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The ethics of advancing artificial intelligence in healthcare: analyzing ethical considerations for Japan's innovative AI hospital system

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Public and private investments into developing digital health technologies—including artificial intelligence (AI)—are intensifying globally. Japan is a key case study given major governmental investments, in part through a Cross-Ministerial Strategic Innovation Promotion Program (SIP) for an "Innovative AI Hospital System." Yet, there has been little critical examination of the SIP Research Plan, particularly from an ethics approach. This paper reports on an analysis of the Plan to identify the extent to which it addressed ethical considerations set out in the World Health Organization's 2021 Guidance on the Ethics and Governance of Artificial Intelligence for Health. A coding framework was created based on the six ethical principles proposed in the Guidance and was used as the basis for a content analysis. 101 references to aspects of the framework were identified in the Plan, but attention to the ethical principles was found to be uneven, ranging from the strongest focus on the potential benefits of AI to healthcare professionals and patients ($n = 44$; Principle 2), to no consideration of the need for responsive or sustainable AI ($n = 0$; Principle 6). Ultimately, the findings show that the Plan reflects insufficient consideration of the ethical issues that arise from developing and implementing AI for healthcare purposes. This case study is used to argue that, given the ethical complexity of the use of digital health technologies, consideration of the full range of ethical concerns put forward by the WHO must urgently be made visible in future plans for AI in healthcare.

KEYWORDS

artificial intelligence, healthcare, ethics, Japan, AI Hospital, innovation

1. Introduction

Despite the ethical complexity of emerging digital health technologies such as artificial intelligence (AI), public and private investments in them are intensifying (1, 2). Developments in AI—"the science and engineering of creating intelligent machines that have the ability to achieve goals like humans via a constellation of technologies" (3)—have contributed to an unprecedented potential for massive amounts of health-related data to be processed. Applications of AI range from assistance in clinical decision-making to administrative support, and can aid in analyzing data ranging from medical images to personal health data retrieved from devices connected through the Internet of Things (4). These abilities create new incentives to agglomerate health data and for public-private partnerships to most efficiently extract value (5). Yet, recent research highlights major ethical issues in AI in healthcare,

including concerns about privacy and data ownership, the risk of harm through biased systems and a lack of human oversight, and the need for provisions to support stakeholders if disruptions to healthcare occur, such as by providing training for healthcare professionals (HCPs) (6, 7).

The Japanese government is investing heavily in AI in healthcare through its shift towards "Society 5.0," where AI is deployed to solve societal issues, providing support for an aging population and balancing the impact of a shrinking workforce (8, 9). Japan faces an urgent need to offset growing imbalances in its healthcare system as a result of a super-aging society, exacerbated through the Covid-19 pandemic (2). In 2020, the proportion of the population aged over 65 years was 28.6—a significantly higher percentage than in other highly industrialized societies such as in the United States (16.6 percent), France (20.8 percent), or Germany (21.7 percent), with neighboring South Korea at 16 percent. To this end, the Japanese government is working to create a regulatory environment favorable to developing AI and to public-private partnerships, and offers a useful case study yielding insights into the potential possibilities and pitfalls of such an approach (2).

A key component of Japan's governmental investment is a Cross-Ministerial Strategic Innovation Promotion Program (SIP) for an "Innovative AI Hospital System" (8, 10–12). First outlined in 2018 with targets set for 2022, it includes a five-part plan for AI in healthcare. Elements of the plan include developing agglomerated medical databases; an AI-powered system to facilitate informed consent; using AI to support screening for diseases including cancer; creating exemplary "AI hospitals;" and encouraging collaborations between governmental, industry, and academic actors. The SIP promotes AI as beneficial to patients and to HCPs by increasing efficiency and reducing burden. Though it is one of the major structured programs for implementing AI in healthcare in Japan and represents a significant investment of public funds in AI, there has been little critical examination of its ethical dimensions.

AI increasingly crosses national borders as technological developments in one locale set precedents to be replicated in other countries. In the absence of "specific ethical principles for use of AI for health" globally, the World Health Organization [WHO; (13)] released their Guidance on the Ethics and Governance of Artificial Intelligence for Health in 2021, collating concerns and principles for the application of AI in healthcare elicited from and reviewed by external experts. In the Guidance, which additionally offers a framework for governance, the WHO proposes six ethical principles for AI in healthcare on autonomy, human well-being, transparency and explainability, responsibility and accountability, inclusiveness and equity, and responsive and sustainable systems.

Despite the urgency of the ethical issues posed by AI, both in Japan and outside of it, the implementation of ethical principles is largely left to the discretion of developers of AI technologies themselves, due to a lack of regulation (14). This means that an orientation to the ethics of AI from the point of conception of plans for its development is essential to ensure that AI is created and implemented in beneficial and not harmful ways. Yet, "medical AI applications have been found to sometimes be designed without any explicit ethical considerations" (14). Japan is an important case study through which to examine how ethical concerns are accounted for in the development of AI for healthcare, as it is a front-runner in its active promotion, and sets a key precedent on a global scale (2). Lessons from the Japanese context can be used to inform policy and practice in other countries seeking to advance AI for healthcare.

As Karimian et al. (15) have argued, "developers of AI algorithms must be vigilant regarding potential dangers." These risks are heightened in the case of AI in healthcare, and it is essential that government documentation providing direction for the advancement of AI in healthcare reflect attunement to these risks. In light of this, given that the WHO Guidance sets an international standard for ethical AI in healthcare, and considering the importance of Japan's SIP in its plans for AI in healthcare, this paper reports on an analysis of the most-recent SIP Research Plan at the time of this writing, to identify the extent to which the Plan reflects the ethical principles in the WHO Guidance. I argue that the Plan shows insufficient consideration of the ethics of AI in healthcare and contend that consideration of a broader range of ethical concerns must urgently be made visible in such plans for AI.

2. Methodology

A framework was constructed for a content analysis, based on the description of each of the ethical principles set out in the WHO Guidance on Ethics and Governance of Artificial Intelligence for Health. Subcodes were created for each principle based on their description in the Guidance. A total of 30 sub-codes were created (Table 1). This coding framework was then applied by the author to the original Japanese text of the SIP Research Plan on the "Innovative AI Hospital System" [AI(人工知能)ホスピタルによる高度診断・治療システム 研究計画] (10). While the first version of the Plan was released in 2018, the document has been regularly reviewed, with the April 25, 2022 analyzed here as it is the most recent version of the document at the point of analysis, and at this time of writing.[1]

A modified version of directed content analysis as proposed by Hsieh and Shannon (16) was used, through which the number of sentences within the Plan which reflected an orientation towards the ethical principles included in the framework above (Table 1) was tabulated. Where there were multiple phrases with a common code in a single sentence, these were collectively coded as one instance. Due to the structure of the original principles, some of the subcodes included in different principles overlapped, and where a sentence could potentially be coded under multiple subcodes, it was coded under a single subcode which, through reference to the original guidelines, appeared to best fit the broader principle. Where a particular sentence matched a broader principle but not a specific subcode, it was coded as a part of the broader principle. These results were then collated to indicate how frequently each component of the principles was referenced in the guidelines. The results are reported in Table 2, wherein "frequency" refers to the number of references in the Plan to a particular component of each of the WHO principles, as operationalized for this study. "Total by principle" refers to the number of total

1 https://www8.cao.go.jp/cstp/gaiyo/sip/keikaku2/10_aihospital_1.pdf