



## Exploring the social, ethical, legal, and responsibility dimensions of artificial intelligence for health – A new column in *Intelligent Medicine*

Achim Rosemann<sup>a, b</sup>, Xinqing Zhang<sup>c, \*</sup>

<sup>a</sup> Centre for Computing and Social Responsibility, De Montfort University, Leicester, UK

<sup>b</sup> Department of Sociology, Philosophy and Anthropology, University of Exeter, UK

<sup>c</sup> School of Humanities and Social Sciences, Peking Union Medical College, Chinese Academy of Medical Sciences, Beijing 100005, China

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### ABSTRACT

This essay is the starting point of a new column in *Intelligent Medicine* that invites interdisciplinary perspectives on the social, ethical, legal, and responsibility aspects of the use of artificial intelligence (AI) in medicine and health care. Papers in this column will examine the practical, conceptual, and policy dimensions of the use of AI for health-related purposes from comparative and international perspectives. We invite contributions from around the world in all application areas of AI for health, including health care, health research, drug development, health care system management, as well as public health and public health surveillance. The column aims to provide a forum for reflective and critical scholarship that contributes to the ongoing academic and policy debates about the development, use, governance, and implications of AI in medical and health care settings.

To launch the column, we first provide an overview of recent approaches that have been developed to identify and address the effects and potential impacts of science and technology innovations on human societies and the environment. These include ethical, legal, and social implications/aspects (ELSI/A) research, responsible research and innovation (RRI), sustainability transitions research, and the use of international standard-setting instruments for responsible and open science issued by the United Nations Educational, Scientific, and Cultural Organization (UNESCO), the World Health Organization (WHO), and other international bodies. In Part Two of this essay, we discuss some of the central challenges that arise with regard to the integration of AI and big data analytics in medical and health care settings. This includes concerns regarding (i) the control, reliability, and trustworthiness of AI systems, (ii) privacy and surveillance, (iii) the impact of AI and automation on health care staff employment and the nature of clinical work, (iv) the effects of AI on health inequalities, justice, and access to medical care, and (v) challenges related to regulation and governance. We end the essay with a call for papers and a set of questions that could be relevant for future studies.

## 1. Introduction: Science, ethics and social responsibility

### 1.1. ELSI/A research: bridging the natural and social sciences

Since the early 1990s, with the launch of the Human Genome Project, research on the ethical, legal and social implications or aspects (ELSI/A) of emerging sciences and technologies has started to play an important role around the world, not only in the biosciences and biomedicine, but also in nanotechnology, digital technologies, data sci-

ence, artificial intelligence (AI), and other research fields [1–4]. In the European Union (EU), the USA, as well as China, Japan, and other countries, the ELSI/A labels have been adopted by public funding bodies that finance interdisciplinary research alongside large-scale scientific projects, with the aim to identify, publicly discuss, and address urgent societal issues arising from these programmes [5–7]. Throughout the last three decades, the term ELSI/A research has also frequently been used as a more general descriptor for scholarship on the ethical and societal aspects of innovation processes, including re-

ELSI/A, Ethical, legal and social implications/aspects; RRI, Responsible Research and Innovation

\* Corresponding author at: School of Humanities and Social Sciences, Peking Union Medical College, Chinese Academy of Medical Sciences, Beijing 100005, China.

E-mail address: [xqzhang@pumc.edu.cn](mailto:xqzhang@pumc.edu.cn) (X. Zhang).

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search that is not conducted as part of specific scientific projects [8]. Aiming to understand the complex effects of scientific research on human wellbeing, societies, and the environment, ELSI/A studies have produced a growing body of work that has shed light on many of the challenges and potential problems of scientific innovation, including the effects of commercialisation, intellectual property rights (IPR), and patenting, and issues related to the international transfer of technologies [9–12].

In the domains of medicine and health care, ELSI/A research has explored issues related to social justice, inclusion, and solidarity [13–14], the implications of structural inequalities [15], the potential for discrimination, risks, and the violation of patient rights [16–17], and other issues in various areas of medical research, such as assisted reproductive technologies [18], xenotransplantation [19], genomic and precision medicine [20–21], biobanks [22–23], and the collection and sharing of medical and other personal data [2,24].

### 1.2. Criticism of ELSI/A and the emergence of responsible innovation

The interdisciplinary character of ELSI/A research and the possibility for collaborations with natural and medical scientists have created opportunities for constructive normative reflection, policy advice, and mutual criticism [5]. However, ELSI/A research has been criticised for various reasons. For example, some have argued that due to the proximity of ELSI/A research to large-scale scientific projects and funding, there has been a lack of independence and that, as a result, ELSI/A studies have sometimes played a legitimising role for new technologies [8,25]. Others have suggested that ELSI/A research has focused too much on the expected future consequences of innovation processes, while avoiding critical engagement with the present-day contexts and politics of research [26–28]. In response to this criticism, there have been attempts to extend the focus of ELSI/A research, for example, through critical studies of bioethics [29–31], and research that has explored the interplay between science, industry, and national(ist) aspirations of power and economic growth [25,32–34].

Parallel to these developments, a new framework has gradually emerged since the late 2000s: responsible research and innovation (RRI). The term appeared first in the EU [35–37], where RRI was included as a cross-cutting theme in the Horizon 2020 funding programme (2014–2021) [37]. RRI was also adopted by funding bodies in the UK, the Netherlands, and other countries [38]. RRI was initially portrayed as a novel way to engage with the societal dimensions of scientific research and development. However, as Zwart, Landeweer, and van Rooij [5] pointed out, RRI is not a radical departure from ELSI/A research. RRI and ELSI/A share the motivation to change the ways in which research and innovation processes are conducted by emphasising social responsibilities and alignment with societal values. RRI adds, however, a concern with the broader economic and ecological impacts of innovation processes [5] and demands that scientific research should address societal challenges, including grand challenges such as the United Nation’s sustainable development goals (SDGs) [36,38,40]. ELSI/A and RRI also share a commitment to an anticipatory, forward-looking methodology that describes and analyses potential impacts of research and innovation processes [37]. Both approaches promote stakeholder participation, public engagement and co-creation [5]. An increasingly important question in both ELSI/A and RRI is how research and innovation can be made more inclusive, participatory, and interactive. RRI in particular has promoted the inclusion of knowledge, views, and concerns of citizens and other societal stakeholders throughout the innovation process, with the aim to identify public expectations and to respond to the needs and values of the diverse, pluralistic societies that characterise the 21st century [35,37,39]. This involves a commitment to gender and diversity issues in innovation processes, such as the realization of gender

equality, inclusive engagement, and broad access to scientific benefits for all groups in society [39–40].

RRI has also been used to reflect on innovation processes in medicine and health care. For example, Silva et al. [41] developed an integrative framework for responsible innovation in health that supports developers and policy makers in the development of more equitable, socially responsive, and sustainable health research and services [41–42]. Lehoux et al. showed how the use of the RRI approach in health innovation can help to prioritise specific health system challenges, increase transparency in innovation decisions, and make the responsibility trade-offs faced by health care entrepreneurs explicit [42–43]. Iordanou [44], in turn, has used RRI’s commitment to stakeholder deliberation and inclusive decision-making to argue for increased patient participation in the design and planning of medical and health care research, including in the context of small- to mid-size companies.

### 1.3. Beyond ELSI/A and responsible innovation

Researchers and social scientists outside of the EU, for example, in China, Japan, Argentina, and Brazil, have also engaged with the RRI concept [45–51]. However, Vasen [46,52] and Wakunuma et al. [53] have argued that the use of RRI policies in different parts of the world requires significant alterations, to adjust them to the diverse practices, contexts, values, and regulatory standards that shape innovation processes around the world. Tash and Jensen [54] suggest in this regard that the United Nations Educational, Scientific, and Cultural Organization (UNESCO)’s 2017 Recommendation on Science and Scientific Researchers [55] and other UNESCO frameworks such as the forthcoming Recommendation on Open Science [56] and Recommendation on AI Ethics [57] could act as a bridge to facilitate socially responsible innovation in a heterogeneous global world. Signed by governments from 190+ states, these frameworks link innovation processes to the United Nation’s SDGs and integrate many of the principles, ideas, and purposes that ELSI/A and responsible innovation approaches have sought to achieve in recent decades, including a commitment to human rights and global justice. While the main aim of these frameworks is to inform scientific practice and policy, they can also serve as a reference point for academic research on the implementation of responsible, ethical, and socially robust innovation processes around the world, including in the domains of health and health care [58]. Other instruments, such as the World Health Organization (WHO)’s Code of Conduct for Responsible Research [59] and the recently published WHO Guidance on the Ethics and Governance of Artificial Intelligence for Health [60], can play similar roles.

Other debates on responsibility in science and technology innovation have stressed the need for environmental awareness and the realization of “sustainability transitions” that enable cleaner and more sustainable research, production, and consumption [61–63]. Demands for sustainability transitions are also relevant in the context of medicine, medical innovation, and health care. For example, the growing digitalization of health care services and reliance on big data and AI have fuelled demands for energy and raw materials such as lithium and produce new forms of e-waste [64].

In this new column in *Intelligent Medicine*, we invite contributions that draw on and/or contribute to debates in all of the above areas, or related fields of scholarship that examine the social, ethical, legal, environmental, economic, technical, and other responsibility dimensions of AI for health.

## 2. AI in medicine and health care: what issues arise?

AI refers to “the ability of algorithms encoded in technology to learn from data so that they can perform automated tasks” with little or no human intervention [60]. As various recent reports have stated,

AI offers novel possibilities to improve diagnosis and clinical care, enhance health research and drug development, assist with the deployment of public health interventions and new forms of public health surveillance, facilitate the development of personalised medicine, “smart” prosthetics, and telemedicine, and support the management and planning of health systems [65–67]. Despite these potential benefits, AI also presents a wide range of issues and challenges. As more AI-based technologies in medicine are developed and applied, a systematic interdisciplinary exploration and analysis of these challenges is important. In the next sections, we discuss five areas in which problems may arise.

### 2.1. Control, reliability, and trustworthiness of AI

AI has the potential to transfer decision-making from humans to machines [68]. While this may lead to more accurate, rapid, and efficient medical and health management judgments, it also raises various concerns. Many AI technologies operate as “black box” systems, whose internal processes and conclusions remain hidden or are difficult to explain to users [69]. This can lead to a lack of transparency and undermine the autonomy of health plan operators, medical practitioners, and patients [65,68]. Health care recipients may experience a loss of control and autonomy, especially if medical decisions are non-transparent and shared decision-making amongst patients and medical practitioners is lacking [70]. These problems of control and autonomy will become increasingly prominent in the context of ongoing efforts to automatise the programming of AI technologies, through computer programs that can independently build, deploy, and scale up new AI models and applications [60]. A related challenge concerns the reliability and trustworthiness of AI. Errors in algorithms and data, or the use of biased data sets, can lead to incorrect or unfair decisions of AI systems [71]. Erroneous or biased judgments can affect patient safety and the effective implementation of health care [72]. Bias in data sets and algorithms can also lead to unfair allocation of resources and discriminate against certain groups, for example, by ignoring people or groups with few resources or special health needs [73].

### 2.2. Privacy and surveillance

A second set of challenges relates to the safeguarding of privacy and the use of health care and other personal data for marketing and surveillance, including for non-medical purposes. AI and machine learning rely on large data sets, with various types of data that can include information about disease risks, lifestyle, mental health, family situation, sexual orientation, and other sensitive data [20,24,74]. The use of new mobile devices, tracking apps, wearables, implants, and AI-powered prosthetic hands and limbs generates real-time data, including information on user location and type of activities [75–77]. There are justified concerns that the use of these data may lead to violations of patients’ privacy and to discrimination, for example, on the basis of a person’s health status or future health risks [20,23]. This includes a concern about the rights of children, who may be subjected to discrimination based on information collected during childhood [60]. There is also a risk that the sharing of data with third parties leaves people vulnerable to the misuse of their data, including as a result of cyber-theft and accidental disclosure [78]. Moreover, governments and intelligence agencies may use the data for security purposes, social and political surveillance, as well as population monitoring and to increase social control [79]. Additionally, companies have a commercial interest in health and other personal data, and they may use and sell these data for marketing and other purposes [80–81]. For these reasons, access to and utilization of patient data by medical services and third parties, including firms and government bodies, can affect individuals’ dignity and psychological wellbeing

[82]. Misuse or problematic use of personal data can also violate human rights, such as the right to be protected against arbitrary or unlawful interference with a person’s “privacy, family, home or correspondence” [83]. These issues raise questions about who should be allowed to use patient and population data, and for which purposes and under which conditions.

### 2.3. Impact on labour, employment, and the nature of clinical work

The growing use of AI in health care is expected to change the nature of clinical work and health care provision [60]. One expectation is that AI will facilitate the automation of routine tasks and administration. Some suggest that as a result, doctors and other health care staff will have more time available for patients [84]. However, others argue that if patients interact more frequently with AI, for example, in the context of telemedicine, the time that medical practitioners spend with patients will be decreased [85]. Furthermore, although AI may replace certain routine tasks, physicians and nurses will be required to spend more time administering technology, analysing data, and learning how to use new AI applications [60].

A related question is whether AI in health care will lead to unemployment and whether employees can be upskilled or reskilled to avoid displacement and to adjust to AI-supported medicine [65]. Loss of jobs due to AI automation is a widespread concern and has been projected for almost every part of the health workforce, including certain types of doctors and other experts [86]. Others assert that AI will create new jobs in health care that may counterbalance the potential losses, and that AI may help to alleviate health workforce shortages, including in low- and middle-income countries where lack of medical staff is often a major problem [87–88]. While these scenarios vary, there is a consensus that the embedding of AI and other digital technologies in health care and medical research will require the retraining of health care staff to allow them to adapt to new roles [65,84]. The 2021 WHO Guidance on the Ethics and Governance of Artificial Intelligence for Health [60] also raises the concern of the “uberization” of health care [89], which could make the jobs of doctors and medical practitioners less stable and secure [60]. According to the authors of this report, the creation of AI-driven health care platforms may lead to the growth of a “gig economy” in the health sector, in which nurses, physicians, and other staff work on demand, as temporary contractors with no employment stability [60,89]. This development, they warn, could also undermine the relationship between patients and health care providers, resulting in more fleeting interactions, reduced quality of care, and a loss of trust [60].

### 2.4. Inequalities, justice, and access to health care services

A frequent promise is that AI will improve access to health care services [87], including for patients in low- and middle-income countries and remote, rural areas [90]. Other authors sketch a less optimistic scenario, in which health inequalities will increase and the benefits of AI-based medicine will be accessible mainly to the wealthy [91]. There are good reasons to question the hyped representations of AI, and to explore the conditions that may improve access to the potential advantages of AI-supported health care.

The realization of the benefits of AI and related digital technologies depends on the availability of significant human and technical resources, including access to large quantities of high-quality medical data [90,92]. However, at the global level, these resources are unequally distributed [93]. Consequently, the possibilities to invest in the development of AI infrastructures and research differ markedly between countries. Language variation, incompatible data formats, and differences in coding scripts can cause additional problems when attempting to maximise the potential of AI around the world [94]. These issues also create new forms of dependency on technology

providers and (big tech) companies located in higher-income countries. Differences exist for example, between countries that can accumulate and independently use and control large data sets and countries that have little capacity to collect high-quality data. Other countries may be able to amass data but lack the ability to protect them, which makes them vulnerable to forms of “data colonialism” [95], i.e., the use of data by third parties, locally or overseas, for commercial or other purposes, without “due respect for consent, privacy, and autonomy” [60]. In addition, many AI technologies are developed by scientists and firms in and for high-income countries, and by people with insufficient understanding of the characteristics and needs of populations in developing or middle-income countries [60]. These factors can result in unrealistic expectations of what AI can achieve, incorrect applications, false predictions, and incompatibility with local health care systems and practices [96].

A key challenge to fair and equal access to AI-supported health care services are existing digital divides, which refers to gaps in the distribution of and access to digital technologies, resources, and knowledge between different demographic groups and regions [97]. Digital divides exist in relation to gender, age, socioeconomic background, ethnicity, religion, and other demographic factors [98], as well as amongst different world regions [99]. Global and regional digital divides are linked to other inequalities and challenges, including unequal access to education and scientific careers, low income, high prevalence of unskilled or semi-skilled labour, lack of computers and digital technologies in schools, and scarce funds to invest in technological infrastructures and innovation [100]. Many of these factors will also affect the use of AI around the world, including in medicine and health care and, as a result, can reinforce and increase existing social and health disparities [60]. For these reasons, the deployment of AI in health care settings must be accompanied by broader efforts to decrease socioeconomic asymmetries and digital divisions [101]. Only then may the potential of AI to decrease global health inequalities be realised.

### 2.5. Challenges related to regulation and governance

Regulations typically seek to strike a balance between protecting the public, medical practitioners, and services, and the promotion of growth and innovation. As in other areas of medical practice and research, the safety of patients and their families must be the focus of regulatory attention [65]. As documented above, the safety, psychological integrity, and physical wellbeing of patients can be at risk if AI is developed or applied incorrectly or used for problematic purposes [102]. Moreover, potential incidents such as cyber-theft, accidental data disclosure, surveillance, and non-consensual transfer or sale of personal data to third parties, pose broader challenges to the wider society, beyond the health care sector [78].

While existing frameworks that govern health professionals, services, and research (including the development of new medical technologies and devices) could be used to regulate AI in medical practice and research to a degree, AI introduces many new challenges that require specific attention. We will discuss some of these below.

The first challenge relates to the autonomy and self-learning capacities of AI. If AI systems operate and evolve independently of designers and service providers, who can be held accountable for issues that arise and how can responsibility be defined? According to the 2021 WHO Guidance on the Ethics and Governance of AI, this creates a responsibility gap, “which could place an undue burden on a victim of harm or on the clinician or health care worker who uses the technology but was not involved in its development or design” [60]. A related problem concerns what Dixon-Woods and Pronovost describe as the “many hands problem”, i.e., the fact that the development and use of AI systems involves many agents and that responsibility is diffused amongst them [103]. This makes it legally and morally difficult to as-

sign responsibility to a specific actor, and it can result in inadequate compensation for harm done to patients [60,103].

Another challenge concerns the questions of who is best equipped to regulate AI in health applications, and who should be involved in the design and implementation of regulatory oversight procedures. In recent years, various companies and industry associations have issued AI guidelines, norms, and best practice standards [104–105]. Most of these documents have been developed in the absence of legally binding or authoritative international standards, and without or with only a little input from citizens and technology users [106]. Many of these rules are likely to have a performative function, to signal to the public that firms assume the responsibility of preventing harm and misuse. Wagner [107] and others [60,108] have criticised these efforts as a form of “ethics washing” that ignore many ethical and societal concerns in favour of corporate interests. For these reasons, it is important to ensure joined up regulation that is developed not only with clinicians, entrepreneurs, and computer scientists, but also with the broadest possible range of societal stakeholders, including researchers in social and human sciences and representatives of civil society [65]. Indeed, as recommended by various international frameworks for open science and co-creation, inclusive, participatory, and interactive decision-making should play a central role in the development of AI regulation and policies, and be integrated in the design, development, and application of AI for health from an early stage [56, 57,109].

A fourth challenge is that state regulation and laws that cover the definition, development, testing, and routine use of AI in health care are only gradually emerging. In the EU, the Artificial Intelligence Act was published in April 2021 [110]. This act is one of the first attempts to address regulatory gaps at the state level, but it falls short of addressing the specific challenges of AI in medicine [111]. In the USA, China, and other countries that are leaders in AI development, legal frameworks for AI are still in preparation. For example, China has not yet, at the time of writing, implemented ethical guidelines or policies for AI in medicine.

A fifth challenge concerns the global governance of AI for medicine and health care. The development, commercialization, and use of AI for health-related purposes takes place in an inter-connected world that is characterised by international collaborations, trade, and knowledge transfer, and the collection and use of data from around the world. Nevertheless, regulatory guidance, ethical principles, and compliance with international human rights related to AI differ widely between countries [60,104]. Regulatory differences also exist between the public and the private sector, and governments often have limited power to regulate international internet and big tech companies that operate at the global level [112–113]. This high level of regulatory heterogeneity offers opportunities to evade regulatory restrictions in some countries, and to develop, test, and sell new AI applications in less stringently regulated countries [114]. The WHO suggests in this regard that “additional international oversight and enforcement may be necessary to ensure convergence on a core set of principles and requirements that meet ethical principles and human rights obligations” [60]. One step in this direction is the forthcoming UNESCO Recommendation on AI Ethics [57], which will reportedly “address issues around transparency, accountability and privacy, contain action-orientated policy chapters on data governance, education, culture, health care and the economy, and provide governments and policy makers with a global framework for regulating AI” [115]. The implementation of these (and other) international guidelines is likely to be challenging. Some governments may be hesitant to adopt international rules, fearing that this may stifle domestic innovation opportunities and causing them to fall behind international competitors [113]. Other countries may oppose the adoption of international standards for political reasons, for example, because they may undermine opportunities for surveillance, censorship, and social control [116].

Still others may not have the means to implement more comprehensive regulatory rules, or they may prefer a more lenient regulatory environment to attract foreign companies and investors [114].

### 3. Launching the column: call for submissions

We invite contributions regarding all aspects of the social, ethical, legal, and responsibility dimensions of AI in medicine and health care. The preceding sections serve as an entry point to some of the challenges and debates that characterise the deployment of AI for health, but the range of areas that can be covered extends far beyond these topics. Papers can explore the practical, conceptual, and policy dimensions of the use of AI for health-related purposes from both empirical and theoretical angles. We invite comparative and international perspectives from all parts of the world, including regions or countries that have received less attention in the academic and public policy discourse so far. Contributions can relate to all application areas of AI for health, including health care, health research, drug development, health care system management, and public health and public health surveillance.

We invite submissions of full-length, original research articles (up to 6000 words), literature reviews (also up to 6000 words), perspectives and commentaries (up to 1500 and 2000 words, respectively), as well as letters to the editors (up to 500 words) that should be related to previously published articles in this column. All submissions will initially be reviewed by the column editors and, if considered of sufficient quality, will be sent out to peer review, usually to two independent referees that can come from any part of the world.

### 4. Closing questions

We close with a few questions that could be significant for future studies, though authors can take an entirely different direction, as long as it is relevant to the overall focus of the column:

#### 4.1. Changing relationships between health care workers and patients

- In what ways are AI technologies changing the relationship between health care workers and patients?
- Do these technologies allow providers to spend more “quality time” with patients, or do they make care less humane?
- What contextual factors improve or undermine the quality of care, and how do these factors interact with the ways in which AI technologies are used in health care services?

#### 4.2. Ensuring equitable access to health care

- How can AI developers, regulators, and health care workers ensure that AI plays a role in improving the delivery of equitable care?
- What kind of expectations and needs do patients and health care staff articulate, and how can these be addressed? Is AI always the best way to address these needs and expectations?
- Does AI reduce the geographic and demographic gaps in access to high-quality care, as is often claimed? Or does it increase existing divides? Who benefits and who is potentially left out?
- Does the introduction and use of AI for health exacerbate digital divides within societies, and between higher- and lower-income countries?

#### 4.3. Attitudes, concerns, and epistemic and value pluralism

- What are the attitudes of patients, their families, health care workers, regulators, medical entrepreneurs, and other health

professionals towards the use of AI technologies in medical settings?

- Do they find these technologies acceptable and, if yes, for what purposes and under what conditions?
- What are the concerns of health care users, patients, and other stakeholders, and how do they think that AI could improve or harm health care practices and patient experiences? What factors influence their perceptions?
- What conflicts of interests and differences in values, language, and knowledge systems exist amongst stakeholders? Which problems emerge from these differences?
- How can these clashes and forms of epistemic and value pluralism be studied and brought out into the open? And how can they be mitigated and addressed?

#### 4.4. Biases in data or algorithms: effects and solutions

- What are the effects of biased data and algorithms? What consequences do these have for patients and their families?
- How can providers and programmers recognise and address potential biases in (emerging) applications? What are the challenges in identifying and preventing these biases?

#### 4.5. Public health decisions and resource allocation

- How should governments and providers assess fair resource allocation for existing interventions and AI technologies?
- Is AI really the best option to address specific health care problems? What alternatives exist, and how can the solutions that offer the best value for patients and health care systems be determined?
- What factors influence the adoption, possible benefits, and efficiency of AI in low- and middle-income countries?
- What methods should be used to assess whether AI is more cost-effective and appropriate than existing or “low-technology” solutions? In what ways should these methods differ between higher- and lower-income countries?

#### 4.6. Inclusive decision-making

- How can the processes of decision-making around AI research and use for health-related purposes become more inclusive, participatory, and interactive?
- How can decision-makers ensure that the application of AI is aligned with the priorities, needs, concerns, and values of health care users, patients, their families, and other societal stakeholders?

#### 4.7. Environmental impact and sustainability challenges

- What are the environmental impacts of the increasing digitalization of and reliance on AI and big data in health care services and medical care? And how can more sustainable and environmentally conscious forms of health care provision be realised?

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## Author contributions

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## Declaration of Competing Interest

The authors declare that they have no competing interests.

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