

# ARTIFICIAL INTELLIGENCE IN HEALTHCARE

Advancing Patient-Centric Care  
through Co-design and  
Responsible Implementation

October 2023



## Introduction

The European Patients' Forum (EPF) is an independent non-profit group that represents nearly 80 patient organisations from all disease areas, reaching an estimated 150 million patients with chronic conditions across the EU. Our mission is to advance the interests of patient communities by strengthening their collective impact across Europe through effective advocacy, education, empowerment, and partnership.

This position paper explores the applications, benefits, and challenges associated with Artificial Intelligence (AI) in healthcare from a patient perspective, and provides key recommendations for a responsible deployment of AI solutions.<sup>1</sup>

The considerations and recommendations presented in this paper are based on a survey<sup>2</sup> conducted by EPF in Spring 2023, targeting patient organisations and individual patient advocates, and the discussions with participants of a bootcamp<sup>3</sup> on Artificial Intelligence conducted by the Data Saves Lives<sup>4</sup> initiative that took place in March 2023. Their valuable insights, coupled with the expertise of EPF's Digital Health Working Group<sup>5</sup>, EPF's members, and Secretariat, have shaped our recommendations.

This paper is addressed to policymakers, developers, and research partners who play a vital role in legislating, developing, and deploying AI solutions in healthcare. Our goal is to communicate with this diverse group of stakeholders about the importance of developing AI solutions in healthcare that genuinely benefit patients by upholding the principles of patient safety, transparency, privacy, human autonomy, co-design, accountability, and education.

# AI Applications and Potential Benefits

## Improving Healthcare Through AI

From wearables, personalised health apps and virtual health assistance to optimisation of drug development, research and public health surveillance, the rapid advancements in AI technology offer new opportunities to revolutionise the delivery of healthcare.

With these advancements, healthcare professionals can be assisted in **making more accurate diagnoses**, predict disease outcomes, and provide personalised interventions to patients, leading to improved patient outcomes and reducing healthcare costs.<sup>6</sup> While AI automates certain tasks, healthcare professionals can focus more on interacting with patients in a meaningful way, listening to them and addressing their concerns, which can positively affect the patient-healthcare professional relationship and health outcomes.

Results from the survey conducted in Spring 2023, assessing the perceptions of 146 patient organisations towards AI in healthcare, highlight their enthusiasm for the potential benefits of AI. Respondents particularly welcomed the potential of **artificial intelligence to improve the accuracy of diagnosis**, for example in the interpretation of medical imaging. They also noted the **positive role of AI in enhancing the quality and efficiency of research and innovation in healthcare**, including drug discovery and medical devices development, with the goal of offering better treatment options to patients. Patient organisations also appreciated the support artificial intelligence can provide to healthcare professionals in delivering more personalised care, for example finding a treatment option tailored to the patient's unique genetic, physiological and behavioral characteristics.<sup>7</sup>

Another potential benefit highlighted by the survey respondents was the promotion of patients' self-management and adherence to treatments with the help of AI-powered digital tools that monitor adherence remotely, mobile phone applications, and reminder systems.<sup>8</sup>

It should also be highlighted that AI has the potential to support preventive measures and enable the transition of healthcare systems from the current disease-care models towards more person-centric and personalised ones. One such example is the use of AI in the screening of healthy populations and identification of patterns and risk factors that predict the likelihood of developing certain chronic or serious conditions in specific population groups or individuals, or in the prevention of cross-border health threats.

More generally, the survey results show that the patient community welcomes the digital transformation of healthcare and hopes that such transition will enhance the quality, safety, and sustainability of care, and transform healthcare into a more participatory process.

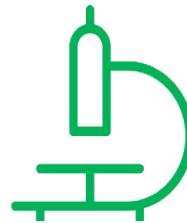
Nonetheless, it should be highlighted that digitalisation should be seen not as an end in itself, but rather as a means to a mentally and physically healthier society, increased autonomy and empowerment, and more personalised and affordable health care.

## 2023 Survey Results: What can AI do for patients?

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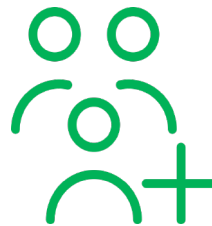
**MORE TIME  
TO CARE**



**ENHANCE QUALITY  
AND EFFICIENCY OF  
R&D**



**IMPROVE QUALITY OF  
DIAGNOSIS**



**DELIVER  
PERSONALISED  
HEALTHCARE**

# Ethical Concerns and Risks

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## AI in Healthcare: What Is at Stake?

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While AI has the potential to bring substantial benefits to patients and the functioning of the healthcare system, it also carries certain risks and ethical concerns that must be thoroughly addressed to prevent potential harm.

Patient organisations have identified the issue of biased and **unrepresentative data as a major risk associated with the use of AI in healthcare**. This can result in biased AI-enabled decisions, which can further perpetuate healthcare disparities, discrimination, unequal treatment, and unequal access to healthcare. Such risks can be amplified due to unequal access to AI-supported solutions and insufficient digital (health) literacy skills among patients, as the data from such populations could be excluded from the data sets on which the algorithms are trained.<sup>9</sup>

**“The involvement of patients could result in an increased understanding of digital health solutions, which in turn could positively affect patients’ acceptance of and trust in such tools.”**

Moreover, in the current practice, the involvement of patients in the design of AI healthcare solutions, particularly during the initial stages of development, is limited.<sup>10</sup> As a result, some AI technology fails to address the specific needs of the patients it is intended to assist. **Patient engagement throughout the lifecycle of AI solutions could ensure a realistic assessment of how they can enhance patient well-being, improve accessibility, and serve patients’ needs.** Moreover, the involvement of patients could result in an increased understanding of digital health solutions, which in turn could positively affect patients’ acceptance of and trust in such tools.<sup>11</sup>

Survey results have highlighted the importance of co-design and patient engagement for patient organisations, with 82% of respondents expressing the belief that patients and healthcare professionals should play a substantial role in various aspects of developing and implementing AI-powered tools and technologies. In contrast, only 2% advocated for their minimal involvement. To ensure higher levels of patient engagement, **governments should put in place key initiatives for promoting digital inclusion and digital health literacy**, expanding access to digital technologies in healthcare and ensuring better infrastructure and connectivity for underserved communities.

**Safety issues due to unvalidated AI tools and lack of transparency**, including traceability and explainability, were also identified among the major risks to patient safety.

Such risks should be addressed through rigorous validation processes and assessment of AI healthcare tools to ensure their safety, performance, and reliability, as well as appropriate post-market surveillance and follow-up. It is important to establish and maintain clear communication and transparency with the public regarding the benefits, risks, and intended uses of AI solutions.

It is also crucial that AI solutions are designed to assist and support human actors, and not to replace them. Human oversight is needed to identify and address additional biases and unintended consequences, and it allows for better accountability.

In addition, it is vital to acknowledge the potential **risks associated with the leakage, unauthorised disclosure, or unintended use of health data**. Such mishandling and misuse of sensitive data could have far-reaching consequences, including discrimination, unjust treatment, and stigmatisation. Patients' data on mental health, sexual and reproductive health, disabilities, cancer, and chronic diseases are particularly vulnerable to automated individual decision-making, profiling, and biometric monitoring. In response to these concerns, it is imperative that the advancement of AI is underpinned by a robust framework of privacy and security principles that protect health data and patient confidentiality, and that a clear regulatory framework that addresses cases of data misuse, leakage, and unauthorised disclosure is in place.

# 9 Principles to Regulate AI in Healthcare

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1.

**RESPECT HUMAN DIGNITY**

2.

**ADDRESS DATA QUALITY AND INTEGRITY**

3.

**ENGAGE PATIENTS AND HEALTHCARE PROFESSIONALS**

4.

**ENSURE ACCESSIBILITY AND INCLUSIVITY**

5.

**KEEP HUMANS IN CONTROL**

6.

**PROTECT HEALTH DATA AND PATIENT CONFIDENTIALITY**

7.

**FOSTER RESPONSIBILITY AND ACCOUNTABILITY**

8.

**ENHANCE TRANSPARENCY**

9.

**PRIORITISE EDUCATION, TRAINING, AND DIGITAL LITERACY**



# EPF Recommendations

AI technology is developing at astonishing speed, and regulatory intervention is critical to mitigate the potential risks and ethical concerns that come with the use of AI in healthcare. We, therefore, call on European and national policymakers to establish a clear and robust regulatory framework emphasising the following principles, and on developers and research partners to fully comply with such obligations.

## 1. Respect Human Dignity

“Do no harm” and respect for human dignity must serve as the guiding principles for all AI solutions in healthcare, which must prioritise human well-being, safety, and the public interest, aiming to make a positive contribution to society. It is crucial to evaluate the potential harm that may arise from inaccurate predictions, such as incorrect diagnoses leading to under or over-treatment, and assess the risks to human physical and mental integrity. To ensure adherence to these principles, we recommend the full and harmonised implementation of the existing EU regulatory framework applicable to medical AI tools, namely the Medical Devices Regulation (MDR)<sup>12</sup> and the In Vitro Diagnostic Medical Devices Regulation (IVDR)<sup>13</sup>, as well as the upcoming AI Liability Directive<sup>14</sup> and the Artificial Intelligence Act (AI Act)<sup>15</sup>, which aim at providing clear requirements and obligations for specific uses of AI and ensuring the safety of AI solutions. Regular review of the regulatory framework and its implementation should ensure it remains fit for purpose. We also make the case for the establishment of ethics committees with the aim of promoting ethical guidelines throughout the whole lifecycle of AI tools.

## 2. Address Data Quality and Integrity

Only by **addressing data quality and integrity** concerns and implementing proactive measures to monitor and mitigate biases can AI in healthcare achieve inclusiveness, equity, and improved patient outcomes. We recommend that AI solutions are continuously monitored and evaluated to identify any disproportionate effects on specific groups, prioritise diversity and representativeness, and establish and clearly communicate the mechanisms for flagging bias and discrimination. Such processes should be in place throughout the lifecycle of the AI tool, from training and testing to deployment. In this regard, the European Health Data Space<sup>16</sup> (EHDS) can ensure that data is of good quality and by default suitable for AI purposes. Moreover, promoting diversity in the hiring process among research partners and developers and ensuring stakeholder engagement can help ensure a diversity of perspectives and prevent such biases.<sup>17</sup>

## 3. Engage Patients and Healthcare Professionals

Ensuring that the proposed **AI solution is suitable and appropriate is only possible by actively engaging patients and healthcare professionals**. Inclusive development processes involving end-users can



improve user experiences while avoiding biases or discriminatory outcomes. Patient communities can provide expertise on specific conditions and offer valuable insights into the usefulness and appropriateness of AI tools. Stakeholder participation will also help to boost acceptance and build trust in the new technology and improve patient empowerment.

## 4. Ensure Accessibility and Inclusivity

**Accessibility and inclusive design**, which consider the needs of diverse users, including individuals with physical and mental disabilities, must be the fundamental principles for the development and deployment of AI solutions. It is essential to prioritise user-centric design that ensures equal access and usability for all individuals, regardless of age, gender, or abilities.

## 5. Keep Humans in Control

**It is of utmost importance that humans remain in control of medical decisions.** AI tools should only be designed to support and complement human skills, and never assume decision-making powers. Therefore, human autonomy has to be the guiding principle for designing AI solutions in order to leave meaningful opportunities for human choice. We also recommend that proper procedures are in place to handle situations where AI solutions generate low confidence or conflicting results.

## 6. Protect Health Data and Patient Confidentiality

**Protecting health data and patient confidentiality** is paramount, and technical robustness and safety by design are key considerations to ensure that the technology is reliable, secure, and can withstand potential cyber-attacks. We recommend the development of a plan for preventing, mitigating and managing these risks, as well as providing training to patients and healthcare professionals in safe-data protocols to ensure the safeguarding of sensitive patient information. We call for appropriate investment by hospitals and Member States to ensure the hospital systems are cyber-secure in line with international standards. The existence of such protocols is essential to enhance public trust in digitalised health systems and data sharing overall. In addition, data usage for profiling, insurance and employment purposes must be strictly prohibited.

## 7. Foster Responsibility and Accountability

**Fostering responsibility and accountability** in the development and use of AI solutions is crucial for their ethical and fair deployment. To minimise negative impacts, conducting impact assessments throughout the process is essential, as well as establishing mechanisms for redress. The legislation must be clear and comprehensive on accountability and legal responsibility in the event of unforeseen circumstances or adverse outcomes.

## 8. Enhance Transparency

The **principle of transparency** is crucial for building and maintaining patients' trust in and understanding of AI solutions used in healthcare. To ensure transparency, various aspects of AI tools must be clearly disclosed. This includes providing information on the purpose of the AI tool, informing

users if they are interacting with a non-human agent, and informing them of potential risks and limitations. Such an approach would also enhance accountability and responsibility. Moreover, to achieve a fair balance between data privacy and the benefits of data-driven insights, it is essential to establish which information can be used when, by whom, and for what purpose. Therefore, we recommend that the right to object and the right to be forgotten are integrated into the development of AI solutions.

## 9. Prioritise Education, Training, and Digital Literacy

To ensure patient safety and foster trust in AI solutions, as well as maximise the positive opportunities that AI can offer, it is imperative to **prioritise education, training, and digital literacy** for both patients and healthcare professionals. By strengthening these areas, we can enhance public understanding of AI tools and equip individuals with the skills necessary to utilise them responsibly. This, in turn, would encourage public confidence in the use of AI, address concerns related to digital hesitancy, and mitigate health inequalities.

## Footnotes

1. When referring to AI solutions, this paper considers tools and technologies powered by AI which mimic human cognitive abilities to analyse, present, and understand health data. Patients can be impacted by the use of AI in healthcare directly (wearables, chatbots, health apps, detection of disease, personalised medicine etc) or indirectly (drug development, drug optimisation, resource allocation, administrative process, data mining, etc). This paper takes into consideration both the indirect and direct impact, with an emphasis on the latter.
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