MEDINFO 2023 — The Future Is Accessible
J. Bichel-Findlay et al. (Eds.)

doi:10.3233/SHTI231331

Implementation of Digital Health Ethics: A First Step with the Adoption of 16 European Ethical Principles for Digital Health

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Abstract. The potential for technology to transform health care is tremendous, but advances in digital health may also bring privacy and data security challenges that may exacerbate inequalities. Hence, it is critical that the development of digital health is included in a framework of humanistic and ethical values. France drew up its roadmap for accelerating the shift towards digital health with ethics at the forefront, along with security and interoperability pillars. Criteria such as digital health for all, transparency of data processing, trustworthy AI, and eco-responsibility and sustainability of digital health were elaborated. Under the French Presidency of the Council of the European Union, building on the proposal of ethical criteria from France, eHealth network representatives unanimously adopted 16 European ethical principles for digital health, formalizing trust commitments towards European citizens and paving the way for the European Health Data Space.

Keywords. Digital health ethics, inclusive digital health, data processing transparency, trustworthy AI, eco-responsible digital health.

1. Introduction

The digitalization of the healthcare sector allows for better care and empowers individuals through better control on their health data. Yet, digital health also comes with questions and concerns. Building trust is key to enable its growth and use. For example, while the COVID pandemic has confirmed the important role of digital health, the experience of the European Digital Covid Certificate [1] has also highlighted the need for an ethical basis. In parallel, the proposed regulation for a European Health Data Space addresses uses of health data, ranging from primary use (in the context of the provision of health care and patient healthcare pathways), to secondary use of data (re-use of health data for research, innovation, and policy-making). This regulation aims at answering

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citizens' expectations to manage and control the use of their own data while meeting the needs of European stakeholders to access and re-use health data. It will impact the entire health data ecosystem by creating a European digital single market for health. Hence, it is critical that further development of digital health combined with European challenges, as strategic sovereignty, are to be included in a framework of humanistic and civic values.

France is often considered as the country of Enlightenment (*Lumières*) which called for an autonomous human order where the individual becomes the measure of all things. Thus, when, in 2019, France drew up its roadmap for accelerating the shift towards digital health, ethics were at the forefront, along with security and interoperability pillars. However, if security and interoperability were already structured, embodied in rules and policies, digital health ethics were a white page. Over the last three years, the Ministerial Delegation for digital health of the French Ministry of Health has been working with all stakeholders to shape digital health ethics and define ethical rules and policies. On the eve of the French Presidency of the Council of the European Union (PFUE), France was ready to make a proposal to promote ethics of digital health at the European level.

2. Methods

2.1. Ethics of digital health

The Hippocratic Oath is an important commitment; physicians continue to honor it today. The oath articulates strong principles, still relevant in the 21st century [2]: "*I will respect all persons, without any discrimination*" […], "*I will act to protect them*" […], "*I will inform patients*" […], "*I will never mislead their trust"* […], "*I will keep their secrets*" […]. These principles, often gathered according to the four principles of [3] - beneficence, non-maleficence, autonomy, and justice - have been extremely influential in the field of medical ethics. On the other side, digital health should not be considered as an end in itself but as a tool to support the improvement of quality of care for patients. As such, digital health should be accessible to all, easy and intuitive to use, must serve its users and not the other way around (it's not up to users to adapt to digital technology), and should be developed in a sustainable and responsible way. Hence, we defined digital health ethics as the intersection of medical and digital ethics (see Fig. 1).

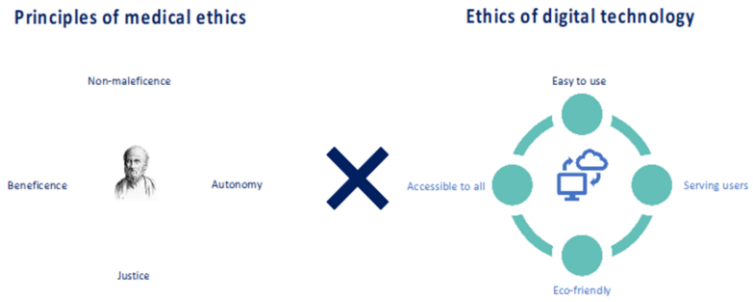

Figure 1. Digital health ethics defined as the intersection of medical and digital ethics.

2.2. French ethical criteria for digital health

As from 2019, led by the Delegation for digital health of the French Ministry of Health, various initiatives have been launched in France to define digital health ethics. A tremendous work brought together all digital health stakeholders [4] (patients, health practitioners, vendors, philosophers, sociologists, ethicists, biomedical informatics researchers, etc.) to structure ethics for digital health as a set of operational ethical criteria, attached to the main health digital tools, i.e., health mobile apps, hospital information systems, medical practice software, information system for social and medico-social facilities, to certain activities, i.e., telehealth, or to methods, i.e., artificial intelligence (AI) [5]. In 2021, ethical criteria were defined and gathered into four categories:

- *Digital health for all* meaning thinking from initial design of any digital service to not exclude any audience, developing intuitive digital services "easy to use" (to fight against digital divide), developing user interfaces that can cope with patients with disabilities, providing guidance on how to get started with a digital tool, and offering access to a human support when necessary.
- *Transparency of personal data processing*: a distinction should be made between data processing serving the primary use (patient care) and those serving secondary uses, e.g., marketing. Digital health services and tools should guarantee total transparency on any personal data processing serving secondary use, propose an "à la carte" consent allowing to choose the secondary uses they want to consent to, assure the same quality of service whether the user consents or not to data processing for secondary uses, and be transparent about any access to personal data including access by subcontractors (who accessed my data, when, and for what purpose?).
- *Trustworthy AI*: AI services must inform the user when interacting with an AI, there should be a clear information about the processes implemented by vendors to limit/control biases (especially discriminatory biases), about the performance of the service, and explainability of AI results should be offered to the extent possible.
- *Eco-responsibility of digital health* supported by computation of digital health services carbon footprint, eco-design of the code, accessibility of the service at low speed and on devices that are not necessarily of the latest generation, data hosting on servers implementing processes to reduce resources and energy consumption.

2.3. European ethical principles for digital health

The eHealth Network (eHN) has been created after the Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare. The eHN is the main governance body for digital health at the European level, bringing together representatives of health ministries for the 27 EU Member States to define a common strategy for digital health across Europe.

During the first weeks of the French Presidency of the council of the European Union in early 2022, eHN representatives gathered in multiple close-knit meetings to build on the proposal of ethical criteria from France. They unanimously adopted European ethical principles for digital health on January 26, 2022, formalizing trust commitments towards European citizens and paving the way for the European Health Data Space.

3. Results

European ethical principles are organized in four dimensions, each being detailed in four principles (cf. Fig. 2), allowing to embrace the scope of ethics for digital health:

PRINCIPES EUROPÉENS POUR L'ÉTHIQUE DU NUMÉRIQUE EN SANTÉ
EUROPEAN ETHICAL PRINCIPLES FOR DIGITAL HEALTH

Inscrire le numérique en santé dans un cadre de valeurs humanistes ***Base Digital Health on humanistic values***
1. Le numérique en santé complète et optimise les pratiques de santé en effectuées en présentiel *Digital Health complements and optimizes face-to-face healthcare*
2. Les personnes sont informées des bénéfices et des limites du numérique en santé *Individuals are informed about-the benefits and limits of Digital Health*
3. Les personnes sont informées des modalités de fonctionnement des services numériques en santé et peuvent facilement paramétrer leurs interactions avec ces outils *Individuals are informed about the functioning of Digital Health services and can easily customize interactions with them*
4. Lorsqu'une intelligence artificielle est mise en œuvre, le maximum a été fait pour qu'elle soit explicable et sans biais discriminatoire *When artificial intelligence is used, all reasonable efforts are made to make it explainable and without discriminatory bias*
Donner la main aux personnes sur le numérique et sur leurs données de santé ***Enable individuals to manage their Digital Health and data***
5. Les personnes ont un rôle actif dans l'élaboration des cadres européens et nationaux du numérique et des données de santé *Individuals are actively involved in shaping the European and national frameworks of Digital Health and data*
6. Les personnes peuvent récupérer facilement et de manière fiable leurs données de santé dans un format couramment utilisé *Individuals can easily and reliably retrieve their health data in a commonly used format*
7. Les personnes peuvent facilement obtenir des informations sur la manière dont leurs données de santé ont été ou peuvent être consultées et dans quel but *Individuals can easily get information on how their health data have been or may be accessed and for which purpose*
8. Les personnes peuvent facilement et de manière fiable donner l'accès à leurs données de santé et exercer leurs droits, y compris leur droit d'opposition quand il est applicable *Individuals can easily and reliably grant access to their health data and exercise their rights, including objection when applicable*
Développer un numérique en santé inclusif ***Make Digital Health inclusive***
9. Les services numériques en santé sont accessibles à tous, y compris aux personnes en situation de handicap ou avec un faible niveau de litéracie *Digital Health services are accessible by all, including by people with disabilities or low levels of literacy*
10. Les services du numérique en santé sont intuitifs et faciles à utiliser *Digital Health services are intuitive and easy to use*
11. Les personnes ont accès à des formations sur le numérique en santé *Individuals have access to Digital Health training*
12. Les services numériques en santé proposent une assistance humaine lorsqu'elle est nécessaire *Digital Health services include support through human communication when needed*
Mettre en œuvre un numérique en santé éco-responsable ***Implement eco-responsible Digital Health***
13. Les impacts environnementaux du numérique en santé sont identifiés et mesurés *Environmental impacts of Digital Health are identified and measured*
14. Les services numériques en santé sont développés dans le respect des bonnes pratiques d'éco-conception *Digital Health services are developed in compliance with eco-design best practices*
15. La ré-utilisation et le recyclage des équipements informatiques en santé sont prévus *Re-use and recycling of Digital Health equipment is ensured*
16. Les acteurs du numérique en santé s'engagent à réduire leur empreinte écologique *Digital Health stakeholders are committed to reducing their ecological footprint*

Figure 2. European ethical principles.

- *Base digital health on humanistic values*: Dimension 1 extends the fundamental principles of healthcare to digital health, in particular the fact that each person's needs have to be taken into consideration and that each person needs to be kept informed. This dimension is about respecting the right for individuals to have their digital health managed based on humanistic values, such as choosing options consistent with their preferences, values, or life projects.

- *Enable individuals to manage their digital health and data*: Dimension 2 underlines the key notions of the GDPR for digital health, such as the control or portability of individual's digital health data. This allows for a patient-centric approach and means that individuals are in control of the access to and processing of their data, both in real life and in digital health governance. This dimension aims at going beyond the GDPR implementation in Member States, making it a concrete reality on the field.
- *Make digital health inclusive*: Dimension 3 deals with the need to ensure all individuals benefit from digital health by taking into account all issues they may face, *e.g.*, digital divide, low levels of literacy, and all forms of disabilities.
- *Implement eco-responsible digital health*: Dimension 4 engages all actors to commit in moving towards eco-friendly digital health and to carrying out concrete actions in this area. Disease prevention undoubtedly involves reducing our carbon footprint. Taking into account the challenges of climate change and sustainable development is key today in all sectors, and especially in the health sector. As reported by the World Health Organization, climate change is responsible for at least 150,000 deaths per year, a figure that is expected to double by 2030.

4. Discussion

European ethical principles form the basis of European citizens' trust in digital health. They provide a trust framework which is not a full inventory but rather focuses on the main challenges faced today, expressed in a direct and simple way. It goes beyond security and interoperability requirements. Some of these principles already form part of existing laws or already inspire future laws at both European and Member States' levels.

5. Conclusions

More needs to be done to adapt the European ethical principles for digital health to the needs of individuals benefitting from digital health services, or regarding their technical implementation in practice. Working on the practical compliance with the European ethical principles provides a virtuous track for ensuring the trust of citizens. Therefore, a common and shared responsibility of EU Member States and the European Commission to regularly monitor progress on each principle implementation is essential.

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