (Baltimore)*, 3,* 103, 18, 2024, e38050.

ta support plausible mechanisms, and observational studies in heavily polluted regions report higher NMSC incidence.[37]

5.5. Multiplicative Evidence

A 2024 scoping review synthesized climate-related influences on skin cancer, identifying UV, occupation, air pollution, and temperature as the strongest evidence-based factors, though interactions remain underexplored (Table 1). [38]

6. Vulnerable Populations

Climate change does not distribute risk equally. Specific groups face disproportionate vulnerability to skin ageing and cancer due to biology, occupation, or socioeconomic context.

6.1. Outdoor and Rural Workers

Agricultural, construction, and fisheries workers endure prolonged unprotected UV exposure. According to the WHO/ILO joint estimates, 30% of global non-melanoma skin cancer (NMSC) deaths between 2000–2019 were attributable to occupational UV exposure [19]. Rural populations also face limited access to dermatological services, compounding risk.[39]

6.2. Climate Migrants and Displaced Populations

Migration driven by desertification, flooding, and political instability can abruptly increase UV and heat exposure in populations unaccustomed to such climates. Limited healthcare access in refugee camps further exacerbates vulnerability.[40]

6.3. Immunocompromised Individuals

Patients with organ transplants or chronic immunosuppression experience amplified risk for UV- induced carcinogenesis. Climate-driven stressors may accelerate malignant progression by reducing immune surveillance.[41]

6.4. Children and the Elderly

Children's thinner skin and incomplete repair mechanisms make them more sensitive to cumulative photodamage, while elderly populations face reduced DNA repair and antioxidant capacity[10]. Moreover, heatwaves disproportionately affect elderly individuals with impaired thermoregulation[6].

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[37] M. Aryan Kya, *Geospatial Patterns of Non-Melanoma Skin Cancer in Relation to Climate Changes in Iran*, in *Asian Pac J Cancer Prev*, 25, 3, 2024, 1053–1063.

[38] T.P.G. Watson, M. Tong, J. Baillie*, et al., Relationship between climate change and skin cancer: a scoping review,* in *Public Health,* 227, 2024, 243–249.

[39] M.H. Fitzhugh, J. Wang, J.G. Powers, *Climate change and rural populations in dermatology,* in *Int J Womens Dermatol*, 11, 2, 2025, e214.

[40] G.S. Silva, M. Rosenbach, *Climate change and dermatology: introduction to a special issue, cit*., 7, 1, 2021, 3–7.

[41] A. Anderson, F. Bruce, H.P. Soyer, C. Williams, R.B. Sauderson, *The impact of climate change on skin health*, in *Med J Aust*, 218, 9, 2023, 388–390.

6.5. Low-Income Communities

Populations in low-income countries often experience “double exposure”: high UV/pollution levels and lack of access to sunscreen, shade, or dermatological care. Socioeconomic inequities create structural barriers to prevention.[42]

7. Prevention and Protective Strategies

Given the convergence of climate stressors on the skin, prevention requires an integrated, multi-level approach. Strategies must not only reduce acute exposures but also build resilience into the skin’s barrier, immune, and repair systems. Crucially, these measures should be contextualized within climate adaptation frameworks to ensure equity and accessibility for high-risk groups. The following subsections outline these synergistic strategies across behavioral, clinical, and structural levels to mitigate the dermatological burden of climate change.

7.1. Behavioral Measures

Behavioral prevention remains the first and most scalable line of defense. Because climate change amplifies both environmental dose (UV, heat) and behavioral drivers (time outdoors, lighter clothing), everyday habits can meaningfully bend risk curves when applied consistently.

- *Sun protection*: Consistent use of broad-spectrum SPF 30+ sunscreen, protective clothing, and hats.[43] This includes an emphasis on mineral sunscreens (zinc oxide, titanium dioxide), particularly tinted formulations which offer enhanced protection against high-energy visible light (HEVL), and the synergistic use of topical antioxidants like Vitamin C to neutralize free radicals that bypass sunscreen filters.
- *Behavioral campaigns*: Public health interventions like SunSmart in Australia have reduced melanoma incidence in younger cohorts.[44]

7.2. Clinical and Technological Measures

Clinic-based strategies complement individual behaviors by shifting prevention and detection ‘upstream.’ Advances in imaging, machine learning, and barrier-repair approaches can reduce diagnostic delays, blunt extrinsic ageing pathways, and selectively target high-risk patients.

- *Early detection*: AI-enhanced dermoscopy and segmentation tools improve diagnostic accuracy and can be deployed at scale.[45]

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[42] C.Y. Wright, D.J. Du Preez, D.A. Millar, *et al.*, *Epidemiology of skin cancer in Southern Africa,* in *Int J Environ Res Public Health*, 17, 3, 2020, 1017*;* R. Purcell, J. Mcgirr, *Rural health service managers’ perspectives on preparing for climate change,* in *Aust J Rural Health, 26, 1, 2018, 20–25.*

[43] B. Diffey, Climate change, ozone depletion and the impact on ultraviolet exposure of human skin. *Phys Med Biol*, 49, 1, 2004, R1–R11.

[44] J. Makin, *Implications of climate change for skin cancer prevention in Australia,* in *Health Promot J Austr,* 22, 2011, S39–S41.

- *Barrier restoration*: Antioxidant and anti-inflammatory skincare formulations can mitigate oxidative stress and extrinsic ageing.[46]
- *Chemoprevention*: Compounds such as nicotinamide show promise in reducing actinic keratoses and NMSC risk.[47]

7.3. Policy and Structural Measures

Because exposure is strongly shaped by the built and policy environment, durable gains require structural solutions. Urban form, workplace standards, and international treaties can lower population-level dose—especially for those least able to protect themselves.

- *Occupational protections*: Mandated provision of shade, clothing, and breaks for outdoor workers.[48]
- *Urban planning*: Increasing residential greenness and shaded environments reduces heat and UV burden.[49]
- *Global treaties*: The Montreal Protocol remains a landmark in reducing ozone-depleting substances and mitigating UV-related cancers.[50] (Table 2)

8. Research Gaps and Future Directions

Despite rapid progress, several high-leverage research gaps remain. Addressing them would clarify causality, quantify synergy, and accelerate the translation of findings into equitable prevention strategies:

1. *Synergistic exposures*: Few studies quantify how UV, heat, and pollution interact to accelerate ageing or carcinogenesis.
2. *Longitudinal cohorts*: Most evidence is cross-sectional; long-term cohort data stratified by climate zone are essential.[51]
3. *Equity lens*: Vulnerable populations, including climate migrants and immunocompromised groups, remain underrepresented.
4. *Translational research*: Development of low-cost, scalable interventions (e.g., antioxidant-enriched sunscreens, portable shade infrastructure) is critical for low-resource settings.

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[45] P. Thapar, M. Rakhra, D. Prashar, *et al.*, *Skin cancer segmentation and classification with hybrid ML,* in *PLoS One, 20, 6,* 2025, *e0322659;* J.L. Thomas, A.H.M. Heagerty, P. Goldberg Oppenheimer, *Emerging diagnostics for skin cancer,* in *Glob Chall*, 9, 5, 2025, 2400274.

[46] I. Khmaladze, M. Leonardi, S. Fabre, C. Messaraa, A. Mavon, *The Skin Interactome: A holistic genome–microbiome–exposome approach to skin health and ageing*, in *Clin Cosmet Investig Dermatol*, 13, 2020, 1021–1040.

[47] T.P.G. Watson, M. Tong, J. Baillie*, et al., Relationship between climate change and skin cancer: a scoping review,* in *Public Health,* 227, 2024, 243–249.

[48] Y. Buhr, I.M. Hübner, E.W. Breitbart, *UV protection in climate change: health policy relevance and necessary framework conditions*, in *Aktuelle Dermatologie*, 51, 12, 2025, 456-460.

[49] C.Y. Wright, D.J. Du Preez, D.A. Millar, *et al.*, *Epidemiology of skin cancer in Southern Africa,* in *Int J Environ Res Public Health*, 17, 3, 2020, 1017.

[50] S. Madronich, G.H. Bernhard, P.J. Neale, *et al*, *Continuing benefits of the Montreal Protocol and protection of the stratospheric ozone layer,* in *Photochem Photobiol Sci,* 23, 6, 2024, 1087–1115.

[51] T.P.G. Watson, M. Tong, J. Bailie, K. Ekanayake, R.S. Bailie, *Relationship between climate change and skin cancer: a scoping review*, in *Public Health*, 227, 2024, 243–249.

9. Conclusion

Climate change is reshaping the cutaneous exposome by amplifying UV radiation, temperature extremes, and pollutant exposure. Together, these factors accelerate skin ageing and increase skin cancer risk through mechanisms of oxidative stress, DNA damage, epigenetic drift, and immune dysregulation. Epidemiological evidence confirms rising NMSC and melanoma burden, particularly in outdoor workers and vulnerable populations.

Prevention requires a multilevel response: personal sun-safe behaviors, clinical innovation in detection and chemoprevention, and policy frameworks that protect high-risk populations. Equity must remain central, as climate change disproportionately harms the most exposed and least resourced.

Dermatology thus stands at a climate-health frontier, where integrating mechanistic insight with prevention strategies can mitigate the skin-related toll of a warming world.

Public Health and Regulatory Implications

Climate change poses a complex challenge at the intersection of environmental governance, public health, and the protection of fundamental human rights, including the right to health. The increasing burden of climate-related cutaneous aging and skin cancer represents not only a medical concern but also a regulatory and ethical issue, as preventable environmental exposures continue to disproportionately affect vulnerable populations.

Rising ultraviolet radiation, air pollution, and extreme heat events amplify cumulative skin damage and carcinogenic risk, raising questions of institutional responsibility in environmental protection and health prevention. From a biolaw perspective, the failure to integrate skin cancer prevention and dermatologic protection into climate adaptation policies may be viewed as a shortcoming in the implementation of preventive health obligations. Public authorities have a duty to ensure that climate-related health risks are adequately recognized, monitored, and mitigated through evidence-based regulation and public health interventions.

Moreover, climate-driven inequalities in exposure and access to dermatologic care highlight ethical concerns related to distributive justice and health equity. Outdoor workers, children, the elderly, and socioeconomically disadvantaged groups are often more exposed to environmental risk factors while simultaneously facing barriers to preventive services and early diagnosis. Strengthening regulatory frameworks that promote equitable access to sun-protective measures, occupational safeguards, and skin cancer screening programs is therefore essential to uphold principles of fairness and social responsibility.

Future Directions: Legal, Ethical, and Policy Perspectives

Future directions should emphasize the integration of skin health into climate-related legal and policy frameworks at both national and international levels. Regulatory strategies should explicitly acknowledge skin aging and skin cancer as climate-sensitive conditions and incorporate preventive dermatology into environmental health legislation, occupational safety standards, and urban planning policies.

The Right to Oblivion in a Comparative European Perspective

Gianluca Scarchillo*

ABSTRACT: This paper analyses the "Right to be 'medically' forgotten" – starting with a brief introduction on how this concept has evolved during the last decades – with specific regard to the medical field. It focuses on cancer survivors and their right to live a life without injustices and discriminations caused by the stigma of the disease. By using the comparative method, this work aims to address the European perspective on the issue, as well as the need for a more harmonised legal framework.

KEYWORDS: Oblivion; cancer survivors; legal medicine; comparative law; European law

1. Oblivion: From a Condemnation of Memory to a Legally Recognized Right

"Dimenticanza (non come fatto momentaneo, per distrazione o per difetto di memoria, ma come stato più o meno duraturo, come scomparsa o sospensione dal ricordo)":[1] with these words, the Treccani Encyclopedia defines oblivion, linking in no more than two lines the analyzed concept to *time*, which plays – as will be further outlined – a fundamental role in the essay. Indeed, the term *oblivion* does not refer to a temporary amnesia, but rather to an actual "scomparsa o sospensione dal ricordo": its consequences are eternal and definitive, and they erase every trace related to the object of forgetfulness.

In Ancient Rome, oblivion carried an extremely negative meaning: when serious convictions occurred, those people affected by the so-called *damnatio memoriae* experienced the erasure of every memory relating to their person and existence. No document, image or inscription would ever mention the name of the convicted person again, decreeing his disappearance from society – almost as that person had never existed. But while in the past oblivion was a punishment,[2] nowadays the situation has been re-

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[1] https://www.treccani.it/vocabolario/oblio/ (last viewed: 28/08/2025). Translation by the author: forgetfulness (not as a temporary occurrence, due to distraction or memory deficiency, but as a more or less enduring condition, such as disappearance or suspension from recollection.

[2] The term *damnatio memoriae* literally means "consignment to obscurity".

versed: the erasure of every reference to someone is no longer the nefarious consequence of a political measure, but rather a right (at least in abstract terms) safeguarded by law,[3] which allows its holder to prevent certain (unfavourable) information relating to his existence, by now outdated and no longer socially relevant, from continuing to cause him damages in the present.

Therefore, the right to oblivion can be defined as “il diritto a non restare indeterminatamente esposti ai danni ulteriori che la reiterata pubblicazione di una notizia può arrecare all’onore e alla reputazione di un soggetto”.[4] These few lines immediately reveal the two factors that most influence both the configuration and the limitation of the right in question: on the one hand, time, which is reflected in the adverb ‘*indeterminatamente*’ (indefinitely) as well as in the adjective ‘*reiterata*’ (repeated); on the other hand, the exposure of the person to media attention, which is evoked by the activity of ‘*pubblicazione di una notizia*’ (publishing information). Taking the analysis a step further, this definition also highlights the counterpart of the right to oblivion: since it involves the erasure of certain references – whose publication was considered lawful in the past – the right to oblivion inevitably conflicts with the freedom of the press and the freedom to be informed, risking to place individual interests above the needs of the community.

But let us take a step back. If, in general terms, the right to be forgotten entails the possibility for the applicant not to be indefinitely burdened by his or her past, one must ask which specific aspects of that past are being targeted for removal. This question necessarily prompts a reflection on the evolution that the right to be forgotten has undergone over the decades, as well as on the influence that progress – particularly of a technical and scientific nature – has exerted on its configuration and protection.

1.1. The Evolution of the Right to Be Forgotten and Its Different Meanings

The right to be forgotten is closely connected to the concepts of privacy and confidentiality; indeed, it may be said to belong “alle ragioni e alle regioni del diritto alla riservatezza”.[5] These are concepts whose protection is widely regarded as necessary within the European context. It is therefore unsurprising that the right to be forgotten has found its most significant expressions and its most substantial recognition in legal scholarship and case law of the Old Continent, which has always been attentive to the protection of human dignity and personal identity – spheres to which privacy and confidentiality are inevitably linked.

However, the idea of protecting individuals’ most intimate and private sphere did not originate in Europe, but in America – the very continent that is now known for being reluctant to grant extensive privacy rights to its citizens. In fact, it was two U.S. lawyers, Samuel D. Warren and Louis D. Brandeis, who questioned the need to protect individuals from invasions of privacy by journalists and photographers – a need that arose as a result of the development of society, which made it necessary to consider new

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[3] The use of the expression ‘in abstract terms’ is not random: although legally recognized, nowadays the right to oblivion still risks facing some obstacles in its concrete application and harmonization.

[4] C. Mistri, M.C. De Angelis, *I principali profili giuridici del diritto di cronaca e di critica nei più recenti interventi giurisprudenziali delle sezioni civili della Corte di cassazione*, in *Magistratura indipendente*, 2018. Translation by the author: the right not to be indefinitely exposed to further damage that the repeated publication of certain information may cause to a person’s honour and reputation.

[5] G.B. Ferri, *Diritto all’informazione e diritto all’oblio*, in *Riv. dir. civ.*, 1990, 808. Translation by the author: to the reasons and the realms of the right to confidentiality.

rights. It is no coincidence that their essay, entitled *The Right to Privacy* and published on December 15, 1890, in the *Harvard Law Review*, opens with a reflection on this very point: masterfully, the authors write ”That the individual shall have full protection in person and in property is a principle as old as the common law; but it has been found necessary from time to time to define anew the exact nature and extent of such protection. Political, social, and economic changes entail the recognition of new rights, and the common law, in its eternal youth, grows to meet the demands of society”.[6] They continue by explicitly mentioning the new inventions that have invaded the sacred boundaries of private and domestic life, stating that “Recent inventions and business methods call attention to the next step which must be taken for the protection of the person, and for securing to the individual what Judge Cooley calls the right ‘to be let alone’. Instantaneous photographs and newspaper enterprise have invaded the sacred precincts of private and domestic life; and numerous mechanical devices threaten to make good the prediction that ‘what is whispered in the closet shall be proclaimed from the house-tops’”.[7]

The purpose of their work is to verify whether there is a principle in law that can be invoked to protect individual privacy and, if so, to understand the nature and extent of the protection granted.[8] The article ends with a provocative question, which has prompted the global community to reflect on the issues arising from the invasion of privacy and the possibility of containing the intrusive tendencies of the media: in an almost theatrical manner, the Boston lawyers conclude their essay by writing that “The common law has always recognized a man’s house as his castle, impregnable, often, even to its own officers engaged in the execution of its commands. Shall the courts thus close the front entrance to constituted authority, and open wide the back door to idle or prurient curiosity?”.[9]

From the reflections of Warren and Brandeis, the point just stated clearly emerges: the concept of privacy – and, today, the related right to be forgotten – are intrinsically and inevitably linked to the freedom of the press. It is precisely to this freedom that American jurists make explicit reference when discussing the risks of the press and journalism, the main means of communication known in the nineteenth century. In this context, in which the world of the Internet was not even on the horizon, the previously mentioned definition of the concept of the ‘right to be forgotten’ fits well, from which it follows that any potential violation of such a right depends on the *reiterated* (and, therefore, *repeated*) publication of news harmful to the individual.

Today, however, this definition has become partly outdated: the technological evolution that Warren and Brandeis had already considered in their reflections has only intensified over the past decades, forcing legal practitioners to engage with an entirely new world that requires constant updates in the articulation and interpretation of rights.

In light of this, it is therefore appropriate to specify that, in modern times, the right to be forgotten does not have a single meaning; rather, with the advent of the digital era, three different interpretations[10] of this right can be identified today.

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[6] S.D. Warren, L.D. Brandeis, *The Right to Privacy*, in *Harvard Law Review*, 4(5), 1890, 193.

[7] *Ivi*, 195.

[8] *Ivi*, 197: “It is our purpose to consider whether the existing law affords a principle which can properly be invoked to protect the privacy of the individual; and, if it does, what the nature and extent of such protection is”.

[9] *Ivi*, 220.

[10] For an extensive discussion on this point, see G. Finocchiaro, *Il diritto all’oblio nel quadro dei diritti della personalità*, in *Diritto dell’informatica*, 4-5, 2014, 592 ss.

In brief, the first interpretation refers to the “diritto di un soggetto a non vedere pubblicate alcune notizie relative a vicende, già legittimamente pubblicate, rispetto all’accadimento delle quali è trascorso un notevole lasso di tempo”.[11] At this stage, no reference is made to the world of the Internet – the central aspect lies in the *republication* of news after a certain lapse of time.

However, the perspective changes in the second half of the twentieth century with the advent of the Internet and the World Wide Web: the republication of information loses its relevance, since “nella Rete l’informazione non è cancellata, ma permane disponibile o quantomeno astrattamente disponibile”.[12] If data is never truly deleted and always remains accessible to the users, who with a simple search can retrieve photos and articles uploaded online even many years earlier, then republication ceases to play the decisive role it once had, giving way instead to the *continuous online presence* of the data in question.

Finally, the third interpretation of the right to be forgotten refers to “al diritto alla cancellazione, al blocco, al congelamento dei dati o all’opposizione al trattamento dei dati previsti dalla Direttiva 95/46/CE”.[13] Although this Directive is no longer in force,[14] this understanding of the right remains valid and highly relevant today and it is closely connected to the protection of personal data: indeed, it enables the data subject to request the deletion of information stored in digital networks and to object to its processing.[15]

1.2. A “Fourth Interpretation”: Oncological Oblivion

Having made this necessary general premise concerning the right to be forgotten, we can now turn our attention to another, more specific interpretation of this right which might perhaps be regarded as a fourth and distinct meaning. The notion of *oblivion* underlies a particular right that has only recently gained recognition within European legal systems, one that transcends the strictly legal domain to intersect with the medical and healthcare sphere: the so-called oncological oblivion, or the “diritto ad essere ‘medicalmente’ dimenticato”.[16] This legal category belongs to the broader framework of citizens’ rights

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[11] *Ibid*. Translation by the author: right of an individual not to have certain news published concerning events, already lawfully reported, about which a considerable amount of time has passed.

[12] *Ibid*. Translation by the author: on the Internet, information is not erased but remains available, or at least potentially available.

[13] *Ibid*. Translation by the author: the right to erasure, to the blocking or freezing of data, or to object to the processing of data as provided for by Directive 95/46/EC.

[14] Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995, on the protection of individuals with regard to the processing of personal data and on the free movement of such data, was in fact repealed by 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 (the so-called GDPR, *General Data Protection Regulation*).

[15] Art. 4 (2) GDPR “processing means any operation or set of operations which is performed on personal data or on sets of personal data, whether or not by automated means, such as collection, recording, organisation, structuring, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, restriction, erasure or destruction”.

[16] Translation by the author: right to be ‘medically’ forgotten. The quote is taken from M. Mezzanotte, *Brevi note in tema di diritto ad essere ‘medicalmente’ dimenticato: il caso del diritto all’oblio ontologico*, in *Consulta OnLine*, 2, 2023, 486 ss. It should be noted, however, that not everyone considers the use of the expression *‘oblio oncologico’* appropriate from a technical-legal perspective. On this point, see, among others, M. Faccioli, *Il diritto all’oblio on-*

not to disclose their clinical information once they have recovered from certain categories of diseases, with the aim of ensuring the full and satisfactory reintegration of former patients into society – thus preventing discrimination in specific areas such as employment, insurance, or even adoption proceedings.

It is a view that may indeed be shared that the right to be forgotten is not merely "uno schermo contro l'informazione"[17] rather, it is, in general terms, "uno strumento di protezione dell'individuo contro tutti quei dati che non sono più aggiornati in relazione a una condizione attuale, che ne distorcono le sembianze e che non lo rappresentano più agli occhi della collettività con le peculiarità che ha, in presenza di un interesse che deve essere considerato prevalente".[18] From this perspective, medical information too may be considered detrimental to an individual's image and reputation within society, in cases where, despite having recovered, the person continues to be stigmatized for a previous clinical condition. It is in this sense, therefore, that we can speak of a right to be forgotten within the medical and healthcare domain.[19]

The recognition of this type of right allows cancer survivors[20] not to endure indefinitely the consequences of the illness that affected them: those who have already faced a difficult path to recovery "shouldn't have to pay twice for their diagnosis".[21] Indeed, having already endured the physical, psychological, and

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cologico nella l. n. 193/2023: la via italiana alla tutela giuridica dei cancer survivors, in *BioLaw Journal – Rivista di BioDiritto*, 1, 2024, 92 ("Tale sintagma è senza dubbio efficace ed evocativo sul piano del linguaggio comune, ma dal punto di vista tecnico-giuridico appare piuttosto lontano dal modo in cui viene comunemente inteso il c.d. diritto all'oblio nella moderna società dell'informazione", translation by the author: this phrase is undoubtedly effective and evocative in terms of common language, yet from a technical-legal point of view it appears rather distant from the way in which the so-called right to be forgotten is commonly understood in the modern information society).

[17] M. Mezzanotte, *op. cit.*, 486. Translation by the author: a shield against information.

[18] *Ibid.* Translation by the author: a tool for the protection of the individual against all those data that are no longer up to date with respect to his or her present condition, that distort his or her image, and that no longer represent him or her in the eyes of the community in accordance with the characteristics he or she currently possesses, in the presence of an interest that must be regarded as prevailing. Continuing (487), the Author states, with specific reference to the right to oncological oblivion: "a differenza della *privacy* storica intesa come quel diritto a negare che fatti un tempo resi pubblici con i media tornino all'attenzione della collettività, il diritto all'oblio oncologico consente la cancellazione dei dati personali in ragione del tempo trascorso dalla fine dei trattamenti sanitari senza che la patologia sia ricomparsa". Translation by the author: unlike privacy in relation to past events, understood as the right to prevent facts once made public by the media from resurfacing to the attention of the community, the right to oncological oblivion allows for the erasure of personal data by reason of the time elapsed since the end of medical treatments, provided that the disease has not reappeared.

[19] In the scientific literature on the subject, the right to be forgotten in the medical field is examined with specific reference to cancer survivors. Although this is statistically the area in which former patients are most frequently subjected to discrimination on account of their clinical history, the right to be forgotten may more generally apply to other diseases as well (e.g. hepatitis C). In what follows, therefore, references will mainly concern cancer survivors, without losing sight, however, of the fact that the right to be forgotten-conceived as an instrument serving the protection of human dignity and confidentiality-ought to safeguard all categories of patients.

[20] For the rationale behind the use of this expression, see the previous note.

[21] The quote is taken from M. Lawler, F. Maunier, *Don't make cancer survivors pay-twice – the right for them to be "forgotten" should be law everywhere*, in *BMJ*, 2022. Similarly, L. Borgia, *I diritti umani oltre la malattia: i sopravvissuti al cancro e il diritto all'oblio oncologico*, in *Archivio giuridico online*, 2, 2023, 903; refers to a 'doubling of the penalty' that prevents cancer survivors from returning to a normal life.

financial[22] repercussions of the illness they have fought, these individuals should not be forced to bear its aftermath also on the social level – something that would occur if they were not guaranteed a position of full equality with those who have 'always been healthy'. When higher insurance prices are imposed on former patients (on the assumption that their risk of default is greater), or differentiated working conditions are established for them (with resulting economic disparities), or when the process of adopting a child is made more difficult (thus hindering the creation of stable emotional and family bonds), the individual ceases to be an insured person, an employee, or an adoptive parent – like anyone else in the same position – and once again becomes a 'patient', subjected this time not to the care of a doctor, but to the prejudices of society. In this regard, one may speak of a "categoria di cittadini 'fantasma' in attesa di un *exitus* sancito non dalla scienza, ma dalla società: sono i cosiddetti 'lungo-sopravvissuti' (*long survivors*) per i quali non viene mai assicurato il 'fine pena' sociale".[23]

1.2.1. The Mother's Right to Be Forgotten: Anonymous Childbirth and the Right of Access to One's Origins

The right to be 'medically' forgotten does not, however, end with the protection of those who have successfully overcome certain diseases. This right may also take shape in the woman's claim, as a mother giving birth, not to be mentioned on her child's birth certificate.

The legal tool in question is known as anonymous childbirth, deriving from the mother's request not to be identified. Such prerogative is granted to her under Article 30 of D.P.R.[24] no. 396 of 3 November 2000,[25] and responds to the need to prevent abortions and child abandonment.

This article must, moreover, be read in conjunction with Article 93, paragraph 2 of Decree[26] no. 196 of 30 June 2003, which provides that the medical record containing data identifying the anonymous mother may be released, to those having an interest and in accordance with the law, once one hundred years have elapsed since its creation:[27] it is thus established that access to information concerning the woman

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[22] Related to financial consequences, the terms *financial toxicity* and *financial distress* are commonly used.

[23] L. BORGIA, *op. cit.*, 893. Translation by the author: a category of 'ghost' citizens awaiting an *exitus* sanctioned not by science but by society: they are the so-called 'long survivors,' for whom the 'end of sentence' is never socially granted. With regard to the subject of oncological oblivion and the protection of cancer survivors, see below for a more in-depth analysis.

[24] Decreto del Presidente della Repubblica.

[25] "1. La dichiarazione di nascita è resa da uno dei genitori, da un procuratore speciale, ovvero dal medico o dalla ostetrica o da altra persona che ha assistito al parto, rispettando l'eventuale volontà della madre di non essere nominata". Translation by the author: The declaration of birth may be made by one of the parents, by a special attorney, or by the physician, midwife, or other person who attended the delivery, in compliance with the mother's possible wish not to be named.

[26] Decreto legislativo (D. lgs).

[27] "2. Il certificato di assistenza al parto o la cartella clinica, ove comprensivi dei dati personali che rendono identificabile la madre che abbia dichiarato di non voler essere nominata avvalendosi della facoltà di cui all'articolo 30, comma 1, del decreto del Presidente della Repubblica 3 novembre 2000, n. 396, possono essere rilasciati in copia integrale a chi vi abbia interesse, in conformità alla legge, decorsi cento anni dalla formazione del documento". Translation by the author: the certificate of assistance at birth or the medical record, where containing personal data identifying the mother who has declared her wish not to be named pursuant to Article 30, paragraph 1, of Presidential Decree no. 396 of 3 November 2000, may be released in full copy to those with a legitimate interest, in compliance with the law, once one hundred years have elapsed from the document's creation.

who does not wish to be named is precluded "per un periodo ascrivibile all'intero arco della vita sia della madre che del figlio".[28]

At the legislative level, mention must also be made of Article 28, paragraph 7 of Law no. 184 of 4 May 1983, which expressly excludes the possibility for an adopted person to access information regarding his or her origins and the identity of biological parents in cases where the mother has exercised the right not to be declared in the birth certificate.[29]

Given the absence of a normative balance between the mother's right to remain anonymous and the adoptee's right to know their origins, the Constitutional Court, in its landmark judgment no. 278 of 2013, declared the unconstitutionality of the aforementioned provision, insofar as it failed to allow the judge to contact the mother and ascertain whether her wish to remain unnamed persisted.[30] In doing so, the Court highlighted both the unreasonableness of the irrevocability of the mother's declaration and the divergence between the Italian solution and the solution provided under French law, which allows the woman to revoke her previously expressed dissent and ensures – borrowing the ECHR[31] phrasing – "sufficient proportion between the competing interests".[32]

More than a decade after the decision of the Constitutional Court, the Italian legal system still lacks legislation governing the balancing of interests in the matter of anonymous childbirth. In some cases, this may result in an excessive sacrifice of the child's position: it is sufficient to recall, for instance, the importance, in the medical field, of prevention and of the knowledge of family medical history – something that is difficult to reconstruct in the absence of information about the biological parents. In the healthcare context, therefore, the choice of anonymous childbirth ensures the woman's safety and self-

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[28] G. TOSCANO, *Prime riflessioni sul parto anonimo nell'ordinamento giuridico italiano*, in *Actualidad Juridica Iberoamericana,* 17 bis, 2022, 743. Translation by the author: for a period encompassing the entire lifespan of both the mother and the child.

[29] "7. L'accesso alle informazioni non è consentito nei confronti della madre che abbia dichiarato alla nascita di non volere essere nominata ai sensi dell'articolo 30, comma 1, del decreto del Presidente della Repubblica 3 novembre 2000, n. 396". Translation by the author: access to information is not permitted with regard to the mother who, at the time of birth, declared her wish not to be named pursuant to Article 30, paragraph 1, of Presidential Decree no. 396 of 3 November 2000.

[30] The Court "dichiara l'illegittimità costituzionale dell'articolo 28, comma 7, della legge 4 maggio 1983, n. 184 (Diritto del minore ad una famiglia), come sostituito dall'art. 177, comma 2, del decreto legislativo 30 giugno 2003, n. 196 (Codice in materia di protezione dei dati personali), nella parte in cui non prevede – attraverso un procedimento, stabilito dalla legge, che assicuri la massima riservatezza – la possibilità per il giudice di interpellare la madre – che abbia dichiarato di non voler essere nominata ai sensi dell'art. 30, comma 1, del d.P.R. 3 novembre 2000, n. 396 (Regolamento per la revisione e la semplificazione dell'ordinamento dello stato civile, a norma dell'articolo 2, comma 12, della legge 15 maggio 1997, n. 127) – su richiesta del figlio, ai fini di una eventuale revoca di tale dichiarazione". Translation by the author: the Court declares the unconstitutionality of Article 28, paragraph 7, of Law no. 184 of 4 May 1983 (Right of the child to a family), as replaced by Article 177, paragraph 2, of Legislative Decree no. 196 of 30 June 2003 (Personal Data Protection Code), insofar as it does not provide – through a procedure established by law, ensuring the utmost confidentiality – for the possibility of the judge contacting the mother, who has declared her wish not to be named pursuant to Article 30, paragraph 1, of Presidential Decree no. 396 of 3 November 2000 (Regulation on the revision and simplification of civil status law, under Article 2, paragraph 12, of Law no. 127 of 15 May 1997), upon request of the child, for the purposes of a possible revocation of such declaration.

[31] European Court of Human Rights.

[32] *Case of Odièvre v. France* (Application no. 42326/98), ECHR, 13 February 2003.

determination; at the same time, however, it may give rise to significant diagnostic difficulties, which call for greater attention from the legislature in future regulatory interventions on the subject.

2. Focus: The Right to Oncological Oblivion

Although the right to be 'medically forgotten' may assume different forms within the medical field and, even within the same sphere of information concerning previous illnesses, may refer to a variety of pathological situations, attention should now be focused on a specific right – already mentioned in the course of this paper – that constitutes the cornerstone of the discipline of oblivion in the healthcare sector: the right to oncological oblivion.

To do so, we must begin with a definition of the subjective legal situation under consideration: it consists of a sort of "*privacy* storica dei dati sanitari, in cui il diritto all'identità personale (inteso come situazione medica attuale) rappresenta il punto di riferimento fondamentale, da intendersi come la pretesa ad essere rappresentati secondo lo stato di salute attuale".[33] Also in the medical field, therefore, the key concepts around which the notion of oblivion revolves are privacy—linked to confidentiality and respect for human dignity-and contemporaneity: health data,[34] in fact, as they reveal information about the individual's state of health, can only be regarded as an expression of his or her personal identity; at the same time, the actuality of one's health condition inevitably recalls the element of time, that variable which profoundly affects the balancing of conflicting interests in matters concerning oblivion. The right to confidentiality of personal data, to which the right to be forgotten belongs, also encompasses the protection of individual choices regarding health: Those who are ill must not only be able to decide freely to whom, how, and when to disclose the medical information concerning them, but they must also be placed in the position of not being compelled to share such information with potential employers, insurers, or judicial authorities once they have recovered and a sufficient period of time[35] has elapsed – on the basis of medical-scientific studies – to presume that the disease will not recur. It may be argued that the erasure of the memory of the illness constitutes the final step in the recovery process: from this perspective, the right to oncological oblivion is not merely an instrument enabling the normal reintegration of the recovered patient into social life, but also a means of fully restoring the individual's health. The exclusion and discrimination that survivors risk facing may, indeed, have a serious and detrimental impact on their psychological and mental health, which deserves to be safeguarded no less than their physical health.

In order to fight cancer not only as a *disease* but also as a *stigma*, in recent years a significant debate has arisen at the European level on the right to be 'medically' forgotten. From this perspective, of extraordi-

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[33] M. Mezzanotte, *op. cit.*, 487. Translation by the author: privacy in relation to past health data, in which the right to personal identity (understood as one's current medical condition) constitutes the fundamental point of reference, to be conceived as the claim to be represented in accordance with one's current state of health.

[34] The GDPR defines "data concerning health» as «personal data related to the physical or mental health of a natural person, including the provision of health care services, which reveal information about his or her health status" (Article 4(1)(15) of Regulation (EU) 2016/679).

[35] Approximately, this is a period ranging from five to ten years.

nary importance has been the adoption by the European Parliament of a resolution[36] calling on the Member States to introduce regulation on the oncological oblivion by 2025, as well as the publication of a Communication by the European Commission[37] highlighting the need to improve the quality of life of cancer patients and survivors.

2.1. The Regulation of the Right to Be Forgotten in Italy: Law No. 193/2023

In response to the appeals emanating from European institutions, Italy[38] has likewise enacted legislation aimed at "the prevention of discrimination and the safeguarding of the rights of individuals who have been affected by oncological diseases". Specifically, Law No. 193 of 7 December 2023, which came into force on 2 January 2024, "establishes provisions relating to equal treatment, non-discrimination, and the guarantee of the right to be forgotten for persons who have recovered from oncological conditions".

The legislation, under Article 1, first provides a strictly legal definition of the right at issue, which is understood as the right of survivors "di non fornire informazioni né subire indagini in merito alla propria pregressa condizione patologica".[39]

The statutory provisions then proceed to specify the circumstances in which such right applies. Article 2, entitled 'Accesso ai servizi bancari, finanziari, di investimento e assicurativi' (Access to banking, financial, investment, and insurance services), prohibits, for the purpose of entering into or renewing contracts in these sectors, the requirement that the contracting party disclose information regarding oncological diseases, provided that ten years have elapsed since recovery and no recurrence has occurred. Where the illness manifested prior to the age of twenty-one, this period is halved – to five years from the date of recovery.

Article 3 amends Law No. 184 of 4 May 1983 concerning adoption, excluding oncological diseases from the scope of health assessments of prospective adoptive parents – always subject to the temporal conditions aforementioned. Similarly, Article 4 contains analogous provisions relating to access to 'competitive examinations and selection procedures, employment, and vocational training'.

Article 5, finally, containing 'Disposizioni transitorie e finali' (Transitional and final provisions), entrusts the Data Protection Authority with oversight of the implementation of the law in question. Furthermore, paragraph two anticipates the definition – by decree of the Ministry of Health[40] – of the list of oncological diseases for which shorter periods than those provided in the preceding articles may apply. This as-

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[36] European Parliament resolution of 16 February 2022 on strengthening Europe in the fight against cancer — towards a comprehensive and coordinated strategy (2020/2267(INI)): the European Parliament "requests that by 2025, at the latest, all Member States should guarantee the right to be forgotten to all European patients 10 years after the end of their treatment, and up to five years after the end of treatment for patients whose diagnosis was made before the age of 18".

[37] Communication from the commission to the European Parliament and the Council Europe's Beating Cancer Plan (COM/2021/44 final) of 3 February 2021: "Europe's Beating Cancer Plan aims not only to ensure that cancer patients survive their illness, but that they live long, fulfilling lives, free from discrimination and unfair obstacles".

[38] Prior to the Resolution referred to in the preceding paragraph, several European countries had already enacted legislation in this area: France, Belgium, Luxembourg, and the Netherlands. Today, in addition to Italy, Portugal, Romania, and Spain have also adopted laws on the subject.

[39] Translation by the author: not to disclose information or to undergo inquiries concerning their prior pathological condition.

[40] To this end, Decree No. 22 of 22 March 2024 was adopted, published in the *Official Gazette* on 24 April 2024.

pect should not be underestimated, as it demonstrates the foresight of the legislator, who is aware of the differences among various types of cancer – not all of which are comparable in terms of prognosis and hospitalization timelines. Accordingly, Article 5, paragraph 2 of Law No. 193/2023 "sembra muovere proprio dall'esigenza di rendere il dettato normativo più rispondente alla complessità della realtà e dei costanti sviluppi delle cognizioni medico-scientifiche".[41]

The introduction of *ad hoc* legislation on oncological oblivion within the Italian legal system undoubtedly represents a significant achievement for *cancer survivors*; yet, within the broader category of former patients, those who have recovered from cancer are not the only ones at risk of having their rehabilitation process compromised due to prejudice and consequent discrimination suffered in the workplace and society at large. Indeed, other illnesses may give rise to similar reintegration difficulties within the community. The risk, with legislation that is excessively 'sectoral', lies in bridging the gap between the 'healthy' and the 'recovered' while simultaneously creating new distinctions in treatment among different categories of recovered individuals.[42]

From this perspective, the hope is to guarantee the broadest possible scope of protection for *all* survivors, regardless of the type of illness overcome – perhaps this objective will be achieved through the addition of further provisions concerning other diseases, or, at the case law level, through an expansive interpretation of the provisions introduced by the legislator.

2.2. A Comparative Overview: Foreign Legislation on the Right to Oblivion

Even before the publication of the European Parliament Resolution, issued on 16 February 2022 with the aim of strengthening Europe in the fight against cancer, citizens of some European countries enjoyed the right to be forgotten in relation to cancer. Today, however, European legislations on the subject are largely aligned, also in light of the intervention of the European Union, which has urged those Member States still lacking specific regulations in this area to take action in order to ensure effective protection for cancer survivors.

A first comparative reference can only be made with regard to France, whose legislation on the right to be forgotten is now almost ten years old: the first French law on the subject dates back to 28 January 2016 and is (still today) contained in Article L. 1141-5 of the Code de la santé publique.[43] Under this article, people who have suffered from cancer cannot be discriminated against in the insurance field, and information relating to their clinical situation can no longer be collected after a period of ten years from the end date of the treatment protocol – a period that is halved if the disease arose before the age of 18. The first part of this provision is still valid and in force today; nevertheless, changes have recently been made with regard to the time interval between the end of treatment and the realisation of the right to be forgotten. Starting from 2 March 2022, indeed, the period after which information on the disease becomes irrelevant for insurance purposes has been reduced to five years in all cases (regard-

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[41] B. Perego, *Dati sanitari e profili discriminatori: il caso dei "cancer survivors" alla luce della legge n. 193/2023 in materia di oblio oncologico*, in *Osservatorio costituzionale*, 2, 2024, 88–89. Translation by the author: appears to stem precisely from the need to render the normative framework more responsive to the complexity of reality and to the ongoing developments in medical-scientific knowledge.

[42] On this point, see the reflections of M. Faccioli, *op. cit.*, 91.

[43] For regulatory reference, please see https://www.legifrance.gouv.fr/codes/article_lc/LEGIARTI000045272010 (last viewed: 30/08/2025).

less of the age at which the person fell ill). This is the first point of difference between French and Italian legislation, to which is added the possibility, under French law, of extending the provisions on cancer oblivion to diseases other than cancer – in particular, chronic diseases – provided that science demonstrates the ability of treatments to significantly and lastingly limit the effects of the diseases at issue. Finally, the difference in the fields of application of the law should not be underestimated: no reference is made in the legislation examined to sectors other than insurance.

The EU resolution was preceded by legislation in the Netherlands, which regulated the issue of cancer oblivion with the decree of 2 November 2020 on insurance assessments of former cancer patients.[44] The title of the decree makes it clear that, in this case too, the scope of the legislation is limited to the insurance sector (as in France). The provision in Article 2 of the decree is interesting, according to which 'the question of whether a candidate has been diagnosed with cancer in the past constitutes a disproportionate violation of privacy': the explicit reference to the concept of privacy emphasises the important link between the right to be forgotten (including in the healthcare sector) and the right to confidentiality. The conditions that prevent such a disproportionate intrusion into a person's most intimate sphere are now clear: the full recovery of the individual and the passage of a reasonable period of time since the end of the illness, which in the Netherlands is ten years (or five if the subject was under 21 at the time of diagnosis) – just as in Italy.

These regulations have undoubtedly provided the basis for further reflection on the oncological oblivion at the European level,[45] contributing to the aforementioned Resolution of the European Parliament, which also prompted a few Member States to regulate this field.

After the European Resolution and before Italy, Romania also adopted the Law n. 200 of July 7, 2022[46] (to enact the Law on patients' rights n. 46/2003) to protect former oncological patients.

Once again, the right not to provide information or documents concerning one's oncological condition applies solely to the insurance sector. In this case, it is important to observe the timing: indeed, in this case, there is a middle ground between the timelines examined so far, with a seven-year limit within which it is possible to request oncological information (five years if the diagnosis occurred before the individual turned 18 years old).

Finally, the most recent European country to address the issue has been Spain, with Real Decreto-ley 5/2023 (of 28 June),[47] which, as part of a broader legislative reform, provides for the nullity of any clause or agreement excluding from the conclusion of a consumer contract those who have suffered from cancer,[48] as well as for the prohibition on requesting oncological information once five years have elapsed since the completion of medical treatment, provided that no relapse has occurred.

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[44] Please refer to the website https://zoek.officielebekendmakingen.nl/stb-2020-453.html (last viewed: 30/08/2025).

[45] Indeed, we mentioned here the laws of France (the firsts in Europe) and the Netherlands (with similarity to the Italian model from a temporal point of view). However other countries already had their own legislation on the right to be forgotten before the European Resolution (Belgium and Luxembourg). Moreover, today also Portugal has a law on the oncological oblivion. For further information, please refer to the literature on the topic, including: M. FACCIOLI, *op cit.*, 78 ss.; M. MEZZANOTTE, *op. cit.*, 488 ss.; B. PEREGO, *op. cit.*, 70 ss.

[46] Full text available at: https://legislatie.just.ro/Public/DetaliiDocumentAfis/257381 (last viewed: 30/08/2025).

[47] Full text available at: https://www.boe.es/eli/es/rdl/2023/06/28/5/con (last viewed: 30/08/2025).

[48] The same applies to people living with HIV (*Human Immunodeficiency Virus*)/AIDS (*Acquired Immunodeficiency Syndrome*).

In summary, the Member States' legislations on oncological oblivion seem very similar, all seeking the safeguard of the dignity of former oncological patients. These legislations also foresee the ban on collecting data on the former oncological patients' health conditions once complete recovery can be assumed, based on the assessments of the medical-scientific community.

A few differences, already mentioned in this comparative analysis, remain: first, it is clear that the Italian legislator sought to establish a high level of protection for former patients, not only through the prohibition on the collection and processing of data in insurance contracts. Indeed, the Law n. 193/2023 protects the person who has healed from cancer, even in the access to job positions and in the adoption process – unlike what happens in other countries.

An additional point of divergence among the legal systems under examination concerns, as anticipated, the temporal dimension. In Italy (as well as in the Netherlands), a period of ten years must elapse from the conclusion of therapy before the patient's medical data cease to be usable for the purposes identified by the relevant legislation. By contrast, it happens that in other European jurisdictions the timeframes are different. France and Spain provide, for example, a period of five years; Romania, on the other hand, has opted an intermediate solution (seven years). Based on these considerations, we can – and indeed *must* – highlight the risk of discrimination among former oncology patients within the European Union: depending on the Member State, the period during which an individual continues to be deemed 'not socially cured' varies significantly – being in some cases even double compared to others. This will exert a substantial impact on the opportunities to be reintegrated as a fully-fledged member of society and, as a consequence, will influence the individual's overall state of health.

According to the guidelines of the European Society for Medical Oncology (ESMO), after five years from the completion of treatment, the risk of relapse for former patients becomes equivalent to the general risk of the healthy population of developing the disease *ex novo.*[49] It would therefore be appropriate for the European Union to intervene in order to further harmonize legislations on the right to oncological oblivion, thereby giving normative effect to the indications emerging from the scientific community and, above all, in order to reduce the risk of discriminations.[50]

3. Concluding and Prospective Remarks

When personal identity is at stake, history belongs to the individual who has written it: in all cases where someone's experience does not bear public relevance, that person should be able to retain mastery over the information concerning he or her. This applies both with regard to the right to be forgotten in the strict sense, as everyone's right not to remain indefinitely exposed to potentially harmful in-

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[49] https://www.esmo.org/press-releases/the-right-to-be-forgotten-esmo-calls-on-eu-countries-to-ensure-equal-financial-rights-for-cancer-survivors (last viewed: 08/31/2025): "By five years, most cancers, if not all, have a risk of relapse which is considerably decreasing to a point where it likely becomes smaller than the risk of developing a new cancer, which is a risk shared by all healthy individuals".

[50] G. Scocca, F. Meunier, *Towards an EU legislation on the right to be forgotten to access to financial services for cancer survivors*, in *European Journal of Cancer*, 162, 2022, 136. "A Pan-European solution based on the implementation of the RTBF is feasible within current treaties and seems the best approach to tackle the issue. The EU Action would provide a common and harmonised regulatory framework among the Member States to avoid discrimination and ensure equality among EU citizens being cured of cancer".

formation, and in the broader sense, as the right not to suffer discrimination for each one's history (including medical history). What follows is a serious impairment of fundamental rights: as has been shown, the right to be forgotten is firmly rooted in the concepts of privacy, confidentiality, and human dignity. A failure to protect the right to 'forgetfulness' thus translates into a failure to protect the individual.

Applied to oncological oblivion, "la prassi, ormai vietata in Italia ma ancora ammessa in altri ordinamenti, di acquisire informazioni sulla salute e sulle condizioni cliniche pregresse a fini assicurativi, di accesso ai servizi bancari, nei concorsi pubblici e nelle procedure di adozione, dimostra come la storia clinica […] possa costituire un ostacolo al pieno esercizio dei diritti fondamentali".[51]

All this is confirmed by the testimonies of cancer survivors: due to their cancer history, it often proves difficult for those who have overcome the disease to achieve financial independence, with serious repercussions also on their mental health[52] and, consequently, on the healing process itself. It has become increasingly clear that the illness may significantly aggravate not only the clinical condition of patients and/or survivors, but also their overall quality of life: survivors are more likely to suffer from stress and depression,[53] a condition that is further exacerbated when their reintegration into society is hindered by entrenched prejudices regarding the disease and its consequences. Breaking the vicious cycle of disease–psychopathology–disease is therefore essential, by intervening in the quality of life of patients (and former patients) and by improving the system of support available to them – starting from legislative measures such as those examined in this study, aimed at eliminating discrimination against cancer survivors.

Whether it concerns intrusions into private life or discrimination stemming from medical history, human dignity must be respected and safeguarded in every domain. On the one hand, harmful news damaging the reputation of an individual, relating to past events for which no legitimate public interest any longer exists, may threaten his or her full social reintegration, once again imposing a stigmatizing label on that person. On the other hand, reintegration into the community also proves difficult for those who, having already endured serious illnesses, must still cope, after recovery, with prejudices about their health status and life expectancy. Regardless of the interpretation attributed to the right to be forgotten, it is undeniable that today it represents a primary safeguard, intended to meet the need to protect privacy and human dignity – across the social, occupational, emotional, financial, and familial domains.

Oncological oblivion, particularly, constitutes an important victory in the fight against cancer, as it enables those who have already won the medical battle to avoid subsequently experiencing a form of 'social death' or even a further deterioration of their clinical condition. It is all too often overlooked that health

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[51] G. SDANGANELLI, *Il diritto all'oblio oncologico e i limiti all'uso dei dati sanitari nell'assicurazione digitale*, in *Federalismi.it*, 12, 2025, 247. Translation by the Author: the practice, now prohibited in Italy but still permitted in other jurisdictions, of acquiring information regarding health and past clinical conditions for insurance purposes, access to banking services, public recruitment, and adoption procedures, demonstrates how each one's clinical history […] may constitute an obstacle to the full exercise of fundamental rights.

[52] F. MEUNIER, *Protecting cancer survivors from financial discrimination throughout the EU: A cross-European perspective*, in *European Journal of Cancer*, 209, 2024.

[53] F. MASSONI, P. RICCI, M. CRUSCO, E. ONOFRI, L. PETRONE, C. SACCO, L. RICCI, M. RICCIARDI, T. ARCHER, S. RICCI, *Psychopatology and neoplastic disease: medico-social and medico-legal considerations*, in *Clinica Terapeutica*, 168 (1), 2017, 48-53.

is not merely physical but also mental:[54] preventing a relapse must not rely solely on appropriate medical check-ups, but also on the protection of mental health – a topic that, unfortunately, still suffers from inadequate awareness. Only the integration of physical, social, and mental well-being can ensure an adequate level of health for the individual, who – if deprived of one or more elements of this triad – risks seeing his or her ability to participate actively in society, as well as the possibility of leading a healthy life, seriously compromised.

The taken path – with the pressures coming from the EU environment for Member States to adopt legislation on the right to be forgotten – is definitely the right one. Anyway, when it comes to law there's always space for improvement, where improvement is taken to relate to the regulatory harmonization, stemming from a holistic and multifactorial approach, which would allow *real equality* not only among 'healed' and 'healthy' ones but also among the healed themselves across different legal systems.

Therefore, the next step could be the introduction of a real European legislation, in order to sustain, coordinate or complete the action of Member States. Having already determined – due to the 2022 Resolution – a clear improvement of former cancer patients' life conditions, it is to be hoped the prevision of a tighter protective framework of protection which harmonizes the subject matter at the European level (across different points of view: the temporal requirements for the application of the legislation, its fields of application, the diseases concerned, etc.).

Introducing the right to be forgotten, we began with ancient Rome – where the erasure of memories related to a person was a punishment (*damnatio memoriae*) – took a comprehensive journey, and reached the modern era, in which, sometimes, the memories themselves are a sentence. When considering oblivion in its classical meaning, the punishment is not forgetting but rather its opposite: the eternal collective memory of what happened, which doesn't allow the individual to move forward. Similarly, if we stare at the oblivion in what has here been defined as a 'Fourth Interpretation' (the right of being 'medically' forgotten), the punishment is the clinical history of the former diseased, which marginalizes him from society on the foundation, in this case, of a fatality (the disease) and not due to any fault.

It is therefore necessary to persevere along the path that is being followed, namely to continue to adapt the law to the new concept of oblivion, in order to avoid inequalities and discriminations – with full respect for human dignity, in order to ensure complete protection both during and after the disease. The protection of human dignity in the medical field comes from the combined provisions of Articles 2 and 32 of the Constitution,[55] which are mentioned at the beginning of Law No. 193 of December 7, 2023,

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[54] T. Archer, S. Ricci, F. Massoni, L. Ricci, M. Rapp-Ricciardi, *Cognitive Benefits of Exercise Intervention*, in *Clinica Terapeutica*, 167 (6), 2016, 180-85; on this point, see p. 182 "Health has been described variously to conform with a state of physical, mental and social well-being through which individuals apply their own abilities, cope with the normal stresses of life, live and work productively, fruitfully and constructively, with adequate community contribution".

[55] Article 2 states: "La Repubblica riconosce e garantisce i diritti inviolabili dell'uomo, sia come singolo sia nelle formazioni sociali ove si svolge la sua personalità, e richiede l'adempimento dei doveri inderogabili di solidarietà politica, economica e sociale". Translation by the author: the Republic recognises and guarantees the inviolable rights of the individual, both as an individual and in the social groups where human personality is expressed and requires the fulfilment of the mandatory duties of political, economic and social solidarity. Article 32 states: "La Repubblica tutela la salute come fondamentale diritto dell'individuo e interesse della collettività, e garantisce cure gratuite agli indigenti. Nessuno può essere obbligato a un determinato trattamento sanitario se non per disposizione di legge. La legge non può in nessun caso violare i limiti imposti dal rispetto della persona umana". Transla-

adopted in order to prevent discriminations and protect the rights of people who have been affected by oncological diseases. Similarly, the aforementioned articles also form the cornerstone of another very important normative act of healthcare legislation: Law No. 219 of December 22, 2017,[56] promulgated with the aim of protecting the right to life, health, dignity, and self-determination of the individual. We know, in fact, that the defense of human dignity requires respect for the privacy of the individual, which translates into the patient's *freedom of choice* to share informations about his health with relatives and family members (information that cannot be disclosed without his or her *consent*, in accordance with the relationship of trust established with the doctor). Conversely, in the phase following recovery, respect for individual confidentiality translates into the inadmissibility of requests for informations relating to the contractor's medical history, if the latter, by virtue of the time elapsed, is no longer considered relevant. Once again, thereby, human dignity is confirmed as the cornerstone of medical considerations and the essential point of balance in the relationship between science and law "in un contesto dove l'incentivazione della ricerca e dello sviluppo scientifico e tecnologico deve essere direttamente proporzionale alla protezione dell'individuo".[57]

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tion by the author: The Republic protects health as a fundamental right of the individual and in the interest of the community and guarantees free medical care to the indigent. No one may be obliged to undergo any given health treatment except under the provisions of the law. The law may not under any circumstances violate the limits imposed by respect for the human person.

[56] Provisions for informed consent and advance directives.

[57] G. SCARCHILLO, *La responsabilità medica: risarcimento o indennizzo? Riflessioni, evoluzione e prospettive di diritto comparato*, in *Responsabilità civile e previdenza*, 5, 2017, 1508. Translation by the author: in a context where the promotion of research and scientific and technological development must be directly proportional to the protection of the individual.

At the Origins of Medical Liability in the West: The Roman Legal Experience between the First Century BCE and the First Century CE

Domenico Dursi [*]

ABSTRACT: The essay examines the earliest considerations concerning physicians' liability in ancient Rome, as elaborated by jurists active between the first century BC and the first century CE, a development that significantly coincides with the consolidation of medical practice in Rome. The texts of the classical jurists preserved in the Digest reveal that particular emphasis was placed on cases in which physicians caused harm to slaves, thereby producing an economic loss for their owners, a loss that was actionable and compensable under the Lex Aquilia. Equally noteworthy is the jurists' treatment of the concept of fault (*culpa*), which was articulated primarily in terms of lack of professional skill (*imperitia*). The paper thus contributes to the understanding of the conceptual origins of professional liability in Western legal thought.

KEYWORDS: Roman law; medical liability; Roman jurist; Justinian's Digest; Lex Aquilia

SUMMARY: 1. Introduction – 2. Materials and Methods – 3. Conclusion.

1. Introduction

The theme of medical liability has, for quite some time, attracted considerable attention in both the medical and legal domains. It may be regarded as one of the major issues of our time, one that immediately revealed the need for a multidisciplinary approach. Indeed, in addition to developments in forensic medicine, numerous contributions over the years have addressed the topic from both a dogmatic standpoint and in light of case-law developments, particularly within civil and criminal law. The purpose of these pages is therefore not to add further arguments to those already established in positive law, but rather to analyze the terms of the question where it all began: in ancient Rome which, to paraphrase the title of a celebrated volume, invented law in the West.[1]

To the best of my knowledge, from this perspective the subject seems to lack substantial treatments expressly devoted to it.[2] What follows is therefore a journey into legal history, in full awareness of the historicity of law, which does not permit bold parallels or claims of continuity with current problems of medical liability—problems that are, obviously, shaped by forms of knowledge and techniques unknown

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[1] A. SCHIAVONE, *Ius. L'invenzione del diritto in Occidente*, Torino 2017.

[2] Among the limited studies on the matter, see F. RICO-PEREZ, *La responsabilidad civil del medico en Roma*, in *Estudios en omenaje al Profesor Juan Iglesias*, III, Madrid 1988, 1603 ff.

to the Romans.[3] Moreover, the consequences for a physician who harmed a patient were closely connected to the patient's *status personae* since, as is well known, the Roman world recognized slavery and it suffices to recall that slaves were regarded as things belonging to the *dominus*. As obvious, in other words, the elements of discontinuity with the present overwhelmingly outweigh the few elements of continuity, which are not entirely absent. Accordingly, I shall examine the texts of Roman jurists preserved in the Digest who, so far as we know, were the first to address physicians' liability, with the aim of conducting a preliminary exploration of some of their reflections on the subject by employing the historical-exegetical method.

Before proceeding to a strictly legal analysis, a few brief remarks are necessary regarding the spread of the medical art and its practice at Rome.

According to Pliny the Elder,[4] the first physician to arrive in Rome was a certain Archagathus, a native of the Peloponnese, in 219 BCE; yet rudimentary forms of medical practice in Rome are thought to have existed even prior to the arrival of physicians. This assertion, on closer inspection, is corroborated by the fact that the earliest attestations of the lexeme *medicus*, as has been noted,[5] are found in several comedies by Plautus (one of which, the *Menaechmi*, assigns physicians a prominent role) who, in 219 BCE, was at the height of his activity. Nor can it be assumed that the spread of medical knowledge in Rome predates this on the basis of what is read in Justinian's Institutes with regard to the *Lex Aquilia*: in paragraphs 6 - 7 of Book IV[6] it is affirmed that a surgeon could be held liable for damage where he had performed an operation on a slave with an unfavorable outcome determined by his neglect of the patient after the operation. The imperial manual comments that in such a case there was clearly fault; likewise, continues the introductory work, the physician would be liable for a poorly executed operation or for having administered the wrong medicine: again, cases of *culpa*.

Since it is not possible here to examine exhaustively the content of those passages, some clarification of the chronological issues under consideration is in order. The *Lex Aquilia* is now almost unanimously dated to around 286 BCE,[7] and thus one might infer that by that time there were already clear references to medical liability. On closer inspection, however, such a deduction lacks foundation, for we know only two *capita* of the plebiscite in question: the first concerning the killing of a slave or of *pecudes*, and the

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[3] For these problems, see R. Orestano, *Introduzione allo studio del diritto romano*, Bologna, 1987; see also A. Schiavone, *La storia spezzata. Roma antica e Occidente moderno*, Torino 2020.

[4] Nat. Hist. 29.12: […] venisse Romam Peloponneso Archagathum Lysiae filium L. Aemilio M. Licinio cons. aano urbis DXXXV. Natural History 29.12: […] that Archagathus, son of Lysias, had arrived in Rome from the Peloponnese during the consulship of Lucius Aemilius and Marcus Licinius, in the year 535 from the founding of the City.

[5] C. de Filippis Cappai, *Medici e Medicina nell'Antica Roma*, Cavallermaggiore, 1992, 53 ff. See also, with respect to the bibliographical references, C. Pennacchio, *Medicus amicus. Etica professionale nel mondo antico*, in G. Limone (a cura di), *Persona*, I, Capua, 2016, 259 ff. For a general survey of medicine at Rome M. Vegetti, P. Manuli, *La medicina e l'igiene*, in A. Momigliano – A. Schiavone (directed by), *Storia di Roma*, IV, Torino, 1989, 389 ff.

[6] Inst. 4.3.6 – 7: *Praeterea si medicus, qui servum tuum secuit, dereliquerit curationem atque ob id mortuus fuerit servus, culpae reus est. 7. Imperitia quoque culpae adnumeratur, veluti si medicus ideo servum tuum occiderit, quod eum male secuerit aut perperam ei medicamentum dederit.* Institutes 4.6-7: 6 Again, if a surgeon operates on your slave, and then neglects altogether to attend to his cure, so that the slave dies in consequence, he is liable for his carelessness. 7. Sometimes, too, unskilfulness is undistinguishable from carelessness—as where a surgeon kills your slave by operating upon him unskilfully, or by giving him wrong medicines.

[7] The bibliography on this point is vast; I confine myself here to referring to M. F. Cursi, *Danno e responsabilità extracontrattuale nella storia del diritto privato*, Napoli, 2010.

third concerning the wounding, breaking, or burning of slaves and animals. So far as we know, there is no reference to the activity of physicians, which was, in all likelihood, brought within the scope of the *Lex Aquilia* by the interpretive activity of later jurists, especially once they began to reflect on the subjective element in assessing liability and on its extension to fault, precisely the element referenced in the passages just mentioned.

What is certain is that by the first century BCE the figure of the physician was fully established,[8] such that the earliest reflections by jurists on the problems of medical liability date from this period, as well as the first 'scientific' reflections on the medical art, given that right at the turn between the first century BCE and the first century CE Aulus Cornelius Celsus's treatise *de Medicina* appeared.[9]

2. Materials and Methods

The materials studied consist of the writings of the ancient Roman *iuris periti* preserved in Justinian's Digest, which allow us to trace a progressive emergence of the problem of physicians' liability starting, not by chance, in the first century BCE, when, as noted, the figure of the physician had become entirely familiar within Roman society.

The method of analysis employed is, as indicated, the historical-exegetical one, aimed at understanding the extent of the ancient jurists' statements in the context in which they operated—in short, attempting to reconstruct the 'Roman law of the Romans'.[10]

The text from which it is useful to take our point of departure is:

> Alf. 2 *dig*. 9.2.52.*pr*.: *Si ex plagis servus mortuus esset neque id medici inscentia aut domini neglegentia occidisset, recte de iniuria occiso eo agitur.*[11]

This passage, collected in the Justinianic anthology, was excerpted from a work, also entitled Digesta, by Alfenus Varus, a jurist and member of Rome's ruling class (he was consul suffectus in 39 BCE) in the first century BCE. He was one of the auditores of Servius Sulpicius Rufus, among the foremost exponents of Roman legal science of the age, whose thought he often reports, although in the present case it is impossible to establish whether we are in the presence of Servius's views.[12] What is certain is that the passage sets forth a casuistic rule concerning the following factual situation: a slave was wounded by a third party and, after an interval of time, died as a result of those injuries.[13] The question put to the jurist was whether the person who had caused the injuries should be liable ex lege Aquilia under the first caput, that is, for the killing of the slave, or simply for the injuries, sanctioned under the third caput, *vis-à-vis* the dominus of the slave who, it bears repeating, was, from a strictly legal point of view, a piece of

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[8] C. DE FILIPPIS CAPPAI, *op. cit*., 69.

[9] For the features of ancient medical literature, see I. MAZZINI, *La medicina dei greci e dei romani*, I, Roma 1997, 97 ff.

[10] This expression goes back to ORESTANO, *op. cit*., 457 ff.

[11] ALFENUS, Digest book 2 D. 9.2.52 pr.: Where a slave dies from the effect of blows, and this is not the result of the ignorance of a physician or of the neglect of the owner, an action for injury can be brought for his death.

[12] About this issue see M. MIGLIETTA, *«Servius Respondit». Studi intorno a metodo e interpretazione nella scuola giuridica serviana – Prolegomena I*, Trento, 2010, part. 21 nt. 15.

[13] In this sense, see also S. SCHIPANI, *Resposnabilità «ex lege Aquilia» criteri di imputazione e problema della «culpa»*, Torino, 1969, 177 ff.

property belonging to his dominus. Alfenus states that in such a case the third party is required to compensate the owner for the death of the slave only if, in the interval, no further factor has intervened to interrupt the causal nexus, such as, for example, the physician's lack of expertise or the *dominus*'s negligence.[14]

Leaving aside the many aspects of interest in the passage, what is relevant for our purposes is the reference to the *inscientia medici* that is the physician's lack of expertise, which would give rise either to contractual liability or, at least in the present case, to Aquilian liability under the first *caput*, inasmuch as there would be a nexus between the physician's *inscientia* and the death.[15] The lexeme *inscientia* is in fact infrequent in the jurists' vocabulary and refers essentially to a state of unawareness incompatible with the performance of technical tasks and, in any case, it indicates nonconformity with a model of conduct to which the physician should have adhered.[16] We are therefore fully within the ambit of *culpa*, so that we may note how, for Alfenus Varus, a physician would be civilly liable if he caused the death of a slave through *culpa*.

In the same period, a reference to physicians' liability appears in a passage from Cicero's *de natura deorum*:

> Cic. *de nat. deo* 3.78: *Sic, si homines rationem bono consilio a dis immortalibus datam in fraudem malitiamque convertunt, non dari illam quam dari humano generi melius fuit. Ut si medicus sciat eum aegrotum, qui iussus sit vinum sumere, meracius sumpturum statimque periturum, magna sit in culpa, sic vestra ista providentia reprendenda, quae rationem dederit is, quos scierit ea perverse et inprobe ussuros* […].[17]

This passage is drawn from a philosophical work by the Arpinate in which the author inquires into the nature of the gods. Here the reference to the physician serves as a *similitudo* intended to illustrate the gods' fault, consisting in their having bestowed reason upon human beings while knowing that they would misuse it. We read, indeed, that the gods would be blameworthy just as a physician would be who had prescribed wine for therapeutic purposes to a patient even knowing that the latter would drink it undiluted and thus risk a rapid death. In the passage under examination Cicero locates the physician's fault in his awareness that the prescribed therapy, in the specific case, would produce adverse effects due to the patient's improper use of the particular 'drug.' It would seem, therefore, that the physician had also to make a prognostic assessment regarding the patient's correct adherence to the prescribed therapy. In other words, the physician's liability would arise not only when he had prescribed an incorrect medicine, but also where he ought to have foreseen the patient's improper use of it, an aspect that, to a certain extent, it falls outside the physician's sphere of control.

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[14] For a detailed exegesis, see S. GALEOTTI, *Ricerche sulla nozione di damnum. II. I criteri d'imputazione del danno tra lex e interpretario prudentium*, Napoli, 2016, 184 ff.

[15] C.A. CANNATA, *Sul problema della responsabilità nel diritto privato romano. Materiali per un corso di diritto romano*, Catania, 1996, 113 s.

[16] SCHIPANI, *op. cit.*, 179.

[17] CICERO, *On the nature of gods* 3.78: A physician would be greatly to blame if he knew that the sick man, whom he had ordered to take wine, would take it too little diluted, and that the result would be immediate death, and in the same way this providence of yours must be censured for having given reason to those of whom it knew that they would make a wrong and wicked use of it.

Indeed, this represents a considerable expansion of the physician's professional liability which, so far as I am aware, finds no support among the jurists. Considering this, it cannot be ruled out that the Arpinate is not referring to legal fault in the strict sense, but rather to a broader, so to speak, philosophical concept.

Further traces of medical liability are found in a text by Ulpian who, although writing in the second century CE, reports an opinion of Labeo, active between the first century BCE and the first century CE:

> Ulp. 18 *ad ed.* D. 9.2.9pr.: *Item si obstetrix medicamentum dederit et inde mulier perierit, Labeo distinguit, ut, si quidem suis manibus supposuit, videatur occidisse: sin vero dedit, ut sibi mulier offerret, in factum actionem dandam, quae sententia vera est: magis enim causam mortis praestitit quam occidit.*[18]

The passage refers to the case of a midwife who had administered a medicament to a woman who, following its intake, died. Faced with such a situation, Labeo drew a distinction depending on whether the midwife had applied the drug directly, with her own hands, or whether she had handed it to the woman and suggested that she take it. In the former case, according to the Augustan jurist, the midwife was to be considered responsible for the woman's death; if, however, she had merely supplied the drug and suggested its intake, she would be liable not under the direct Aquilian action but by means of an *actio in factum*, since the situation lacked the requisites for proceeding under the *actio ex lege Aquilia*. Indeed, Ulpian, alongside his citation of Labeo, glosses that in the second hypothesis it would not have been so much the act of killing, but rather the act of procuring death.

A few clarifications are in order. First, for the Roman jurists the midwife did exercise the ars medica, as Ulpian clearly affirms.[19] Furthermore, although the passage refers to a woman without specifying her *status libertatis*, it appears evident that she was a slave.[20] Had she been a free woman, there would have been no discussion of the *Lex Aquilia*, which concerned damage to things and was therefore applicable to slaves, who, as noted, were regarded as *res* from a strictly legal standpoint. At most, the discussion would have concerned the applicative profiles of the *Lex de sicariis et veneficiis*, concerning homicide perpetrated by means of weapons or poisons, a hypothesis that might encompass the administration of a *venenum*, a term which, according to its etymological roots and as consistently noted by jurists, denoted both a medicinal substance and a poison.[21] In the present case, however, proof of *dolus* would

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[18] Ulpianus, *On the Edict*, Book 18 D.9.2.9pr.: Moreover, where a midwife administers a drug to a woman and she dies in consequence, Labeo makes a distinction, namely: that if she administered it with her own hands she is held to have killed the woman, but if she gave it to the latter in order that she might take it, an action in factum should be granted, and this opinion is correct; for she rather provided the cause of death, than actually killed the woman.

[19] Ulpianus, 8 de omn. trib. D. 50.13.1.2: Sed et obstetricem audiant, quae utique medicinam exhibere videtur. Ulpianus, On All Tribunals, Book 8: Governors hear midwives, who are also considered to practice medicine.

[20] See M. Genovese, *Responsabilità aquiliana nell'occidere tramite medicamentum dare dell'ostetrica e/o di altri: notazioni critico-propositive su D. 9.2.9 pr.-1 (Ulp. 18 ad ed.)*, in *Scritti per A. Corbino*, III, Tricase (Le), 311.

[21] Gai 4 ad leg. XII Tab. D. 50.16.236pr.: *Qui "venenum" dicit, adicere debet, utrum alum an bonum: nam et medicamenta venena sunt, quia eo nomine omne continetur, quod adhibitum naturam eius, cui adhibitum esset, mutat. cum id quod nos venenum appellamus, Graeci φάρμακον dicunt, apud illos quoque tam medicamenta quam quae nocent, hoc nomine continentur: unde adiectione alterius nomine distinctio fit. admonet nos summus apud eos poetarum Homerus: nam sic ait: φάρμακα, πολλὰ μὲν ἐσϑλὰ μεμιγμένα, πολλὰ δὲ λυγρά.* Gaius, *On the Law of the Twelve Tables*, book 4 D. 50.16.236pr: Those who speak of poison, should add whether it is good or bad, for medicines are poisons, and they are so called because they change the natural disposition of those to whom they are

have been necessary, at least until the promulgation of two *senatus consulta*, cited by Marcianus,[22] of uncertain chronology, presumably not earlier than the emperor Claudius.[23] In light of this, it seems possible to hold that criminal liability on the part of a physician who had administered a medicine that proved lethal would arise only in the presence of *dolus*, at least until those above mentioned *senatus consulta.*

As to the damage, it must then be considered that it derived either from an error in the choice of the drug or in the dosage indicated, thus we are dealing with lack of professional skill, a species of *culpa.*[24] Finally, where intake of the substance had been merely suggested, the *dominus* of the slave could not proceed against the midwife by means of the direct Aquilian action, since, according to some, the jurist considered lacking the contact between the thing damaged – the slave – and the wrongdoer – the midwife; that is, the circumstance that the *damnum* was not *corpore corpori datum*[25] or, as has also been suggested, that there was no *occidere* in the sense attributed by Labeo to the term, used by the jurist to mean an act of violence, even minimal, performed 'manually' by the agent upon the victim.[26] These are, in truth, two largely overlapping perspectives, so that, in order to proceed with the direct Aquilian ac-

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administered. What we call poison the Greeks style *farmakon*; and among them noxious drugs as well as medicinal remedies are included under this term, for which reason they distinguish them by another name. Homer, the most distinguished of their poets, informs us of this, for he says: "There are many kinds of poisons, some of which are good, and some of which are bad." On this passage, see M. FIORENTINI, *I giuristi romani leggono Omero. Sull'uso della letteratura colta nella giurisprudenza classica,* in *BIDR,* 107, 2013, 186 ff.; more recently C. PENNACCHIO, *Farmaco, veleni, medicamenti. Breve storia di un ossimoro*, in *Studia et documenta historiae iuris*, 80, 2014, 117 ff.; N. PAPAKONSTANTINOU, *Roman declamation, Roman Law and Ancient Legal Medicine*, in *Rivista di diritto romano*, 23, 2023, 37 ff.

[22] Marc. 14 inst. D. 48.8.3.2.-3: 2: *Adiectio autem ista "veneni mali" ostendit esse quaedam et non mala venena. ergo nomen medium est et tam id, quod ad sanandum, quam id, quod ad occidendum paratum est, continet, sed et id quod amatorium appellatur: sed hoc solum notatur in ea lege, quod hominis necandi causa habet. sed ex senatus consulto relegari iussa est ea, quae non quidem malo animo, sed malo exemplo medicamentum ad conceptionem dedit, ex quo ea quae acceperat decesserit. 3. Alio senatus consulto effectum est, ut pigmentarii, si cui temere cicutam salamandram aconitum pituocampas aut bubrostim mandragoram et id, quod lustramenti causa dederit cantharidas, poena teneantur huius legis.* MARCIANUS, *Institutes*, book 4 D. 48.8.3.2.-3: 2: The expression "injurious poisons" shows that there are certain poisons which are not injurious. Therefore, the term is an ambiguous one and includes what can be used for curing disease as well as for causing death. There also are preparations called love philtres. These, however, are only forbidden by this law where they are designed to kill people. A woman was ordered by a decree of the Senate to be banished, who, not with malicious intent, but offering a bad example, administered for the purpose of producing conception a drug which, having been taken, caused death. 3. It is provided by another Decree of the Senate that dealers in ointments who rashly sell hemlock, salamander, aconite, pine-cones, bu-prestis, mandragora, and give cantharides as a purgative, were liable to the penalty of this law. On the senatus consulta referred to in the Marcian passage, see E. HOBENREICH, *Due senatocosnulti in tema di veneficio (Marcian. 14 inst. D. 48.8.3.2-3)*, in *Archivio Giuridico*, 208.4, 1988, 75 ff.

[23] HOBENREICHT, *op. cit*., 94 ff.; P. BUONGIORNO, *'Senatus consulta Claudianus temporibus facta'. Una palingenesi delle deliberazioni senatorie dell'età di Claudio (41-54 d.C.)*, Napoli, 2010, 412 ff.

[24] GENOVESE, *op. cit*., 317.

[25] *Ex variis* G. VALDITARA, *Sulle origini del concetto di damnum iniuria datum*, Torino, 1998, 14; *contra* see A. CORBINO, *Il danno qualificato e la Lex Aquilia*, Padova, 2008, 127 ff.; more recently, see S. GALEOTTI, *Ricerche sulla nozione di damnum. I. Il danno nel diritto romano tra semantica e interpretazione*, Napoli, 2015, 217 ff., for which reliance ought not to be placed on the actio in factum, but instead on the direct action, since no definitive proof exists as to the certain attribution of the damage to the author.

[26] GENOVESE, *op. cit*., 322 ff.

tion, some physical contact between the agent and the victim was, in any event, required. Moreover, the absence of contact with the victim meant that the midwife's suggestion to take the drug, amounted to an indirect cause of death. Dieter Nörr, for his part, noted that the phrase *causa mortis* found in the fragment would have originated from the *verba legis* of the *Lex Cornelia de sicariis et veneficiis* re-employed in rhetorical contexts, and used by Labeo and by the jurists of his time to indicate the indirect causality of the *occidere.*[27]

Finally, it should be noted that Labeo's approach was adopted almost *verbatim* by another jurist, Juventius Celsus, head of the Proculian *secta* who, not by chance, tended to recognize themselves precisely in Labeo's *magisterium*. In particular, again thanks to Ulpian,[28] we learn that this Hadrianic jurist, though not explicitly referring to a physician or a midwife, emphasized how different it is to kill from to cause death; in the latter case, he underscored, the *actio ex lege Aquilia* would not have been due, but rather an *actio ad exemplum* modeled on the facts. And to clarify what it means to 'cause death,' he adduced the example of one who had given poison in place of a medicine – precisely the case discussed by Labeo – whom he considered analogous to a person who had handed a sword to a man not in possession of his senses.

What is certain is that with Labeo a line of interpretation was established which, consolidated by Celsus, was then adopted by Ulpian. The latter not only makes it his own but also records the stages in the formation of this approach: on the other hand, it is not unusual, in the history of Roman legal thought, to identify interpretive trajectories linking Ulpian to Labeo, often mediated by the Proculians.[29]

Ulpian, finally, preserves a testimony of Proculus, founder and eponym of the Proculian sect:

> Ulp. 18 *ad ed.* D. 9.2.7.8: *Proculus ait, si medicus servum imperite secuerit, vel ex locato vel ex lege Aquilia competere actionem.*[30]

With a lapidary statement, Proculus asserts that a physician who has performed a surgical intervention unskillfully upon a slave may be proceeded against either on the basis of the contract of letting (*actio ex locato*) or under the *Lex Aquilia* for extra-contractual liability. The importance of this excerpt is evident. First, it emerges that medical art could be the object of a contract of lease.[31] Second, albeit indirectly, the requisite skill with which the physician must perform the intervention comes to the fore, and thus,

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[27] D. NÖRR, *Causa mortis. Auf den Spuren einer Redewendung*, München, 1986, 160 ff.; 210 ff.

[28] Ulp. 18 ad ed. D. 9.2.7.6: *Celsus autem multum interesse dicit, occiderit an mortis causam praestiterit, ut qui mortis causam praestitit, non Aquilia, sed in factum actione teneatur. unde adfert eum qui venenum pro medicamento dedit et ait causam mortis praestitisse, quemadmodum eum qui furenti gladium porrexit: nam nec hunc lege Aquilia teneri, sed in factum.* ULPIANUS, on the edict book 18 D.9.7.2.6: Celsus says that it makes a great deal of difference whether the party actually kills, or provides the cause of death, as he who provides the cause of death is not liable under the Lex Aquilia, but is to an action in factum. With reference to this, he cites the case of a party who administered poison as medicine, and who he says provided the cause of death; just as one who places a sword in the hands of an insane person, for the latter would not be liable under the Lex Aquilia, but would be to an action in factum. On the passage see D. NÖRR, *Causa mortis. Auf den Spuren einer Redewendung*, cit., 169 ff.

[29] Ulpian refers to Labeo on no fewer than 350 occasions, which makes him the jurist most frequently cited after Julian. The enumeration in T. HONORÉ, *Ulpian*, Oxford, 1982, 211 ff.

[30] ULPIANUS, on the edict book 18 D.9.7.2.8: Proculus holds that if a physician should operate upon a slave unskillfully, an action will lie either on the contract, or under the Lex Aquilia.

[31] G. COPPOLA, *Cultura e potere. Il lavoro intellettuale nel mondo romano*, Milano, 1994, 168.

once again, the element of fault in the assessment of the physician's liability,[32] to be understood specifically as *imperitia*, that is, a deficiency of the technical competence, skill, or experience necessary to perform specific tasks. Indeed, Celsus, Proculus's follower and near contemporary, explained, with reference to the contract of letting, also recalled in the passage at issue, that lack of skill falls within fault and is relevant whenever a contract is concluded with a person in view of his technical expertise.[33] The physician, as a bearer of technical expertise, was therefore not bound merely to ordinary diligence in providing his services, but rather to true professional diligence.[34]

It has, in fact, been observed[35] that *imperitia* constitutes a requirement additional to the causal *nexus*, in the sense that both the act of killing and the lack of skill are necessary; conversely, the physician's conduct, although it may have caused the death, would not, in itself, amount to the typical conduct of killing, unless it were characterized by lack of skill.

The continuation of the passage makes it clear that a physician who has intervened surgically with lack of skill is to be held liable either under the *actio locati* or under the action based on the *Lex Aquilia*. In other words, Proculus specifies that the physician's liability may be contractual or extra-contractual, but in both cases, it is grounded in *imperitia*.

The task, then, is to understand in which case one might proceed *ex locato* and in which under the *Lex Aquilia*. It has been argued that the two actions were available to the *dominus* in elective concurrence, since the physician's liability would arise not only in the contractual sphere but also in the extra-contractual one. In particular, it has been argued that the justification for intervening on the body of the slave would lie in the specific professional competence attributed to the physician: the *imperite* conduct in the concrete case would exclude the ground of justification, thereby restoring to the physician's act the character of *iniuria* which the contract would otherwise have precluded.[36]

It appears to me, that another interpretation may also be plausible. One might suppose that the jurist, in his statement, was referring to two distinct hypotheses: first, that in which the *dominus* turned to a physician and concluded with him a *locatio operis*; and second, that in which the slave, of his own accord, in the presence of some ailment, turned autonomously to a physician, in which latter case lack of skill would give rise to Aquilian liability. That slaves would resort on their own to a physician must in fact have been a frequent hypothesis; otherwise, it would be difficult to explain why almost all the texts concerning medical liability are commentaries on the *Lex Aquilia*.

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[32] In this sense, see also RICO-PEREZ, *op. cit.*, 1609.

[33] Ulp. 32 ad ed. D. 19.2.9.5: *Celsus etiam imperitiam culpae adnumerandam libro octavo digestorum scripsit: si quis vitulos pascendos vel sarciendum quid poliendumve conduxit, culpam eum praestare debere et quod imperitia peccavit, culpam esse: quippe ut artifex, inquit, conduxit.* ULPIANUS on the edict book 32 D. 19.2.9.5: Celsus also states in the Eighth Book of the Digest that want of skill should be classed with negligence. Where a party rents calves to be fed, or cloth to be repaired, or an article to be polished, he must be responsible for negligence, and whatever fault he commits through want of skill is negligence, because he rents the property in the character of an artisan. On the meaning of artifex and on the legal aspects connected with this figure, see most recently P. MARRA, *Artifex. Profili giuridici dei lavori specialistici nell'antica Roma*, Soveria Mannelli, 2025.

[34] In a similar sense, see S. GALEOTTI, *Ricerche sulla nozione di damnum. II. I criteri d'imputazione del danno tra lex e interpretario prudentium*, cit., 191.

[35] SCHIPANI, *op. cit*., 325.

[36] In these terms, see COPPOLA, *op. cit*., 172; most recently, S. GALEOTTI, *Ricerche sulla nozione di damnum. II. I criteri d'imputazione del danno tra lex e interpretario prudentium*, cit., 192 f.

3. Conclusions

An examination of the ancient texts shows that the *ars medica*, largely of Greek origin, had already reached Rome by the early first century BCE, and was later systematically codified, nearly a century afterwards, in Celsus' Latin treatise *De Medicina.* Around this phenomenon the Romans undertook a *cogitatio iuridica*, the genuine and autochthonous fruit of their genius. Indeed, it is to the period between the first century B.C. and the first century A.D. that we may ascribe the earliest *testimonia* of some of the most illustrious jurists of the age – Alfenus Varus, Labeo, Proculus – concerning hypothesis of medical liability. In truth, the casuistry centers on harm inflicted upon slaves in the context of activities performed by physicians, cases which, in view of the peculiar legal regime of slavery, were examined from the standpoint of the patrimonial damage suffered by the *dominus* of the slave. What primarily comes into play are cases that fall within the scope of the *Lex Aquilia* and are thus treated as extra-contractual liability. In my view, this depended on the fact that, in most cases, no contractual relationship existed between *dominus* and *medicus* concerning the care of the *servus*; more likely it was the latter who, in the presence of some 'sickness', presented himself directly to the physician. From the analysis of the texts there also emerges the subjective element of lack of skill, one of the possible articulations of fault, an indication that were taking shape rules of conduct to which the physician, as the practitioner of an *ars*, was required to adhere: in essence, one might say, technical competence was required for the performance of the *ars* and, consequently, a qualified form of diligence.

It should also be noted that in certain statements attributable to Proculus reference is made to the possibility for the *dominus* to proceed on the basis of the *actio locati*, a sign that a *locatio operis* may have been concluded between *dominus* and *medicus* with the care of the slave as its object. In such a case the criteria proper to contractual liability would apply.

The sources, for the period under consideration, do not preserve any record of cases where the physician caused physical harm in the practice of his art to a free man. Wholly conjecturally, one might imagine the existence of some form of contractual liability, perhaps along the lines of the *actio locati*, but on this point it seems more prudent to adopt a *non liquet*. If, instead, the application of a *medicamentum* by a physician to a free person resulted in death, the *Lex Cornelia de sicariis et veneficiis* would most likely have applied, provided the physician's intent had been proven; finally, it seems reasonable to conjecture that where the death of a free patient occurred during or following a surgical intervention, the same law would have applied if the physician's lack of skill emerged as, properly speaking, we read in jurists of the second century CE, and, *a fortiori*, in the presence of *dolus*.

In conclusion, the examination of ancient sources highlights how, at the dawn of the spread of the medical art in Rome, jurists addressed, as far as the evidence allows us to ascertain, essentially issues concerning the physician's liability, outlining a set of rules and orientations which, at least in their core elements, can be traced with remarkable continuity throughout the European legal tradition. This, as is well known, a matter distinct from those typically pertaining to social medicine; nevertheless, one may already discern, albeit faintly, the theme of the relationship between physician, patient, and society, which undoubtedly constitutes one of the central pillars of modern social medicine. Moreover, through the jurists' reflections— though in filigree—we can apprehend some of the juridical frameworks within which the medical art was then practiced, among which, as we have seen, was the *locatio operis*: this bears witness to the fact that even in ancient Rome medical practice was inscribed within an horizon not only technical, but also normative and social.

La tutela della salute come dovere di cura e come dovere di solidarietà. Riflessioni per una salute sostenibile

Ines Ciolli[*]

THE PROTECTION OF HEALTH AS A DUTY OF CARE AND AS A DUTY OF SOLIDARITY. REFLECTIONS ABOUT A SUSTAINABLE HEALTH

ABSTRACT: The protection of health provided for in Article 32 of the Constitution has been subject to broad interpretation by the Constitutional Court, but, above all, to an extension by the legislator, who has interpreted the fundamental right to health in the light of the principles of equality and solidarity. Today, however, new problems are arising in the face of new technologies and greater availability of treatments, including expensive ones, which the National Health Service is nevertheless attempting to provide. The challenge is to protect everyone and to provide greater protection for vulnerable individuals, and the legislature, as well as the Constitutional court, seem to be converging on this perspective of integrated and supportive care and protection.

KEYWORDS: Rights; duties; solidarity; health; sustainability; vulnerability

ABSTRACT: La tutela della salute prevista dall'articolo 32 della Costituzione è stata oggetto di un'interpretazione ampia da parte della Corte costituzionale, ma soprattutto di un'estensione da parte del legislatore, che ha interpretato il diritto fondamentale alla salute alla luce dei principi di uguaglianza e solidarietà. Oggi, tuttavia, stanno emergendo nuovi problemi di fronte alle nuove tecnologie e alla maggiore disponibilità di trattamenti, anche costosi, che il Servizio sanitario nazionale tenta comunque di garantire. La sfida è tutelare tutti e offrire una maggiore protezione ai soggetti vulnerabili, e il legislatore, così come la Corte costituzionale, sembrano convergere verso questa prospettiva di cura e tutela integrate e solidali.

PAROLE CHIAVE: Diritti; doveri; solidarietà; salute; sostenibilità; vulnerabilità

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tutela della salute – 3.1. Il dovere di tutelare i più vulnerabili – 4. Ancora sulla sostenibilità del SSN: è sostenibile ciò che riteniamo tale. Riflessioni conclusive.

1. La tutela della salute in Costituente: al diritto di essere curato non corrisponde un dovere di mantenersi in salute

In Assemblea costituente, il 24 aprile 1947, l'on. Sullo, insieme ad altri, propose un emendamento che mirava a cancellare il testo dell'art. 26 del Progetto di Costituzione, che conteneva già a grandi linee i due commi dell'attuale art. 32 Cost.[1]. L'On. Sullo argomentò tale scelta come dettata dalla natura superflua dell'articolo, poiché a suo giudizio non corrispondeva né a una tutela di un diritto di libertà, né a quella di un diritto sociale e soprattutto la tutela della salute e dell'igiene a suo avviso non meritavano di essere iscritte nel dettato costituzionale visto che in passato la tutela legislativa aveva comunque garantito l'effettività delle prestazioni. Concordava sul punto anche l'On. Nitti che nella seduta del 19 aprile 1947 propose la cancellazione del diritto alla salute contenuto nell'art. 26 del Progetto sebbene per ragioni diverse; a suo avviso, la Costituzione non poteva contenere una prescrizione costituzionale alla quale non si sarebbe potuto dare seguito e che non avrebbe conosciuto un'attuazione nel breve e medio periodo, perché non vi erano mezzi adeguati a garantire quelle tutele. L'attuale art. 32 Cost. fu approvato grazie all'impegno dell'On. Caronia, che non solo comprese l'importanza di una tutela costituzionale della salute, ma apprezzò la combinazione di un diritto individuale e di un interesse della collettività. Sotto il profilo dei doveri, l'On. Merighi aggiunse al dibattito la necessità di contemplare un dovere di cura in capo alla Repubblica che riguardasse non solo i lavoratori e gli indigenti, ma tutti i cittadini. In questa prospettiva, la salute assumeva la struttura di un diritto sociale e contemporaneamente di un dovere di mutua solidarietà che costituisce un tratto «caratterizzante la forma di stato sociale disegnata dalla Costituzione», come ha ribadito negli anni successivi la stessa Corte costituzionale[2].

L'on. Merighi aggiunse anche che le condizioni di indigenza che legittimano la gratuità delle cure dovevano essere contestualizzate e intese non in senso assoluto o letterale, perché proprio la malattia e il costo delle cure possono causare condizioni di povertà[3]. Sulla base di quelle osservazioni, in tempi più recenti la dottrina ha considerato l'indigenza come un concetto relativo, che si può riferire a persone

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[1] Art. 26: «La Repubblica tutela la salute, promuove l'igiene e garantisce cure gratuite agli indigenti. Nessun trattamento sanitario può essere reso obbligatorio se non per legge. Sono vietate le pratiche sanitarie lesive della dignità umana».

[2] CORTE COST., sent. nn. 37/1991, 324/1989, 1011/1988; 294 e 177/1986.

[3] Assemblea costituente, seduta del 7 maggio 1947. Sul punto si è soffermata successivamente la Corte costituzionale affermando che: «Questa Corte ha ripetutamente affermato che la tutela del diritto alla salute non può non subire i condizionamenti che lo stesso legislatore incontra nel distribuire le risorse finanziarie delle quali dispone; ma ha anche precisato (sentenze nn. 267/ 1998, 416/1995, 218/1994, 304/1994, 247/1992, 455/1990) che le esigenze della finanza pubblica non possono assumere, nel bilanciamento del legislatore, un peso talmente preponderante da comprimere il nucleo irriducibile del diritto alla salute protetto dalla Costituzione come ambito inviolabile della dignità umana. Ed è certamente a quest'ambito che appartiene il diritto dei cittadini in disagiate condizioni economiche, o indigenti secondo la terminologia dell'art. 32 della Costituzione, a che siano loro assicurate cure gratuite», sent n. 309/1999, punto 3 del *Considerato in diritto*.

«medicalmente bisognose», proprio per il fatto che la malattia può portare all'indigenza a causa del costo delle cure, quando queste non sono gratuite o accessibili[4].

In Assemblea Costituente, ove il dibattito fu assai articolato, si pose anche la questione del dovere morale del cittadino di preservare la sua stessa salute[5], senza però che il tema trovasse un ampio riscontro sotto il profilo del dovere individuale di curarsi, mentre fu affrontato con maggiore attenzione quello relativo ai doveri di solidarietà nei confronti anche dei soggetti vulnerabili, anche se poi all'art. 2 Cost. si scelse una formula inclusiva che richiede l'adempimento di doveri inderogabili di solidarietà politica, economica e sociale, legittimando un bilanciamento tra diritti individuali e interesse della collettività[6] ; bilanciamento non privo di potenziali contrasti[7].

Nonostante la ricchezza del dibattito in Costituente, nella Carta costituzionale non resta traccia del dovere individuale di preservare la propria salute[8]. Oggi, però, quel dovere di mantenere la propria integrità psico-fisica, allora rigettato dai Costituenti in sede di redazione dell'art. 32 Cost., sembra tornato al centro del dibattito sia per il costo delle cure che il paziente "deve meritare" attraverso comportamenti virtuosi, sia in tema di dovere di curarsi e di curare, che è tornato alla ribalta con la pandemia da Covid 19[9].

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[4] B. Caravita, *La disciplina costituzionale della salute*, in *Diritto e società*, 1, 1984, 49; M. Luciani, *Salute (diritto alla)* (voce), in *Enciclopedia Giur*idica, XXVII, 1991, 9; B. Pezzini, *Il diritto alla salute: profili costituzionali*, in *Diritto e società*, 1, 1983, 26. Ha parlato di indigenza come valutazione delle singole condizioni individuali e di una nozione che includa tutti coloro che non possono far fronte alle cure, senza dunque considerare il reddito come unico parametro di valutazione della condizione di povertà, B. Pezzini, *Soggetti, contenuto e responsabilità della scelta terapeutica nel Servizio Sanitario*, in L. Chieffi (a cura di), *Il diritto alla salute alle soglie del terzo millennio. Profili di ordine etico, giuridico ed economico*, Torino, 2003, 57.

[5] Assemblea costituente, seduta del 24 aprile 1947.

[6] M. Luciani, *Salute*, I, *Diritto alla salute – dir. cost.*, in *Enc. giur.*, XXVII, Roma, Istituto dell'Enciclopedia Italiana, 1991, 1 ss. Specifica come il bilanciamento possa avvenire *tra* «la libera autodeterminazione del singolo, da un lato, e la necessità di preservare la salute pubblica e con essa la salute dei soggetti più vulnerabili, dall'altro», e anche tra interessi individuali e forme di solidarietà sanitaria*, G. M. Racca, Salute, in Enciclopedia del diritto, I Tematici, III, 2022, 1003. Per un aggiornamento di quel rapporto tra diritto individuale e interesse della collettività anche* R. Balduzzi*, Salute (diritto alla)*, in *Dizionario di diritto pubblico* diretto da S. Cassese*,* vol. VI, Milano, 2006*; B. Caravita, L'Italia ai tempi del coronavirus. Rileggendo la Costituzione italiana,* in *Federalismi.it,* 2020, 4 e ss. Per una ricostruzione giurisprudenziale della questione, cfr. F. Minni, A. Morrone, *Il diritto alla salute nella giurisprudenza della Corte costituzionale italiana*, in *Rivista AIC,* 3, 2012, 1 e ss. Sul bilanciamento tra il diritto alla salute, che contiene anche il rispetto della persona umana e altri diritti e interessi in gioco, compresi quelli finanziari, si vedano anche Corte cost., sentt. nn. 309/1999, 509/2000, 252/2001, 432/2005, 354/2008, 299 e 269/2010, 61/2011, 141/2019, ove la Consulta insiste sull'esistenza di un nucleo indefettibile che è rintracciabile dal legislatore ed è modulabile anche sulla base delle conoscenze scientifiche e di quelle tecnologiche ed è altresì legato anche a una concezione ampia di tutela della persona umana.

[7] Lo ha ribadito M. Luciani, *Il diritto alla salute. Una prospettiva comparata*, Italia, Servizio Ricerca del Parlamento europeo. Unità Biblioteca di diritto comparato, 2022, 43-44, reperibile in https://www.europarl.europa.eu/RegData/etudes/STUD/2022/698893/EPRS_STU(2022)698893_IT.pdf, ove si osserva come vi siano profili nei quali il diritto individuale alla salute si prospetta come *versus* dell'interesse collettivo, sia aspetti nei quali il primo è *cum* l'interesse collettivo.

[8] In merito all'assenza di un vero e proprio dovere di curarsi si sono pronunciati A. Pace, *Problematica delle libertà costituzionali. Parte speciale*, 2° ed., Padova, 1990, 43 s.; A. Baldassarre, *Diritti sociali,* XI, Roma, Istituto dell'Enciclopedia Italiana, 1989, 32.

[9] Il Consiglio di Stato ha menzionato un dovere di cura che fa capo agli operatori sanitari, sebbene si possa più propriamente parlare di un trattamento sanitario obbligatorio rivolto agli operatori sanitari, contenuto nell'ottica del

Il secondo profilo attiene a un dovere individuale, già oggetto del giudizio di legittimità costituzionale da parte della Consulta, che l'ha interpretato nella sua accezione più restrittiva (trattandosi di una limitazione del diritto di autodeterminazione), quando ha evidenziato più precisamente un dovere

> «di non ledere, né porre a rischio con il proprio comportamento la salute altrui, in osservanza del principio generale che vede il diritto di ciascuno trovare un limite nel reciproco riconoscimento e nell'eguale protezione del coesistente diritto degli altri. Le simmetriche posizioni dei singoli si contemperano ulteriormente con gli interessi essenziali della comunità, che possono richiedere la sottoposizione della persona a trattamenti sanitari obbligatori, posti in essere anche nell'interesse della persona stessa, o prevedere la soggezione di essa ad oneri particolari»[10].

Tale dovere di non ledere la salute altrui si poteva rintracciare nell'obbligo contenuto nel Decreto-legge 1° aprile 2021, n. 44, *Misure urgenti per il contenimento dell'epidemia da COVID-19, in materia di vaccinazioni anti SARS-CoV-2, di giustizia e di concorsi pubblici,* chiamato ad integrare un dovere di cura, che ricade sugli operatori sanitari e che si identifica con il dovere di vaccinarsi, come ha ricordato il Consiglio di Stato[11]. Quest'ultimo ha sottolineato anche come quel dovere di cura sia la risultante di un ordinamento democratico e come «la legge non sia mai diritto dei meno vulnerabili o degli invulnerabili, o di quanti si affermino tali e, dunque, intangibili anche in nome delle più alte idealità etiche o di visioni filosofiche e religiose, ma tutela dei più vulnerabili», dovendosi rammentare che la solidarietà è «la base della convivenza sociale normativamente prefigurata dalla Costituzione»[12].

Nella prima accezione, invece, nel dovere di cura e di curarsi si può scorgere un tentativo di legittimare anche culturalmente una forma di selezione rispetto all'erogazione dei servizi e una idea di cura che sia meritocratica, lontana però da una concezione universalistica, che finora ha sostenuto il Servizio sanitario nazionale e le lotte per la sua affermazione e la sua difesa; crollando tale baluardo, sarà più semplice differenziare le forme di tutela della salute, siano esse legate a questioni territoriali o socio economiche.

Queste nuove accezioni restrittive della tutela della salute sembrano far emergere un dibattito sotterraneo in tema di prestazioni che il SSN è tenuto ad erogare a quei soggetti che mettono volontariamente a rischio la propria salute (fumatori, obesi o alcolisti); prestazioni che non possono essere negate per il sol fatto che si tratta di soggetti ipoteticamente meno attenti alla propria integrità, ma che sono invece argomenti sollevati da esigenze economiche in presenza di una risorsa scarsa (ad esempio gli organi da

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«*alterum non laedere*». Tuttavia, la Corte nella sent. n. 137 del 2019 sembra aderire a un più ampio concetto di dovere di cura che non passa per i TSO: la legge regionale della Puglia n. 27/ 2018 ha riconosciuto alla Giunta regionale il compito di individuare i reparti dove l'accesso è consentito ai soli operatori sanitari che hanno accettato di sottoporsi alle vaccinazioni raccomandate; si tratta dunque di un dovere di tutelare la salute dei malati più vulnerabili e non di un dovere individuale di curarsi. Sul punto R. ROMBOLI, *Obbligo di vaccinazione anti Covid e principi costituzionali: a proposito del d.l. n. 44/2021*, 2021, 673 e ss.

[10] CORTE COST., sent. n. 18/1994, punto 2 del *Considerato in diritto* nel quale si prospetta un'accezione più ampia di dovere di cura quando questo è imputabile all'ordinamento nel suo complesso; cfr. anche CORTE COST. sent n. 22/2022 e 15/2023 con nota di L. BUSATTA, *Giustizia costituzionale e obblighi vaccinali: alla Corte l'occasione, in cinque tempi, per consolidare il proprio orientamento*, in *Osservatorio AIC*, 2023, 121, 132 ove sottolinea il dovere professionale dell'operatore sanitario, previsto *ex lege*, di tutelare le persone con le quali entra in contatto e lo definisce proprio dovere di cura.

[11] CONSIGLIO DI STATO, Sez. III, sent. n. 7045 del 2021, cfr. M. GASPARRO, *Obbligo vaccinale per il personale sanitario: il giudice amministrativo fa il punto alla luce della normativa europea e costituzionale*, in *Corti supreme e salute*, 2022, 31 e ss.

[12] CORTE COST., sent n. 75/1992.

trapiantare o il costo di cure oncologiche di ultima generazione) e branditi da coloro che ritengono che tali risorse debbano essere riservate a chi le "merita", in quanto assume comportamenti considerati virtuosi. La questione si era già posta durante la pandemia quando alla scarsità delle risorse a fronte di un numero di pazienti esorbitante, cominciava a serpeggiare l'idea che si potesse scegliere di curare i pazienti più giovani o comunque quelli che potevano avere maggiori prospettive di vita (difficili da valutare in condizioni di emergenza); posto che le valutazioni sanitarie e bioetiche spettano al medico, dal punto di vista dei principi costituzionali, con i quali il servizio sanitario universale è in linea, qualunque forma di differenziazione in termini di erogazione delle cure rappresenta una violazione di quegli stessi principi di solidarietà ed eguaglianza, oltre che dell'art. 32 Cost[13].

In tal modo, si è tornati al dibattito degli Anni Novanta che insisteva sulla condizionalità dei diritti a prestazione, che riguarda in misura maggiore la sanità e l'erogazione dei servizi finanziati attraverso la contribuzione generale, in tempi recenti insidiata in verità da un numero crescente di adesioni a servizi di principio aggiuntivi ma troppo spesso nella sostanza sostituivi del SSN offerti dalle assicurazioni sanitarie[14]. Si tratta di un dibattito che dovrebbe essere considerato superato, visto che persino gli studiosi di Paesi ove l'adesione a principi liberisti è più consistente sostengono che il costo dei diritti non solo è inevitabile, perché le democrazie essendo dei sistemi complessi devono sostenere dei costi, ma questi ultimi hanno un effetto remunerativo altissimo in termini di solidarietà ed uguaglianza, perché garantirli incrementa la coesione e la pace sociale, strumenti indispensabili per la costruzione di una comunità politica coesa e di una cittadinanza attiva[15].

Il dibattito in Costituente conteneva già poderosi anticorpi a quella visione economicista della tutela della salute, ma a causa delle ripetute crisi economiche e finanziarie (solo nell'ultimo ventennio si sono avvicendate la crisi economica e finanziaria del 2008, quella pandemica e quella scaturita dalla guerra in Ucraina, ancora in corso), tornano alla ribalta quelle istanze di condizionamento dei diritti, sebbene siano in aperto contrasto anche con il rispetto della persona umana, che pure era stata al centro del dibattito costituente e che è menzionata sia nell'art. 32, comma 2 Cost. sia nell'art. 3, comma 2, Cost.

La salute degli anziani e più in generale dei vulnerabili, per esempio, rappresenta oggi una nuova frontiera assistenziale che da una parte vede il successo del SSN che ha garantito buone cure e ha consentito una longevità e una buona qualità della vita anche nella terza e quarta età; dall'altra questi benefici richiedono i giusti investimenti e adeguate risorse economiche[16]. Spetta al legislatore nell'uso delle ricorse privilegiare politiche della prevenzione e dell'integrazione socioassistenziale, che comportano costi minori e garantiscono maggiore autonomia e quindi un benessere complessivo dei vulnerabili, delle per-

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[13] Sugli aspetti bioetici delle scelte del medico in condizioni emergenziali, cfr. A. REMEDIO, *Criteri di priorità per l'allocazione di risorse sanitarie scarse nel corso della pandemia da CoViD-19*, in *Biolaw Journal*, 2021, 13 e ss.

[14] Sulla difficile convivenza tra assicurazioni sanitarie e servizio sanitario nazionale universale cfr. N. DIRINDIN, *La sanità pubblica tra indifferenza e* laisser faire, in *Rivista delle Politiche Sociali / Italian Journal of Social Policy,* 2016, 187 ss.

[15] Per una critica della centralità del costo dei diritti si veda S. HOLMES, C. R. SUNSTEIN, *The Cost of Rights: Why Liberty Depends on Taxes*, New York-London, 1999, trad. it. di E. CAGLIERI, *Il costo dei diritti. Perché la libertà dipende dalle tasse*, Bologna, 2000.

[16] La salute deve avere come contenuto e come tutela il benessere psicofisico della persona, come ha previsto la Carta istitutiva dell'Organizzazione mondiale della sanità, istituita nel 1946; di recente un accenno al rapporto tra salute e benessere psicofisico è stato operato anche dalla Corte costituzionale, nelle sentt. nn. 143/2024; 180/2017; 221/2015; 432/2005.

sone con disabilità, della terza e quarta età; in tal modo, si possono elaborare soluzioni compatibili con le priorità prescritte in Costituzione, senza incorrere in eccessivi costi aggiuntivi. Del resto, non si tratta, dal punto di vista organizzativo, di ricorrere a nuovi approcci terapeutici, ma di far riferimento a un modello già approvato nella Conferenza Internazionale sulla *Primary Health Care* del 1978 ad Alma Ata, che è a oggi ancora valido e sostenibile[17]. Quel dibattito scientifico (e politico) costituì il sostrato sul quale si edificò il SSN italiano, che nacque infatti lo stesso anno con la legge del 23 dicembre 1978, n. 833*, Istituzione del servizio sanitario nazionale*; oggi quel modello può essere integrato con un approccio "*One-health*", del tutto in linea con le indicazioni di Alma Ata. Persino diverse Missioni del Piano nazionale di ripresa e resilienza (PNRR) evocano un modello prossimo a quello "*One health*", riferendosi a una tutela integrata della salute, che tenga conto anche della qualità dell'ecosistema e di quella degli altri esseri viventi, creando così finalità unitarie che esulano dalle singole materie per approdare a un piano di sviluppo globale e unitario del Paese[18].

2. Il diritto alla salute come diritto finanziariamente condizionato?

La qualifica del diritto alla salute come diritto fondamentale comporta un contenuto precettivo, ovvero si esplicita l'appartenenza della salute al novero di quei diritti inviolabili dei quali parla genericamente l'art. 2 Cost. e si evoca una sorta di priorità logica, che deve essere intesa nel senso che la privazione della salute ostacola il pieno godimento anche degli altri diritti costituzionali[19]. Ciò non vuol dire che i diritti fondamentali siano gerarchicamente sovraordinati agli altri, visto che nessun diritto è considerato come un diritto tiranno rispetto agli altri[20]. Si è parlato piuttosto della qualifica di fondamentale come un «elemento di resistenza rafforzata nelle operazioni di bilanciamento»[21].

Il progetto originario presentato all'Assemblea per la discussione, infatti, non prevedeva il riconoscimento della qualifica di "fondamentale", che fu introdotta proprio allo scopo di garantire la salute in modo più chiaro e incisivo[22]. Né la qualifica di fondamentale comporta che il diritto alla salute si sottragga al bilanciamento con le risorse finanziarie, ma si deve considerare un bilanciamento ineguale[23]. I vincoli fi-

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[17] Sul necessario approccio integrato alla salute si è soffermato G. Maciocco, *A Trent'anni da Alma Ata. Cure primarie: evoluzione storica e prospettive*, in *Toscana Medica*, 6, 2008, 35 e ss. L'A. ricostruisce il modello di "*primary care*" basato sulla prevenzione, sulla continuità delle cure, sulla costituzione di *team* assistenziali e sul ruolo attivo dei pazienti nella medicina di base e nella gestione delle malattie.

[18] Su "*One health*" in una prospettiva costituzionale, C. Panzera, *Il paradigma* One Health *tra concezioni evolutive della salute e interpretazione sistematica della Costituzione*, in *Corti Supreme e salute*, 2025, 601 ss.; D. Morana, One Health, *tutela costituzionale della salute e ragionevoli bilanciamenti: spunti dalla giurisprudenza,* cit., 587 ss.; B. Pezzini, *One-Health e Corti supreme: le coordinate di un paradigma*, in *Corti Supreme e salute*, 2025, 1 e ss.; M. Cerioni, *Il diritto costituzionale alla salute tra gli approcci "*One Health*" e "*Planetary Health*". Re-innovazione del concetto di "salute" come frutto di "nuove reti" ermeneutiche tra principi costituzionali*, in M. Cerioni, M. De Angelis (a cura di), *Re-innovare la sanità*, Roma, 2024, 215 ss.

[19] M. Luciani, *Il diritto alla salute. una prospettiva comparata,* cit.*,* 16.

[20] Lo ha ben chiarito la Corte costituzionale nella sent. n. 83 del 2013.

[21] D. Morana, *op. cit.,* 593.

[22] La discussione ha avuto luogo nella seduta del 24 aprile 1947.

[23] M. Luciani, *Sui diritti sociali*, in *Studi Mazziotti*, Padova, 1995, II, 97 ss.; L. Antonini, *Il ruolo, da riscoprire in chiave "umanistica", della Corte dei conti nello sviluppo costituzionale italiano*, in *Bilancio, comunità persona*, 2019, 20; A.

nanziari esistono e non devono essere ignorati, ma una volta che il legislatore ha individuato il nucleo incomprimibile del diritto è tenuto a difenderlo e a finanziarlo[24].

La tutela della salute, grazie ai progressi scientifici e tecnologici, si arricchisce di tutele e di finalità sempre più articolate. Spetta dunque al legislatore stabilire quali prestazioni siano indispensabili e quali compatibili con i costi ormai crescenti di farmaci di ultima generazione, vaccini, *screening* sempre più sensibili e predittivi.

Maggiore sono le scelte a disposizione e maggiori sono le sfide che il legislatore deve affrontare, poiché una più lunga aspettativa di vita e di cura influisce sulle modalità di intervento volte a soddisfare il diritto alla salute e a garantire equità di prestazioni tra i cittadini (e non solo). L'art. 32 Cost è così strettamente legato al diritto alla vita, che pur non comparendo quest'ultimo nel testo costituzionale, può essere considerato come un convitato di pietra, una garanzia implicita e come espressione indiretta del *primum vivere* che è stato più volte evocato durante la pandemia da Covid 19[25].

Tornando al profilo del diritto alle cure, quando si sceglie di edificare un SSN universalistico si aderisce a una visione solidaristica, che è legittimata dagli 2 e 3 Cost: sono prescritti doveri di solidarietà riferiti a tutta la comunità politica ed è la Repubblica che di fronte a un diritto costituzionalmente previsto deve garantire la tutela e deve rimuovere ogni ostacolo che impedisca la realizzazione delle finalità costituzionalmente previste. Data questa interpretazione, è chiaro che difficilmente quel dettato si coniuga con una diversa interpretazione del diritto vincolato finanziariamente, ovvero subordinato alle esigenze economiche-finanziarie. A lungo, invece, il vincolo finanziario è stato considerato uno strumento volto a proteggere l'universalità del SSN. Anche la Corte ha interpretato il contenimento delle prestazioni come una misura volta alla razionalizzazione della spesa sanitaria, senza la quale l'universalità del SSN sarebbe compromessa da disavanzi eccessivi; in altre parole, la Corte sembra voler convincere che una particolare attenzione nelle spese sanitarie conserva il SSN stesso e consente una migliore allocazione delle risorse destinate alla salute[26]. Molto dipende però da quali risparmi e come sono distribuiti. Non c'è dubbio che ogni attività di interesse pubblico debba perseguire un controllo della spesa, ma l'interpretazione assunta dalla Corte costituzionale negli anni Novanta, successivamente confermata e rinforzata dalla riforma costituzionale che ha introdotto l'equilibrio di bilancio (L. cost. n.1/2012), ha imposto più stretti vincoli finanziari e la questione ha assunto una prospettiva di soddisfazione parziale del diritto che poteva limitarsi al suo "nucleo essenziale". L'introduzione in Costituzione di un nuovo art. 81 Cost. era stato considerato l'occasione per superare il bilanciamento ineguale; ma anche in presenza di un principio co-

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CAROSI, *La Corte costituzionale tra autonomie territoriali, coordinamento finanziario e garanzia dei diritti*, in *Rivista AIC*, 2017, 6.

[24] CORTE COST., Sent n. 275 del 2016.

[25] Considera il *primum vivere* alla base delle soluzioni emergenziali adottate durante la pandemia, ma anche del diritto alla salute, insieme al principio del *salus rei publicae*, M. LUCIANI, *Il sistema delle fonti del diritto alla prova dell'emergenza*, in *Rivista AIC*, 2020, 113.

[26] CORTE COST., Sent nn. 70/2017 e 140/2024. Sulla questione si veda C. BUZZACCHI, *Payback e Costituzione. La politica sanitaria tra tetti di spesa e contributi di utilità sociale,* in *Corti Supreme e salute*, 2024, 869 e ss., la quale spiega i meccanismi e le finalità del finanziamento organico e strutturale, necessario per sostenere il SSN. Sulla decisione n. 140/2024 in materia di payback anche M. MILANESI, *Il payback dei dispostivi medici in Corte cost., sentenza n. 140/2024. Ovvero: sul crescente rilievo costituzionale del contenimento della spesa*, in *Osservatorio AIC*, 2024.

stituzionale che impone vincoli di bilancio, non si può considerare un diritto alla stregua dei suoi limiti finanziari: si tratta di oggetti di diversa natura che non possono essere considerati interscambiabili[27].

Tuttavia, una tendenza a considerare i diritti esigibili in funzione delle risorse disponibili ha riscosso un certo successo e la stessa Corte costituzionale nella sent. n. 455/1990 ha avallato quella interpretazione coniando il termine «diritto costituzionale condizionato», legittimando così una certa gradualità anche nell'attuazione del diritto alla salute. La sensibilità che il Giudice delle leggi ha dimostrato nei confronti del contenimento della spesa pubblica *a tout prix* si è riverberata anche sul tenore delle sue stesse sentenze, nelle quali ha provato a valutare i potenziali effetti finanziari della sua giurisprudenza[28]. Quanto all'applicazione dei vincoli di bilancio, la Consulta già nella sent. n. 88/2014, aveva affermato che «Il nuovo sistema di finanza pubblica disegnato dalla legge cost. n. 1 del 2012 ha dunque una sua interna coerenza e una sua completezza, ed è pertanto solo alla sua stregua che vanno vagliate le questioni di costituzionalità sollevate nei confronti della legge»[29], lasciando intendere, perciò, che l'equilibrio di bilancio avrebbe potuto essere elemento attivo del bilanciamento e non più solo una precondizione o una finalità di cui il legislatore *in primis* e la stessa Corte in seconda battuta avrebbero dovuto tenere conto. È nelle sentenze nn. 10 e 70/2015 che il giudice costituzionale afferma con maggiore forza il vincolo di bilancio come super principio che travalica la tutela dei diritti fondamentali: il solo nucleo fondamentale del diritto riesce a prevalere sul bilancio. Non solo è assai complesso tracciare il perimetro del nucleo essenziale del diritto, stabilire cosa comprendere e cosa possa essere considerato superfluo; ma è altresì irrazionale scomporre un diritto fondamentale in parti accessorie e necessarie: il diritto è una garanzia complessa che di volta in volta rivela alcuni aspetti e alcune tutele specifiche che sfuggono a una regola generale e a una compressione lineare dovuta all'esigenza di contenere le spese e di equilibrio di bilancio[30]. Ciò vale in particolar modo per la tutela della salute che è tra i diritti più complessi dal punto di vista strutturale, sicché rimarrebbe intatta solo la libertà di cura e non il diritto alle prestazioni da parte dello Stato. Inoltre, come si è già accennato, l'individuazione del cosiddetto "nucleo incomprimibile" spetta al legislatore che solo può mediare in Parlamento tra diverse esigenze e dunque bilanciare diritti e interessi in gioco; una volta però che ha individuato tale nucleo incomprimibile (che può anche essere assai esteso quando si tratta del diritto alla salute e in un contesto tecnologico avanzato) è tenuto a salvaguardarlo oltre i condizionamenti finanziari.

Una critica strutturale al condizionamento finanziario dei diritti è arrivata con la "giurisprudenza Carosi" che ha ribaltato la prospettiva e ha riaffermato una tutela piena dei diritti anche di quelli a prestazione, i quali non possono essere considerati sullo stesso piano dei vincoli di bilancio[31].

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[27] D. MONE, *Corte costituzionale italiana, Corte di giustizia dell'Unione europea e tutela delle identità nazionali quando il principio dell'equilibrio/pareggio di bilancio comprime i diritti fondamentali*, in *Dirittifondamentali.it.*, 2015 e se si vuole I. CIOLLI, *L'art. 81 della Costituzione: da limite esterno al bilanciamento a super principio, in Forum di quaderni costituzionali*, 2015.

[28] Cfr. CORTE COST., sentt. nn. 30/2004, 342/2002, 180/2001.

[29] ID, sent. n. 88/2014, Punto 6 del *Considerato in diritto*.

[30] M. LUCIANI, *L'equilibrio di bilancio e i principi fondamentali: la prospettiva del controllo di costituzionalità*, in *Corte costituzionale*, *Il principio dell'equilibrio di bilancio secondo la riforma costituzionale del 2012*, Atti del Seminario svoltosi in Roma, Palazzo della Consulta, 22 novembre 2013, Milano, 2014, 20 s. reperibile al seguente link: https://www.cortecostituzionale.it/documenti/convegni_seminari/Seminario2013_Luciani.pdf.

[31] ID., *La "giurisprudenza Carosi"*, in *Scritti in onore di Aldo Carosi*, a cura di G. COLOMBINI, Napoli, 2021, 577 s.

Quella giurisprudenza riconosce pienamente l'importanza di una oculata utilizzazione delle risorse pubbliche e di una rendicontazione chiara e trasparente, perché essa si ricollega al circuito democratico rappresentativo e rende concreta la responsabilità politica. Ciò comporta che tale responsabilità consente di giudicare l'operato dei rappresentanti politici[32]; ma non deve essere inteso nel senso che il vincolo di bilancio debba sempre essere perseguito a tal punto da considerare i diritti fondamentali a intensità graduale, ovvero commisurati alle risorse in campo: sarebbe come dire che in presenza di risorse scarse (ma le risorse sono limitate per definizione), il diritto costituzionalmente previsto deve ridurre le garanzie da approntare. La Corte costituzionale ha rigettato questa interpretazione estrema e ne ha assunto una diversa nella sentenza n. 10 del 2016 e poi la n. 275 del 2016, nella quale ha affermato che «è la garanzia dei diritti incomprimibili ad incidere sul bilancio, e non l'equilibrio di questo a condizionarne la doverosa erogazione»[33].

Di recente, il legislatore nazionale ha ulteriormente esplicitato la priorità della tutela della salute e dei diritti sociali in generale, quando, ha previsto nel Bilancio di previsione 2024, (adottato con Legge 30 dicembre 2023, n. 213, *Bilancio di previsione dello Stato per l'anno finanziario 2024 e bilancio pluriennale per il triennio 2024-2026*) che il contenimento della spesa pubblica «escludesse dal calcolo quelle spese destinate alle politiche sociali, alla famiglia e alla sanità»; a questo proposito, la Corte costituzionale nella sent. n. 195/2024 ha osservato che «la modalità prescelta dal legislatore presenta caratteri di forte novità rispetto alle precedenti manovre di contenimento della spesa regionale», perché ha attribuito alle spese destinate a fornire prestazioni inerenti ai diritti sociali, alle politiche sociali e alla famiglia, nonché alla tutela della salute «una preferenza qualitativa, idonea a distinguerle da quelle rilevanti ai fini del riparto del contributo». Nella stessa sentenza ha ribadito, sulla scia della sent. n. 275/2016, che la tutela della salute e la spesa pubblica in questo delicatissimo settore è una spesa costituzionalmente necessaria[34]. Nella successiva sent. n. 45/2025 ha ribadito che il criterio individuato dal legislatore è volto ad attuare il principio della spesa costituzionalmente necessaria[35] prevedendo che, in un contesto di risorse scarse, debbano essere prioritariamente ridotte le altre spese indistinte, rispetto a quelle che si connotano come funzionali a garantire la tutela dei diritti sociali, delle politiche sociali e della tutela della salute. In altre parole, la Corte ha esplicitato quella tesi che conferisce ai diritti costituzionali una particolare resistenza anche rispetto ai vincoli di bilancio, sempre però in un quadro generale di contenimento della spesa. Si deve però sottolineare una certa differenziazione tra il diritto alla salute che sembra godere di

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[32] Cfr. Corte cost., sent. n. 247/2017, nella quale la Corte stabilisce che il bilancio è «un bene pubblico», sul punto A. Carosi, *La Corte costituzionale tra autonomie territoriali, coordinamento finanziario e garanzia dei diritti*, in *Rivista AIC*, 4. 2017; C. Buzzacchi, *Autonomie e Corte dei conti: la valenza democratica del controllo di legalità finanziaria*, in *Costituzionalismo.it*, 1, 2020, 1 e ss.; G. Rivosecchi, *Il bilancio nel diritto pubblico italiano*, in *Nomos*, 2021.

[33] Corte cost., sent. n. 275/2016, Punto 11 del *Considerato in diritto*. Si vedano tra i numerosi commenti, di L. Carlassare, *Bilancio e diritti fondamentali, limiti «invalicabili» alla discrezionalità del legislatore,* in *Giurisprudenza costituzionale,* 2016, 294 ss.; A. Lucarelli, *Il diritto all'istruzione del disabile: oltre i diritti finanziariamente condizionati*, in *Giurisprudenza costituzionale*, 2016, 299 ss. Se si vuole, anche I. Ciolli, *I diritti sociali «condizionati» di fronte alla Corte costituzionale*, in *Rivista giuridica del lavoro e della Previdenza sociale*, 3, 2017, 353 ss.

[34] Sulla decisione si veda la nota di C. Salazar, *Spese costituzionalmente necessarie, coordinamento finanziario e leale collaborazione nella sent. n. 195/2024*, in *Quaderni costituzionali*, 2025, 223.

[35] Si veda la nota di G. Comazzetto, *Il sentiero impervio della perequazione tra vincoli di bilancio e prospettive di riforma. Nota a Corte costituzionale, sentenza n. 45 del 2025*, in osservatorio AIC, 2025, 84 e ss. La spesa costituzionalmente necessaria è stata evocata sin dalla sent. n.169/2017 e ripresa successivamente nelle sentt. nn. 195/2024, 220/2021, 197/2019, 87/2018.

un trattamento preferenziale in termini di risorse e di vincoli di bilancio rispetto agli altri diritti sociali, sui quali si osserva a fasi alterne una certa regressione, prontamente sottolineata dalla dottrina[36].

Il risparmio, come si è già accennato, deve essere perseguito attraverso politiche virtuose e avvedute, perché le prestazioni sanitarie non devono necessariamente essere costose: valorizzare la prevenzione, una medicina territoriale e di base può portare a una riduzione dei costi così come un'attenta contrattazione sui prezzi dei farmaci e sulla diagnostica più sofisticata può condurre a una razionalizzazione della spesa sanitaria.

In altre parole, esistono i presupposti secondo i quali la sostenibilità del SSN, pur in presenza di spese crescenti e di un accentuato invecchiamento della popolazione, è ancora una prospettiva concreta. La sostenibilità, semmai, deve essere declinata non più soltanto in termini economico-finanziari, ma in un'accezione più ampia e soprattutto in una visione integrata che la Corte costituzionale aveva già scorto nel lontano 1987 quando aveva interpretato il diritto all'ambiente salubre come una delle tante tutele rinvenibili nell'art. 32 Cost. Oggi, la visione "One health" legge la sostenibilità della salute attraverso matrici ancor più estese che, almeno formalmente, hanno costituito il sostrato sul quale basare riforma costituzionale del 2022 (la Legge costituzionale 11 febbraio 2022 n. 1, recante "*Modifiche agli articoli 9 e 41 della Costituzione in materia di tutela dell'ambiente*).

Contemporaneamente, anche il diritto dell'Unione europea, che in materia di diritti sociali è stato in passato poco presente, sembra condividere le scelte di una salute integrata e conferirle una tutela privilegiata quando sono coinvolti più diritti ed interessi[37]. La decisione della Corte di Giustizia dell'Unione Europea (25 giugno 2024 nella causa C-626/22) sul caso italiano Ilva è una delle dimostrazioni di una giurisprudenza sempre più attenta alla sostenibilità della salute negli ambienti di lavoro[38].

Le "Corti europee" sembrano voler costruire una giurisprudenza che tenga conto della tutela integrata della salute e dell'ambiente, come dimostra anche la Corte di Strasburgo che proprio sul caso Ilva, con la decisione 24 gennaio 2019 (*Cordella e altri c. Italia*) ha voluto salvaguardare, sulla scorta di una interpretazione evolutiva dell'art. 8 della CEDU, un'ampia tutela ambientale, che comprende anche la tutela della salute globale e della vita stessa. Nel bilanciamento con le attività produttive, la tutela della salute deve godere di una tutela concreta e in questo caso sono le attività economiche a dover essere sostenibili sotto il profilo della salute individuale dei lavoratori e collettiva perché incide su tutti coloro che abitano in specifici luoghi di lavoro, come la Corte EDU ha ribadito nella decisione Canavacciuolo e altri c. Italia del 30 gennaio 2025, che si concentrava sulla salute dei cittadini residenti o lavoratori nella cosiddetta Terra dei fuochi.

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[36] C. COLAPIETRO, S. BARBARESCHI, *Motivazione, tempo e strumentalità del bilancio: le coordinate giurisprudenziali sul rapporto tra diritti fondamentali e risorse finanziare alla luce della sentenza n. 152 del 2020. Rischiose variazioni ritmiche in una straordinaria composizione*, in *Nomos. Le attualità del diritto*, 2021, spec. 24 e ss. in commento alla sent. n. 152 del 2020.

[37] L'evoluzione della tutela dei diritti sociali nell'ordinamento dell'Unione europea è ben argomentata in A.O. COZZI, *Diritti e principi sociali nella Carta dei diritti fondamentali dell'Unione Europea. Profili costituzionali*, Napoli, 2017.

[38] G. ARCONZO, *Per la Corte di giustizia i decreti Salva Ilva ledono il diritto alla salute degli abitanti di Taranto*, in *Quaderni costituzionali*, 2024, 4, pp. 947 ss.; M. CARDUCCI, *L'installazione "ex Ilva" dopo la sentenza della Corte di giustizia UE: le emissioni climalteranti tra interesse "strategico" e generazioni future*, in *Diritti comparati*, 27 giugno 2024.

3. I doveri di solidarietà e la tutela della salute

La solidarietà si affianca al diritto costituzionale sin dalla elaborazione del concetto in chiave politica: la fraternità rivendicata nella Rivoluzione francese e poi proclamata nella Dichiarazione dei diritti dell'uomo e del cittadino del 1789 è un paradigma che assume il rilievo giuridico e costituzionale nella Costituzione di Weimar e poi nelle Carte del secondo dopoguerra[39]. La nostra Costituzione non si limita a parlare di *fraternité* - che pure è un concetto giuridico di rilievo, di recente utilizzato dal *Conseil constitutionnel* anche in combinato con il principio di solidarietà e con quello di dignità umana – ma prescrive nell'art. 2 Cost. i doveri di solidarietà che è ad ampio spettro, includendo aspetti economici, politici e sociali[40].

Leggendo in combinato il diritto alla salute e i doveri di solidarietà economici politici e sociali si legittima proprio l'universalità del diritto, perché il patto tra consociati garantisce tutti anche se ognuno contribuisce in modo proporzionale alle sue risorse attraverso la fiscalità generale. A chiunque si trovi in una condizione di vulnerabilità e quale che sia stato il suo contributo attraverso la fiscalità generale dovrebbe essere garantita la tutela della salute in condizioni di parità; è però chiaro che chi è più vulnerabile godrà maggiormente delle tutele costituzionalmente previste senza che le garanzie siano legate alla sua capacità contributiva. Riscoprire l'importanza dei doveri e in particolare dei doveri di solidarietà è dunque essenziale per una tutela effettiva dei diritti e in special modo del diritto alla salute[41]. Per meglio dire, i doveri di solidarietà offrono una potente copertura all'universalità del SSN e si configurano anche come strumenti capaci di dare attuazione a quelle esigenze di eguaglianza e di tutela della dignità della persona che il SSN esprime, visto che la ripartizione dei costi del diritto tra i cittadini in modo proporzionale al reddito garantisce l'eguaglianza sostanziale[42].

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[39] Si veda G. Alpa, *Solidarietà. Un principio normativo*, Bologna, 2022; C. Colapietro, S. Barbareschi, A. Giubilei (a cura di), *La solidarietà al tempo della pandemia*, Napoli, 2022; P. Sommeranno, *Some Reflections on the Concept of Solidarity and its Transformation into a Legal Principle*, *Archiv des Völkerrechts*, 52, 1, 2014, 10-24.

[40] La recente giurisprudenza del *Conseil constitutionnel*, legge in chiave evolutiva e innovativa il principio di fraternité. Tra le tante decisioni si vedano *Décisions* n° 2023-853 DC, 25 luglio 2023 e n. 2023-1066 QPC 27 ottobre 2023 che legano fraternità e solidarietà anche delle generazioni future; *Décisons* n. 2021-823 DC, 13 agosto 2021 e n. 2023-1039 QPC, 24 marzo 2023 che legano fraternità e dignità umana. Sul tema della *fraternité*, il *Conseil constitutionnel* con decisione n. 2018-717/718 QPC del 6 luglio 2018 aveva già riconosciuto un valore costituzionale alla fraternità e ne aveva riconosciuto la sua evoluzione storica e giuridica. Sul punto, M. Borgetto, *Il principio costituzionale di fraternità nel diritto francese*, Milano, 2022 e più in generale, Id., *La notion de fraternité en droit public français*, Paris, 1991. Si veda anche in tema di solidarietà e diritto alla salute, A. Mazzola, *Il diritto alla salute tra dimensione individuale e dovere sociale*, in *Consulta Online*, 2, 2021, 572 e ss.

[41] Per una riflessione sui doveri costituzionali G. Lombardi, *Contributo allo studio dei doveri costituzionali*, Milano, 1967; F. Grandi, *Doveri costituzionali e obiezione di coscienza*, Napoli, 2014; sul dovere inderogabile di solidarietà, F. Polacchini, *Doveri costituzionali e principio di solidarietà*, Bologna, 2016; F. Giuffrè, *La solidarietà nell'ordinamento costituzionale*, Milano, 2002.

[42] Sul concetto di universalità e sulla tesi dei minori costi di un SSN a fiscalità generale, si veda N. Dirindin, E. Caruso, C. Rivoiro, *Universalismo e vincoli di bilancio nella tutela della salute: una questione politica, prima ancora che finanziari*, in *Politiche sociali*, 3, 2014, 387 e ss.

3.1. Il dovere di tutelare i più vulnerabili

Nel rispetto del principio di uguaglianza sostanziale dell'art. 3, comma 2 Cost., la tutela della salute deve rivolgersi anche ai più vulnerabili, anche se la rimozione degli ostacoli può comportare dei costi aggiuntivi, ineludibili nell'ottica del ripristino dell'uguaglianza.

Oltre a una prescrizione costituzionale, interviene in favore della tutela dei soggetti vulnerabili, una mutata cultura che vede l'inclusione come un nuovo orizzonte, una nuova finalità che la Costituzione, le fonti nazionali, sovranazionali e internazionali sembrano accogliere[43]. L'integrazione dei soggetti vulnerabili è auspicata anche dall'Organizzazione mondiale della sanità (OMS) che considera la salute umana come «esito dell'*interazione tra la dimensione personale psico-fisica dell'individuo e il contesto socio spaziale*, quest'ultimo costituito dall'ambiente sociale, dalle capacità infrastrutturali del territorio, dalla predisposizione di servizi e apparati in grado di garantire l'accesso libero e indipendente alle opportunità di inclusione, formazione e partecipazione»[44].

In ambito nazionale, l'instancabile lavoro della Corte costituzionale in tema di godimento del diritto alla salute si è anche soffermato con particolare attenzione sui diritti delle persone con disabilità e sulla tutela della salute mentale, degli immigrati e delle persone detenute , nel tentativo di superare le macroscopiche e persistenti disuguaglianze che colpiscono queste categorie. Pur con le dovute differenze, nella Convenzione europea dei diritti dell'uomo, nella Carta dei diritti fondamentali dell'Unione europea e nelle disposizioni legislative e costituzionali nazionali emergono almeno finalità comuni, volte a garantire specifiche tutele e garanzie di inclusione.

Dal canto suo, la disciplina nazionale prova a costruire anche una integrazione tra l'assistenza e la cura, come prevedono il D.lgs. n. 229/1999 e la legge n. 328/2000, seguite poi da legislazioni regionali che disciplinano, a loro volta, nei propri territori, questi nuovi aspetti integrati, che consentono la cura e l'assistenza soprattutto di persone con disabilità e delle persone anziane, ma si occupano anche di particolari condizioni di intersezionalità nelle quali è necessario procedere simultaneamente integrando le attività socioassistenziali[45]. Nel nostro Paese vi è ormai una lunga consuetudine di promozione dell'inclusione come uno degli aspetti fondamentali della stessa attività di cura: tale finalità è stata infat-

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[43] Si pensi alle disposizioni sulla condizione di disabilità, quali la Convenzione ONU sui diritti delle persone con disabilità è stata approvata dall'Assemblea generale nel dicembre del 2006 e ratificata dall'Italia con legge n. 18 del 2009. Si veda in merito all'attuazione dell'Agenda 2030 dell'ONU il report che fotografa le difficoltà di raggiungimento dei 17 obiettivi previsti per le persone con disabilità, come dimostra il *Report on Disability and Development* 2018: *Realization of the Sustainable Development Goals by, for and With Persons with Disabilities*. United Nations Department of Economic and Social Affairs 2018, disponibile al seguente link: https://www.un.org/development/desa/disabilities/publication-disability-sdgs.html. Anche la Convenzione europea dei diritti dell'uomo dedica una peculiare attenzione ai soggetti vulnerabili, come ha ricordato nella sua *Lectio magistralis* «Diritti umani e persone vulnerabili», tenuta dall'allora Presidente della Corte europea dei diritti dell'uomo, Robert Spano, all'Università Sapienza il 22 aprile 2022, ora disponibile al seguente link: https://www.cortecostituzionale.it/documenti/convegni_seminari/itervento_spano_20220503170732.pdf.

[44] C. COLAPIETRO, *Disabilità, solidarietà e tutela della salute* in I. CIOLLI (a cura di), *Salute diseguale,* Napoli, 2024.

[45] V. TONDI DELLA MURA, *La disabilità fra «sanità» e «assistenza» (ovvero fra le omissioni della politica e le innovazioni dell'amministrazione-sussidiaria)*, in *Federalismi.it*, 2011, 1 ss.; C. BUZZACCHI, S. LA PORTA (a cura di), *L'integrazione sociosanitaria e il diritto delle Regioni*, Torino, 2022.

ti perseguita anche nella legge di delega in materia di disabilità (22 dicembre 2021, n. 227) e nei successivi decreti legislativi attuativi[46].

La presenza, inoltre, sul nostro territorio di immigrati in condizione di indigenza, che non sempre conoscono la lingua italiana, ha moltiplicato i fenomeni di intersezionalità, ovvero quelle condizioni nelle quali le vulnerabilità e le disuguaglianze si intrecciano e generano effetti che non possono essere compresi analizzando ogni singolo aspetto isolatamente: se le condizioni di persona immigrata, in cattive condizioni di salute, reclusa, appartenente al genere femminile si presentano contemporaneamente, le tutele si rivelano progressivamente inadeguate[47]. Si chiede perciò al SSN di adeguarsi e di trovare soluzioni che riportino l'equità laddove si annida la disuguaglianza[48].

4. Ancora sulla sostenibilità del SSN: è sostenibile ciò che riteniamo tale. Riflessioni conclusive

La salute è oggi al centro del dibattito politico; alle forze politiche si chiede "più salute". Le nuove tecnologie forniscono maggiore assistenza e il progresso scientifico garantisce cure più efficaci e su uno spettro sempre più ampio di patologie. In tali condizioni si può auspicare che il SSN resti sostenibile?

Ciò è possibile, sebbene sia necessaria la concomitanza di alcune condizioni.

In termini di costi e di spesa sanitaria è necessario ricordare che essa è il frutto di una concertazione e di scelte politiche che mediano tra vari interessi in gioco e che è nella legge di bilancio, la più alta espressione di indirizzo politico, che l'allocazione delle risorse si manifesta. Così come si è scelto in passato di ridurre le spese per la sanità, così come la scelta è stata in (minima) parte corretta con l'insorgere della pandemia e sotto la spinta dell'emergenza, è sempre possibile dedicare risorse maggiori per incrementare il benessere psicofisico dei cittadini e la qualità della vita[49].

Anche nella prospettiva futura di un Paese più anziano e con maggiori cronicità, il SSN potrà continuare a essere sostenibile se sarà in grado di ripensare l'organizzazione sul territorio, di articolare l'assistenza primaria e di base e se riuscirà a contenere le prestazioni inappropriate[50].

Lo stato dell'arte non è roseo: il Rapporto Cergas Bocconi del 2021 evidenzia come l'universalità del servizio è messo a dura prova da una serie di prestazioni *out of pocket* che riguardano in larga misura le vi-

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[46] A. VITALE, *Il d. lgs. 62/2024 interviene sulle definizioni di disabilità, valutazione di base, accomodamento ragionevole e progetto di vita individuale in conformità con la Convenzione ONU sui diritti delle persone con disabilità*, in *Osservatorio sulle fonti,* 2024. È stato sottolineato il salto di qualità operato da più recenti disposizioni normative: «In altri termini, la concezione attuale di disabilità deve superare nel concreto la sola identificazione con la menomazione psico-fisica e considerare le esigenze esistenziali, relazionali, affettive e culturali, nonché soprattutto deve includere il ruolo della persona nei contesti ambientali e sociali in cui è inserita»*,* così C. COLAPIETRO*, Disabilità, solidarietà e tutela della salute*, cit. 25.

[47] P. HILL COLLINS, *Intersectionality as Critical Social Theory*, Durham, 2019; A. LORENZETTI, *Genere e condizioni di vulnerabilità nell'emergenza: l'inesorabile emersione di una doppia marginalità*, in E. CATELANI, M. D'AMICO (a cura di), *Effetto Covid. Donne: la doppia discriminazione*, Bologna, 57 e ss.

[48] Non solo la Corte costituzionale si è occupata in più occasioni di salute degli immigrati, ma anche la CEDU in più occasioni, richiamando gli artt. 3, 8, 14 di salute dei vulnerabili in carcere, di salute mentale e capacità di agire.

[49] Si veda UFFICIO PARLAMENTARE DI BILANCIO, *Focus* 3, *Il riparto del fabbisogno sanitario nazionale tra nuovi criteri e attuazioni incompiute*, in www.upbilancio.it, 2024, 11 ss.

[50] Sul punto si vedano, S. RICCI, A. MIGLINO, *Medicina e Società - Dalla tutela dell'integrità fisica al diritto alla salute*, Roma, 2005.

site specialistiche ambulatoriali, gli accertamenti diagnostici e la quasi la totalità della riabilitazione domiciliare e ambulatoriale; sicché si parla di universalismo selettivo, che peraltro non include coloro che hanno maggiori necessità di cura, ovvero i soggetti vulnerabili.

Un aspetto spesso trascurato riguarda i comportamenti del singolo, che possono garantire ulteriori margini di risparmio e un'ottimizzazione delle risorse disponibili. Attraverso la diffusione di una cultura del benessere psicofisico, da perseguire anche mediante serie politiche di alfabetizzazione dei cittadini, si può plasmare una capacità di resistenza nei confronti del mercato sanitario che trasforma ormai le prestazioni sanitarie in consumi e rende difficile distinguere quelle che sono utili e necessarie da quelle superflue e a volte dannose (si pensi ad esempio agli *screening* inappropriati, che possono sia creare inutili allarmi nel paziente ma anche richiesta di nuovi accertamenti per risposte dubbie e a volte risultare addirittura dannosi se non necessari). Le prestazioni superflue gravano sia sulla salute del singolo, sia sul SSN[51].

Più attente politiche di prevenzione possono contribuire a ridurre o mantenere sostenibile la spesa sanitaria anche se la prevenzione richiede investimenti non solo economici ma anche culturali; sono perciò necessarie strategie e campagne per l'educazione alimentare e per l'adozione di stili di vita più virtuosi.

Una riorganizzazione territoriale della medicina, già avviata -non senza problemi - grazie al D.M. 77 del 2022, può ridurre i costi ospedalieri e le prestazioni più costose, affidando il paziente a strutture socio-sanitarie che lo assistono con continuità, risultando così le cure al contempo più efficaci e meno dispendiose economicamente. Valorizzare la tecnologia e servirsi con maggiore frequenza della telemedicina e rilanciare il ruolo e lo *status* dei medici di medicina generale invece che affidarsi a una medicina specialistica, non sempre in modo appropriato, può rappresentare una soluzione non solo virtuosa dal punto di vista finanziario, ma anche umano e culturale, tornando a porre al centro della discussione il concetto di cura e di benessere psicofisico, non la prestazione in sé[52].

Tutto ciò risponde a un dovere di solidarietà e a un uso accorto delle risorse, nel rispetto del principio dell'equilibrio di bilancio. Il SSN merita una seconda *chance*.

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[51] Si parla di "*disease mongering*", ovvero l'attività di medicalizzazione di pazienti, giustificata dal progresso e dall'aumento delle patologie che possono essere curate, al fine di espandere il mercato di medicinali e di prestazioni; sul punto, L. PAYER, *Disease Mongers: How Doctors, Drug Companies, and Insurers are Making You Feel Sick*, New York, 1992. L'aggravio che pesa sul SSN anche quando le prestazioni sono erogate dal privato e con una spesa *out pocket,* ovvero non coperta dal SSN, per il fatto che i rimborsi fiscali di quelle prestazioni gravano su tutta la cittadinanza.

[52] Sull'uso virtuoso della telemedicina, C. BOTRUGNO, *Telemedicina e trasformazione dei sistemi sanitari. Un'indagine di bioetica,* Roma, 2018. La telemedicina avrebbe anche il vantaggio di raggiungere fasce di popolazione spesso dimenticate dallo stesso SSN; si pensi all'uso della telemedicina in carcere, come ricorda ID., *Telemedicina e diritto alla salute in carcere: stato dell'arte, rischi e opportunità*, in *Biolaw journal*, 2021, 401 e ss.

Disability, Legal Definition and its Assessment

Marco Valerio Sarra*

ABSTRACT: The concept of disability has undergone a profound theoretical and regulatory evolution, shifting from a medical paradigm to a bio-psycho-social model. The modern approach defines disability not as a mere individual condition, but as the result of interactions between functional limitations, environmental factors, and social barriers. Law No. 62/2024 enshrines this innovative vision within the Italian legal framework, introducing assessment criteria based on a multidimensional evaluation aimed at providing personalized support for persons with disabilities. This paper critically analyzes the new assessment process established by Law No. 62/2024, evaluating its effectiveness, consistency with the new paradigm, and practical implementation in real-world contexts. It demonstrates that the approach introduced by Law 62/2024 represents a significant advancement in the definition and assessment of disability in Italy: it shifts the focus from merely verifying functional limitations to building life projects truly centered on the individual.

KEYWORDS: Disability; personalized life plan; multidimensional assessment; paradigm; personalization

SUMMARY: 1. Disability Definition – 2. Disability Assessment – 3. Conclusions.

1. Disability Definition

After an initial approach, dating back to the 1980s which framed disability as a purely individual condition specifically, as the inability of a person to perform one or more tasks typically expected of a "normal" individual, criticism of this conception led the World Health Organization (WHO) to adopt, in 2001, a new classificatory framework: "*International Classification of Functioning*" (ICF).[1]

A fundamental turning point was also marked by the adoption of the United Nations Convention on the Rights of Persons with Disabilities (CRPD)[2] in 2006.[3] The Convention defines disability as an evolving concept that includes long-term physical, mental, intellectual, or sensory impairments which, in interaction with various barriers, may hinder a person's full and effective participation in society on an equal

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[1] International Classification of Functioning, Disability and Health.

[2] Convention on the Rights of Persons with Disabilities. Italy ratified the Convention with Law No. 18 of March 3, 2009, committing to align its legislation and policies with the principles established at the international level.

[3] COURT OF JUSTICE UE, *Chacón Navas*, C-13/05, 2006.

basis with others.[4] The CRPD enshrines the principles of equality and non-discrimination, and promotes rights to personal autonomy, accessibility, education, employment, health, and political participation. Furthermore, it emphasizes a human rights-based approach, shifting the focus from care and protection toward empowerment and social inclusion.

The perspective's shift is paradigmatic. The focus moves from the individual's health condition, an objective status, to the environmental context in which the person operates a subjective and relational dimension.[5] Disability is no longer treated as a fixed individual limitation but rather as a phenomenon that can change depending on the environment in which the person is situated.[6]

Today, disability is recognized as the outcome of a complex interaction between an individual's health condition, personal factors, and environmental elements. Consequently, depending on their specific health condition, a person may encounter an unfavorable context that limits or reduces their functional capacities and social participation. This holistic and multidimensional paradigm of disability reorients the attention away from a strictly medical or pathological model, toward viewing the individual as an active part of the community. It acknowledges that impairments alone do not define disability; what matters are the contextual factors, including obstacles or facilitators, within which the individual lives and interacts.[7]

Therefore, disability is no longer considered solely as a function of a health condition but is instead understood as the result of an interaction between the person, their health status, and an environment that may be non-supportive, or outright exclusionary. In this sense, disability is context-relative: different environments can exert quite different impacts on the same individual.

In essence, the concept of disability has evolved from being seen as the problem of a minority group, to a broader, more inclusive and human-centered perspective. It recognizes that everyone may experience limitations or difficulties at different stages of life.[8] The ICF framework supports not only the assessment of limitations but also the identification of personal resources and capabilities, emphasizing life contexts and individual goals. This approach enables professionals and institutions to identify specific barriers and to plan targeted interventions to support individuals in achieving their life projects, thereby fostering real inclusion and respect for the diverse challenges people face.

However, this new conceptualization inevitably introduces significant challenges in terms of assessment (both clinical and psychological) and protection (both administrative and judicial). One clear indication of this is the considerable number of court decisions issued at every level of jurisdiction to recognize even basic rights of persons with disabilities.[9]

A recent ruling by the Italian Constitutional Court[10] is particularly illustrative in this regard. The Court stated that human dignity is violated whenever the legal system itself, through a rule or prohibition, renders a person disabled or dependent when they would otherwise be capable of performing a given activ-

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[4] R. Dalla Mora, *Disabilità: la storia, il linguaggio, la condizione, la convenzione ONU*, 2022.

[5] N. Curto, C.M. Marchisio, *I diritti delle persone con disabilità. Percorsi di attuazione della Convenzione ONU*, 2020.

[6] Court of Justice UE, *HK Danmark*, C-335/11 - C-337/11, 2013.

[7] S. Favalli, *Disabilità, diritti umani e diritto internazionale*, 2021.

[8] G. Griffo, M. Lomuscio, F. Ortali, *Inclusione, disabilità, cooperazione internazionale*. *L'esperienza della cooperazione italiana 2009-2014,* 2016.

[9] N. Foggetti, *La tutela delle persone con disabilità nel diritto internazionale*, 2017.

[10] Constitutional Court, judgement no. 3/2025.

ity independently. This decision underscores what it truly means to support persons with disabilities. The Court held that even a rule that treats everyone equally may be discriminatory if, rather than removing obstacles to personal development and participation, it introduces disproportionate and unnecessary burdens in relation to a specific need.[11]

In other words, a norm can be discriminatory even when it is formally equal, because not all individuals are, in fact, equal. A legal obstacle that may be easily overcome by a person without disabilities cannot be presumed to be equally manageable by someone with a disability. The legislator must take this into account; otherwise, the legal system itself becomes the source of inequality and exclusion.[12]

2. Disability Assessment

A variety of legal instruments have been developed to ensure that people with disabilities have an adequate standard of living and social protection in different areas, such as the right to work, education, healthcare, leisure and more. However, the exercise of these rights fundamentally depends on an essential prerequisite: the formal recognition of the need for the specific support from the State. Indeed, the assessment of the state of need, and consequently of disability, constitutes a critical element within the social protection system, as it serves as the qualifying criterion for eligibility and access to all support services and benefits designed for individuals facing difficulties.[13]

Recently, Legislative Decree No. 62 of May 3, 2024,[14] which implements the enabling act Law No. 227 of December 22, 2021, reformed the disability assessment process.[15]

The enabling act mandated the government to promulgate legislation that would revise and reorganize the regulatory framework in accordance with Articles 2, 3, 31, and 38 of the Italian Constitution and in conformity with the United Nations Convention on the Rights of Persons with Disabilities (CRPD) and its Optional Protocol.[16] The new regulatory framework guarantees that people with disabilities will receive a consistent, transparent and accessible assessment process to formally recognise their condition.

The primary objective of the new legislation is to enable the full exercise of civil and social rights of vulnerable individuals, including the right to independent living, full social and occupational inclusion, and effective access to services, benefits, financial transfers, and other facilitations. Essentially, the reform aims to promote the autonomy and equal participation of persons with disabilities and their caregivers

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[11] CONSTITUTIONAL COURT, judgement no. 152/2020.

[12] The ruling declared unconstitutional the provision that did not allow persons with disabilities to use digital signatures to endorse candidate lists for elections, stating that the exclusion of persons with disabilities from using digital signatures creates the paradox whereby the legal system, instead of removing barriers that hinder the full development of the human person and effective participation in political organization, introduces "an undue burden, neither necessary nor proportionate to the need to verify the authenticity and genuineness of the candidate list's endorsement, which can equally be achieved by allowing voters with disabilities to use electronic means to support the candidate list".

[13] COURT OF CASSATION, judgment no. 24953 of 15 September 2021.

[14] Legislative Decree 3 maggio 2024, n. 62.

[15] LAW FIRM SASSANO, *Le Novità sull'Accertamento della Disabilità*, https://studiolegalesassano.it/2025/04/03/le-novita-sullaccertamento-della-disabilita/; ASSOCIAZIONE INVALIDI CIVILI GENOVA, *Nuova Legge 104/2024, Novità Accertamento Disabilità*, https://www.associazioneinvalidi.org/.

[16] Signed in New York on December 13, 2006.

by eliminating disparities caused by acquired impairments, respecting their potential desire for self-determination, and ensuring their freedom from discrimination.

Article 2 of the referenced law outlined the guiding principles and directives of the delegation, establishing in paragraph 1 that the new legislation must coordinate, both formally and substantively, the existing laws, including those transposing and implementing European regulations. To achieve this, the legislation shall introduce appropriate amendments aimed at ensuring and improving the legal, logical, and systematic coherence of the sector-specific regulatory framework, as well as adapting, updating, and simplifying the normative language. Furthermore, it shall identify the provisions that must be expressly repealed.[17]

Particularly noteworthy is the provision in paragraph 2 of the delegated law. Indeed, it contains both the preferred definition of disability, namely *"persons with long-term physical, mental, intellectual, or sensory impairments which, in interaction with various barriers, may hinder their full and effective participation in society on an equal basis with others"*;[18] and the new provisions that must underpin the revised regulatory framework for its assessment.

The new regulatory framework should be structured around key focal points, including: a) The assessment of disability, to be clearly distinguished from the subsequent multidimensional evaluation based on the bio-psycho-social model, which can be activated upon request by the person with a disability or their representative, following adequate information on the interventions, supports, and benefits available, and aimed at the so-called individualized, personalized, and participatory life project,[19] ensuring the adoption of criteria suitable to duly consider gender differences; b) The adoption of the International Classification of Functioning, Disability and Health (ICF),[20] approved by the 54th World Health Assembly on May 22, 2001, along with related technical-operational evaluation tools, for the purposes of describing and analyzing functioning, disability, and health, in conjunction with the version of the International Classification of Diseases (ICD)[21] adopted in Italy by the World Health Organization and any other validated and consolidated assessment scales available in the scientific literature and clinical practice; c) The separation of assessment pathways provided for elderly persons from those applicable to adults and minors; d) With regard to the assessment of disability and the revision of its basic evaluation processes, the provision that, in accordance with the guidelines of the ICF and taking into account the ICD,

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[17] In any case, the application of Article 15 of the provisions on the law in general is reserved: *"*Laws are not repealed except by later laws by express declaration of the legislator, or for incompatibility between the new provisions and the previous ones, or because the new law regulates the entire matter already governed by the prior law*"*.

[18] United Nations Convention on the Rights of Persons with Disabilities also published at the following address: https://www.un.org/disabilities/documents/convention/convoptprot-e.pdf.

[19] Letter C) of Delegation Law no. 227, dated December 22, 2021: "*con riguardo alla valutazione multidimensionale della disabilità e alla realizzazione del progetto di vita individuale, personalizzato e partecipato"*.

[20] International Classification of Functioning, Disability and Health (ICF), adopted by the World Health Organization in accordance with Articles 21(b) and 22 of the Protocol to the Constitution of the World Health Organization, signed in New York on 22 July 1946, proclaimed in force by Legislative Decree of the Provisional Head of State 4 March 1947, no. 1068.

[21] International Classification of Diseases (ICD), adopted by the World Health Organization in accordance with Articles 21(b) and 22 of the Protocol concerning the Constitution of the World Health Organization, signed in New York on 22 July 1946, made effective by Legislative Decree of the Provisional Head of State 4 March 1947, no. 1068.

the basic assessment shall verify, pursuant to Article 3 of Law No. 104 of February 5, 1992,[22] as amended to align with the United Nations Convention on the Rights of Persons with Disabilities, the condition of disability and the needs for support, intensive support, or restriction of participation of the person for the purposes of related benefits or institutions. This includes simplifying procedural and organizational aspects to ensure timeliness, efficiency, transparency, and protection of the person with a disability, as well as the rationalization and unification into a single procedure of the basic assessment process under Law No. 104/1992 and the various existing types of civil invalidity, confirming and guaranteeing the specificity and autonomous relevance of each form of disability.[23]

Another essential element required by the Parliamentary Bodies from the Government was to entrust a single public entity with exclusive medico-legal competence over the assessment procedures, ensuring homogeneity nationwide and achieving, also for the purpose of reducing judicial litigation, a simplification and rationalization of procedural and organizational aspects of the basic assessment process. This also includes provisions for simplified review or reassessment procedures, to guarantee timeliness, efficiency, and transparency, as well as recognition of protection and representation of persons with disabilities throughout all phases of the disability verification process, ensuring the participation of relevant associations.

Based on this latter point, the reform introduced by the Legislative Decree 62 of 2024 established the "basic assessment", a unified and multidisciplinary procedure aimed at verifying the condition of disability and the intensity of necessary supports. The legislation aims to guarantee individuals access to recognition of their possible disability condition and to remove any obstacles inherent to that condition so as not to endanger the full enjoyment of all rights to which everyone is entitled on an equal basis with others. This is also achieved through the support of all tools necessary to ensure physical, mental, and functional equivalence.

A necessary prerequisite for the new verification procedure is the establishment of a normative benchmark defining what must be ascertained i.e. the conditions, i.e., the conditions that must exist to define a disability condition. The legislation identifies the protected condition as a lasting physical, mental, intellectual, neurodevelopmental, or sensory impairment which, interacting with various barriers, may hinder full and effective participation in different life contexts on an equal basis with others.

The verification procedure introduces major innovations related to the new administrative process for recognition of disability status, which will be conducted through the so-called "basic assessment procedure."

The basic assessment is a unified procedure aimed at recognizing the disability condition as defined above for all individuals[24] encompassing all civil disability verifications provided by current legislation, specifically including: a) Verification of civil disability under Law No. 118 of March 30, 1971, and conditions under Law No. 18 of February 11, 1980, Law No. 508 of November 21, 1988, and Law No. 289 of

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[22] Law no. 104, 5 february 1992.

[23] M.G. Bernardini, *La capacità legale universale come requisito indefettibile della libertà. Notazioni teoriche in un'ottica di riforma,* 2024.

[24] It also applies to minors and to elderly people, without prejudice to the provisions of Article 27, paragraph 11, of Legislative Decree No. 29 of March 15, 2024, for elderly non-self-sufficient individuals who have surpassed seventy years of age. Elderly non-self-sufficient persons aged between 65 and 70 years, in any case, are guaranteed access to the Integrated Care Project (PAI) referred to in Article 1, paragraph 163, of Law No. 234 of December 30, 2021.

October 11, 1990; b) Verification of civil blindness pursuant to Law No. 382 of May 27, 1970, and Law No. 138 of April 3, 2001; c) Verification of civil deafness pursuant to Law No. 381 of May 26, 1970; d) Verification of deaf blindness pursuant to Law No. 107 of June 24, 2010; e) Verification of disability condition in developmental age for school inclusion purposes pursuant to Article 5 of Legislative Decree No. 66 of April 13, 2017; f) Verification of disability condition for employment inclusion pursuant to Law No. 68 of March 12, 1999;[25] g) Identification of prerequisites for granting prosthetic, health, and rehabilitative assistance as provided by essential levels of assistance; h) Identification of elements relevant to defining non-self-sufficiency and severe disability as per the Ministerial Decree of Labor and Social Policies dated September 26, 2016;[26] i) Identification of requirements for access to fiscal, tax, and mobility benefits consequent to disability verification and any other benefits provided by law.

The basic assessment procedure is activated upon request by the interested party or, in the case of minors or legally incapacitated individuals, by their legal guardian, trustee, or support administrator with powers.[27] The initial administrative act is the electronic submission of a medical introductory certificate issued by subjects expressly identified by law, which must include: a) Personal data, tax code, and health card number of the person undergoing the basic assessment; b) Documentation related to diagnostic verification, including anamnesis and follow-up data, including outcomes of pharmacological, surgical, and rehabilitative treatments; c) Diagnosis coded according to the ICD system; d) Course and prognosis of any diagnosed pathologies;[28] e) Possible domicile declaration of the individual.

Alongside the medical certificate submission, the interested party may, in specific cases, request assessment solely based on collected medical and other documentation, without the need for an in-person examination. In this case, the applicant must submit all documentation as well as the WHODAS[29] questionnaire.[30] If this request is denied, the commission cannot reject it outright but must order an examination, similarly for those who did not request assessment based solely on documents.

Upon ordering the examination and acquiring any additional medical or social documentation issued by an accredited public or private facility (which the applicant may submit up to seven days prior), the basic assessment is performed. At this stage, if not already provided, the WHODAS questionnaire completion is requested.

The basic assessment is conducted on a single collegial visit and must be completed within ninety days of receiving the medical certificate; within fifteen days for cases involving oncological patients; and with-

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[25] F. Ippoliti, P. Corbosiero, N. Canitano, F. Massoni, M. Ricciardi, L. Ricci, T. Archer, S. Ricci., *Work-related Stress, over nutrition and cognitive disability*, in *Clinica Terapeutica*, 168, 1, 2017, 42-47; S. Ricci, F. Massoni, M. Di Meo, L. Petrone, N. Canitano, F. Ippoliti, M.E. Cinti, *Correlation among measures of stress, indicators of biohumoral nature and medico-legal considerations*, in *Rivista di Psichiatria*, 48, 2, 2013, 113-20.

[26] T. Archer, S. Ricci, D. Garcia, M. Rapp Ricciardi. *Neurodegenerative Aspects in Vulnerability to Schizophrenia Spectrum Disorders*, in *Neurotossicity Research*, 26, 2014, 400-13.

[27] L. Ricci, B. Di Nicolò, P. Ricci, F. Massoni, S. Ricci, *The exercise of rights beyond therapy: on Human Enhancement*, in *BioLaw Journal*, 1, 2019, 497-512.

[28] F.M. Damato, P. Ricci, R. Rinaldi, *Informed consent and compulsory treatment on individuals with severe eating disorders: a bio-ethical and juridical problem*, in *Clinica Terapeutica*, 174, 4, 2023, 365-369; G. Montanari Vergallo, L. Leondina Campanozzi, M. Gulino, L. Bassis, P. Ricci, S. Zaami, S. Marinelli, V. Tambone, P. Frati, *How Could Artificial Intelligence Change the Doctor–Patient Relationship? A Medical Ethics Perspective*. Healthcare, 13, 18, 2025, 2340.

[29] World Health Organization Disability Assessment Schedule.

[30] WHO Disability Assessment Schedule, an assessment questionnaire based on the ICF that measures health and disability status.

in thirty days for minors. If further documentation or diagnostic investigations are necessary, deadlines are suspended for sixty days, extendable upon request for another sixty days. Additional information may only be requested if necessary to recognize a higher intensity of support or if the application cannot be accepted based solely on the documents already submitted.[31]

The final outcome of the basic assessment is certified with an indefinitely valid certificate in which the commission describes the conditions identified pursuant to Article 12, paragraph 2, letter c), which is recorded in the electronic health record. In the case of recognized disability status, the certificate specifies the necessity and intensity of supports, including exceptional cases pursuant to Article 12, paragraph 2, letter d), and the related validity period. INPS[32] (National Social Security Institute) is also responsible for establishing modalities to ensure timely distribution of economic benefits consequent to the basic assessment, starting from the month following the submission date of the introductory medical certificate. Further procedural modalities, after consulting the Data Protection Authority, as well as the modalities for commission meetings, are established by INPS within six months from the date of entry into force of this decree. The legislation also provides a priority pathway for individuals with severe disabilities and high functional impairments, allowing access to social, socio-health, and socio-assistance benefits as per Article 7, paragraph 2,[33] even before completion of the basic assessment if the infirmity is certified by an accredited public healthcare or social healthcare facility. In case, at the end of the verification procedure, a lower level of support is deemed necessary than initially granted urgently, the latter measures will be revoked accordingly.

The assessment of disability for individuals under seventy years old,[34] which from January 1, 2027, will be under the exclusive competence of INPS, will be entrusted to so-called "basic evaluation units" composed of two physicians appointed by INPS, a healthcare professional representing principal associations of persons with disabilities,[35] a professional from psychological or social fields, and chaired by one of the two physicians appointed by INPS holding specialization in legal medicine. For assessments of minors,

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[31] L. RONDANINI. *L'accertamento della condizione di disabilità: il certificato medico integrative*, https://www.erickson.it/it/mondo-erickson/laccertamento-della-condizione-di-disabilita-il-certificato-medico-integrativo.

[32] Istituto Nazionale della Previdenza Sociale.

[33] Legislative Decree 62/2024, art. 7, paragraph 2: "By regulation of the Minister of Labor and Social Policies pursuant to Article 17, paragraph 3, of Law no. 400 of 23 August 1988, adopted in agreement with the Ministers of Health and of Economy and Finance and with the Political Authority delegated for disability, following an understanding reached at the Unified Conference referred to in Article 8 of Legislative Decree no. 281 of 28 August 1997, within six months from the date of entry into force of this decree, the reimbursable services under paragraph 1 and the specific modalities for requesting the provision are identified".

[34] Legislative Decree 62/2024, art. 9, paragraph 7: "The assessment of the condition of non-self-sufficiency for people aged seventy and over is carried out pursuant to Article 27 of Legislative Decree No. 29 of 15 March 2024.".

[35] Legislative Decree 62/2024, art. 9, paragraph 4: "The base evaluation units referred to in paragraphs 2 and 3 are integrated with a healthcare professional acting on behalf of, respectively, the National Association of Civilian Disabled (ANMIC), the Italian Union of the Blind and Visually Impaired (UICI), the National Entity for the Protection and Assistance of Deaf-Mmutes (ENS), and the National Association of Families and People with Intellectual Disabilities and Neurodevelopmental Disorders (ANFFAS), identified according to the specific disability conditions under assessment".

one of the two physicians must hold specialization in pediatrics, child neuropsychiatry, equivalent or related specialties, or specialization in the pathology characterizing the person's health condition.[36]

Participation of at least three members is mandatory during the evaluation, with the chairperson's vote counting double in case of a tie, determining the outcome. The person being examined must be allowed to be assisted by their trusted physician.

Other regulated aspects include the rationalization, simplification, and harmonization of assessment procedures. Thanks to additional funding granted to the assessing entity, it must ensure proximity of the evaluation procedure, simplification of the administrative process, including internal reorganization identifying specific responsibilities and competences of bodies and offices, and homogeneity of assessments nationwide.

The final evaluation following the verification procedure must specify: a) The person's health condition as described in the introductory medical certificate with ICD codes;[37] b) Assessment of lasting and significant impairments of health status functional, mental, intellectual, or sensory in accordance with ICF guidelines and considering ICD; c) Identification of functional and structural deficits hindering the person's health-related activities per ICF capacity framework; d) Determination of the person's functioning profile concerning mobility and autonomy in basic and instrumental activities of daily living requiring continuous support;[38] e) Evaluation of the impact of functional and structural impairments on capacity, per ICF classification, in activity and participation domains, including work and higher education domains (for minors, including learning and school domains);[39] f) Assessment of support needs level mild, moderate, intensive, high, or very high linked to ICF activity and participation domains.

The final disability recognition certificate effectively replaces all previous certifications, and its submission automatically constitutes a request for all social, socio-assistance, and socio-health benefits to which the person is entitled.[40]

An important innovation beneficial to persons with disabilities, if correctly applied, concerns communication duties of the basic evaluation units upon recognizing disability status. The commission must communicate not only the examination outcome and related interventions, supports, and benefits directly owed following disability certification but also inform about the right to develop and activate an individualized, personalized, and participatory life project as a further integration tool within the person's living environment.

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[36] INPS Circular of 27 December 2024; INPS Circular No. 1980 of 23 June 2025; Italian Budget Law 2025.

[37] Legislative Decree 62/2024, art. 12, comma 1: "...with regulation of the Minister of Health..., to be adopted by 30 November 2026, the basis of the ICD and ICF classifications and in accordance with the disability definition pursuant to Article 2, paragraph 1, letter a), the updating of the definitions, criteria and procedures for determining civil invalidity, civil blindness, civil deafness and civil deaf-blindness as provided for by the Minister of Health Decree of 5 February 1992, published in the Official Gazette No. 47 of 26 February 1992".

[38] Law 22 giugno 2016, no. 112

[39] R. FERRARA, L. IOVINO, M. DI RENZO, P. RICCI, *Babies under 1 year with atypical development: perspectives for preventive individuation and treatment*, in *Frontiers in Psychology*, 2022, 1-9; G.M. TROILI, R. BUSINARO, F. MASSONI, L. RICCI, L. PETRONE, P. RICCI, S. RICCI, *Investigation on a group of autistic children: Risk factors and medical social considerations,* in *Clinica terapeutica*, 164, 4, 2023; T. ARCHER, S. RICCI, F. MASSONI, L. RICCI, M. RAPP-RICCIARDI, *Cognitive benefits of exercise intervention,* in *Clinica Terapeutica*, 167, 6, 2016, 180-185.

[40] S. RICCI, A. MIGLINO, *Medicina e Società: dalla tutela dell'integrità fisica al diritto alla salute*, Roma, 2005, 1-99.

To simplify this process, upon request by the interested party, the commission must transmit the disability certificate, once uploaded to the electronic health record (FSE),[41] to an authorized entity to initiate the individualized life project procedure, which also serves as a formal initiation request for the project under Law 241/90.

At this point, the importance of the "life project" becomes clear as an essential element for truly overcoming psycho-physical barriers between the vulnerable individual and society. This project is now established as a subjective right of the disabled person, a necessary and fundamental tool to ensure independent, socially inclusive, and personally fulfilling life, understood as the capacity to determine tools best suited to individual needs.

The life project is regulated under Chapter III, Articles 18 and following, aiming to improve personal and health conditions of the disabled in various life domains, facilitating social inclusion and participation, ensuring, to the greatest extent possible, equality with other community members, through listening to the disabled person's individual objectives and seeking appropriate tools for the specific case.

In other words, the life project aims at identifying tools, resources, interventions, benefits, services, and reasonable accommodations necessary,[42] to eliminate or prevent barriers obstructing the disabled person's full enjoyment of rights, also activating supports necessary for inclusion and participation in diverse life contexts, including education, higher education, housing, work, and social life.[43]

The disabled individual becomes, understandably, the central figure of the procedure, requesting activation, contributing to content determination, and exercising prerogatives to modify or integrate the project according to personal desires, expectations, and choices.

The project's development is entrusted by law to "multidimensional evaluation units", [44] activated upon request by the interested party, conducting evaluation based on a multidisciplinary bio-psycho-social approach, considering ICF and ICD indications. The procedure comprises four phases: a) Acknowledgment of the basic assessment, detection of the person's goals according to their desires and expecta-

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[41] Fascicolo Sanitario Elettronico.

[42] Law no. 104 of February 5, 1992: "Art. 5-bis (Reasonable accommodation). - 1. In cases where the application of legal provisions does not ensure to persons with disabilities the enjoyment and actual and timely exercise, on an equal basis with others, of all human rights and fundamental freedoms, reasonable accommodation, pursuant to Article 2 of the United Nations Convention on the Rights of Persons with Disabilities, done at New York on December 13, 2006, identifies the measures and adjustments necessary, relevant, appropriate and adequate, that do not impose a disproportionate or excessive burden on the obligated party".

[43] R. FERRARA, F.M. DAMATO, L. RICCI, L. IOVINO, S. RICCI, P. RICCI, M.C. LAZNIK, G. CICINELLI, *Parents-children co-regulation as therapeutic variable and target in autism spectrum disorders. From observation of drive to need of cooperative parent-mediated therapy*, in *Clinica Terapeutica*, 174, 6, 537-44, 2023; R. FERRARA, L. RICCI, P. RICCI, L. IOVINO, S. RICCI, F.M. DAMATO, G. CICINELLI, R. KELLER, *How autistic women are aware of their body and take care of their health? Focus on menstruation cycles and gynaecological care*, in *Clinica Terapeutica*, 175, 3, 2024, 168-175.

[44] D. Legislative Decree 62/2024, art. 24, paragraph 2: *"The members of the multidimensional assessment unit are: a) the person with a disability; b) the person exercising parental responsibility in the case of a minor, the guardian or the substitute administrator, if empowered; c) the person referred to in article 22, if named by the interested party; d) a social worker, an educator, or another operator of territorial social services; e) one or more healthcare professionals designated by the health authority or by the district health service tasked with ensuring social-health integration; f) one representative of the educational institution in the cases referred to in article 6 of Legislative Decree 13 April 2017, no. 66; g) where necessary, a representative of the employment insertion services for people with disabilities referred to in article 6 of Law no. 68 of 12 March 1999, in the cases referred to in article 1, paragraph 1, of the same law; h) the general practitioner or the pediatrician chosen by the person with a disability*".

tions, and definition of functioning profile, including capacity and performance per ICF, in chosen life domains; b) Identification of barriers and possible facilitators in the above domains and adaptive competences; c) Formulation of assessments regarding physical, mental, intellectual, and sensory health profile, needs, and quality of life domains, considering the disabled person's priorities; d) Definition of goals to be achieved with the life project, starting from census of any existing specific support plans and their objectives.

At the conclusion of the assessment process, the Multidimensional Evaluation Unit formulates an individualized *Life Project Plan*, which identifies the necessary support measures, allocates the associated *project budget*, and determines the *reasonable accommodations* required to ensure the effective enjoyment of fundamental rights and freedoms. This is carried out while taking into account any proposals made by the individual with a disability, subject to prior verification of their appropriateness and adequacy. The project budget is defined simultaneously. The Life Project must specify the following: a) the personal goals of the individual with a disability, as derived from the outcome of the multidimensional assessment; b) the interventions identified in the following domains: education, social interaction and affectivity; vocational training and employment; housing and social living environment; health and healthcare; c) the services and measures relating to care and assistance processes, as well as the reasonable accommodations aimed at promoting the highest attainable quality of life and enhancing the participation of the individual with a disability across various life domains. These must also ensure full inclusion and equitable access on a basis of equality with others to civil and social rights and fundamental freedoms, including entitlements under the Prime Ministerial Decree of January 12, 2017 (published in the Official Gazette No. 65 of March 18, 2017); d) operational and individualized action plans related to the objectives of the Life Project, including prioritization where applicable. In cases where preexisting plans are in place, alignment shall be ensured in terms of objectives, benefits, and interventions; e) the professionals and stakeholders responsible for the delivery of support services, with clear delineation of roles and responsibilities; f) the designated *project implementation coordinator*; g) the timeline and modalities for periodic evaluations and updates of the plan, to ensure continued relevance and appropriateness of the services and supports provided, relative to the stated objectives; h) a detailed inventory of human, professional, technological, instrumental, and financial resources public, private, and from the third sector either already available or mobilizable at the community level, including the family support network and informal support systems. These collectively constitute the *project budget*, as outlined in Article 28.

A critical element for the successful implementation of the Life Project is the precise definition of roles and responsibilities for all actors involved, including third-sector organizations. Each party must be clearly assigned their tasks in the execution of the plan.

The State, regional authorities, and local institutions, within their respective competencies, are mandated to ensure the effective implementation and national consistency of the Life Project, regardless of the individual's age, personal, or social circumstances. They must also provide for the measures set forth in existing legislation to combat poverty, marginalization, and social exclusion, and extend any applicable support to both the individual's family unit and their caregivers.[45] This includes, for instance, the possibility of acquiring a vehicle equipped with assistive driving technologies an enabling factor for mobility

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[45] COURT OF CASSATION, Labour Section, judgment no. 31591, 9 December 2024.

and independence that would otherwise constitute a significant barrier to achieving a standard of living comparable to that of individuals without disabilities.

3. Conclusions

In conclusion, the life project represents a radical methodological shift from a predominantly performance-based model to a participatory, person-centered paradigm. This approach is now more consistent with the framework of constitutional principles such as substantive equality, self-determination, and human dignity, reflecting a profound rethinking of public institutional interventions through the establishment of a transparent, participatory, and person-centered administrative process.

The inadequacy of a regulatory framework based solely on the provision of services or benefits in response to administrative requests is now definitively established. The traditional, fragmented, and standardized performance model is superseded by a person-centered approach that recognizes and values individual aspirations, preferences, values, and life choices.

The individualized life project, which is both personalized and shared, emerges as the pivotal instrument facilitating this paradigm shift. Interventions are no longer designed generically *for persons with disabilities*, but are developed *with the person with disabilities* through a process beginning with active listening, multidimensional assessment, and the collaborative definition of life goals. This process aims not only to meet needs but to ensure full social inclusion, active participation, and self-realization in contexts chosen by the individual.

The life project is not a standardized, replicable assistance model but a unique and dynamic construct based on a comprehensive and integrated evaluation of the individual. It is oriented toward enhancing capacities, promoting autonomy, and supporting the full exercise of citizenship rights. This approach is the only way to realize the principle of substantive equality and foster a truly inclusive society one in which everyone, regardless of disability, is empowered to live a life of equal opportunity and dignity.

Traditional Chinese Medicine and Medical Liability: Regulatory and Judicial Developments and Future Prospects

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ABSTRACT: The growing popularity of Traditional Chinese Medicine (TCM) in Italy raises important medical-legal and ethical issues. Although increasingly present in hospitals, universities and in the management of chronic diseases, TCM is not recognised as an autonomous discipline: it is classified as an unconventional practice reserved for doctors. The absence of specific legislation creates uncertainty regarding informed consent, standards of care and professional responsibility. The article also analyses recent case law and ethical principles, highlighting the need for a clearer regulatory framework, accurate documentation, interdisciplinary communication and continuous training to ensure safety and professional protection.

KEYWORDS: Acupuncture; medical act; medical liability; traditional Chinese medicine; legislation

SUMMARY: 1. Background – 2. Unconventional Medicine – 3. Material and Method – 4. Results – 5. Discussion – 6. Conclusions.

1. Background

In our system, there are no provisions stipulating what medical activities are, but a medical act is what is taught as such in universities.

Article 100 of R. D. July 27, 1934 no. 1265 (Unified text of Health Laws) provides that "no one may practice as a medical surgeon [...] unless he or she is of legal age and has obtained a professional qualification in accordance with the regulations in force".

Professional licensure, acquired by passing a state examination,[1] presupposes a medical degree. It should also be taken into account that, according to the legislative decree of the Provisional Head of State that established the Orders of Surgeons, Veterinarians, Pharmacists and Colleges of Midwives,[2]

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[1] Art. 33, co 5, Italian Constitution.

[2] Legislative Decree PCS no. 233 of September 13, 1946.

registration in the professional register[3] is necessary for the practice of the health profession and that one of the requirements to be registered is to have "obtained an academic degree given or confirmed by a university or other institution of higher learning".[4]

So, the Medical Act is recognized in an indirect way by the Ordinance: those disciplines covered in university teaching are medical. Consider now that the Unified Law on Higher Education[5], with Article 1, states: "The purpose of higher education is to promote the progress of science and to provide the scientific culture necessary for the exercise of offices and professions".

The scientific model in our tradition is the Galilean experimental model. Therefore, the medical activity to which the law indirectly refers is scientific because it is the subject of university teaching[6].

2. Unconventional Medicine

Healing practices that do not belong to evidence–based medicine and that the European Parliament in a resolution of May 1997 called unconventional medicine are assuming great importance.

In some EU countries, non–conventional medicines have been specifically regulated.

In Italy, the medical activity to which the law makes indirect reference is conventional and scientific medicine, because the only one that is the subject of university teaching. From this it follows that, according to the legislative system, in the past, non–conventional medicine could not have been included in the definition of a medical act and as such, not constituting a medical activity, could have been practised by anyone without incurring the offence of abusive exercise of the profession, provided for and punished by Article 348 of the criminal code. This logical conclusion was also highlighted by judicial decisions.

In 1981, the Court of Perugia stated[7] that

> the health profession is that which includes the diagnostic–curative activities forming part of the current order of studies in medicine. The activities carried out by 'Healers' are not taught by universities nor subject to examination in State examinations and since they do not form part of the medical profession, their exercise does not constitute abusive professional practice[...].

The same principle was reiterated for Chiropractic.

According to the Constitutional Court,[8] Article 348 of the Criminal Code only punishes anyone who abusively exercises a profession for which a special State authorisation is required. Since the Italian legal system does not require any authorisation for the profession of 'chiropractor', which our law ignores,

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[3] Art. 8 L.D. CPS 233/46.

[4] Art. 9 D. l. vo CPS 233/46.

[5] The text in question was approved by Royal Decree 1592 of August 31, 1933.

[6] S. Ricci, A. Miglino, *Atto Medico e Consenso Informato,* 2009; F. Massoni, C. Simeone, E. Luzi, C. Palla, S. Ricci, *Appropriateness prescribing and doctor's professional responsibility,* in *La Clinica Terapeutica*, 163, 4, 2012, 193–99; F.M. Damato, P. Ricci, R. Rinaldi, *Informed consent and compulsory tratment on individuals with severe eating disorders: a bio-ethical and juridical problem,* in *Clinica Terapeutica,* 174, 4, 2023, 365–69; K. Chan, *The Evolutional Development of Traditional Chinese Medicine (TCM) Outside the Chinese Mainland. Challenges, Training, Practice,* in *Research, and Future Development. World Journal of Traditional Chinese Medicine,* 2, 4, 2016, 6-28.

[7] Court of Perugia, Italy, 16 February 1981, (see on acupuncture) in *Riv It Med leg*, 1981, 847.

[8] Constitutional Court, 2 February 1988, no. 149, in *Giust Cost*, 1988; 1, 489.

until such time as the State decides to regulate it and require a special authorisation for its exercise, it will remain a professional occupation protected by Article 35, paragraph 1, of the Italian Constitution, in all its forms and applications, and a free private initiative referred to in Article 41 of the Italian Constitution, with Article 348 of the criminal code being absolutely inapplicable.[9]

This jurisprudential conception, which was absolutely adherent to the letter of the law, has been overtaken by case law in the course of time, which has sought to better protect the health of citizens.

For Acupuncture, in Italy, the Supreme Court, in a ruling of 6 April 1982,[10] held that

> a medical degree is required for the practice of acupuncture: anyone practising acupuncture who lacks such a qualification commits the offence set out in Article 348 of the Criminal Code aimed at protecting public health. In fact, although acupuncture does not constitute a subject of teaching in Italian universities, it can only be practised by doctors or surgeons, knowledge of medicine or surgery being necessary to make an exact diagnosis and to avoid harmful consequences for the patient.

For the S.C., therefore, "acupuncture falls within the broader category of the profession".

The jurisprudence on the merits has conformed to this guideline.

According to the court of Gela,[11] since all acts aimed at diagnosing illnesses and prescribing remedies to treat them (even if different from those ordinarily practised) are typical acts of a doctor, the practice of Iridology (the case at issue in the decision), since it is aimed at making a diagnosis and prescribing a therapy (even if it is based on natural methods), is the performance of a health profession and, as such, subject to the prescribed State authorisation.

It follows from this that those practising Iridology commit the crime of abusive exercise of the medical profession, since they perform acts that are typical and exclusive to a doctor, such as examining patients, diagnosing an illness and prescribing a cure, without holding a medical degree.

The Turin Magistrate's Court[12] assumes that healthcare activity is that which takes place in the diagnosis of an organic alteration or a functional disorder of both body and mind, in the identification of the necessary remedies and in the administration of remedies of the same, carried out directly by the doctor or, possibly, by means of paramedics under the control of the healthcare professional. Therefore, both Pranoterapy, Hypnotic Induction and Acupuncture are therapeutic techniques whose exercise requires a licence to practise as a doctor, without which one incurs the offence referred to in Article 348 of the Criminal Code.

And again: the Civil Cassation[13] ruled that "integrates the crime of abusive exercise of the medical profession under Article 348 of the Criminal Code the conduct of those who make diagnoses and issue prescriptions and health prescriptions for homeopathic products. Such activities are in fact part of the exercise of a health activity that presupposes – for legitimate performance – the possession of a valid and suitable title".

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[9] CRIMINAL CASSATION, Italy, sez. VI, 4 April 2005 no. 12626, in *Rass Dir Farmaceutico*, 2005; 6, 1213.

[10] K. CHAN, H. LEE, I. CHAPTER, *The Historical Evolution of Chinese Medicine and Orthodox Medicine in China*, in *The Way Forward for Chinese Medicine,* 2002; 1–21.

[11] PRETURA OF GELA, Italy, 16 January 1995, in *Cass Pen,* 1995, 1663 and in *Giur Merito,* 1995, 509.

[12] PRETURA OF TORINO, Italy, 19 January 1983, Coccolo, in *Riv It Med leg,* 1984, 221.

[13] ITALIAN COURT CASSATION, 6th civil section, 25 February 1999, no. 2652, in *Rass Dir Farmaceutico,* 1999; 479.

As we can see, jurisprudence, motivated by the aim of protecting the health of the citizen regarding those who do not possess adequate clinical knowledge, has taken a different path from that indicated by the law, including in medical activity practices that, although not the subject of higher education, involve therapeutic functions.

In Italy, the legal status of non–conventional medicines in the mid–1990s was ambiguous.

On one hand, there were regulatory provisions from which it appeared that our system excluded non–conventional medicines because they were not included in the curricula of university studies; on the other hand, there was case law that attributed the nature of a medical act to certain practices in the medical field that are not included in such curricula.

It may well be said, then, that an unconventional practice is legally considered a medical act when it is the subject of university teaching or jurisprudential decisions qualifying it as such.

This second eventuality is, however, absolutely problematic.

In most cases, judges deal with the issue from the point of view of the abusive exercise of the medical profession and make their determinations from time to time. There can therefore be different and even contradictory positions and, until the Supreme Court of Cassation rules (a body at the top of the judicial organisation, whose task is, inter alia, to ensure the exact observance and uniform interpretation of the law), one cannot be certain whether a discipline is to be definitively considered medical (Only in the case of acupuncture and homeopathy has the Supreme Court ruled).

Moreover, the Supreme Court's own guidelines may change.

Ours is a system that we could define as 'dynamic', precisely to indicate, without thereby expressing any value judgement, that the legal status of non–conventional medicine is not unitary: only practices that are taken into consideration by the academic or jurisprudential world can rise to the legal dignity of a medical act.[14]

The practice of Traditional Chinese Medicine (TCM) has deep roots in history and has influenced the health and well–being of millions of people worldwide. The basic knowledge of TCM mainly includes the theories of yin–yang, the five elements, zang–fu, 'Qi', blood and body fluid, meridians and collaterals. The main TCM techniques include acupuncture, moxibustion, herbal medicine, tuina, diet and Qigong. Diagnosis in TCM is based on a detailed analysis of the patient's symptoms, physical appearance, pulse and tongue. Once the underlying causes of the disease have been identified, treatment aims to restore the individual patient's energy balance.

The fundamental principles that the physician must respect while exercising his profession are well defined by legal and deontological norms and the main aspects to be respected fall under the terms of prudence, expertise and diligence.

The same fundamentals of professional liability relating to imprudence, inexperience and negligence and non–compliance with laws and regulations apply to the acupuncture doctor.

The contract of care between physician and patient justifies the physician's act, which hinges on two essential foundations: informed consent and the provision of medical care, both of which are part of the required conduct.[15]

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[14] ISTITUTO PARACELSO*, Elementi essenziali di agopuntura cinese*, Roma; 2002, 2^ ed.

[15] S. RICCI, *et al., op. cit;* F.M. DAMATO, P. RICCI, R. RINALDI, *op. cit.*

From the point of view of forensic medicine, the medical act is a complex act involving several intersecting steps: prevention, diagnosis, treatment, rehabilitation, certification. The fundamental element is that it is not possible to practise a treatment without first making a diagnosis, an activity only possible by a doctor[16].

Acupuncture cannot be practised without a diagnostic indication, which is exclusively a medical act and therefore acupuncture is a medical act.[17]

> Acupuncture, like other therapies such as homeopathy, homotoxicology, phytotherapy and other homologous therapies, is counted among the unconventional therapies, which require specific knowledge of medical science and which carry out a health activity consisting, that is, in a diagnosis of an organic alteration or functional disorder of the body or mind and in the identification of remedies and their administration by a physician or paramedical staff under medical supervision.

To date, TCM is the subject of growing interest and integration, giving rise to crucial reflections on the medical responsibility associated with a therapeutic system so different from Western paradigms.

A significant turning point for non–conventional medicine is the approval of the new Essential Levels of Care (LEA), completed with the decree published in the Italian Official Gazette on 23 June 2023.

3. Material and Method

The main documents that have considered Non–Conventional Medicines, from the inception of the issue to the present day, were analysed.

Reference was made to the indications derived from the scientific literature for the use of acupuncture and other TCM techniques.[18] The guidelines[19] of the main national and international health protection

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[16] P. Ricci, F. Massoni, L. Ricci, E. Onofri, G. Donato, S. Ricci, Quality of life in dementia sufferers: The Role of Diet and Exercise, in Current Alzheimer Research, 15, 5, 2018, 400–07; T. Archer, S. Ricci, F. Massoni, L. Ricci, M. Rapp–Ricciardi, Cognitive benefits of exercise intervention, in Clinica Terapeutica, 167, 6, 2016, 180–85.

[17] F. Massoni, et al., *op. cit.*; Italian Court of Cassation, 6th Criminal Section, maxima of 27 March 2002 no. 482.

[18] K. Chan, The Evolutional Development of Traditional Chinese Medicine (TCM) Outside China Mainland: Challenges, Training, Practice, Research, and Future Development, in World J Tradit Chin Med, 2, 4, 6–28; K. Chan, X. Hu, V. Razmovski–Naumovski, N. Robinson, Challenges and opportunities of integrating traditional Chinese medicine into mainstream medicine: A review of the current situation, in European Journal of integrative medicine, 7, 1, 2015, 67–75; M.V. Rosati, C. Sacco, A. Mastrantonio, G. Giammichele, G. Buonprisco, P. Ricci, G.F.Tomei, F. Tomei, S. Ricci, *Prevalenza della patologia venosa cronica negli operatori sanitari e ruolo della stazione eretta*, 38, 3, 2019, 201–10; M.S. Wu, K.H. Chen, I.F. Chen, S.K. Huang, P.C. Tzeng, M.L. Yeh, F.P. Lee, J.G. Lin, C. Chen, *The Efficacy of Acupuncture in Post–Operative Pain Management: A Systematic Review and Meta–Analysis*, in *PLoS One*, 11, 3, 2016, e0150367; M.V. Rosati, A. Sancini, F. Tomei, C. Sacco, V. Traversini, A. De Vita, D.P. De Cesare, G. Giammichele, F. De Marco, F. Pagliara, F. Massoni, L. Ricci, G. Tomei, S. Ricci*, Correlation between benzene and testosterone in workers exposed to urban pollution*, in *Clinica terapeutica*, 168, 6, 2017, e380–e387; S.A. Kim, S.H. Lee, J.H. Kim, M. Van Den Noort, P. Bosch, T. Won, S. Yeo, S. Lim, *Efficacy of Acupuncture for Insomnia: A Systematic Review and Meta–Analysis*, in *Am J Chin Med*, 49, 5, 2021, 1135–1150; A. Sancini, S. Ricci, F. Tomei, M.V. Rosati, C. Sacco, A. Pacchiarotti, N. Nardone, P. Ricci, A. Suppi, D.P. De Cesare, V. Anzelmo, R. Giubilati, B. Pimpinella, *Work related stress and blood glucose levels*, in *Annali di Igiene Medicina Preventiva e di Comunità*, 29, 2, 2017, 123–33; T. Li, Y. Zhang, Q. Cheng, M. Hou, X. Zheng, Q. Zheng, L. Li, *Quantitative study on the efficacy of acupuncture in the treatment of menopausal hot flashes and its comparison with nonhormonal drugs*, in *Menopause*, 28, 5, 2021, 564–72; M. Jiang, C. Lu, C. Zhang, J. Yang, Y. Tan, A. Lu, K. Chan, *Syndrome differentiation in modern research of traditional Chinese medicine*, in *Journal of Ethnopharmacology*, 140, 3, 2012, 634–42; R. Ferrara, R. Nappo, F. Ansermet, P. Ricci, F. Massoni, G. Carbone, A. Sparaci,

bodies were studied in depth, integrated with the laws of the Italian State and the decisions of the Court of Cassation. In addition, the codes of ethics in the succession of years, the Federation of Medical Orders and the decrees relating to LEAs were analysed.

4. Results

One of the first indications of the regulation of Traditional Chinese Medicine (TCM) in Europe came with Resolution No. 75 of the European Parliament of 29 May 1997,[20] on the Status of Non–Conventional Medicines and Resolution No. 1206 of the Council of Europe of 4 November 1999[21] in which the member states were invited to address the problems associated with the use of Non–Conventional Medicines (NCMs).

In 1999, the World Health Organisation (WHO)[22] published the Guidelines on Basic Training and Health Care Safety in Acupuncture. These guidelines presented what professional experts and healthcare regulators considered to be appropriate training programmes for acupuncture practitioners, as well as for physicians and primary healthcare personnel wishing to provide acupuncture treatment.

In the Italian FNOMCeO (Federazione Nazionale Ordini Medici Chirurghi e Odontoiatri – National Federation of Surgeons and Dentists) Guidelines on Non–Conventional Medicines and Practices (Terni, 18 May 2002), Acupuncture, together with other Non–Conventional Medicines, was recognised as falling within the exclusive competence and professional responsibility of the surgeon and dentist since it was ‘to all intents and purposes a medical act’. The document recognised nine non–conventional medicines: Acupuncture, Traditional Chinese Medicine, Ayurvedic Medicine, Homeopathic Medicine, Anthroposophical Medicine, Homotoxicology, Phytotherapy, Chiropractic and Osteopathy.

In “The Consensus Conference on Non–Conventional Medicines in Italy, Special Session of the 43rd National Congress of the Italian Society of Psychiatry, Bologna, 20 October 2003 (published in ‘La Professione’, organ of the FNOMCeO)” the following is reported “The Italian Republic protects health as a fundamental right of the individual, safeguards the principle of scientific pluralism and guarantees the citizen’s freedom of therapeutic choice and the professional qualification of health workers, enhancing in particular the physician’s autonomy in therapeutic choices”.[23]

E. Nonnis, L. Ricci, S. Ricci, *The impact of dsm–5 on the diagnosis of autism spectrum disorder*, in *Pychiatric Annals*, 51, 1, 2021, 38–46.

[19] G. Bodeker, C.K. Ong, C. Grundy, G. Burford, K. Shein, *WHO Global Atlas of Traditional, Complementary and Alternative Medicine*, in *Kobe WHO Publications*, 118, 11, 2005, 947; A. Miglino, L. Ricci, S. Ricci, *Liability in the medical profession*, in *Panminerva medica*, 56, 1, 2014, 127–56; F. Massoni, P. Ricci, P. Crusco, L. Ricci, S. Ricci, *Applicability of the guidelines for the evaluation of the professional responsibility of the physicians*, in *Policlinico – Sezione medica*, 120, 1, 2014, 37–42; F. Massoni, P. Ricci, E. Onofri, L. Ricci, E. Luzi, S. Ricci, *Evidence Based Medicine between guidelines and conflict of interest*, in *Panminerva medica*, 56, 1, 2014, 89–94; A. Miglino, L. Ricci, S. Ricci, *The right to hearth as a liberty of self–determination*, 56, 1, 2014, 13–24.

[20] European Parliament, Resolution no. 75 of 29 May 1997.

[21] Council of Europe, Resolution no. 1206 of 4 November 1999.

[22] World Health Organization, *Guidelines on Basic training and Safety in Acupunture*, 1999, https://iris.who.int/handle/10665/66007.

[23] Italian Court of Cassation, 4th Criminal Section, Judgment no. 2865 of 8 February 2001.

The right to choose, acknowledged to each person as the focal point of any modern consideration of respect for the individual's will with regard to his or her state of health and illness, has already been implicitly expressed and materialised with the recourse, by increasingly broad strata of the population, to certain disciplines and therapeutic practices not under the overall term of 'Non–Conventional Medicines (NCMs)'.

The World Health Organisation, with WHO Resolution 56.31 of 28 May 2003,[24] then prompted the Member States to formulate and implement national policies and regulations in the field of unconventional medicine, with particular attention to staff training. In particular, the need to have certified training and to be enrolled in a specific register with one's professional association is emphasised, which has made the practice of acupuncture without a qualification an abusive exercise of the medical profession.

With sentence no. 2258 of 27 March 2003, the sixth section of the Criminal Court of Cassation specified that

> Acupuncture, like other therapies such as homeopathy, homotoxicology, phytotherapy and other homologous therapies, is counted among the 'unconventional' therapeutic practices which require specific knowledge of medical science and which carry out a health activity consisting in a diagnosis of an organic alteration or functional disorder of the body or mind and in the identification of remedies and their administration by the doctor himself or by paramedical staff under the doctor's supervision. A medical degree is required to practise acupuncture: anyone practising acupuncture without such a qualification commits the offence referred to in Article 348 of the Criminal Code aimed at protecting public health. In fact, although acupuncture is not a subject taught in Italian universities, it can only be practised by doctors or surgeons, knowledge of medicine or surgery being necessary to make an exact diagnosis and to avoid harmful consequences for the patient.[25]

It is also pointed out that acupuncture is an invasive practice, which, in addition to the typical hypnotic and anaesthetic effect that it causes on the patient, is exposed to all the risks connected with an intervention of this nature, such as that of serious injuries caused by invasion of inappropriate parts of the human body, not to mention the risk of infections due to the use of tools that have not been sterilised in compliance with the standards currently provided for and periodically checked by the health services.[26]

As far as the official indications of the FNOMCeO are concerned, the first references to unconventional medicine are to be found in the 1998 Code of Medical Deontology, under Title II – General Duties of the Physician, Chapter IV – Diagnostic Findings and Therapeutic Treatments – Article 13 Unconventional Practices – Reporting of Abuse. The article states that:

> The power to choose non–conventional practices in respect of the decorum and dignity of the profession is expressed in the exclusive sphere of direct and non–delegable professional responsibility, it being understood, however, that any non–conventional therapy must not exempt the citizen from specific treatments of proven efficacy and requires the acquisition of consent. It is forbidden for the doctor to collaborate in any way or to favour those who abuse the profession even in the area of so–called 'unconventional practices.

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[24] https://apps.who.int/gb/ebwha/pdf_files/WHA56/ea56r31.pdf.

[25] ITALIAN COURT OF CASSATION, criminal 22528/03, in *Riv It Med Leg and Dir San*, 2003, 427.

[26] See ID, 6th criminal section, maximum sentence no. 482/2003.

Similar considerations are given by the 2006 Code of Medical Ethics, under Title II: General Duties of the Physician, Chapter IV – Article 15 Unconventional Practices.

On 12 December 2009[27] the National Council of the FNOMCeO revises the "Guidelines for Training in Non-Conventional Medicines and Practices reserved for Doctors–Surgeons and Dentists of the Health Commission-Conference State-Regions".

This document was sent on 14 January 2010 to the Presidents of the Provincial Orders. Since the list was drawn up in 2002, all activities except Osteopathy and Chiropractic, as health professions that are not the exclusive domain of medical practitioners, remain the exclusive domain of medical and dental practitioners.

The code of medical ethics, deliberated by the FNOMCeO on May 18, 2014,[28] deals with unconventional medicines within Article 15: "Unconventional Systems and Methods of Prevention, Diagnosis and Treatment", which states:

> The physician may prescribe and adopt, under his direct responsibility, unconventional systems and methods of prevention, diagnosis and treatment while respecting the decorum and dignity of the profession. The physician shall not withdraw the person being treated from scientifically based and proven treatments. The physician shall ensure both the quality of his or her specific training in the use of unconventional systems and methods and circumstantial information for the acquisition of consent. The physician shall not cooperate with or encourage the practice of non–medical third parties in non–conventional disciplines recognized as exclusive and reserved activities of the medical profession.
>
> In Italy, an important milestone in the regulation of the practice of acupuncture is represented by the Agreement between the Government, the Regions and the Autonomous Provinces of Trento and Bolzano concerning the criteria and modalities for the training and related practice of acupuncture, phytotherapy and homeopathy by surgeons and dentists.

With the State–Regions Agreement of February 7, 2013, indications are determined regarding the:

- Need to proceed with the quality certification of training in acupuncture, phytotherapy and homeopathy, identifying the minimum and uniform criteria and requirements throughout the country for suitable training paths.
- Identification of professionals practicing these activities, which, however, remain reserved to the competencies identified by state law to surgeons and dentists, veterinarians and pharmacists.
- protection of the health of citizens for which lists of professionals practicing Acupuncture, Phytotherapy and Homeopathy are established at the provincial professional orders of surgeons and dentists.

It is also important to refer to Law no. 24 of March 08, 2017 (so-called Gelli-Bianco):[29] "Provisions on the safety of care and the person being cared for, as well as on the professional liability of health profession

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[27] https://portale.fnomceo.it/wp-content/uploads/import/201801/67825_linee-guida-fnomceo-formazione-nelle-medicine-e-pratiche-non-convenzionali.pdf.

[28] https://portale.fnomceo.it/wp-content/uploads/2018/03/CODICE-DEONTOLOGIA-MEDICA-2014.pdf.

[29] ITALIAN PARLIAMENT, Law no. 24 of March 08, 2017, *Gelli–Bianco*, available at this link: https://www.gazzettaufficiale.it/eli/id/2017/03/17/17G00041/sg.

practitioners", which reformed medical liability. In particular, art. 5 (Good clinical care practices and recommendations under guidelines) and art. 6 (Criminal liability of the health profession practitioner) form the cornerstone of the new legislation.

Article 5 stipulates the obligation on health profession practitioners to follow the recommendations set forth in the guidelines or, in the absence of guidelines, the obligation to follow good clinical care practices.

Article 6 introduces into the Criminal Code article 590 sexies, relating to the case of manslaughter and culpable personal injury committed in the medical field. The new norm provides for a hypothesis of non–punishability of the doctor in the presence of specific elements:

> if the event has occurred due to inexperience, punishability is excluded when the recommendations provided by the guidelines as defined and published in accordance with the law or, in the absence of these, the good clinical–assistance practices are complied with, provided that the recommendations provided by the aforementioned guidelines are appropriate to the specifics of the concrete case.

With the decree published in the Official Gazette on June 23, 2023[30] the new LEAs, essential levels of care, are approved. The National Health Service is required to provide in public health facilities, allowing citizens to request treatments included in the list. Among the specialist services, we find acupuncture for analgesia and other forms of acupuncture in the catalogue.

For other indications, supported by scientific literature, services not included in the national LEA declaratory, some regions have planned to use their own resources to provide additional services. Examples are:

- The Region of Val D'Aosta that by Council Resolution no. 1241 of 09/13/2019,[31] in Art. 15 Acupuncture services provides that:

> The Azienda USL Valle d'Aosta is authorized to provide, upon prescription of the specialist physician, with charges borne by the SSR, outpatient acupuncture services, limited to those aimed at the treatment of: nausea and vomiting in pregnancy; side effects of therapy in the cancer patient; migraine headache and painful manifestations of the chronic musculoskeletal and osteoarticular system, on prescription of the specialist algologist, following failure or contraindication to common pain–relieving therapies

- The Emilia–Romagna Region by Council Resolution 714 of 26.05.2014[32] Resolves that:

> The services identified by OMNCER, referred to in M.D. July 22, 1996 and Oct. 18, 2012, cod 99.91 "acupuncture for anaesthesia" and cod 99.92 "other acupuncture," are as follows: Acupuncture: Recurrent or chronic lumbar musculoskeletal pain, with or without sciatalgia; Acupuncture: Prophylaxis of musculoskeletal headache; Acupuncture: Prophylaxis of migraine headache.

- The Region of Tuscany by Resolution of the Regional Council no. 674 of 2014[33] amends the Regional Tariff Nomenclator of Outpatient Specialty Care Services, for the part relating to complementary medicine services, providing the following services:

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[30] https://www.gazzettaufficiale.it/eli/gu/2023/08/04/181/sg/pdf.

[31] https://bit.ly/3Lsbw8e.

[32] https://bit.ly/4jE2H7T.

[33] https://www.amabonline.it/images/DOCUMENTI_LEGALI/39.delibera_674–2014–.pdf.

manual medicine manipulations;

- acupuncture combined with other techniques such as: moxibustion, plum blossom needle, electrostimulation, auriculotherapy, scalp acupuncture and cupping;
- acupuncture, moxibustion, plum blossom needle, auriculotherapy, scalp acupuncture and cupping;
- pediatric tuina.

5. Discussion

Acupuncture is considered for all intents and purposes to be a valid and safe therapeutic technique. Based on data in the literature, it has long been recommended and recognized for chronic[34] or painful conditions.[35] In addition to these therapeutic indications, there are many other conditions that can benefit from acupuncture, such as sleep disorders,[36] hot flashes[37] during menopause, and side effects of anticancer drugs or cancer symptoms.[38]

Currently, benefit has also been recognized for the use of acupuncture in some complex pain syndromes such as fibromyalgia[39] or in the rehabilitation of post ischemic stroke patients.[40]

Legal recognition of this discipline is of crucial importance to the acupuncture practitioner's practice and to the protection of the patient who benefits from the treatments. Certainly, the legal status of acupuncture must be evaluated according to the principle mentioned before, according to which an unconventional practice is considered a medical act in two eventualities: 1) when it is made the subject of university teaching, or 2) of jurisprudential decisions explicitly qualifying it as a medical act.

According to the aforementioned rulings of the Sixth Section of the Criminal Cassation, the most recent of which is no. 22528 of 2003, the practice of acupuncture received legitimacy from the second eventuality. However, a point of decisive interest is the reference to university educational regulations used as a guide to determine the scope of competence of a profession (given by the Criminal Cassation, 6th section, no. 482 of March 27, 2003). In the same, it is noted that the University of Rome "La Sapienza", since the beginning of this century, has activated a Level II Master's Degree in Acupuncture, whose qualification for admission is the master's degree in medicine–Surgery and Dentistry.

Thus, the legal status of this NCM appears to depend now on the first eventuality between the two hypotheses mentioned above: that is, acupuncture is a medical act insofar as it is contemplated by a uni-

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[34] XXXIV AIAM National Congress Of Acupuncture, *Professional Responsibility in Acupuncture and Traditional Chinese Medicine and Proposed Guidelines for the Treatment of Osteoarticular Diseases*, April 2021, "Sapienza" University of Rome.

[35] M.S. Wu, K.H. Chen, I.F. Chen, *et. al., op. cit.*

[36] S.A. Kim, S.H. Lee, J.H. Kim, *et al., op. cit.*

[37] T. Li, Y. Zhang, Q. Cheng, *et al., op. cit.*

[38] M.A. Fangfang, Z. Hewei, L.I. Bingxue, C. Peiyu, Y.U. Mingwei, W. Xiaomin, *Acupuncture and moxibustion for malignant tumor patients with psychological symptoms of insomnia, anxiety and depression: a systematic review and Meta–analysis*, in *J Tradit Chin Med*, 43, 3, 2023, 441–56.

[39] J.A. Valera–Calero, C. Fernández–De–Las–Peñas, M.J. Navarro–Santana, G. Plaza–Manzano, *Efficacy of Dry Needling and Acupuncture in Patients with Fibromyalgia: A Systematic Review and Meta–Analysis*, in *Int J Environ Res Public Health*, 19, 16, 2022, 9904.

[40] L.M. Chavez, S.S. Huang, I. Macdonald, J.G. Lin, Y.C. Lee, Y.H. Chen, *Mechanisms of Acupuncture Therapy in Ischemic Stroke Rehabilitation: A Literature Review of Basic Studies*, in *Int J Mol Sci*, 18, 11, 2017, 2270.

versity course of study. Which undoubtedly invests it with a greater dignity, as a therapeutic instrument hitherto ambiguously tolerated, but contemplated by the legal system in order to realize in the most complete manner the citizen's right to health, where it takes the form of freedom of choice of the treatment deemed most appropriate.

It is barely necessary to point out that the possible provision of non-conventional medicine within the framework of vocational education and training courses set up by the regions is not equivalent to deeming them medical activities tout court, given that, as we have seen, only those disciplines covered in university teaching are medical. According to Article 33, Paragraph 6, of the Constitution, "Institutions of high culture, universities and academies, have the right to give themselves autonomous orders within the limits established by the laws of the State". Therefore, all universities, whether public or private, operate within the framework of state regulations that allow for the recognition of academic degrees in the national territory and therefore, by virtue of EU regulations, also in the European sphere.

This notwithstanding, the Regions certainly identify, for the purpose of accreditation, the subjects (associations, scientific societies, public and private training institutions using qualified professionals with specific curricular skills) within the "criteria and modalities for quality certification of training of the practice of acupuncture, of phytotherapy and homeopathy by surgeons, dentists, veterinary surgeons and pharmacists" as training subjects for 'the implementation of the Training Pathway in Acupuncture addressed to Doctors and Dentists' in accordance with the State–Regions Agreement of February 07, 2013, as well as continuing education and refresher training (so–called CME – Continuing Medical Education).

6. Conclusions

Traditional Chinese Medicine (TCM) is a comprehensive and unique medicine that has proven its effectiveness in many fields of prevention and health protection. Collaboration and integration between TCM and Western medicine could lead to a more comprehensive approach in taking care of the person [41] As of today, the inclusion of Acupuncture in the LEAs represents an important step forward for TCM and to guarantee an additional service to the patient and legally recognized following the inclusion of the discipline in university educational offerings, as was the case following the establishment of the Level II Master's Degree in Acupuncture at the "Sapienza" University of Rome.

The elements in the state of the facts in evidence are thus:

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[41] K. Chan, X. Hu, V. Razmovski–Naumovski, N. Robinson, *op. cit.;* L. Zhao, K. Chan, *Building a bridge for integrating Chinese medicine into conventional healthcare: Observations drawn from the development of the Chinese quality of life instrument*, in *American Journal of Chinese Medicine*, 33, 6, 2005, 897–902; N. Robinson, *The Importance of Evidence for the Integration of Traditional and Complementary Medicine into Western Healthcare?*, in *World Journal of Traditional Chinese Medicine*, 2, 1, 2016, 74-79; D.A. Guo, J.Y. Han, *Integration of Traditional Chinese medicine and modern science is the way forward*, in *World Journal of traditional Chinese medicine*, 1, 2, 2016, 1; J. Ren, X. Li, J. Sun, M. Han, G.Y. Yang, W.Y. Li, N. Robinson, G. Lewith, J.P. Liu, *Is Traditional Chinese Medicine Recommended in Western Medicine Clinical Practice Guidelines in China? A systematic analysis*, in *BMJ Open*, 5, 6, 2015; W. Huang, D. Pach, V. Napadow, K. Park, X. Long, J. Neumann, *et al., Characterizing Acupuncture Stimuli Using Brain Imaging with fMRI – A Systematic Review and Meta–Analysis of the Literature*, in *PLoS ONE*, 7, 4, 2012, e32960; J.S. Han, Y.S. Ho, *Global trends and performances of acupuncture research*, in *Neuroscience and Biobehavioral Reviews*, 35, 3, 2011, 680–87.

(a) unconventional medicines (Acupuncture, Homeopathy, Phytotherapy), in their application, insofar as they presuppose a diagnosis of an organic alteration or functional disturbance of the body or mind, fall within the scope of the medical act and therefore within the exclusive competence and jurisdiction of a physician;[42]

(b) since acupuncture is recognized as an invasive practice, in compliance with the standards provided for and periodically verified by the health services, it cannot but fall exclusively within the scope of the medical act;[43]

(c) is legally recognized following the inclusion of the discipline in university educational offerings;

(d) requires a quality certification of training identified through the minimum and uniform criteria and requirements on the national territory of suitable training paths.[44] This is especially in the identification of public and private training subjects participating in it;

(e) protection of the health of citizens for which lists of professionals practicing Acupuncture, Phytotherapy and Homeopathy are established at the provincial professional orders of surgeons and dentists.

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[42] See Presidential Decree no. 221 of April 5, 1950.

[43] Cf. maximum sentence no. 482/2003 Italian Court Cass., 6th criminal section.

[44] Cf. State–Regions Agreement of 07.02.2013.

Human enhancement e principi di libertà, uguaglianza, solidarietà e dignità

Arnaldo Miglino, Pasquale Ricci, Lidia Ricci[*]

HUMAN ENHANCEMENT AND THE PRINCIPLES OF LIBERTY, EQUALITY, SOLIDARITY AND DIGNITY

ABSTRACT: This paper addresses the implications of employing information and biological technologies in execution of medical and ultra-medical interventions, aimed at human enhancement. Reconsidering these principles-especially those of equality and dignity-supported by the conceptual framework of the medical act and the ethical norms that govern it, leads to the conclusion that no wealthy individual should be allowed to achieve, unlike others, the enhancement of the psychophysical abilities of Homo sapiens. Rather, the best biotechnologies should help sick or disabled individuals to recover their health, restoring their dignity and allowing them to participate fully in social relations.

KEYWORDS: Ultra-medical act; human dignity; human enhancement; liberty; equality

ABSTRACT: Si discute il problema dell’uso delle tecnologie informatiche e biologiche nell’esecuzione dell’atto medico e di quello ultramedico, teso cioè allo *human enhancement*. Riconsiderando tali princìpi, soprattutto di uguaglianza e dignità, fruendo anche del concetto di atto medico e della deontologia che lo contraddistingue, si giunge alla conclusione per cui non dovrebbe essere consentito a nessun facoltoso di conseguire, contrariamente ad altri, il potenziamento delle capacità psicofisiche di Homo sapiens. Invece, le migliori biotecnologie dovranno aiutare i soggetti malati, o in condizione di disabilità, a recuperare uno stato di salute che renda loro dignità includendoli a pieno titolo nelle relazioni sociali.

PAROLE CHIAVE: Atto ultramedico; dignità umana; potenziamento umano; libertà; uguaglianza

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1. Introduzione

L'intelligenza artificiale (IA) coinvolge ormai anche le scienze mediche e biologiche: è già utilizzata massivamente per testare in maniera più rapida ed economica l'efficacia potenziale delle molecole maggiormente promettenti in diversi ambiti terapeutici, eseguire esami diagnostici predittivi, fornire soluzioni di medicina di precisione e personalizzata, o di telemedicina[1]. È facile prevedere che l'alleanza fra conoscenze informatiche e biotecnologiche, presto o tardi, possa giungere a sviluppare enormemente le abilità fisiche e cognitive dell'Homo sapiens[2] facendone, per così dire, un super umano.

In un ordinamento liberal democratico, come quello italiano, ognuno è libero di fare tutto ciò che la legge non vieta[3]. Quindi ogni cittadino potrebbe chiedere e ottenere l'applicazione di strumenti informatici e biotecnologici al fine di potenziare le sue abilità fisiche e cognitive, per quanto la scienza possa consentirgli. Nemmeno il regolamento UE 2024/1689 lo impedisce, pur contenendo una serie di divieti d'uso dell'IA[4]. Ciò pone problemi che attengono non solo al diritto alla salute, ma anche ai principi di libertà, uguaglianza, solidarietà e dignità umana. È quindi interesse della medicina sociale affrontare la questione.

2. Discussione

2.1. Biotecnologie, intelligenza artificiale e diritto alla salute

Ai fini della nostra indagine si osserva innanzitutto che le tecnologie capaci di super dotare gli umani tenderebbero a realizzare una migliore condizione psico-fisica e quindi *salute*, da intendersi, secondo la definizione contenuta nella Carta costitutiva dell'Organizzazione Mondiale della Sanità (OMS)[5], non solo come assenza di malattia o infermità, ma quale completo benessere fisico, psichico e sociale[6]. Questa nozione s'impone perché, quando un termine ha un significato tecnico oltre che d'uso comune, deve essere inteso tecnicamente anche dal punto di vista giuridico[7], soprattutto se, come nel caso in questione, la definizione ha anche una portata normativa. Pertanto la salute, quale completo benessere fisico, psichico e sociale, è oggetto di un diritto soggettivo, che si rivolge innanzitutto ai poteri pubblici: è un diritto di libertà[8], con portata internazionale e sovranazionale.

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[1] M. GUIDI, *L'interazione tra la normativa dell'UE in materia di protezione dei dati personali e il regolamento UE 536/2014 sulle sperimentazioni cliniche*, in *Diritto dell'informazione e dell'informatica* (II), 2, 1 giugno 2024, 157.

[2] Y. HARARI, *21 lezioni per il XXI secolo*, Firenze – Milano, 2019, 119-122.

[3] M. DI CELSO MAZZIOTTI, G.M. SALERNO, *Manuale di diritto costituzionale*, Padova, 2010.

[4] Cfr. art. 5 del regolamento citato.

[5] Il Protocollo relativo alla costituzione dell'Organizzazione mondiale della sanità (OMS), stipulato a New York il 22 luglio 1946, è stato recepito nell'ordinamento italiano con Decreto legislativo del Capo Provvisorio dello Stato del 4 marzo 1947 n. 1068.

[6] Così si esprime il preambolo della Carta costituzionale dell'OMS: «*La santé est un état de complet bien-être physique, mental et social, et ne consiste pas seulement en une absence de maladie ou d'infirmité*».

[7] F. TESAURO, *Istituzioni di diritto tributario*, Torino, 1994, 37.

[8] Si parla di diritti di libertà in relazione a quei diritti che, con la creazione dello stato liberale, assicurano all'individuo un ambito di libertà e indipendenza nei confronti del potere pubblico. Cfr. A. MIGLINO, *Sulla indivisibili-*

Secondo l'art. 25 della *Dichiarazione universale dei diritti dell'uomo*[9], ogni persona ha il diritto a cure mediche e a un tenore di vita sufficiente per ottenere salute e benessere. L'art. 12 del *Patto internazionale relativo ai diritti economici, sociali e culturali*[10] riconosce la pretesa di ogni individuo di godere delle migliori condizioni di salute fisica e mentale che sia in grado di conseguire. L'art. 3 della *Carta dei diritti fondamentali dell'Unione Europea*[11] garantisce a ognuno integrità fisica e psichica.

Per quanto riguarda l'ordinamento italiano, in virtù dell'art. 32 della Costituzione, comma 1, la salute è oggetto di un fondamentale diritto dell'individuo e interesse della collettività. Considerato anche l'ambito internazionale in cui è inserito, si tratta di un diritto inviolabile dell'uomo che la giurisprudenza, per sottolinearne l'importanza, ha definito altresì "primario"[12]. Attiene all'ottimale sviluppo della persona umana e si configura come libertà sia negativa che positiva. Negativa, in quanto i poteri pubblici devono astenersi dall'invadere la sfera decisionale privata (l'art. 32 Cost. impedisce i trattamenti sanitari obbligatori privi di interesse per la collettività); positiva, in quanto il cittadino può ottenere l'intervento dei pubblici poteri per la soddisfazione delle sue esigenze (il medesimo articolo garantisce cure gratuite agli indigenti)[13].

In base alle disposizioni richiamate e al concetto normativo di salute proveniente dall'OMS, il superamento delle normali capacità fisiche e cognitive dell'essere umano appare esercizio di una facoltà derivante non solo implicitamente dalla struttura di ogni ordinamento liberale, ma da un esplicito diritto soggettivo attraverso il quale ognuno ha facoltà di perseguire il benessere che l'arte medica e le connesse tecnologie siano in grado di assicurargli. Del resto, l'intero sistema delle libertà riconosciute dalle Costituzioni democratiche è teso a far sì che l'individuo realizzi un proprio progetto di vita: perché impedirlo se egli intende farlo mediante il potenziamento del corpo?

Tuttavia, come la giurisprudenza italiana ha precisato, i diritti fondamentali stanno in rapporto di integrazione reciproca, sicché non ce n'è uno che possa prevalere sugli altri. Conseguentemente, devono essere tutelati sempre in maniera sistemica, altrimenti si avrebbe l'illimitata espansione di uno di essi, «che diverrebbe "tiranno" nei confronti delle altre situazioni giuridiche costituzionalmente riconosciute e protette, che costituiscono, nel loro insieme, espressione della dignità della persona»[14]. Per fare in modo che il diritto alla salute non divenga tiranno, bisogna bilanciarlo con gli altri diritti di libertà, mediante tutti gli strumenti appartenenti alla logica e alla razionalità giuridica[15]. Il bilanciamento fra posi-

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tà dei diritti fondamentali, in *Revista da Faculdade de Direito*, Universidade Federal do Paranà - UFPR, 2006, 45, 5-11.

[9] La Dichiarazione è stata approvata dall'Assemblea Generale delle Nazioni Unite il 10 dicembre 1948. Con essa i diritti umani sono entrati in maniera decisiva nella scena internazionale (cfr. S. ZAPPALÀ, La tutela internazionale dei diritti umani, Bologna, 2011, 31).

[10] Il Patto è stato adottato a New York il 19 dicembre 1966, è entrato in vigore il 3 gennaio 1976 e ratificato dall'Italia con la Legge 25 ottobre 1977 n. 881. Ha la finalità di integrare e specificare quanto più generalmente raccomandato con la Dichiarazione.

[11] La Carta è stata proclamata dal Consiglio d'Europa a Nizza il 7 dicembre 2000 e, in virtù dell'art. 6 del Trattato sull'Unione europea (introdotto dal Trattato di Lisbona del 13 dicembre 2007), ha ora lo stesso valore giuridico del Trattato stesso e del Trattato sul funzionamento dell'Unione europea.

[12] Cfr. CORTE COSTITUZIONALE 26 luglio 1979, n. 88, in *Foro Italiano*, 1979, I, 2542; CORTE COSTITUZIONALE, 18 dicembre 1987, n. 559, in *Rivista Italiana di Medicina Legale*, 1990, 227.

[13] S. RICCI, A. MIGLINO, *Medicina e società*, Roma, 2005, 4-6.

[14] Cfr. CORTE COSTITUZIONALE, 9 maggio 2013, n. 85, in *Il Foro amministrativo* - C.d.S, 5, 2013, 115.

[15] A. MIGLINO, *Interpretazione e sistema giuridico*, Milano, 2015, 168-169.

zioni giuridiche soggettive è una necessità logica di ogni ordinamento quando un fatto, o una materia, siano suscettibili di essere disciplinati da più diritti reciprocamente in conflitto. Tale fenomeno, richiamato anche col termine "collisione", riguarda non solo i diritti, ma anche i principi[16]. Poiché i principi di solidarietà, uguaglianza e dignità fondano le democrazie moderne al pari di quello di libertà[17], bisogna verificare se collidano con la facoltà di dotarsi di un corpo che trascenda la fisiologia umana sino ad ora conosciuta.

Per quanto riguarda la solidarietà, oggetto di uno specifico dovere ex art. 2 della Costituzione italiana[18], la si intenda pure nel senso più impegnativo, in modo da obbligare chi sia dotato di super condizioni fisiche a usarle in favore degli altri, così come discenderebbe dal pensiero di uno dei maggiori filosofi politici e morali del ventesimo secolo, massimo esponente del liberalismo ugualitario: John Rawls. Per questo autore, chi ha ricevuto dalla "lotteria naturale" maggiori capacità rispetto ad altri è così avvantaggiato da rientrare in una "aristocrazia naturale". Ma i fatti, come nascere con certe attitudini, non sono né giusti né ingiusti. Ciò che è giusto o ingiusto è la maniera in cui le istituzioni li trattano. Le società aristocratiche o castali sono ingiuste perché ne fanno il fondamento di privilegi. Invece, una società giusta, pur permettendo a chi è favorito dalla buona sorte di trarre vantaggio dalle sue condizioni personali, gli impone di metterle a disposizione dei meno fortunati[19]. Applicando questo ragionamento a chi si fosse procurato una forma biofisica eccezionale tramite le tecnologie informatiche e biologiche, si giungerebbe a sostenere tutt'al più che le istituzioni potrebbero imporgli di mettere al servizio della collettività le sue acquisite caratteristiche superiori.

A questo punto bisogna fare una rilevante distinzione, riguardante i mezzi economici idonei a procurarsi caratteristiche del genere. Se essi fossero di fatto (perché irrisori) o di diritto (perché elargiti dai pubblici poteri) disponibili per tutti, non si porrebbero particolari problemi di solidarietà visto che le persone sarebbero in grado di procurarsi il medesimo status psico-fisico. Invece se, come è facile prevedere (soprattutto riguardo ai primi sviluppi biotecnologici), solo pochi disponessero delle risorse necessarie a trasformarsi in super umani e le impiegassero a tal fine, difficilmente sarebbero inclini alla solidarietà. Chi ritiene di essersi meritato il denaro crede anche di meritare ciò che con esso compra sicché, acquisendo un vantaggio biologico su chi invece non se lo può permettere, sarebbe indotto a non compensare la sua condizione di superiorità con l'essere solidale. Infatti, come appurato da un noto pensatore riguardo all'esperienza nordamericana, la crescita delle disparità di condizioni sociali ed economiche è giustificata da chi se ne avvantaggia come riconoscimento del suo merito ed è vissuta come umiliazione da chi la subisce: i primi diventano sempre più arroganti e i secondi viepiù frustrati vedendosi diminuire la stima della collettività. In questa situazione, chi ritiene di essersi fatto da solo difficilmente proverà umiltà e gratitudine, senza le quali è improbabile prendersi cura del bene comune[20] e quindi rispettare le norme che l'impongano.

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[16] R. Alexy, *Teoria dei diritti fondamentali*, Bologna, 2012, 109-116.

[17] A. Miglino, *Democrazia moderna. Valori e principi*, Ogliastro Cilento (SA), 119-128, 152.

[18] Art. 2 Cost.: «La Repubblica riconosce e garantisce i diritti inviolabili dell'uomo, sia come singolo sia nelle formazioni sociali ove si svolte la sua personalità, e richiede l'adempimento dei doveri inderogabili di solidarietà politica, economica e sociale».

[19] J. Rawls, *Una teoria della giustizia*, Milano, 1997, 75-85, 97-103.

[20] M.J. Sandel, *La tirannia del merito*, Milano, 2023, 19-20, 31-34, 37, 47.

Vi è poi da dire che l'essere umano è un animale simbolico[21] e che, per il bisogno di sentirsi importante, facilmente si lega al denaro, al successo e al potere quali simboli della sua personalità[22]. Non sembra dunque che, acquisita una posizione di preminenza biologica, sia facilmente disposto a sminuirne il significato sociale ponendosi al servizio degli altri.

Insomma: il principio di solidarietà, ammesso che possa essere precisamente definito con una serie di regole, non troverebbe facile attuazione nel campo in cui si sta discutendo: senza una reale spinta emotiva solidaristica a niente varrebbero imposizioni di legge.

Bisogna ora chiamare in causa il principio di uguaglianza, che si esprime giuridicamente in due criteri: di uguaglianza formale, oppure sostanziale. Il primo, in Italia garantito dall'art. 3, comma 1, Cost., si traduce nel divieto, rivolto soprattutto al legislatore, di trattare in maniera irrazionalmente uguale situazioni diverse, oppure in maniera uguale situazioni assimilabili[23]. Il criterio, che pur si esprime mediante proibizioni, divieti di discriminazione, e quindi con misure 'negative'[24], non impedisce a chi lo voglia di spendere le sue risorse economiche al fine di potenziare le proprie capacità biologiche anziché per altri usi. Né un divieto del genere potrebbe derivare dal principio di uguaglianza sostanziale, per cui bisogna rendere uguali le posizioni di partenza dei singoli, riequilibrando le singole situazioni di fatto[25] che versano in condizioni di deficit di libertà e uguaglianza effettive[26]. Il principio, nella misura in cui non impone ai soggetti divieti di agire per migliorare la loro posizione, non impedisce neppure il perfezionamento della condizione psico-fisica di chi lo desideri. Le azioni positive sono invece idonee ad assicurare anche a coloro che non possono permetterselo il potenziamento delle normali facoltà sensitive, cognitive e intellettive, al fine di perequarle a quelle di chi già ne goda. Ma non è detto che i pubblici poteri dispongano delle risorse necessarie per offrire a tutti una *chance* del genere ragion per cui, fino a quando ciò non sia possibile, il principio di uguaglianza sostanziale non impedirebbe ad alcuni facoltosi soggetti di procurarsi una condizione di superiorità biotecnologica sui comuni mortali.

Tuttavia, le espressioni giuridiche del principio di uguaglianza di cui si è parlato non esauriscono pienamente il suo significato secondo le origini storiche che lo caratterizzano. Come è noto, esso era diretto contro la pluralità dei sistemi giuridici fondati sugli ordini sociali, contro un sistema che divideva gli esseri umani in caste[27]. I privilegi goduti dagli aristocratici erano creduti meritati per superiorità di nascita, che faceva di loro degli appartenenti a un mondo distinto da quello della maggior parte della popolazione. Per questo, ad esempio, la nobildonna Èmilie du Châtelet (1706 – 1749), pur essendo una delle persone più colte e illuminate dell'Europa del XVIII secolo, amante di Voltaire, non aveva difficoltà a spogliarsi davanti ai suoi servi «non ritenendo cosa ben certa che anche i domestici fossero uomini»[28]. Proprio Voltaire (1694 – 1778), pur celebre e prestigioso per la sua attività di filosofo e letterato, fu trascinato via dalla tavola mentre mangiava ospite di un duca e, su ordine di questi, fu preso a frustate. Non

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[21] E. Cassirer, *Saggio sull'uomo. Una introduzione alla filosofia della cultura umana*, Roma, 2009, 81.
[22] A. Miglino, *Quark sociali e simbolopatia*, Roma, 2024, 97-113.
[23] P. Caretti, U. Di Siervo, *Istituzioni di diritto pubblico*, Torino, 2001, 437.
[24] M. Ainis, *La piccola eguaglianza*, Torino, 2015, 63.
[25] C. Lavagna, *Istituzioni di diritto pubblico*, Torino, 1982, 407.
[26] A. Barbera, C. Fusaro, *Corso di diritto pubblico*, Bologna, 2001, 174.
[27] U. Rescigno, *Corso di diritto pubblico*, Bologna, 1989, 66.
[28] A. De Tocqueville, *L'Antico Regime e la rivoluzione*, Milano, 1989.

solo non ebbe giustizia, bensì, per essersi lamentato dell'offesa patita, fu imprigionato nella Bastiglia[29]: non era aristocratico.

Ma, «se i nuovi trattamenti per allungare la vita o per migliorare le capacità fisiche e cognitive saranno costosi, l'umanità potrebbe dividersi in caste biologiche»[30]. Il pericolo è reale e bisogna evitare che si concretizzi, facendo valere il principio d'uguaglianza secondo il suo spirito originario: impedire che la comune umanità delle persone venga superata dalla formazione di prerogative, quali esse siano: politiche, sociali, economiche, culturali, biologiche. Un superamento del genere è pregiudizievole alla pari dignità, che fonda il principio di uguaglianza e sta a monte delle sue varie declinazioni giuridiche. Il concetto è ben rappresentato dalla Costituzione italiana che, da una parte, abolisce i titoli nobiliari[31] e dall'altra, prima ancora di istituire i principi di uguaglianza formale e sostanziale, con l'art. 3, comma 1, proclama: «Tutti i cittadini hanno pari dignità sociale»[32]. Bisogna quindi rivolgere l'attenzione al concetto di dignità umana.

2.2. Concezioni del valore individuale

Il Lessico universale italiano Treccani così definisce la dignità: «Condizione di nobiltà morale in cui l'uomo è posto dal suo grado, dalle sue intrinseche qualità, dalla sua stessa natura di uomo, e insieme il rispetto che per tale condizione gli è dovuto e ch'egli deve a sé stesso»[33]. Già da questa nozione si vede come la parola dignità possa comprendere due diversi concetti: uno, riguardante lo specifico merito dell'individuo; l'altro, attinente alla mera appartenenza al genere umano. Per essere ben compresi nella loro portata, essi necessitano di una considerazione storica e comparata.

Nel cosiddetto Antico Regno (3000 – 2150 a.C.), sin dalle prime dinastie e fino al termine della civiltà egizia, il faraone si afferma come monarca per diritto divino ed è considerato addirittura dio in terra. Signore di tutto il paese, accentua ogni funzione pubblica per mantenere la *maat* (l'ordine cosmico). A tal fine si serve di una vasta burocrazia, a capo della quale sta il *ciaty*[34]. I sudditi rendono culto al re in modesti oratori alle porte di ogni tempio, all'interno del quale non sono però ammessi[35]. Alla fine dell'Antico Regno si sviluppa una classe nobiliare detentrice di privilegi giuridici e sociali. Anche se un ordinamento di tal fatta non appare idoneo a riconoscere a tutti pari dignità, con la XVIII dinastia (1543 – 1292 a.C.), e soprattutto dopo il regno di Tutmosi III (regnante dal 1479 al 1424 a.C.), sono eliminate le prerogative giuridiche nobiliari e si instaura l'uguaglianza dinanzi alla legge delle varie classi della popolazione, sebbene diverse per censo[36].

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[29] A.V. Dicey, *Introduzione allo studio del diritto costituzionale*, Bologna, 2003, 158.

[30] Cfr. Y. Harari, *op. cit.*, 122.

[31] Cfr. art. XIV delle Disposizioni transitorie e finali.

[32] Art. 3 Cost.: «Tutti i cittadini hanno pari dignità sociale e sono eguali davanti alla legge, senza distinzione di sesso, di razza, di lingua, di religione, di opinioni politiche, di condizioni personali e sociali. È compito della Repubblica rimuovere gli ostacoli di ordine economico e sociale, che, limitando di fatto la libertà e l'eguaglianza dei cittadini, impediscono il pieno sviluppo della persona umana e l'effettiva partecipazione di tutti i lavoratori all'organizzazione politica, economica e sociale del Paese».

[33] Cfr. voce Dignità, in Lessico Universale Italiano, Istituto della enciclopedia della lingua italiana fondata da Giovanni Treccani, Roma, 1970, VI, 327.

[34] E. Bresciani, *L'Antico Egitto*, in *La Storia*, *Dalla preistoria all'Antico Egitto*, 1, 2004, 647.

[35] K.A. Kitchen, *Il faraone trionfante. Ramses II e il suo tempo*, Roma-Bari, 1987, 217.

[36] Cfr. E. Bresciani, *op. cit.*, 649-650.

Dai celebri poemi epici *Iliade* e *Odissea* possiamo ricavare informazioni sulle relazioni sociali elleniche del periodo in cui si pensa essi siano stati scritti: VIII-VII secolo a.C. Infatti, se è alquanto agevole tramandare la descrizione di un oggetto antico, non è altrettanto semplice parlare di un mondo di rapporti non più sussistenti: si può quindi ritenere che Omero, o altri eventuali autori, pur riferendosi a un indefinito passato miceneo, abbiano descritto i tratti propri del sistema di vita a loro contemporaneo[37]. In questi poemi predomina la figura dell'aristocratico, re o principe, chiamato *diotrefes,* che significa allevato, istruito da Zeus, oppure *dioghenes*, discendente di Zeus. In tal modo il sentimento di superiorità dei nobili rispetto al resto della popolazione è icasticamente rappresentato come frutto di un rapporto speciale con la divinità. Loro stessi si definiscono *aristoi*, i migliori. Formano una classe privilegiata cui si accede per nascita e quindi, ad Atene, si qualificano anche come *eupatridi*, cioè nati bene[38]. Onore, violenza e razzia sono tutt'uno nella loro mentalità[39]. Nel linguaggio eroico ricevere gloria significa uccidere, dare gloria, invece, essere uccisi. Quando Odisseo si reca nell'Ade e parla coi defunti, chiede al re Agamennone come sia morto: ammazzato da chi difendeva pecore e buoi dalle sue razzie? Combattendo per conquistare una città e le sue donne[40]? Un discorso simile fa lo spettro di Agamennone a quello di Anfimedone, uno dei Proci[41]. Il saggio e autorevole Nestore, re di Pilo, persona mite, nostalgicamente rievoca la sua gioventù quando, in un' incursione nelle terre di Itomeneo, lo uccise e gli prese pecore, porci, vacche, capre e cavalli[42]. Per gli aristocratici è encomiabile praticare l'omicidio, la rapina, lo stupro e la riduzione in schiavitù[43]: il loro onore sta nel prevaricare. Solo Ettore, figura di eroe non ellenico, incarna un significato di dignità legato non al merito guerriero, ma etico: la difesa della famiglia e della sua città. Ma la persona buona (*agathos*), ossia dotata di virtù (*arete*), rimane l'individuo in grado d'imporsi, non quello d'animo nobile; *arete* non indica l'eccellenza dal punto di vista morale, bensì il successo[44]. Con Socrate il significato di questi due termini cambia: i concetti di bontà e virtù vengono informati al principio di giustizia[45]. E proprio Socrate sostiene che la dignità non è data dalla ricchezza e dai natali, ma dal sapere[46]. Intanto, il regime democratico aveva fatto sì che tutti gli Ateniesi di sesso maschile avessero pari dignità politica potendo partecipare attivamente alle funzioni di governo. Pur sempre combattivi, essi cercavano la pubblica stima, l'onore (*time*), nell'agone politico regolato da procedure[47].

Nell'ordinamento dell'antica Roma vi è una netta cesura fra coloro che sono qualificati per partecipare agli affari pubblici e gli altri: il corpo civico è profondamente diviso[48] e l'atteggiamento di chi può dedicarsi all'attività politica è teso a perseguire *dignitas*: onore e gloria per sé e la propria *gens*[49]. Più precisamente, con *honos* il cittadino romano si riferisce alla carica istituzionale, al rango e alla considerazione

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[37] F. CODINO, *Prefazione*, in *Iliade*, Torino, 1990, VIII-IX.

[38] A. MIGLINO, *Democrazia antica. Valori e principi*, Ogliastro Cilento, 2017, 7-8.

[39] A. MIGLINO, *Parola e Potere nella Grecia antica*, Ogliastro Cilento, 18-19.

[40] OMERO, *Odissea*, XI, Milano, 1981, 397-403.

[41] Cfr. *ivi*, XXIV, 106-113.

[42] Cfr. OMERO, *Iliade*, XI, 655-684.

[43] A. MIGLINO, *Parola e Potere nella Grecia antica*, 20.

[44] B. SNELL, *La cultura greca e le origini del pensiero europeo*, Torino, 2002, 232.

[45] A. MIGLINO, *Il senso delle istituzioni*, Roma, 2023, 182.

[46] L. DIOGENE, *Vite dei filosofi*, II, Roma-Bari, 1987.

[47] A. MIGLINO, *Democrazia antica. Valori e principi*, cit., 50.

[48] C. NICOLET, *Il mestiere di cittadino nell'antica Roma*, Roma, 2019, 12-13.

[49] G. ZECCHINI, *Il pensiero politico romano. Dall'età arcaica alla tarda antichità*, Roma, 2019, 19.

sociale che ne conseguono. In tal senso il vocabolo è vicino a *fama* e a *gloria,* mentre *gratia* indica, più specificamente, il favore popolare. Da *honos*, fama, gloria e gratia consegue la *dignitas*, che determina il grado sociale di chi ha acquisito benemerenze pubbliche. Ai più alti livelli di dignitas si gode di *auctoritas*, concetto ambiguo che riguarda chi più ha[50]. La dignitas è il criterio in base al quale i censori eseguono il loro giudizio etico sui cittadini, cosa ovvia in una società organizzata gerarchicamente, in cui «l'uomo non era apprezzato solo perché tale, ma per gli atti e le attività che fosse capace di compiere»[51]. Poiché nel repubblicanesimo classico la *virtus* più importante è la disposizione al sacrificio nell'interesse della *res publica*[52], essa non può appartenere a chi, privo di risorse politiche, sociali ed economiche, nulla può sacrificare per mostrarsi 'virtuoso'.

I padri della chiesa cristiana, il cui pensiero è in vario modo richiamato nello sviluppo teologico-politico medievale, insegnano che tutti sono figli di Dio, creati a sua immagine[53]. Ma nella prassi il cristianesimo trionfante non discute gli assetti politici e sociali consolidati; lo stesso autore della Lettera agli Efesini, sia esso Paolo di Tarso o un suo discepolo, insegna che gli schiavi devono servire i loro padroni con «timore e tremore»[54]. Anche Tommaso d'Aquino legittima la servitù, pur richiamando più volte la *dignitas* e la capacità di ogni individuo di scegliere autonomamente dal punto di vista morale[55]. La ragione fondamentale della dignità umana, come ancora oggi dice il Catechismo della Chiesa cattolica[56], sta nella condivisione della vita di Dio secondo i dettami della fede formulati dal magistero della Chiesa che, quando stabilisce un dogma, «si avvale in pienezza dell'autorità che gli viene da Cristo»[57].

In età feudale, sebbene il sistema dei valori sia cristiano[58], i reali rapporti di potere sono informati al principio secondo il quale il dominio signorile sulla terra comprende il comando sulle persone che la popolano[59]: la pari dignità degli uomini non è concepibile. Alla grande distinzione in ceti (nobiltà, clero, popolo), che si consolida nei secoli XIII e XIV e perdurerà fino alla Rivoluzione francese[60], si aggiunge il fatto che il valore sociale e giuridico dell'individuo dipende dagli elementi più disparati, quali l'onorabilità e la stima sociale, la posizione nell'ambito della famiglia, la fede religiosa, l'età, il sesso, l'attività professionale... (ad esempio, fino al Seicento, nel Regno di Napoli, chi viveva in campagna non poteva testimoniare contro un cittadino; nei territori oltre l'Elba e la foresta boema i contadini non potevano ereditare o fare testamento...)[61].

Nel clima culturale del giusnaturalismo moderno e del contrattualismo (secoli XVII e XVIII) nasce la concezione dei diritti umani, ossia diritti naturali che precedono la formazione della società e quindi devono

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[50] M. Pani, *La repubblica romana*, Bologna, 2010, 35-36.

[51] U. Vincenti, *La Costituzione di Roma antica*, Bari-Roma, 2017, 60.

[52] Cfr. *ivi*, 107-108.

[53] A. Facchi, *Breve storia dei diritti umani*, Bologna, 2008, 26.

[54] Cfr. Paolo di Tarso (pseudo), *Lettera agli Efesini*, 6,5, in G. Barbaglio (a cura di), *San Paolo*, *Lettere*, vol. 2, *Lettere pseudoepigrafiche*, 109, Milano, 1997, 75-113.

[55] M. Flores, *Storia dei diritti umani*, Bologna, 2008, 26.

[56] Cfr. Chiesa cattolica, *Catechismo della Chiesa cattolica*, Roma, 1992, 356, 104.

[57] Cfr. *ivi*, 88, 40.

[58] P. Bellini, *Respublica sub deo. Il primato del Sacro nella esperienza giuridica della Europa preumanistica*, Firenze, 1982, 7-8.

[59] J. Baschet, *La civiltà feudale*, Roma, 2005, 18, 93, 109, 115-116, 134.

[60] V. Piano Mortari, *Gli inizi del diritto moderno in Europa*, Napoli, 1982, 150-151.

[61] Cfr. *ivi*, 151-153.

essere riconosciuti dallo stato a ogni cittadino[62]. Ciò implica che tutti abbiano per natura pari dignità. Nati in sede filosofica, i diritti umani si affermano però quando le forze politiche della borghesia, con le rivoluzioni liberali inglese, americana e francese, li enunciano in testi normativi. Tuttavia, pur quando vengono positivamente riconosciuti dalla legge, i diritti 'naturali' escludono diversi esseri umani, in primo luogo quelli di genere femminile[63]. La francese Marie Gouze, scrittrice e drammaturga conosciuta col nome di Olympe de Gouges, scrive la *Déclaration des droits de la femme et de la citoyenne* (Dichiarazione dei diritti della donna e della cittadina) integrando e parafrasando la Dichiarazione dei diritti dell'uomo e del cittadino (approvata il 26 agosto 1789 dall'Assemblea costituente) per auspicare che i principi contenuti in tale documento si estendano anche alle donne: evidentemente, laddove la celebre *Dichiarazione* parla di uomo lo intende come appartenente al solo genere maschile. D'altro canto, le dichiarazioni di diritti immediatamente scaturite dalle rivoluzioni liberali, pur riconoscendo che gli uomini nascono liberi ed uguali, sono emanate in ordinamenti che contemplano la schiavitù, come quello nordamericano. Thomas Jefferson, il principale estensore della Dichiarazione dei diritti del 1791 (*Bill of Rights*) che ha emendato la Costituzione degli Stati Uniti d'America, possedeva centinaia di schiavi, ma ne affrancò soltanto cinque in punto di morte[64], nonostante nell'art. 1 della Dichiarazione avesse scritto: «Gli uomini nascono liberi ed eguali nei diritti». Evidentemente, non considerava i servi pienamente umani. In definitiva, donne e schiavi non avevano la stessa dignità del maschio libero. Inoltre, «per tutto il XIX secolo è difficile parlare di diritti umani ottenuti in modo stabile e coerente in qualche parte d'Europa o del mondo»[65]. E fino alla metà del XX secolo le potenze coloniali hanno mantenuto nei loro imperi differenze di diritti secondo le categorie etniche sottoposte, anche se in madrepatria la schiavitù era stata abolita[66].

Infine, nel XX secolo, le dichiarazioni internazionali di diritti e le Carte costituzionali, enunciando diritti, lo fanno con riferimento all'essere umano *sic et simpliciter*, a prescindere dalle sue condizioni. Significativamente l'art. 1 della Dichiarazione Universale dei diritti dell'uomo recita: «Tutti gli esseri umani nascono liberi ed eguali in dignità e diritti: essi sono dotati di ragione e di coscienza e devono agire gli uni verso gli altri in spirito di fratellanza». Pur non avendo valore vincolante[67], la *Dichiarazione* è la più importante manifestazione storica di una comune coscienza dell'umanità rispetto ai suoi valori fondamentali[68], l'approdo di un'elaborazione ultra millenaria che ha portato a concepire la pari dignità di tutti gli esseri umani. Valore vincolante ha invece il riconoscimento dei diritti umani nelle Costituzioni dei singoli Stati: nelle democrazie i diritti fondamentali costituiscono non solo il limite, ma anche la finalità dell'azione dei pubblici poteri[69]. Oggi che i diritti dell'uomo sono riconosciuti da fonti giuridiche interna-

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[62] N. MATTEUCCI, *voce Diritti dell'uomo*, in N. BOBBIO, N. MATTEUCCI, G. PASQUINO (diretto da), *Dizionario di Politica*, Milano- Torino, 2000, 304.

[63] Cfr. A. FACCHI, *op. cit.*, 65.

[64] R.H. DAHL, *Sull'uguaglianza politica*, Roma – Bari, 2007, 20.

[65] Cfr. M. FLORES, *op. cit*, 126.

[66] T. PIKETTY, *Una breve storia della disuguaglianza*, Milano, 2021, 141.

[67] La Dichiarazione Universale dei diritti dell'uomo, approvata dall'Assemblea generale delle Nazioni Unite il 10 dicembre 1948, ha valore giuridico di raccomandazione (cfr. B. CONFORTI, *Diritto Internazionale*, Napoli, 1997, 58).

[68] N. BOBBIO. *L'età dei diritti*, Torino, 1997, 20, 28.

[69] L. FERRAJOLI, *La democrazia attraverso i diritti*, Roma-Bari, 2013, 112-122.

zionali e nazionali, sebbene il loro contenuto debba essere precisato attraverso un confronto fra le molteplici tradizioni culturali[70], il problema maggiore non è più quello di giustificarli, ma di proteggerli[71].

L'attribuzione di posizioni giuridiche soggettive presuppone l'individuazione di chi ne deve essere titolare: se i soggetti non sono considerati dotati di una medesima dignità, non ottengono certo gli stessi diritti e doveri (gli schiavi erano privi di personalità in senso giuridico, non potendo essere portatori di diritti. Aristotele diceva addirittura che alcuni nascono schiavi per natura[72]). La pari dignità è dunque il fondamento dell'attribuzione dei diritti e delle tecniche normative che realizzano il principio di uguaglianza. Giustifica nuove formulazioni giuridiche al passo coi tempi e quindi anche il principio secondo il quale nessun facoltoso può conseguire, contrariamente ad altri, il potenziamento delle capacità psicofisiche di Homo sapiens.

2.3. Attività mediche e principio di dignità

Il superamento delle normali capacità fisiche e cognitive dell'essere umano dovrebbe essere vietato non solo perché contrario ai principi di uguaglianza e dignità come sopra intesi, ma anche in relazione alla peculiare accezione di dignità che ci consegna la storia della medicina.

Premesso che l'attuale nozione di atto medico[73], nata in un'epoca caratterizzata dal metodo scientifico, non è propria di altri contesti storici e culturali (alcuni dei quali sono stati precedentemente ricordati), poiché «il primo dovere dei medici è quello di sollevare i pazienti dalla sofferenza e migliorare la qualità e la durata della vita»[74], si può parlare di medicina, medici e sanitari in senso lato, riferendosi a coloro che hanno svolto tali attività, pur in assenza di nozioni e prassi propriamente scientifiche.

Lulu è il nome del primo medico che si sappia, operativo nella città di Ur verso il 2700 a.C. Nei testi sumerici già si distinguono alcune specializzazioni, anche in veterinaria, come dimostrano i titoli di «dottore dei buoi» o «dottore degli asini»[75].

Nell'antico Egitto vi sono tre tipi di medici: il sinu (o saunu), formato su libri e pratica; il sacerdote, che assiste i pazienti con pratiche religiose; il guaritore, che impiega procedimenti magici disgiunti da dogmi sacrali e liturgici. Per lo più i 'clinici' sono sacerdoti. Fin dall'Antico Regno la corte del Faraone ospita professionisti sanitari e fra questi il «medico capo», che cura il sovrano e spesso riceve il titolo di «Direttore generale dei medici dell'Alto e Basso Egitto»[76]. I pubblici poteri non solo controllano la professione medica, ma la finanziano: le terapie sono gratuite per tutti[77]. Narra Erodoto (484 – circa 425 a.C.) che nell'Egitto del suo tempo «ogni medico cura una e una sola malattia; e ci sono medici dappertutto; alcuni curano gli occhi, altri la testa, altri i denti, altri le infezioni del ventre, altri ancora le malattie oscure»[78]. Nel Nuovo Regno (1543 – 1078 a.C.) la gente comune si rivolge anche alle cosiddette "statue gua-

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[70] E. DENNINGER, Diritti dell'uomo e legge fondamentale, Torino, 1998, 47.

[71] Cfr. N. BOBBIO, *op. cit.*, 16.

[72] ARISTOTELE, *Politica*, Libro I, in C.A. VIANO (a cura di), ed. italiana, Milano, 2017, 1253b -1255a, 82-91,.

[73] S. RICCI, A. MIGLINO, *Atto medico e consenso informato*, Roma, 2009, 6: «Atto medico è qualsiasi prestazione che il sanitario svolge in ambito preventivo, diagnostico, curativo, riabilitativo e medico legale».

[74] A. FIORI, *Medicina legale della responsabilità medica*, Milano, 1999, 45.

[75] S. MOSCATI, *Vita di ieri vita di oggi*, Milano, 1978, 156.

[76] G. RACHET, *Dizionario dell'antico Egitto*, Roma, 1991, 200.

[77] Cfr. A. FIORI, *op. cit.,* 9.

[78] ERODOTO*, Le Storie*, Libro II, ed. italiana, 1989, 84, 305.

ritrici", raffiguranti per lo più alti dignitari elevati al rango di protettori dopo la morte, ricoperte di raffigurazioni e testi sacri creduti in grado di preservare e guarire dalle malattie. Sulle statue scorre dell'acqua, che così si carica del potere dei testi magici e poi si raccoglie in ciotole poste nel piedistallo della scultura, per essere usata[79].

Nell'Iliade troviamo menzione di interventi da parte di medici militari[80] ritenuti ispirati dal mondo divino, col quale sono in contatto[81]. In tutta la Grecia la medicina si sviluppa negli *asklepieia*, santuari – ospedali posti in vicinanza di un luogo sacro, dove si accolgono i pazienti, che vi dormono per una notte in compagnia di serpenti sacri sotto il portico di un edificio adiacente al tempio. Il malato riceve parole divine e visioni oniriche, interpretate dagli Asclepiadi, medici sacerdoti che si dicono discendenti del semidio Asklepios[82]. Poi si sviluppano grandi scuole di medicina a Crotone, a Rodi, a Cirene, e soprattutto a Cnido e a Cos[83], patria del celebre Ippocrate (circa 460 – 370 a.C.). Nell'Atene democratica i pubblici poteri, in favore dei meno abbienti, pagano medici pubblici (*demosioi iatroi*) scelti dall'Assemblea[84], e mettono a loro disposizione medicine, ambulatori, edifici per il ricovero. Il tutto è finanziato attraverso un'imposta speciale, lo *iatricon*. L'istituzione di medici pubblici non è propria di Atene, ma anche di altre città elleniche: celebre è il caso di Crotone, che strapagò il famoso Democede (ca. 521 – 483). Vi sono medici anche fra le donne[85] e gli schiavi. Platone dice che in genere, mentre i liberi curano i liberi, sono gli schiavi a visitare gli schiavi, presso il loro domicilio o in ambulatorio[86].

Nel mondo romano, anche nella medicina troviamo una forte differenza fra le classi ricche e quelle povere: solo le prime possono permettersi clinici di fama e seguire le regole di prevenzione del tempo[87]. In età imperiale i poteri pubblici organizzano l'assistenza sanitaria per gli indigenti. Nelle piccole città sono pagati i *medici salariarii* o *medici civitatis;* a Roma i medici pubblici, titolati come archiatri, sono istituiti nel IV secolo nel numero di quattordici: uno per ogni regione della città. In contropartita di una paga fissa gli archiatri devono, fra l'altro, curare gratuitamente i poveri e rilasciar loro certificati di malattia[88]. Anche gli schiavi ricevono cure. Già Catone il censore (234 circa a.C. – 149), ben duro con i suoi servi, tuttavia provvedeva a curarli personalmente[89]. Nel I secolo, il medico e scrittore Scribonio Largo richiede ai sanitari le qualità indispensabili di *misericordia* e *humanitas* e il celebre filosofo stoico Seneca dice: «La medicina presta la sua assistenza anche ai criminali; nessuno ha mai negato la somministrazione dei rimedi salutari al fine di non guarire coloro che sono indegni»[90].

Nell'Alto Medioevo, il povero è considerato un rappresentante di Cristo cui si deve *caritas* (da tale visione ci si è poi allontanati nel XVI secolo[91]). Dall'etica cristiana nasce l'istituzione ospedaliera: «in quel

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[79] E. FERRARIS, *Dal Nuovo Regno all'epoca tarda. Lo splendore dei faraoni*, in *La Storia dell'arte*, 1, 2006, 349.
[80] OMERO, *Iliade*, Libro IV, Torino, 1990, versi 190-195, 126-127.
[81] É. MIREAUX, *I greci al tempo di Omero*, Milano, 1992, 100.
[82] Cfr. *ivi*, 97.
[83] G. RACHET, *Dizionario della civiltà greca*, Torino, 1973, 211.
[84] PLATONE, *Gorgia*, Milano 2022, 455b.
[85] R. FLACELIÈRE, *La vita quotidiana in Grecia nel secolo di Pericle*, Milano, 1994, 185-186.
[86] Cfr. PLATONE, *Le leggi*, Libro IV, Milano, 2005, 720 c-d, 375.
[87] C. D'AMATO, *Vita e costumi dei romani antichi*, 15, *La medicina*, Roma, 1993, 103.
[88] Cfr. *ivi*, 34.
[89] Cfr. *ivi*, 22.
[90] Cfr. *ivi*, 58-59.
[91] J. P. GUTTON, *La società e i poveri*, Milano, 1977, 80.

contesto gli ospedali erano spazi caritativo-assistenziali aperti a chiunque si trovasse nel bisogno, senza giudizio di merito o di colpa, senza distinzione tra esigenza sanitaria e indigenza economica»[92]. Verso il VI secolo, nell'Impero Romano d'Oriente, si crea l'ospedale concependolo non più quale ospizio per viandanti e poveri, ma come struttura capace di fornire prestazioni diagnostiche e terapeutiche con personale specializzato a pazienti di classi sociali diverse, anche disagiate[93]. In Occidente, sin dall'Alto Medioevo i monasteri sono pronti ad accogliere tutti i bisognosi. I pochi luoghi dove si esercita assistenza medica collettiva, quali le infermerie monastiche, o gli *hospitalia* (ospizi) annessi alle chiese, sono gestiti proprio da monaci o da rappresentanti della Chiesa[94]. Il paziente è assistito dai frati sia con le preghiere, per far conseguire al malato la purezza perduta a causa del Maligno, sia purgando, somministrando medicinali, praticando interventi di taglio, fino a quando tale ultima pratica è proibita dal Concilio di Reims nel 1131, sotto il pontificato di Innocenzo II[95]. Dal XII secolo l'*infirmitas* (malattia) si distingue dalla *paupertas* (povertà)[96].

In Italia centrale e settentrionale, nel periodo in cui si passa da una società comunale a una signorile, con l'accentramento del potere politico in poche famiglie, per dare sollievo ai ceti popolari e controllarli istituzionalizzando la carità, si sviluppano gli ospedali quali luoghi destinati all'assistenza degli indigenti, dove la cura del corpo non è disgiunta da quella dell'anima e il ricovero è ancora indifferenziato. Solo nel Settecento si distinguono i bisogni materiali da quelli più propriamente clinici e quindi si espelle il semplice povero da queste strutture[97].

Dal 1880 alla prima guerra mondiale, in Italia, vi è una svolta che permette di porre le basi di un nuovo modello di intervento sociale[98]. In particolare, con la legge n. 5849 del 22 dicembre 1888 – *Legge per la tutela della igiene e della sanità pubblica* – (cosiddetta legge Crispi), si istituisce la figura del medico condotto, assunto e pagato dal Comune, cui spetta assistere i poveri iscritti nelle liste comunali. L'estensione dell'assistenza sanitaria gratuita è tassativamente esclusa a chi povero non sia, tranne casi eccezionali. La legge, comunque, non prevede la fornitura gratuita dei medicinali, neppure ai poveri. Con la legge n. 833 del 23 dicembre 1978 nasce il Servizio Sanitario Nazionale, che assorbe tutte le competenze e le funzioni dei precedenti enti operanti nel campo dell'assistenza clinica e le estende a tutti i cittadini, senza distinzioni individuali o sociali, secondo modalità volte ad assicurare uguaglianza e uniformità in tutto il territorio nazionale[99].

Nel corso dei secoli il valore degli individui è stato stimato, per lo più, in base alle loro condizioni sociali, politiche, economiche e culturali. Solo di recente, negli ordinamenti democratici, si è riconosciuta digni-

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[92] G. Cosmacini, *Storia della medicina e della sanità in Italia*, Roma-Bari, 1995, 49.

[93] M. Conforti, *Cura e caritas: l'assistenza agli infermi dalla tarda Antichità al Medioevo*, in U. Eco (a cura di), *Il Medioevo, 2. Alto Medioevo. Filosofia, Letteratura, Scienze*, Milano-Roma, 2009, 191-195.

[94] M. Conforti, *Medicina e malattia in Occidente tra XI e XII secolo*, in U. Eco (a cura di), *Il Medioevo, 5. Medioevo centrale. Filosofia, Scienze, Letteratura,* Milano-Roma, 2009, 194-197.

[95] G. Cosmacini, *Il mestiere di medico. Storia di una professione*, Milano, 2000, 67-72.

[96] M. Conforti, *Medicina e malattia in Occidente tra XI e XII secolo*, in U. Eco (a cura di), *Il Medioevo, 5. Medioevo centrale. Filosofia, Scienze, Letteratura,* Milano-Roma, 2009, 195.

[97] A. Scotti, *Malati e strutture ospedaliere*, in *Storia d'Italia*, 7, 1984, 237-246.

[98] P. Battilani, *I protagonisti dello Stato sociale italiano prima e dopo la legge Crispi*, in *Povertà e innovazioni istituzionali in Italia Dal Medioevo ad oggi*, 2000, 662.

[99] S. Ricci, *Evoluzione dei principi informatori dell'ordinamento sanitario*, in *Atto medico. Evoluzione e valore sociale*, 2000, 109-110.

tà a ogni uomo per il fatto stesso di essere tale. Significativamente l'art. 3 della Costituzione italiana esordisce: «Tutti i cittadini hanno pari dignità sociale». Questo icastico assunto, soprattutto se interpretato in combinato con l'art. XIV delle disposizioni transitorie e finali della Costituzione abolitivo dei titoli nobiliari, vuole che ogni persona goda della stessa importanza delle altre. Se è interpretato in combinato con l'art. 1 Cost., secondo cui la Repubblica italiana è fondata sul lavoro, può condurre a quanto sostiene un'autorevole dottrina: «La dignità dell'uomo è fondata non su ciò che uno ha (la proprietà), ma su ciò che uno fa (il lavoro, appunto)»[100]. Più in generale, il concetto di dignità già in sede teorica è contraddittorio: si può distinguere fra una dignità di dotazione, che prescinde da meriti e demeriti individuali, e una dignità di prestazione, conseguibile con azioni tese a costruire una determinata identità[101]. Distinguere fra una dignità uguale per tutti e una che dipende da come il singolo conduce la sua esistenza non è certo semplice: in che senso il pluriomicida e l'altruista sono ugualmente o inegualmente degni? Sebbene il problema sia di difficile soluzione, il caso dell'attività medica può servire a dare al quesito una risposta sufficiente ai fini che ora ci interessano. Si è visto che, in ordinamenti diversi nello spazio e nel tempo, con differenti organizzazioni sociali e concezioni della dignità umana, nessuno è stato escluso in linea di principio dalle pratiche terapeutiche, anche se i ceti abbienti hanno potuto fruirne al meglio. La medicina è quindi un'attività di cui è stato ritenuto degno ogni uomo biologicamente tale. Ecco dunque che Seneca, pur mantenendo la distinzione fra degni e indegni propria del suo mondo, dice che anche un criminale deve accedere alle cure. Affinché ciò sia possibile, ai nostri tempi, l'art. 365 del codice penale italiano, dopo aver previsto la punizione dell'omissione di referto da parte di chi esercita una professione sanitaria, precisa che «questa disposizione non si applica quando il referto esporrebbe la persona a procedimento penale». Se così non fosse, chi avesse commesso un reato perseguibile d'ufficio potrebbe evitare di rivolgersi a un operatore clinico. Ma poiché il diritto alla salute del cittadino prevale sulle finalità di difesa sociale e di repressione della criminalità, il medico deve assistere il paziente delinquente con perizia, prudenza e diligenza rispettando il segreto professionale[102].

Si vede bene che la medicina di sempre e l'atto medico di tipo scientifico hanno riconosciuto lo stesso valore agli uomini considerandoli nella loro consistenza meramente biologica, non già sociale, economica, politica, culturale. Tale punto di vista non può che essere mantenuto, quale strumento di valutazione di ciò che è giusto o meno fare del proprio corpo. Il binomio pari dignità – comune dotazione psicofisica non può essere scisso mediante alcuni tipo di *human enhancement*.

2.4. Atto ultramedico

Il superamento delle normali limitazioni del corpo umano, indicato generalmente e genericamente col termine *human enhancement*[103], ossia il potenziamento umano[104], è il risultato di ciò che sembra opportuno chiamare atto ultramedico. Infatti, la definizione di atto medico accolta in via dottrinaria, recependo i contributi della giurisprudenza, in sostanza è tale: «qualsiasi prestazione che il sanitario svolge in

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[100] N. Bobbio, *Diritti dell'uomo*, in *Teoria generale della politica*, 2009, 459.

[101] U. Vincenti, *I fondamenti del diritto occidentale*, Roma-Bari, 2018, 72-73.

[102] N. M. Di Luca, T. Feola, E. Marinelli, S. Ricci, *Nuovo Compendio di Medicina legale*, Torino, 2021, 1-667.

[103] L. Ricci, B. Di Nicolò, P. Ricci, F. Massoni, S. Ricci, *The exercise of rights beyond therapy: on Human Enhancement*, in *BioLaw Journal*, 1, 2019, 497-512.

[104] F.M. Damato, P. Ricci, R. Rinaldi, *Informed consent and compulsory treatment on individuals with severe eating disorders: a bio-ethical and juridical problem*, in *Clinica Terapeutica*, 174, 4, 2023, 365-69.

ambito preventivo, diagnostico, curativo, riabilitativo e medico legale»[105]. Si tratta di una nozione pensata per condotte professionali finalizzate ad assicurare il benessere fisico, psichico e sociale commensurabile agli standard biologici di Homo Sapiens, da cui sembra bene escludere ogni intervento che vada al di là di essi, sebbene produttivo di effetti sulla salute così come definita dall'OMS. Indicare col sintagma «atti ultramedici» il superamento biotecnologico delle facoltà sensitive, cognitive e operative normalmente attinenti alla fisiologia umana, consente di esprimersi in maniera sintetica pur non confondendo il nuovo fenomeno con quanto rientra nella definizione di atto medico. Altrimenti, questa stessa definizione dovrebbe essere ampliata fino a comprendere quanto attiene allo *human enhancement*. Ma, in tal caso, ogni volta si dovrebbe specificare di cosa si stia parlando. Per quanto riguarda la scelta del termine testé operata, si è preferito il prefisso *ultra*, di chiara derivazione latina, perché in grado di sfumare in valore intensivo il sostantivo cui è preposto[106].

2.5. Biotecnologie, intelligenza artificiale e condizione di disabilità

Ovviamente, il discorso fatto sin qui non riguarda l'applicazione delle più avanzate tecnologie informatiche e biologiche – intelligenza artificiale compresa – a servizio dell'atto medico, che persegue la piena realizzazione della dignità del paziente, intesa quale libertà dalla malattia e come affermazione di validità che, secondo la migliore dottrina, è la «efficienza psico-fisica allo svolgimento di qualsiasi attività lavorativa ed extralavorativa (ad esempio, atti ordinari della vita, atti abituali della vita quotidiana)»[107]. Le tecnologie più avanzate potranno, e anzi dovranno, essere usate per ovviare alle situazioni di *handicap* variamente denominate (disabilità, inabilità e simili) nella vasta legislazione in materia di lavoro e invalidità. Nell'ordinamento italiano, per quanto riguarda le tutele assistenziali, il decreto legislativo n. 62 del 3 maggio 2024 ha adottato una nozione onnicomprensiva di «condizione di disabilità»: una duratura compromissione fisica, mentale, intellettiva, del neurosviluppo o sensoriale che, in interazione con barriere di diversa natura, può ostacolare la piena ed effettiva partecipazione nei diversi contesti di vita su base di uguaglianza con gli altri[108]». Al cospetto di tale condizione è sicuramente auspicabile l'uso di algoritmi, intelligenza, impianti artificiali e quant'altro possa aiutare la persona non già a primeggiare sulle altre, ma a recuperare uno stato di salute che gli dia dignità e lo includa a pieno titolo nella società, come vogliono il principio di uguaglianza sostanziale di cui all'art. 3, comma 2, della Costituzione italiana.

3. Conclusioni

Gli esseri umani hanno dato ampie prove di esser pronti a non sentirsi appartenenti a uno stesso mondo, a una medesima realtà, pur essendo biologicamente simili. Soprattutto ora che vi è un ritorno della società dei privilegi[109] , e che s'intravede la possibilità di potenziare le capacità psicofisiche di Homo sa-

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[105] Per questa nozione di atto medico cfr. S. Ricci, A. Miglino, *Atto medico e consenso informato*, Roma, 6, 2009.
[106] L. Serianni, *Grammatica italiana. Suoni Forme Costrutti*, 1988, 553.
[107] C. Gerin, F. Antoniotti, S. Merli, *Medicina legale e delle assicurazioni*, Roma, 1997, 572.
[108] Cfr. art. 2, comma 1, lettera a, D.lgs. 62/24.
[109] E.V. Parsi, *La fine dell'uguaglianza*, Milano, 2012, 89-122.

piens mediante tecnologie informatiche[110] e biologiche (ivi compresa l'IA), dare solo a pochi facoltosi la facoltà di dotarsi di apparati che trascendono la fisiologia umana significherebbe acuire le differenze individuali, creare persone super dotate in posizione dominante sulle altre. Ciò è contrario ai princìpi di dignità e uguaglianza. L'accesso alle biotecnologie idonee a oltrepassare gli attuali limiti dell'essere umano potrà giustificarsi solo se sarà conseguibile da tutti. Il punto di vista medico rende univoco il concetto di dignità umana, fondandolo sulla comune costituzione biologica delle persone, al di là delle differenze politiche, economiche, sociali e culturali che li distinguono. Il potenziamento del corpo, che di fatto comporti la creazione di caste biologiche, fuoriuscirebbe da questo stesso punto di vista e dunque dall'ambito deontologico clinico. Consisterebbe quindi in atti che sembra opportuno denominare "ultramedici". Invece, proprio al fine di salvaguardare i principi di dignità umana e uguaglianza, oltre che di solidarietà, le migliori biotecnologie disponibili dovranno essere utilizzate per aiutare la persona malata, o in condizione di disabilità, non già a primeggiare sulle altre, ma a recuperare uno stato di salute che l'includa a pieno titolo nelle relazioni sociali.

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[110] G. MONTANARI VERGALLO, L. LEONDINA CAMPANOZZI, M. GULINO, L. BASSIS, P. RICCI, S. ZAAMI, S. MARINELLI, V. TAMBONE, P. FRATI, *How Could Artificial Intelligence Change the Doctor–Patient Relationship? A Medical Ethics Perspective,* in *Healthcare*, 13, 18, 2025, 2340.