



## 1. Introduction

This Deliverable "D2.1 – Inventory of the Ethical and Legal Framework" is part of the "WP2 – Legal and Ethical Framework" within Spoke 1 ("Enabling Factors and Technologies for Digital Prevention") of the DARE project. Its aim is to provide an overview of the currently applicable legislative provisions and proposals being developed in the European forum in order to offer a general framework of ethical and legal issues in relation to privacy, artificial intelligence and the most relevant points in relation to the issue of health prevention.

The digitalization of health prevention includes health promotion and prevention actions made possible by digital technologies, which by their nature can significantly improve the ability of healthcare to offer a better and faster service to its patients.

Health, by definition, is a multidimensional right, which contains a plurality of substantive projections intertwined with advancements in medical technology and prospects opened up by scientific research, as well as with the emerging social and cultural needs, made possible by scientific and technological development.

According to Article 32 of the Italian Constitution, "The Republic safeguards health as a fundamental right of the individual and as a collective interest, 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".

Alongside the 'social' or 'positive' dimension that refers to the public commitment for the protection of health (through the predisposition of health policies, facilities, goods and services, the deployment of organizational and financial resources<sup>1</sup> as well as the recognition of free care for indigent people); the right to health has also a 'liberty' or 'non-interference' dimension, taking the form of the right to receive care and treatments as well as to refuse them. Additionally, the protection of health is a fundamental right not only for the individual but also for the entire community. It is precisely in relation to this 'collective'

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<sup>1</sup> All these functions could be refined and improved using AI and exploiting the potential of big data, see Grossi P.V. La determinazione del fabbisogno sanitario nazionale standard e dei suoi criteri di riparto tra Regioni. Arbitrio, discrezionalità e decisione politica alla prova dell'intelligenza artificiale. L'amministrazione digitale - quotidiana efficienza e intelligenza delle scelte (edited by Jean-Bernard Auby, Giovanna De Minico, Giorgio Orsoni). Naples: Editoriale Scientifica, 2023:220-222.

dimension that prevention is recognized as a fundamental component to achieve the full realization of the right to health.<sup>2</sup>

Therefore, it is widely acknowledged that the protection of health cannot be reduced to the therapeutic response to an existing illness but requires actions go ‘beyond the disease’ or, in this case, ‘before the disease’. The importance of health promotion and prevention has been recognized within the Article 35 of the EU Charter of Fundamental Rights, according to which “Everyone has the right of access to preventive health care and the right to benefit from medical treatment under the conditions established by national laws and practices”.

However, the Covid-19 pandemic has clearly and brutally revealed that efforts in this regard were inadequate, as the prevention system proved to be insufficient. At the same time, it has highlighted “a duty to which we have long been called, that of take care of health in a preventive way, bearing in mind the close interdependence not only among human beings themselves, but also among all living things”.<sup>3</sup>

In order to (re)orient the NHS from diagnosis and treatment toward prevention, the integration of digital technology into healthcare is considered to play an essential role. Indeed, digital technologies hold the potential to greatly improve the effectiveness and precision of key public health activities related to primary, secondary and tertiary prevention. Therefore, it is crucial to address the most relevant legal and ethical issues that could hinder the achievement of this important goal.

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<sup>2</sup> D’Aloia A. Oltre la malattia: metamorfosi del diritto alla salute. *BioLaw Journal*. 2014;1:139-140. doi.org/10.15168/2284-4503-10.

<sup>3</sup> Italian Committee for Bioethics (ICB) and Italian Committee for Biosafety, Biotechnology and Life Sciences (ICBBSL). Artificial Intelligence and Medicine: some ethical aspects. 29 May 2020:9. <https://bioetica.governo.it/en/opinions/joint-opinions-icbicbbsl/artificial-intelligence-and-medicine-some-ethical-aspects/>.